

22:2 BERKELEY TECHNOLOGY LAW JOURNAL

Pages
671
to
970

Spring
2007

Production: Produced by members of the *Berkeley Technology Law Journal* on PC computers. All editing and layout is done using Microsoft Word.

Printer: Joe Christensen, Inc., Lincoln, Nebraska.
Printed in the U.S.A.
The paper used in this publication meets the minimum requirements of American National Standard for Information Sciences—Permanence of Paper for Library Materials, ANSI Z39.48—1984.

Copyright © 2007 Regents of the University of California.

All Rights Reserved.

Berkeley Technology Law Journal
University of California, Berkeley
Boalt Hall School of Law
587 Simon Hall
Berkeley, California 94720-7200
(510) 643-6454 (Phone)
(510) 643-6816 (Fax)
btlj@law.berkeley.edu
www.btlj.org

BERKELEY TECHNOLOGY LAW JOURNAL

VOLUME 22

NUMBER 2

SPRING 2007

TABLE OF CONTENTS

ARTICLES

- BIOTECHNOLOGY AND THE BAR: A RESPONSE TO THE GROWING DIVIDE BETWEEN
SCIENCE AND THE LEGAL ENVIRONMENT 671
By Chief Justice Thomas J. Moyer and Stephen P. Anway
- BANKRUPTCY TREATMENT OF INTELLECTUAL PROPERTY ASSETS: AN ECONOMIC
ANALYSIS..... 733
By Peter S. Menell
- PATENT DAMAGES AND REAL OPTIONS: HOW JUDICIAL CHARACTERIZATION OF
NONINFRINGEMENT ALTERNATIVES REDUCES INCENTIVES TO INNOVATE..... 825
By Jerry A. Hausman, Gregory K. Leonard and J. Gregory Sidak
- A BURKEAN PERSPECTIVE ON PATENT ELIGIBILITY..... 855
By Thomas F. Cotter
- A BRAVE NEW WORLD OF DESIGNER BABIES?..... 897
By Sonia M. Suter

SUBSCRIBER INFORMATION

The *Berkeley Technology Law Journal* (ISSN 1086-3818), a continuation of the *High Technology Law Journal* effective Volume 11, is edited by the students of the University of California School of Law, Berkeley (Boalt Hall), and published four times each year (March, June, September, January) by the Regents of the University of California, Berkeley, Journal Publications, Boalt Hall School of Law, 313 Boalt Hall, University of California, Berkeley, CA 94720-7200. Application to Mail at Periodicals Postage Rate is Pending at Berkeley, CA 94704-9998, and at additional mailing offices. POSTMASTER: Send address changes to Journal Publications, 313 Boalt Hall, Boalt Hall School of Law, University of California, Berkeley, CA 94720-7200.

Correspondence. Address all correspondence regarding subscriptions, address changes, claims for non-receipt, single copies, advertising, and permission to reprint to Journal Publications Coordinator, 313 Boalt Hall, Boalt Hall School of Law, Berkeley, CA 94720-7200; (510) 643-6600; JournalPublications@law.berkeley.edu. Authors: see section entitled Information for Authors.

Subscriptions. Annual subscriptions are \$65.00 for individuals, and \$85.00 for organizations. Single issues are \$27.00. Please allow two months for receipt of the first issue. Payment may be made by check, international money order, or credit card (MasterCard/Visa). Domestic claims for non-receipt of issues should be made within 90 days of the month of publication; overseas claims should be made within 180 days. Thereafter, the regular back issue rate (\$27.00) will be charged for replacement. Overseas delivery is not guaranteed.

Form. The text and citations in the *Journal* conform generally to the UNITED STATES GOVERNMENT PRINTING OFFICE STYLE MANUAL (29th ed. 2000) and to THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION (Columbia Law Review Ass'n et al. eds., 18th ed. 2005). Please cite this issue of the *Berkeley Technology Law Journal* as 22 BERKELEY TECH. L.J. ____ (2007).

BTLJ ONLINE

The full text and abstracts of many *Berkeley Technology Law Journal* and *High Technology Law Journal* articles published in previous issues can be found at <http://www.btlj.boalt.org>. Our site also contains a cumulative index, general information about the *Journal*, selected materials related to

technology law, and links to other related pages. Author, volume, and subject indexes may also be found in Volume 20, Number 4 (2005) of the *Journal*.

INFORMATION FOR AUTHORS

The Editorial Board of the *Berkeley Technology Law Journal* invites the submission of unsolicited manuscripts. Submissions may include previously unpublished articles, essays, book reviews, case notes, or comments concerning any aspect of the relationship between technology and the law. If any portion of a manuscript has been previously published, the author should so indicate.

Format. Authors may submit manuscripts in electronic or hardcopy form, though electronic submissions are strongly encouraged. Electronic submissions should be sent as attachments in Microsoft Word format to btlj@law.berkeley.edu. Authors should submit double-spaced, single-sided manuscripts with generous margins. We regret that submissions cannot be returned. Authors should retain an exact copy of any material submitted.

Citations. All citations should conform to THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION (Columbia Law Review Ass'n et al. eds., 18th ed. 2005). In addition, the author should include his or her credentials, including full name, degrees earned, academic or professional affiliations, and citations to all previously published legal articles.

Copyrighted Material. If a manuscript contains any copyrighted table, chart, graph, illustration, photograph, or more than eight lines of text, the author must obtain written permission from the copyright holder for use of the material. A photocopy of such written permission should accompany the submission.

Mailing Address. BTLJ highly prefers electronic submissions sent as Microsoft Word attachments to btlj@law.berkeley.edu, but also accepts hardcopy manuscripts sent to:

Submissions Editor
Berkeley Technology Law Journal
University of California, Berkeley
Boalt Hall School of Law
587 Simon Hall
Berkeley, California 94720
(510) 643-6454 (Phone)

DONORS

The *Berkeley Technology Law Journal* and the Berkeley Center for Law & Technology acknowledge the following generous donors to Boalt Hall's Law and Technology Program:

Benefactors

COOLEY GODWARD KRONISH LLP

DLA PIPER US LP

FARELLA BRAUN + MARTEL LLP

FENWICK & WEST LLP

LATHAM & WATKINS LLP

NIXON PEABODY LLP

ORRICK, HERRINGTON

& SUTCLIFF LLP

SKADDEN, ARPS, SLATE, MEAGHER

& FLOM LLP

WEIL, GOTSHAL & MANGES LLP

WILSON SONSINI GOODRICH

& ROSATI PC

Members

AKIN GUMP STRAUSS HAUER & FELD LLP	HOWREY LLP
BAKER BOTTS LLP	JONES DAY
BINGHAM MCCUTCHEN LLP	KIRKLAND & ELLIS LLP
COVINGTON & BURLING LLP	KNOBBE MARTENS OLSON & BEAR LLP
DAVIS POLK & WARDWELL	MAYER, BROWN, ROWE & MAW LLP
DAY CASEBEER MADRID & BATCHELDER LLP	MCDERMOTT, WILL & EMERY
DREIER STEIN & KAHAN LLP	MORGAN, LEWIS & BOCKIUS LLP
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP	MORRISON & FOERSTER LLP
FISH & RICHARDSON PC	O'MELVENY & MYERS LLP
GUNDERSON DETTMER STOUGH VILLENEUVE FRANKLIN & HACHIGIAN LLP	ROPES & GRAY LLP
HELLER EHRMAN LLP	TOWNSEND AND TOWNSEND AND CREW LLP
	WHITE & CASE LLP

Patrons

BAKER & MCKENZIE	KENYON & KENYON
GREENBERG TRAUERIG LLP	MARGER JOHNSON & MCCOLLOM PC
HICKMAN PALERMO TRUONG & BECKER LLP	TRELLIS IP LAW GROUP
KEKER & VAN NEST LLP	VAN PELT, YI & JAMES LLP

The *Berkeley Technology Law Journal* is a nonprofit organization and welcomes donations. Donors are recognized appropriately for their contributions. For more information, contact the *Berkeley Center for Law and Technology*, Boalt Hall School of Law, 355 Boalt Hall, University of California, Berkeley, California 94720, (510) 642-8073, or e-mail bclt@law.berkeley.edu.

ADVISORY BOARD

ROBERT BARR
*Executive Director of the Berkeley Center
for Law & Technology*
Boalt Hall School of Law
Berkeley, California

ROBERT C. BERRING, JR.
Walter Perry Johnson Professor of Law
Boalt Hall School of Law
Berkeley, California

JESSE H. CHOPER
Earl Warren Professor of Public Law
Boalt Hall School of Law
Berkeley, California

PETER S. MENELL
*Professor of Law and
Director of the Berkeley Center for
Law & Technology*
Boalt Hall School of Law
Berkeley, California

ROBERT P. MERGES
*Wilson Sonsini Goodrich & Rosati
Professor of Law and Director of the
Berkeley Center for Law & Technology*
Boalt Hall School of Law
Berkeley, California

REGIS MCKENNA
Chairman and CEO
Regis McKenna, Inc.
Palo Alto, California

DEIRDRE K. MULLIGAN
*Director of the Samuelson Law,
Technology & Public Policy Clinic and
Clinical Professor of Law*
Boalt Hall School of Law
Berkeley, California

JAMES POOLEY
Pooley & Oliver LLP
Palo Alto, California

MATTHEW D. POWERS
Weil, Gotshal & Manges LLP
Redwood Shores, California

PAMELA SAMUELSON
*Professor of Law & Information
Management and Director of the Berkeley
Center for Law & Technology*
Boalt Hall School of Law
Berkeley, California

LIONEL S. SOBEL
*Professor of Law and Director of the
International Entertainment & Media Law
Summer Program in London, England*
Southwestern University School of Law
Los Angeles, California

LARRY W. SONSINI
Wilson Sonsini Goodrich & Rosati
Palo Alto, California

MICHAEL STERN
Cooley Godward LLP
Palo Alto, California

MICHAEL TRAYNOR
Cooley Godward LLP
San Francisco, California

THOMAS F. VILLENEUVE
Gunderson, Dettmer, Stough, Villeneuve,
Franklin & Hachigian LLP
Menlo Park, California

BOARD OF EDITORS

2006-2007

Editor-in-Chief
CORRIN DRAKULICH

Managing Editor
YAS RAOUF

Senior Article Editors
TIMOTHY P. BEST
ANNA ZICHTERMAN

Senior Executive Editor
TASHICA WILLIAMS

Senior Annual Review Editors
A.H. RAJANI
ALISON WATKINS

Executive Editors

Submissions Editors
ALAN GALLOWAY
JEFF THOMAS

Production Editors
MICHAEL MCCARTHY
LIYING SUN
STEVEN SUTTON

External Relations Editors
SHAKTI NARAYAN
LORI SANTOS

Bluebook Editors
PUNEET KAKKAR
MARGARET THOMSON

Notes & Comments Editor
DANIEL DOBRYGOWSKI

Administrative & Web Editor
PAUL FINLAYSON

Symposium Editors
SAJJAD MATIN
SARALA NAGALA

Internal Relations Editor
NATALIE SKORDILIS

Annual Review Editors
BOBBY GLUSHKO
YASER HERRERA

Article Editors

JAN-MICHAEL COHEN
MICHAEL DAVIS-WILSON
JAYNI FOLEY
SARAH GETTINGS

GALEN HANCOCK
DAVID JACKSON
JEFFREY KUHN
JEREMY MULDER

WINSTON SU
NIKI WOODS
CHRISTOPHER YEH

BERKELEY CENTER FOR LAW & TECHNOLOGY

Executive Director

ROBERT BARR

Faculty Directors

PETER MENELL
PAMELA SAMUELSON

ROBERT MERGES
HOWARD SHELANSKI '92

DEIRDRE MULLIGAN
MOLLY VAN HOUWELING

Assistant Director

LOUISE LEE

Assistant Director

DAVID GRADY

*Affiliated Faculty and
Scholars*

SALLY ABEL
STEPHEN BARNETT
ROBERT BERRING '74
ROBERT BLACKBURN
KAREN BOYD '96
ALISSA CENTIVANY
AARON EDLIN
JOSEPH FARRELL
RICHARD GILBERT

BRONWYN HALL
THOMAS JORDE
RAHUL KAPOOR
MICHAEL KATZ
JACK LERNER
DAVID MOWERY
ERIN MURPHY
DAVID NIMMER
RAYMOND OCAMPO
DANIEL RUBINFELD

ANNALEE SAXENIAN
SUZANNE SCOTCHMER
CARL SHAPIRO
MARJORIE SHULTZ
LON SOBEL
DAVID TEECE
HAL R. VARIAN
OLIVER WILLIAMSON
BRIAN WRIGHT

MEMBERSHIP

2006-2007

Associate Editors

RICHARD DAVID
MENG DING
AARON GERSHBOCK
JOHN HASTRUP
JUSTIN LEE

ELVIN LEE
THOMAS LLOYD
BEN PETERSEN
JEREMY PRICE
JENNIFER SAIONZ

MICHAEL SAUNDERS
CYNTHIA SU
JOHN TSAI
JEFF TUNG
CECILIA ZINITI

Members

TAMMY ARANKI
JASON BASSETTI
ANDREW BRAGIN
JEREMY BROWN
MATT BROWNING
WILLIAM BRYAN
CONSTANCE CHOI
SUSHEEL DASWANI
NATE DAVIS
ANDREW DICKSON
ASHLEY DOTY
EDWARD ELLIOTT
RYAN ENCHELMAYER
AARON EPSTEIN
ROBERT ESPOSITO
SEAN FERNANDES
JENNIFER FILES
TOM FLETCHER
JESSE GERACI

TAMAR GUBINS
RICHARD GUO
DAVID HASKEL
JADE HOFFMAN
KATI HONG
PJ INCE
DOMENIC IPPOLITO
JOSHUA KAMZAN
JOSH KEESAN
DAVID KELLER
KIYWHANNA KELLUP
DANIEL KIM
CHRIS KNIGHT
MYKOLA KOVALENKO
PATRICIA KUO
SALLY LEE
LINDA LEE
WILLIAM LIN

JEANNINE MARQUES
WILL MCGINTY
ALIA NAJJAR
SHAKTI NARAYAN
KIM NATIVIDAD
ALPA PATEL
WOLFRAM POHL
DANNY PRATI
ABDUS SAMAD PARDESI
LORI SANTOS
AARON SCHOHN
LAURA SULLIVAN
OLIVIA TRAN
DANIEL WOBBEKIND
CAMERON YAHR
JOHN YOW
KAI ZHU
MARGARET ZIEGLER

BIOTECHNOLOGY AND THE BAR: A RESPONSE TO THE GROWING DIVIDE BETWEEN SCIENCE AND THE LEGAL ENVIRONMENT

By Chief Justice Thomas J. Moyer[†] & Stephen P. Anway^{‡‡}

TABLE OF CONTENTS

I. INTRODUCTION	673
II. ADMISSIBILITY OF SCIENTIFIC EVIDENCE	674
A. PRE- <i>DAUBERT</i> —THE <i>FRYE</i> TEST	675
B. <i>DAUBERT</i> —THE TRIAL COURT AS A “GATEKEEPER”	677
C. POST- <i>DAUBERT</i> — <i>JOINER</i> AND <i>KUMHO TIRE</i>	679
III. DNA FORENSICS	682
A. SCIENTIFIC OVERVIEW	683
B. THE ADMISSIBILITY OF DNA AS SCIENTIFIC EVIDENCE	684
C. FUTURE LEGAL ISSUES INVOLVING DNA FORENSICS	687
IV. GENETIC ENGINEERING	689
A. SCIENTIFIC OVERVIEW	690
B. LEGAL ISSUES ASSOCIATED WITH GMOs	692
1. <i>Intellectual Property Rights and GMOs</i>	692
2. <i>Safety Issues Associated with GMOs</i>	694
a) Human Health and Consumer Choice Concerns with GMOs	694
b) Environmental Concerns with GMOs	696
c) <i>Alliance for Bio-Integrity v. Shalala</i>	697
V. GENETIC PRIVACY	701
A. COLLECTION AND STORAGE OF GENETIC INFORMATION	701
B. LEGISLATION GOVERNING DISCRIMINATION BASED ON GENETIC DATA	705
1. <i>Federal Legislation</i>	705

© 2007 Chief Justice Thomas J. Moyer and Stephen P. Anway

[†] Chief Justice of the Supreme Court of Ohio, 1987-present; Vice Chairman of the Board of Directors of the Advanced Science and Technology Adjudication Resource Center, 2004-present.

^{‡‡} Attorney at the international law firm Squire, Sanders & Dempsey L.L.P., 2004-present; judicial clerk to Chief Justice Moyer, 2002-2004.

2. <i>State Legislation</i>	708
C. JUDICIAL APPROACHES TO GENETIC PRIVACY	709
1. <i>Genetic Privacy Protection Under the ADA—Norman- Bloodsaw v. Lawrence Berkeley Laboratory</i>	709
2. <i>The Scope of ADA Coverage and its Impact on Genetic Discrimination—Bragdon v. Abbott</i>	712
3. <i>Conclusions</i>	714
VI. A RESPONSE TO THE GROWING DIVIDE BETWEEN LAW AND BIOTECHNOLOGY	714
A. THE PROBLEM OF BIOTECHNOLOGY CASES AFTER <i>DAUBERT</i> — SUBJECTIVE JUDGMENT BY THE GATEKEEPER	716
B. CONVENTIONAL EFFORTS TO EDUCATE JUDGES	719
1. <i>Judicial Seminars on Scientific Matters</i>	720
2. <i>Scientific Publications for Judges</i>	723
C. A FORUM TO MEDIATE BETWEEN SCIENCE AND THE LEGAL ENVIRONMENT	725
1. <i>The ASTAR Resource Judges</i>	726
2. <i>Training and Certification of the Resource Judges</i>	726
3. <i>Implementation of the ASTAR Resource Judge Program</i>	728
4. <i>The Future of ASTAR</i>	730
VII. CONCLUSION	730

The future is now with respect to biotechnology; we now have the tools to shape succeeding generations of human nature. The question facing legislatures is not “can we?” but “should we?” To find a durable answer to this question as it arises in the judicial system requires a sophisticated blend of scientific information and adjudication techniques that can be applied to cases raising novel biotechnology issues.

This Article is based on a lecture delivered by the Honorable Thomas J. Moyer, Chief Justice of the Supreme Court of Ohio, in the Republic of Chile during March 2004 as part of the United States Speaker/Specialist Program sponsored by the United States Department of State. The lecture focused on the reality that every judicial system in the world will soon face legal issues that arise from advancements in biotechnology. To assist these judicial systems in the management of such cases, the Chief Justice discussed the manner in which the United States has addressed the increasingly difficult relationship between biotechnology and law.

Yet, however embedded in descriptive terms, Chief Justice Moyer’s lecture had a more forward-looking objective: the creation of an institution that would mediate between science and the legal environment. To that end, Chief Justice Moyer, together with Dr. Franklin Zweig, president of the Einstein Institute for Science, Health, and the Courts in Washington D.C., has endorsed a national program designed to prepare

judges to preside over cases involving complex scientific issues. That program is known as “ASTAR”—the Advanced Science and Technology Adjudication Resource Center. Now moving from concept to reality, ASTAR will soon affect the manner in which biotechnology cases are adjudicated in state and federal courts around the nation. This Article explores that program and, in so doing, examines many of the legal issues that biotechnology inspires.

I. INTRODUCTION

During the past two decades, our nation has experienced an explosive growth of scientific and technological knowledge. That knowledge has given rise to an increasing number of legal disputes involving science- and technology-related issues.¹ Although legislative parliaments are better suited to resolve legal issues presented by advancements in science and technology, courts often render legal decisions first about emerging technologies because parliaments are slower to act.

State and federal courts have thus been forced to react, often without the requisite scientific training or education to make an informed decision regarding whether scientific evidence is a cutting-edge breakthrough or what has been called “junk science.”² Key cases from the United States Supreme Court and state supreme courts further complicate this issue by affording trial courts discretion to evaluate not only the methodology behind the science but also the reasoning process to reach the scientific conclusion. Increases in the complexity of technology, particularly in areas of biotechnology such as DNA forensics, genetic engineering, and genetic privacy, only aggravate the problem.

This Article explores a ground-breaking institution, known as the Advanced Science and Technology Adjudication Resource Center (“ASTAR”), which offers standardized training to judges around the nation to handle the increasing volume of complex, high-tech cases on court dockets. With the participation of over thirty-five states, ASTAR aims to provide a response to the problem facing every jurisdiction in the nation: that, in the words of U.S. Supreme Court Justice Stephen Breyer, “a judge is not a scientist and a courtroom is not a scientific laboratory,” but that “to

1. *See* *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 149 (1997) (Breyer, J., concurring) (citing Judicial Conference of the United States, Report of the Federal Courts Study Committee 97 (Apr. 2, 1990) (“Economic, statistical, technological, and natural and social scientific data are becoming increasingly important in both routine and complex litigation.”)).

2. *See also* C. WRIGHT & V. GOLD, *FEDERAL PRACTICE AND PROCEDURES* § 6266, at 265 (1996).

do our legal job properly we [need] to develop an informed, though necessarily approximate, understanding of the state of . . . scientific art.”³

To better understand the need for an institution such as ASTAR, Part II of this Article begins with a brief background on the evolution of the admissibility of scientific evidence in federal and state courts and focuses on the evolving role of judges as “gatekeepers” to determine the admissibility of scientific evidence. This Article then examines three areas of biotechnology that will soon challenge (or have already begun challenging) the scientific literacy of courts. Part III discusses the use of DNA forensics in criminal trials. Part IV examines the practice of genetic engineering and relates the ongoing and future legal issues inspired by genetically modified organisms. Part V explores genetic privacy and the ability of insurance companies and employers to discriminate on the basis of genetic information. Finally, Part VI argues that ASTAR is an institution well on its way to assisting courts in resolving both these biotechnology issues and those beyond the scope of this Article.

II. ADMISSIBILITY OF SCIENTIFIC EVIDENCE

In understanding the evolving relationship between biotechnology and the legal environment, it is useful to first appreciate the evolution of the rules governing the admissibility of scientific evidence. Scientific evidence is “any demonstrative and testamentary information that uses the techniques of science to assist the trier of fact in deciding which of two or more theories explain what, why, who, and when something happened which is the object of contention in a trial.”⁴ Scientific techniques, however, can often be manipulated to reach a desired result.⁵ The primary

3. Shirley S. Abrahamson, *Forward*, 83 JUDICATURE 102, 102 (1999). Justice Breyer has noted that “law itself increasingly needs access to sound science” and that scientific technology “increasingly underlies legal issues of importance to us all.” *Id.* As a result, Justice Breyer has exhorted judges to “build legal foundations that are sound in science, as well as in law . . . to resolve many of the most important human problems of our time.” *Id.*

4. Anna M. Michalak, *Environmental Contamination with Multiple Potential Sources and the Common Law: Current Approaches and Emerging Opportunities*, 14 FORDHAM ENVTL. L. REV. 147, 195 (2002) (citing William G. Eckert & Ronald K. Wright, *Scientific Evidence in Court*, in INTRODUCTION TO FORENSIC SCIENCES 69 (William G. Eckert ed., 1997)).

5. The Supreme Court expressed its dissatisfaction with adversarial expert testimony nearly a century-and-a-half ago, noting that “[e]xperience has shown that opposite opinions of persons professing to be experts may be obtained to any amount . . . wearying the patience of both court and jury, and perplexing, instead of elucidating, the questions involved.” *Winans v. N.Y. & Erie R.R.*, 62 U.S. 88, 101 (1858). Courts impose a differ-

charge of American courts as technology pervaded society, therefore, was to consider—or, more precisely, to reconsider—the standard that should govern the admissibility of expert testimony relating to scientific evidence.⁶ This Part reviews the evolution of this standard and traces the growing importance of the trial court as the “gatekeeper” to the admissibility of scientific evidence.

A. Pre-*Daubert* — The *Frye* Test

Prior to 1993, many courts had adopted the rule that scientific evidence was admissible if the scientific technique from which the evidence was derived was sufficiently established to have gained “general acceptance” in the relevant scientific community.⁷ The D.C. Circuit Court of Appeals first enunciated this “general acceptability” standard in *Frye v. United States*⁸—a 1923 decision involving a primitive form of the modern polygraph.⁹ Although *Frye* received little immediate attention, judges began to invoke the “general acceptability” test as litigants increasingly offered novel and dubious forms of scientific evidence in court.¹⁰ In time, the *Frye* test became the prevailing analytic framework by which to de-

ent admissibility standard for expert witnesses in part because, unlike lay witnesses, expert witnesses need not have knowledge of the facts relevant to the case. As a result, the pool of available expert witnesses is significantly larger than the pool of lay witnesses, which “enables parties to shop for expert testimony—especially with the growth of the expert witness business.” Tim Cram, Arthur J. Hartz & Michael D. Green, *Ascertaining Customary Care in Malpractice Cases: Asking Those Who Know*, 37 WAKE FOREST L. REV. 699, 719 (2002). In addition, “the psychology of adversarial litigation and subtle pressure on adversarial experts contribute to greater disagreement by experts.” *Id.*

6. For a discussion of the various evidentiary approaches courts employed during the technology era, see John D. Borders, Jr., Note, *Fit to Be Fryed: Frye v. United States and the Admissibility of Novel Scientific Evidence*, 77 KY. L.J. 849, 864-73 (1989).

7. See *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923); see also Richard L. Marcus, *The Agenda-Setter for Complex Litigation*, 149 U. PA. L. REV. 1257, 1264 (2001) (noting that this test “had been roundly attacked by commentators but still prevailed in most courts”).

8. 293 F. at 1014.

9. *Id.* Prior to the widespread adoption of the *Frye* standard, “most courts only asked whether the expert was ‘qualified’ before admitting the expert’s testimony and, in some jurisdictions, whether the subject matter in issue was beyond the range of knowledge of the average juror.” Joseph Sanders, *The Merits of the Paternalistic Justification for Restrictions on the Admissibility of Expert Evidence*, 33 SETON HALL L. REV. 881, 885 (2003).

10. Heather G. Hamilton, *The Movement from Frye to Daubert: Where Do the States Stand?*, 38 JURIMETRICS J. 201, 203 (1998).

termine the admissibility of scientific evidence—a distinction that it would hold for more than half a century.¹¹

The “general acceptability” standard, however, came under attack in the 1960s and 1970s.¹² This attack was partially attributable to the consumer and environmental movements of the time.¹³ Critics argued, for example, that the *Frye* test was too conservative because it imposed a waiting period before a scientific technique was “generally acceptable.”¹⁴ Thus, “an alleged victim of chemical poisoning or some other toxic tort [would be] denied compensation just because his offer of proof could not meet the exacting standards of ‘acceptance’ in a broader scientific community.”¹⁵ This fact—coupled with the view that *Frye* was “elitist and unhelpful” in an era in which the prevailing intellectual mood was anti-establishment¹⁶—set the stage for a reevaluation of the *Frye* test when the legal community drafted the Federal Rules of Evidence in 1974.

When the drafters of the Federal Rules of Evidence codified the principles governing the admissibility of “expert testimony” in Rule 702, they made no mention of “general acceptability.”¹⁷ That rule provided that “[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or educa-

11. Paul C. Giannelli, *The Admission of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 COLUM. L. REV. 1197, 1205 n.41 (1980).

12. Peter Huber, *Junk Science in the Courtroom*, 26 VAL. U. L. REV. 723, 732 (1992).

13. *Id.* Huber has described the impetus behind the departure from *Frye* thus: For half a century, *Frye* served reasonably to exclude exotic, unreliable evidence from the courtroom. The rule came under attack, however, in the 1960s and ‘70s. The consumer and environmental movements were gathering momentum at this time. The prevailing intellectual mood was anti-establishment, and *Frye* was seen as elitist and unhelpful, particularly in cases involving new pollutants, and unfamiliar hazards. In the legal world, meanwhile, theories of liability were evolving to give plaintiffs the advantage at trial. *Frye* critics felt that an alleged victim of chemical poisoning or some other toxic tort should not be denied compensation just because his offer of proof could not meet the exacting standards of “acceptance” in a broader scientific community.

Id. at 732.

14. Sanders, *supra* note 9, at 886.

15. Huber, *supra* note 12, at 732.

16. *Id.*; see also Joseph T. Walsh, *Keeping the Gate: The Evolving Role of the Judiciary in Admitting Scientific Evidence*, 83 JUDICATURE 140, 141 (1999).

17. Fed. R. Evid. 702.

tion, may testify thereto in the form of an opinion or otherwise.”¹⁸ Given that Rule 702 did not contemplate the “general acceptance” of a scientific technique as a criterion of admissibility, several federal courts interpreted the rule to supersede *Frye*.¹⁹ Other circuits, by contrast, concluded that *Frye* survived the adoption of Rule 702.²⁰ The United States Supreme Court ended this debate in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*²¹

B. *Daubert*—The Trial Court as a “Gatekeeper”

Daubert addressed whether scientific evidence was admissible in a lawsuit brought by infants and their guardians ad litem against a pharmaceutical company to recover for birth defects. The infants allegedly sustained these defects as a result of their mothers’ ingestion of the anti-nausea drug Bendectin.²² The court of appeals affirmed the decision of the trial court to disallow the evidence because the scientific technique from

18. *Id.* With its emphasis on the reliability of the expert, the rule thus “appear[ed] almost at cross-purposes to *Frye*’s focus on the subject matter of the expert’s opinion.” Walsh, *supra* note 16, at 141. Nonetheless, Rule 703 permitted an expert to rely upon inadmissible scientific information to formulate an opinion provided that such information is “of a type” that experts would reasonably rely upon “in [a] particular field.” *Id.* Rule 703 thus “seem[ed] to suggest a *Frye*-like test without the general acceptance requirement.” *Id.*

19. In support of this view, courts emphasized that the notes accompanying the Federal Rules of Evidence did not mention the vitality of the *Frye* standard in its discussion of the rules governing expert testimony. *See, e.g.*, *United States v. Downing*, 753 F.2d 1224, 1234 (3d Cir. 1985). In *Downing*, Judge Becker noted that, to be admissible, expert testimony on eyewitness identification must survive the preliminary inquiry of the trial court. *Id.* at 1226. The Third Circuit held that a trial judge should conduct an in limine proceeding in which it should consider: (1) the reliability of the scientific principles the expert employed against (2) the likelihood that the evidence may overwhelm or mislead the jury. *Id.* The Fifth Circuit set forth a similar test for determining the admissibility of scientific evidence in *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1110 (5th Cir. 1991) (en banc), *cert. denied*, 503 U.S. 912 (1992).

20. *See, e.g.*, *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985). The Honorable Joseph Walsh, a justice of the Delaware Supreme Court, has noted:

Courts seeking to reconcile *Frye*’s general acceptance test with the more specific criteria imparted by Rules 702 and 703 struggled to provide a consistent practical guide for practitioners. To the extent that *Frye* was viewed as unduly conservative, courts sought to relax its application to avoid the exclusion of evidence, particularly in criminal cases. Also, as more scientific studies and methodology were brought to bear in toxic and pharmaceutical based tort actions, courts struggled to permit the use of innovative science to establish causation.

Walsh, *supra* note 16, at 141.

21. 509 U.S. 579 (1993).

22. *Id.* at 582.

which the evidence was derived was not “generally accepted” as reliable in the relevant scientific community.²³ The United States Supreme Court reversed, holding that Rule 702 displaced the *Frye* test and that the principle of scientific soundness applied to novel as well as conventional techniques.²⁴ That Rule 702 superseded the *Frye* test did not mean, however, that the Federal Rules placed no limitations on the admissibility of scientific evidence.²⁵ To the contrary, the Court concluded that “under the rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”²⁶

To assess whether scientific evidence is reliable, the Court listed four non-exclusive factors that the trial court should consider: first, whether the theory or technique at issue is susceptible to testing and has been subjected to such testing;²⁷ second, whether the theory or technique has been subjected to peer review and publication;²⁸ third, whether there is a known or potential rate of error associated with the theory or technology;²⁹ and

23. *Daubert v. Merrell Dow Pharmaceuticals*, 951 F.2d 1128, 1129-31 (1991).

24. *Daubert*, 509 U.S. at 589; David W. Barnes, *General Acceptance Versus Scientific Soundness: Mad Scientists in the Courtroom*, 31 FLA. ST. U. L. REV. 303, 309-10 (2004) (citing *Daubert*, 509 U.S. 579, 592 n.11 (1993)).

25. *Daubert*, 509 U.S. at 589.

26. *Id.*

27. *Id.* at 593. The rationale supporting such an inquiry, the Court reasoned, derived from the fact that:

Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. “Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.”

Id. (quoting Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 645 (1992)).

28. *Id.* The Court noted, however, that:

Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability . . . and in some instances well-grounded but innovative theories will not have been published. . . . The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94.

29. *Id.* at 594. To provide examples of judicial decisions that have examined the error rate and the existence and maintenance of standards controlling the operation of the scientific technique, the Court cited *United States v. Smith*, 869 F.2d 348, 353-54 (7th Cir. 1989) (surveying rate-of-error studies concerning spectrographic voice identification

fourth, whether the theory has been generally accepted in the relevant scientific community.³⁰

The effect of *Daubert*, therefore, was to take “the decision-making process out of the hands of the scientific community, and [to] place[] it in the hands of the trial judge.”³¹ In so doing, the Court described the role of the trial judge as a “gatekeeper”—one that requires judges to admit reliable science and to screen out “junk science.”³² *Daubert* thus converted trial courts from “passive recipients of scientific and technical data” into engaged evaluators of scientific techniques.³³

C. Post-*Daubert*—*Joiner* and *Kumho Tire*

In recent years, the Supreme Court has revisited the doctrinal basis underlying *Daubert* and provided further guidance on the role of the trial judge as a gatekeeper.³⁴ In *General Electric Co. v. Joiner*,³⁵ the Court re-examined its prior assertion in *Daubert* that a judge’s inquiry “must be solely on principles and methodology, not on the conclusions that they generate.”³⁶ Specifically, the Court in *Joiner* addressed the question of whether the judge may examine the reasoning process that linked the methodology (which the judge could consider under *Daubert*) with the con-

technique) and *United States v. Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978) (reviewing the standard of one organization that governs spectrographic analysis), respectively.

30. *Daubert*, 509 U.S. at 594 (noting that “general acceptance” can yet have a bearing on the inquiry). In analyzing this “general acceptance” factor against the backdrop of *Frye*, the United States Court of Appeals for the Sixth Circuit has noted that:

[G]eneral acceptance is no longer *the* test for admissibility of scientific evidence but now is only one factor to consider. Therefore, it is now less compelling to argue that we should take judicial notice of a report by scientists in the field in order to gauge the “general acceptance” of DNA matching by those in the field.

United States v. Bonds, 12 F.3d 540, 553 n.10 (6th Cir. 1993). Justice Blackmun, writing for the majority in *Daubert*, further noted that the four factors do not constitute “a definitive checklist or test.” 509 U.S. at 593; *see also* David S. Caudill & Lewis H. LaRue, *Why Judges Applying the Daubert Trilogy Need to Know About the Social, Institutional, and Rhetorical—and Not Just the Methodological—Aspects of Science*, 45 B.C. L. REV. 1, 14 (2003).

31. Thomas L. Cooper, *Expert Witness Testimony—Frye Revealed—The Impact of Trach-Fellin II*, 75 PA. B.A. Q. 10, 11 (2004).

32. Walsh, *supra* note 16, at 141, 143.

33. Timothy Zick, *Constitutional Empiricism: Quasi-Neutral Principles and Constitutional Truths*, 82 N.C. L. REV. 115, 181-82 (2003).

34. Walsh, *supra* note 16, at 141.

35. 522 U.S. 136 (1997).

36. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595 (1993).

clusion (which the judge could not).³⁷ Answering that question in the affirmative, the Court “affirmed the discretionary authority of a federal judge to reject an expert’s rationale, even where the methods and principles which formed the expert’s opinion are recognized as valid.”³⁸

More recently, the Supreme Court elaborated on the role of the trial judge as a “gatekeeper” in *Kumho Tire Co. Ltd. v. Carmichael*.³⁹ The issue in *Kumho Tire* was whether the subject of an expert’s testimony—tire technology—fell outside the scope of *Daubert* because it was not based on “scientific knowledge.”⁴⁰ Reasoning that Rule 702 makes no distinction between “technical” and “scientific” knowledge, the Court concluded that *Daubert* applies to all expert witnesses, scientific and non-scientific experts alike, who rely on skill or experience to formulate opinions.⁴¹ The Court emphasized that the trial court’s decision with respect to the admissibility of expert testimony is afforded considerable discretion “not only in the acceptance or rejection of the expert’s opinion, but also in the evaluation of the factors leading to that conclusion.”⁴²

Although *Daubert* and its progeny significantly affected the Federal Rules governing the admissibility of scientific evidence, these decisions do not bind state courts.⁴³ Nevertheless, the majority of states have adopted a counterpart to Rule 702, which now codifies similar principles to those of *Daubert*.⁴⁴ Several states—most notably Florida—have rejected the *Daubert* standard and continue to employ the *Frye* test.⁴⁵ Other

37. Gerald J. Todaro, *The Admissibility of Medical Testimony in Ohio: Daubert, Joiner, and Ohio’s Relevance-Reliability Standard*, 46 CLEV. ST. L. REV. 319, 321 (1999).

38. *Id.* at 321-22.

39. 526 U.S. 137 (1999).

40. Walsh, *supra* note 16, at 142.

41. *Kumho Tire*, 526 U.S. at 147.

42. Walsh, *supra* note 16, at 142.

43. *Daubert*, *Joiner*, and *Kumho Tire* do not bind state courts because they were predicated on a federal rule—Federal Rule of Evidence 702—and not on the United States Constitution or federal statute.

44. See J. Eric Smithburn, *The Trial Court’s Gatekeeper Role Under Frye, Daubert, and Kumho: A Special Look at Children’s Cases*, 4 WHITTIER J. CHILD & FAM. ADVOC. 3, 9-34 (2004) (reviewing the standards that have been developed to determine the admissibility of expert testimony). *But see* *Turner v. State*, 746 So. 2d 355 (Ala. 1998) (applying the *Daubert* standard solely in DNA cases because only the DNA statute, § 36-18-30 of the Alabama Code, has superseded *Frye*).

45. *Flanagan v. State*, 625 So. 2d 827, 829 (Fla. 1993). In declining to adopt the standard later announced in *Daubert*, the Supreme Court of Florida offered the following explanation:

While the balancing approach solves the primary concern with the per se rule of exclusion, namely that it is too inflexible, the balancing ap-

states have applied *Daubert* only in DNA cases⁴⁶ or have “found *Daubert* [to be] ‘instructive,’ but not necessarily required, of trial courts.”⁴⁷

Despite its widespread acceptance, however, commentators continue to question the merits of *Daubert* and its progeny.⁴⁸ One critic, for example, has noted a “paradoxical assumption” in *Daubert* that “trial judges, as gatekeepers, can effectively and competently apply their level of scientific knowledge to determine the reliability of all sciences . . . as well or conceivably better than each individual well-credentialed scientist who proffers their [sic] evidence.”⁴⁹ Other critics have suggested that despite “their general enthusiasm and diligence,” judges “tend to be highly resistant to the sort of learning that *Daubert* demands.”⁵⁰ Still others contend that judges “tend to be scientifically ignorant, which means that they are not acquainted, let alone conversant, with scientific practice or language.”⁵¹

Whatever the merit of these arguments, judges will face ever-increasing difficulties in their roles as gatekeepers as advancements in biotechnology continue to outstrip the scientific knowledge of courts. The purpose of this Article, therefore, is to explore alternatives that neither defer exclusively to the scientific community regarding the admissibility of scientific evidence (*Frye*) nor endorse the gatekeeping function of trial courts without the impartial aid of the scientific community (*Daubert*). To underscore the need for institutions that provide such an alternative, the

proach may well take the concept of flexibility too far. . . . We acknowledge that the *Frye* rule has come under some criticism since its inception in 1923 as too harsh and inflexible, *see* McCormick on Evidence § 203 (2d ed. 1972); however, we believe that the problems associated with the other recognized judicial approaches foreclose their use.

Stokes v. State, 548 So. 2d 188, 194-95 (Fla. 1989).

46. *See, e.g.*, Turner, 746 So. 2d at 355.

47. Walsh, *supra* note 16, at 142.

48. Mary Elliott Rollé, *Unraveling Accountability: Contesting Legal and Procedural Barriers in International Toxic Tort Cases*, 15 GEO. INT'L ENVTL. L. REV. 135, 143-44 (2003) (noting that some scholars “have argued that the [sic] there is an inherent unfairness in allowing judges to decide the question of causation before the trial even begins, particularly given the lack of scientific knowledge many judges have.”).

49. Craig Lee Montz, *Trial Judges as Scientific Gatekeepers After Daubert*, Joiner, Kumho Tire, and Amended Rule 702: *Is Anyone Still Seriously Buying This?*, 33 UWLA L. REV. 87, 106 (2001).

50. Walsh, *supra* note 16, at 141 (quoting John M. Conley & David W. Peterson, *The Science of Gatekeeping: The Federal Judicial Center's New Reference Manual on Scientific Evidence*, 74 N.C. L. REV. 1183, 1205 (1996)).

51. Alan G. Gless, *Some Post-Daubert Trial Tribulations of a Simple Country Judge: Behavioral Science Evidence in Trial Courts*, 13 BEHAV. SCI. & L. 261, 263 (1995).

following Parts III, IV, and V examine three areas of biotechnology that will soon challenge—or have already begun challenging—the scientific literacy of courts: (1) the use of DNA forensics in criminal trials; (2) genetic engineering and genetically modified organisms; and (3) genetic privacy and the ability of insurance companies and employers to discriminate on the basis of genetic information.

III. DNA FORENSICS

As science has become increasingly integrated into our judicial system, American courts have embraced modern technologies, such as DNA testing, to provide a universal means for criminal identification. Embracing these modern technologies was born of sound policy; for the advent of genetic fingerprinting in the mid-1980s led to convictions that previously would have been impossible, exonerated criminal suspects before prosecutors filed charges, and freed mistakenly convicted defendants.⁵² With the advent of DNA forensics, however, came new issues that challenged our

52. As of April 2007, 198 defendants had been exonerated by DNA evidence. *See, e.g.*, Raymond Bonner, *Death Row Inmate Is Freed After DNA Test Clears Him*, N.Y. TIMES, Aug. 24, 2001, at A11; Adam Liptak, *DNA Will Let a Montana Man Put Prison Behind Him, but Questions Linger*, N.Y. TIMES, Oct. 1, 2002, at A22; The Innocence Project, <http://www.innocenceproject.org> (last visited Apr. 15, 2007). The first death row prisoner exonerated by DNA evidence was Kirk Bloodsworth in 1994. *See* Center on Wrongful Convictions, Northwestern University School of Law, Illinois Death Penalty Exonerations, <http://www.law.northwestern.edu/depts/clinic/wrongful/Chronology2.htm> (last visited Mar. 16, 2007). Since the exoneration of Bloodsworth, DNA has played a substantial role in exonerating eleven other death row prisoners. *See* Steven J. Mulroy, *The Safety Net: Applying Coram Nobis Law To Prevent the Execution of the Innocent*, 11 VA. J. SOC. POL'Y & L. 1, 7 (2003). The most recent exonerated defendant—and the most unusual—is William Walters, who was convicted for kidnapping in 1914. Allen G. Breed, *DNA Clears Man of 1914 Kidnapping Conviction*, USATODAY.COM, http://www.usatoday.com/tech/news/2004-05-05-1914-dna_x.htm (last visited Mar. 16, 2007). Nine decades after Walters was convicted, a DNA test indicated that the boy with whom Walters was found was not a missing boy, but rather, the illegitimate son of his brother. *Id.*

Further, the use of DNA evidence to exonerate defendants has provided insight into other aspects of criminal investigation. According to the Cardozo Innocence Project, for example, twenty-three percent of cases in which DNA was used to reverse the defendant's conviction involved a false confession. *Crime, False Confessions and Videotape*, N.Y. TIMES, Jan. 10, 2003, at A22. In addition, “[i]n sixty of the first eighty-two DNA exonerations, mistaken eyewitness identification played a major part in the wrongful conviction.” Richard A. Rosen, *Innocence and Death*, 82 N.C. L. REV. 61, 70 n.32 (2003). Cases in which defendants were convicted and later exonerated also included “suspicious behavior, and physical and other circumstantial evidence supporting guilt.” *Id.* at 71-72.

existing legal framework, such as genetic privacy in DNA databanks and genetic determinism. This Part examines the manner in which American courts have addressed these issues. To provide the necessary background on DNA forensics, this Part begins with a brief overview of the genetic principles behind DNA. The Part then reviews the history of courts admitting DNA evidence and concludes with a discussion of the future legal issues involving DNA forensics.

A. Scientific Overview

Deoxyribonucleic acid, more simply referred to as DNA, is an organic polymer found within every cell of every organism.⁵³ The monomeric units comprising the polymer contain three parts: a phosphate portion, a ribose sugar portion, and a structure called a nitrogenous base.⁵⁴ Although the first two components are the same in every monomeric unit, the third—the nitrogenous base—differs.⁵⁵ Four nitrogenous bases are found in DNA: adenine, cytosine, guanine, and thymine.⁵⁶ It is the sequence of these bases in DNA that determines genetic identity; the sequence differs somewhat between individual members of a species and much more between members of distinct species.⁵⁷

Held together by hydrogen bonds, these components form a DNA molecule that resembles a ladder twisted to form a helix.⁵⁸ The two outer strands, or the “backbone,” of the ladder are made of the sugar and phosphate portions.⁵⁹ The rungs of the ladder, by contrast, are composed of complementary base pairs—adenine pairing with thymine; cytosine with

53. Micah A. Luftig & Stephen Richey, *DNA and Forensic Science*, 35 NEW ENG. L. REV. 609, 609 (2001).

54. *Id.* The nitrogenous base is selected from one of four chemically distinct bases, see *infra* note 56, each of which—along with its accompanying share of deoxyribose-phosphate backbone—is called a “nucleotide.” Allen C. Nunnally, Note, *Commercialized Genetic Testing: The Role of Corporate Biotechnology in the New Genetic Age*, 8 B.U. J. SCI. & TECH. L. 306, 311 (2002).

55. Luftig & Richey, *supra* note 53, at 609.

56. *Id.* The four nitrogenous bases are often represented by their first letters; thus, “A” (adenine), “G” (guanine), “C” (cytosine), and “T” (thymine). See M. Scott McBride, *Bioinformatics and Intellectual Property Protection*, 17 BERKELEY TECH. L.J. 1331, 1335 (2002).

57. See Luftig & Richey, *supra* note 53, at 609. With the single-letter designations of nitrogenous bases, see *supra* note 56, scientists can concisely describe a sequence of a particular DNA (e.g., “ATTGGCATGGA”). McBride, *supra* note 56, at 1135-36.

58. WAYNE BECKER ET AL., *THE WORLD OF THE CELL* 58 (Catherine Pusateri ed., The Benjamin/Cummings Publishing Company 1996) (1986).

59. *Id.* at 60-61.

guanine.⁶⁰ This complementary pairing is essential for various DNA testing methods and for the basic principles of DNA chemistry.⁶¹

Because the DNA in each human cell is composed of a string of bases approximately three billion bases long, it provides for variations that allow scientists to distinguish between DNA samples.⁶² Given that DNA is uniform throughout all cells of an individual but distinct from the DNA of every other individual, scientists can detect small variations in DNA to differentiate among individuals.⁶³ As a result, scientists can match the genetic profile of an individual to a DNA sample found at a crime scene or on a crime victim.⁶⁴ In 1986, this observation led to the first use of DNA testing in a United States court.⁶⁵

B. The Admissibility of DNA as Scientific Evidence

Though accepted as a means of criminal investigation, the use of DNA forensics to establish guilt or innocence at trial—where the rules of evidence apply—was an unsettled issue of law during the late 1980s. The reluctance of courts to admit into evidence the results of DNA testing “resulted mainly from the lack of reliability in the early form of tests.”⁶⁶ As a result, some scholars have suggested that DNA forensics paved the way for the Supreme Court’s decision in *Daubert* because early courts focused on the reliability of the scientific techniques of DNA testing rather than on whether the techniques were “generally accepted” in the relevant scientific

60. *Id.*

61. *Id.* Certain combinations of bases, termed codons, “specify the production of particular amino acids, which then link to form proteins. Thus, the DNA sequence of the gene of interest will determine which amino acids and, ultimately, which proteins its host cell produces.” John M. Conley & Robert Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents*, 85 J. PAT. & TRADE-MARK OFF. SOC’Y 371, 381 (2003).

62. See Human Genome Project Information, DNA Forensics, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/forensics.shtml (last visited Mar. 16, 2007).

63. Luftig & Richey, *supra* note 53, at 609.

64. The chance that a positive DNA match does not belong to the same person may be less than one in 500 million. SIMSON GARFINKEL, DATABASE NATION 49 (2000).

65. See NAT’L INST. OF JUSTICE NATIONAL COMMISSION ON THE FUTURE OF DNA EVIDENCE, POSTCONVICTION DNA TESTING: RECOMMENDATIONS FOR HANDLING REQUESTS 1 (1999).

66. Jennifer Boemer, Note, *In The Interest of Justice: Granting Post-Conviction Deoxyribonucleic Acid (DNA) Testing to Inmates*, 27 WM. MITCHELL L. REV. 1971, 1974 (2001).

community (although the fact that such procedures were not generally accepted did, to be sure, contribute to that reluctance).⁶⁷

It was against this backdrop that the first appellate court in the United States addressed the issue of DNA forensics in 1988 in *State v. Andrews*.⁶⁸ In *Andrews*, police officers obtained DNA from a semen sample found on a rape victim and matched it to the DNA taken from a blood sample that was drawn from the alleged rapist.⁶⁹ The trial court was thus faced with deciding whether to admit the results of a DNA test at trial.⁷⁰ Consistent with the national doubt regarding the continued viability of *Frye*, the Florida appellate court “confess[ed] some uncertainty as to the standard applicable in this state governing admissibility into evidence of a new scientific technique.”⁷¹ Rather than apply the *Frye* test, however, the court concluded that the “relevancy approach set out in the evidence code is the appropriate standard for determining the admissibility of expert testimony” and that “without some indicia of reliability, opinion evidence on a particular subject could hardly be helpful to a jury.”⁷²

Applying this standard (which the United States Supreme Court effectively adopted five years later in *Daubert*), the *Andrews* court held that the DNA evidence was admissible.⁷³ The court observed that several expert witnesses, including a prominent molecular biologist from the Massachusetts Institute of Technology (MIT), testified that the DNA techniques used to identify the defendant as a rapist were relevant and reliable, notwithstanding the novelty of applying them to establish human identity.⁷⁴

67. See generally David L. Faigman, *The Tipping Point in the Law's Use of Science: The Epidemic of Scientific Sophistication that Began with DNA Profiling and Toxic Torts*, 67 BROOK. L. REV. 111 (2001).

68. 533 So. 2d 841 (Fla. Dist. Ct. App. 1988).

69. *Id.* at 842-43.

70. *Id.* at 843.

71. *Id.*

72. *Id.*

73. *Id.* at 850.

74. *Id.* at 847-49. The professor from MIT was Dr. David E. Housman, who, at the time of trial, specialized in molecular genetics and had published approximately 120 papers on that topic. *Id.* at 847. In addition to serving on advisory boards involving genetics for the National Institute of Health, the Heredity Disease Foundation, and the Tourette's Syndrome Foundation, Dr. Housman visited Lifecodes, Inc.—the company which performed the instant test—to examine the company's testing procedures. The state additionally called two esteemed scientists, Allen Guisti and Dr. Michael Baird, who worked for Lifecodes and had published numerous articles on DNA technology. *Id.* The credibility of these witnesses no doubt played a substantial role in the trial court's decision to admit DNA evidence in *Andrews*.

Given that the DNA print results were “helpful to the jury”⁷⁵ and that “evidence derived from DNA print identification appears based on proven scientific principles,”⁷⁶ the court determined that the DNA evidence satisfied the relevancy and reliability tests. In so doing, the court affirmed the first DNA-based conviction in the United States.⁷⁷

Change was thus afoot. In the decade that followed, every state and Federal Circuit recognized the admissibility of DNA evidence in one form or another.⁷⁸ As a result, courts now readily accept DNA forensic evidence for identification purposes in criminal trials,⁷⁹ postconviction relief proceedings,⁸⁰ and civil litigation (to establish paternity and other family ties in adoption, child support, and immigration cases).⁸¹ Indeed, “the scientific basis for this evidence is now so well established that its admissibility is sanctioned by statute in many jurisdictions”⁸² Consequently, American courts have generally accepted the basis for DNA identification.⁸³ Most recently, a series of federal courts have sustained state laws requiring DNA samples from convicted offenders to be stored in DNA databases.⁸⁴

75. *Id.* at 849.

76. *Id.* at 850.

77. The first court of last resort to address the admissibility of DNA evidence was the West Virginia Supreme Court of Appeals in *State v. Woodall*, 385 S.E.2d 253 (W.Va. 1989).

78. Paul C. Giannelli, *The DNA Story: An Alternative View*, 88 J. CRIM. L. & CRIMINOLOGY 380, 381 (1997).

79. Walsh, *supra* note 16, at 140.

80. See Brooke A. Masters, *DNA Testing in Old Cases Is Disputed: Lack of National Policy Raises Fairness Issue*, WASH. POST, Sept. 10, 2000, at A1, A5 (discussing the practices of different jurisdictions regarding postconviction DNA testing).

81. Denise K. Casey, *Genes, Dreams, and Reality: The Promises and Risks of the New Genetics*, 83 JUDICATURE 105, 109 (1999).

82. Walsh, *supra* note 16, at 142. On January 11, 2006, the U.S. Supreme Court heard arguments to determine whether prisoners have a right to use DNA evidence to seek new trials. In 2004, on a hearing en banc, the Sixth Circuit held, 8-7, that a man sentenced to death for a 1985 murder was not entitled to a new trial, despite recent DNA evidence that allegedly cast doubt on his guilt. *House v. Bell*, 386 F.3d 668 (6th Cir. 2004), *rev'd*, 126 S. Ct. 2064 (2006). The case is reportedly the first time a death row inmate has brought DNA evidence before the U.S. Supreme Court to prove his innocence. Duncan Mansfield, *High Court to Weigh DNA in Death Row Case*, THE BOSTON GLOBE, Jan. 10, 2006, http://www.boston.com/news/nation/articles/2006/01/10/high_court_to_weigh_dna_in_death_row_case.

83. *Id.* Given the widespread admissibility of DNA evidence, the Bush Administration has devoted nearly \$800 million “to perform DNA analysis over the next five years in unsolved rapes and other old cases and to make improvements in the nation’s computerized DNA crime-fighting system.” Richard Willing, *More Funding Directed to DNA Crime Fighting*, USATODAY.COM, http://www.usatoday.com/news/washington/2004-03-07-dna-funds_x.htm (last visited Mar. 16, 2007).

C. Future Legal Issues Involving DNA Forensics

Although the reliability of DNA technology for identification purposes is well settled, the use of such technology to predict or explain behavior will inevitably give rise to new and challenging legal issues.⁸⁵ Many state legislatures, for example, have required DNA samples from convicted sex offenders⁸⁶ and authorized the creation of DNA databanks.⁸⁷ Beyond the questions regarding ownership, access, and genetic privacy, such databases raise concerns about the propriety of using genetic information to discriminate against individuals for insurance or employment purposes.⁸⁸ Genetic information will also raise legal issues about “what constitutes ‘having’ a particular disease as compared with being ‘predisposed’ to contracting a disease”—a distinction that “may have a significant impact on insurance, medical malpractice, product liability, and other health and employment issues that come before the courts.”⁸⁹

84. See, e.g., *Nicholas v. Goord*, 430 F.3d 652, 671 (2d Cir. 2005); *United States v. Kincade*, 379 F.3d 813 (9th Cir. 2004) (en banc), *cert. denied*, 544 U.S. 924 (2005); *Green v. Berge*, 354 F.3d 675, 679 (7th Cir. 2004). See generally Sasha Polonsky, Note, “Banking” on Law Enforcement: Advocating a New Balancing Test for DNA Storage After *United States v. Kincade*, 83 WASH. U. L.Q. 1331 (2005).

85. See generally Mark A. Rothstein, *The Impact of Behavioral Genetics on the Law and the Courts*, 83 JUDICATURE 116, 117 (1999).

86. Jennifer Graddy, *The Ethical Protocol for Collecting DNA Samples in the Criminal Justice System*, 59 J. MO. B. 226, 226-27 (2003). Although every state requires the collection of DNA samples from convicted sex offenders, “beyond th[at] . . . the states differ significantly.” Many states, for example, “require DNA samples from only a narrow group of felons, such as those convicted of homicide and sexual assault.” *Id.* at 227-28. Nevertheless, Alabama, New Mexico, Virginia, and Wyoming require DNA samples from all convicted felons. *Id.* (citing ALA. CODE § 36-18-24 (2001); N.M. STAT. ANN. §§ 29-16-1 to -13 (Michie 2003); VA. CODE ANN. § 19.2-310.2 (Cum. Supp. 2002); WYO. STAT. ANN. §§ 7-19-401 to -405 (Michie 2003)). Several states, such as Arizona, Arkansas, and Delaware, even require DNA samples for certain misdemeanors. *Id.* (citing ARIZ. REV. STAT. ANN. § 31-281 (A) (West 2002); ARK. CODE ANN. § 12-12-1109 (LexisNexis Supp. 2003); DEL. CODE ANN. tit. 29 § 4713 (LexisNexis 1997)).

87. Giannelli, *supra* note 78, at 392-93.

88. For a detailed discussion of these issues, see *infra* Part V.

89. Abrahamson, *supra* note 3. Additionally, as DNA research progresses, legal arguments predicated on genetic determinism may reappear. Rothstein, *supra* note 85, at 119. As one scholar has observed, “behavior genetic arguments are particularly appealing in criminal cases because they can be used to prove that the defendant was compelled to act by uncontrollable genetic factors. *Id.* Justice Joseph T. Walsh of the Delaware Supreme Court has asserted that “the emergence of DNA evidence as a forensic tool for identification purposes and as a prediction of physical and emotional abnormality is a good example of how knowledge [of courts] outstrips the ability of courts to accommodate its implications.” Walsh, *supra* note 16, at 142.

One novel issue of DNA forensics currently facing courts is the admissibility of a new form of DNA, known as “Y-STR DNA.” Y-STR DNA testing can identify male DNA (the Y chromosome) in male/female DNA mixtures, even where the female DNA is present in an overwhelming proportion to the male DNA. As a result, many scientists and lawyers believe that Y-STR DNA will be increasingly helpful in cases of sexual assault between a male perpetrator and a female victim.⁹⁰ Although few published decisions address the admissibility of Y-STR DNA evidence, courts that have confronted the issue have generally concluded that Y-STR DNA is reliable and, therefore, admissible.⁹¹

Another novel issue currently facing courts is the practice of indicting genetic material when law enforcement officers are unable to match DNA found at a crime scene with a named individual.⁹² In an attempt to indict the unknown suspect within the applicable statute of limitations, prosecu-

90. See Cassie Johnson, *Validation and Uses of a Y-Chromosome STR 10-Plex for Forensic and Paternity Laboratories*, 48 J. FORENSIC SCI. 6, 1-9 (Nov. 2003).

91. See, e.g., *Shabazz v. State*, 592 S.E.2d 876, 879 (Ga. Ct. App. 2004). Squire, Sanders & Dempsey L.L.P. (where one of the authors, Stephen Anway, practices law) recently represented a criminal defendant on a pro bono basis in a post-conviction proceeding that involved Y-STR DNA. See *State v. Elkins*, Summit C.P. No. CR 1998-06-1415 (Ohio Ct. Com. Pl. Dec. 9, 2002). The defendant, Clarence Elkins, had been convicted in 1999 for the rape and murder of his fifty-eight-year-old mother-in-law and the rape of her six-year-old granddaughter. The court sentenced Mr. Elkins to life in prison.

Three years later, Mr. Elkins sought a new trial and an order requiring the state to pay for DNA testing. After these requests were denied, Mr. Elkin’s wife raised funds from internet contributors to pay for DNA testing on pieces of evidence admitted at trial. This new testing used Y-STR DNA technology, which had been unavailable six years earlier at his trial. The Y-STR DNA testing revealed another individual’s DNA on both the child’s panties and on the grandmother’s vaginal swab.

Mr. Elkins filed a notice of appeal in 2005. While the appeal was pending, Mr. Elkins reportedly discovered that the DNA found on the two victims appeared to match the DNA of an individual who is currently incarcerated for sexual offenses against minors and who happened to live two doors down from the grandmother. Mr. Elkins—with the support of the Ohio Attorney General—sought to remand the matter to allow the trial court an opportunity to consider the evidence. The request was denied.

On December 15, 2005, Mr. Elkins received another DNA report on outstanding hair strands taken from the victims’ clothing that appeared to closely match the individual who is currently incarcerated for sexual offenses against minors. The prosecutor thereafter filed a motion to dismiss all charges against Mr. Elkins and secure his immediate release. Mr. Elkins was home for Christmas—the first with his wife and children in over seven years.

92. Andrew C. Bernasconi, *Beyond Fingerprinting: Indicting DNA Threatens Criminal Defendants’ Constitutional and Statutory Rights*, 50 AM. U. L. REV. 979, 981-82 (2001).

tors have brought charges against the DNA of the suspect.⁹³ For example, California police, unable to match the DNA found at the crime scene to a named individual, recently indicted the suspect's genetic profile—one day before the statute of limitations would have barred his prosecution.⁹⁴ Although this case marks the first time the police have arrested a suspect after his DNA was indicted, prosecutors in at least nine states have filed charges against or indicted “John Doe” suspects by relying exclusively on the DNA of the suspect.⁹⁵

Notwithstanding questions about the propriety of indicting genetic material (which are beyond the scope of this Article), DNA evidence will continue to present new and challenging issues to every judicial system. Indeed, the assimilation of DNA technology into criminal trials comes just as the role of judges as “gatekeepers” to assess scientific evidence is expanding.⁹⁶ The reality for every judicial system, therefore, is that other novel, more complex issues concerning DNA evidence will require an intricate knowledge of biotechnology. With this concern in mind, the next Part examines another issue of biotechnology that will challenge the scientific knowledge of trial courts—genetic engineering.

IV. GENETIC ENGINEERING

Advancements in biotechnology have empowered scientists to manipulate a variety of factors in our environment, including the food that we

93. *Id.* at 983.

94. *Id.* at 980. Because the police could not determine the identity of the suspect at the time of the indictment, they sought a “John Doe” warrant. *Id.* California police eventually arrested Paul Eugene Robinson and charged him with committing a series of sexual assaults. *Id.* (citing Erin Hallissy & Charlie Goodyear, *Databank Match Brings Arrest on DNA Warrant*, S.F. CHRON., Oct. 25, 2000, at A3).

95. *Id.* at 981-82. The other states in which a genetic material has been indicted include Texas, Wisconsin, North Dakota, Pennsylvania, Oklahoma, New York, Utah, Missouri, and Kansas. See Julian E. Barnes, *East Side Rapist, Known Solely by DNA, Is Indicted*, N.Y. TIMES, Mar. 16, 2000, at B1; Greg Kennedy, *Prosecutors File Charges Against DNA Profile in OU Student's Murder*, THE DAILY OKLAHOMAN, Mar. 21, 2000, at 1A; Lisa Sink & Linda Spice, *Use of DNA Evidence Expands; State Lab Testing Saliva on Envelope*, MILWAUKEE J. SENTINEL, Oct. 26, 2000, at 1B; Brady Snyder & Amy Joi Bryson, *Charge Filed Against DNA*, DESERET NEWS (Utah), Mar. 3, 2000, at A01; *DNA Profile is Used as Basis for Arrest Warrant in Sexual Assault Case*, ST. LOUIS POST-DISPATCH, Dec. 5, 1999, at C2; *Unknown Man Indicted in Austin Rape Case*, HOUS. CHRON., Nov. 5, 2000, at A45.

96. Abrahamson, *supra* note 3; see *supra* Section II.C (discussing the Supreme Court's decisions in *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), and the resultant expansion of the trial court's role as gatekeeper).

consume.⁹⁷ One such advancement is genetic engineering, which has enabled scientists to alter the genetic composition of both plant and animal organisms.⁹⁸ For example, scientists have “mix[ed] genes on the cellular and molecular level in order to create new breeds of plants for human and animal consumption.”⁹⁹ Although genetically engineered breeds provide benefits unavailable with organic breeds, genetic engineering has been fraught with controversy—particularly in the production, sale, and trade of genetically modified foods. This Part examines the current and future legal issues of genetic engineering that courts are facing and will continue to face in coming years. It begins with a scientific overview before turning to two genetic engineering legal issues: intellectual property rights and safety. This Part further illustrates the challenges that courts face when hearing and deciding biotechnology cases: these cases raise highly technical issues that often precede legislation on key issues and require judges to apply a level of scientific knowledge with which most judges are not armed.

A. Scientific Overview

Genetic engineering—also referred to as “bioengineering” or “genetic modification”—is the process of modifying the DNA of an organism by uniting it with another organism’s genes.¹⁰⁰ To render the desired modifications, scientists employ a technology, called recombinant DNA (rDNA), whereby they identify specific genes, make copies of those genes, and introduce the gene copies into recipient organisms.¹⁰¹ The transfer of the

97. See *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 169 (D.D.C. 2000) (discussing, in one of the first reported opinions to address the safety concerns associated with GMOs, that biotechnology allows scientists to manipulate a variety of factors in our environment through genetic engineering).

98. *Id.*

99. Alicia T. Simpson, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods?*, 19 TEMP. ENVTL. L. & TECH. J. 225, 228 (2001) (citing *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 169).

100. Heather N. Ellison, *Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?*, 10 PENN ST. ENVTL. L. REV. 345, 347 (2002).

101. *Id.* One commentator has described the various methods of gene-splicing in the following manner:

Modern gene-splicing techniques allow scientists to introduce genes from a living organism (called the “donor”) into a plant (called a “host”) in several ways, including: (1) direct DNA uptake by the plant cells mediated by chemical or electrical treatments; (2) microinjection of DNA directly into plant cells; (3) biolistics, or firing tiny metal particles coated with the DNA of interest into plant cells; and (4) infecting the plant with a bacterium that scientists have modified to carry the

DNA segments from the donor organism to the host organism occurs when a host cell incorporates the fragment of the donor DNA. The cell then expresses the new gene by producing the protein for which the new gene “codes.”¹⁰² The protein (or its byproduct) alters a characteristic or trait of the host organism, which the host reproduces in succeeding generations.¹⁰³ As a result, “genetic engineers can in a generation or two design plants to produce different types and quantities of proteins, carbohydrates, fats and oils, the primary building blocks of human food.”¹⁰⁴

The benefits associated with genetic engineering have caused a proliferation of “GMOs”—an acronym for “genetically modified organisms,” which we use as shorthand for all bioengineered foods throughout this Part.¹⁰⁵ The benefits of GMOs include improved quality and abundance, longer freshness, enhanced flavor and nutritional value, and enhanced resistance to insect pests (which reduces the cost and health risks associated with insecticide use). Nevertheless, some critics have voiced concerns over the health, consumer choice, and environmental harms of GMOs.¹⁰⁶

DNA into plant cells. In each of these techniques, scientists insert DNA segments from the “donor” organism into the chromosome of the “host” plant cells in a semi-random fashion.

Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 406-07 (2002) (footnotes omitted).

102. McGarity, *supra* note 101, at 407.

103. *Id.* Professor McGarity further explains that “[t]o distinguish those cells that have successfully taken up the donor gene from those that have not, scientists typically attach an additional DNA segment containing a gene that is capable of rendering the host cell resistant to a particular antibiotic, herbicide, or other toxic agent.” *Id.*

104. *Id.* at 408. The first GMO food—a genetically modified tomato—was sold in the U.S. market in 1995. Debra Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD DRUG L.J. 167 (2006).

105. Frank J. Miskiel, *Voluntary Labeling of Bioengineered Food: Cognitive Dissonance in the Law, Science, and Public Policy*, 38 CAL. W. L. REV. 223, 223 (2001). Indeed, “the acreage planted with genetically modified crops has exploded: a third of the country’s corn by 2002 and three-quarters of its soybeans.” *Keeping Seeds Safe*, N.Y. TIMES, Mar. 1, 2004, at A1.

106. Rebecca M. Bratspies, *Bridging the Genetic Divide: Confidence-Building Measures for Genetically Modified Crops*, 44 JURIMETRICS J. 63, 71 (2003). These safety concerns stem from both known and unknown allergenic, toxic, pathogenic, and immunological effects of GMOs and are discussed *infra* Section IV.B.2.a.

B. Legal Issues Associated with GMOs

As GMOs proliferate, so too will the legal issues that surround them. The following Sections examine two legal issues associated with GMOs: ownership and safety.¹⁰⁷

1. Intellectual Property Rights and GMOs

Genetic engineering transformed the agriculture industry.¹⁰⁸ An essential part of this transformation was the ability of start-up biotech companies to “own” genetic innovations—preventing others from capitalizing on the labor and money used to develop genetic inventions.¹⁰⁹ Having the ability to protect such inventions was necessary to provide incentive to start-up biotech companies “whose seed capital depended upon their ability to develop patent portfolios and thereby attract investors.”¹¹⁰

The focus of the scientific community thus turned to patent law.¹¹¹ Given that Congress had not yet addressed whether patents could be granted for genetically modified living organisms, courts were forced to address the issue within the preexisting statutory framework.¹¹² The Patent Act defines a patentable invention as a “process, machine, manufacture, or composition of matter” that is new, useful, and non-obvious.¹¹³

In its 1972 landmark decision *Diamond v. Chakrabarty*,¹¹⁴ the United States Supreme Court interpreted the Patent Act to provide that living organisms—in that case, a man-made bacterium with properties unlike any known naturally-occurring organism—comprised patent-eligible subject

107. Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 DRAKE J. AGRIC. L. 81, 87 (2001).

108. See David R. Nicholson, *Agricultural Biotechnology and Genetically-Modified Foods: Will the Developing World Bite?*, 8 VA. J.L. & TECH. 7, ¶ 12 (2003). This transformation is perhaps best illustrated by the fact that the agriculture-biotech industry is expected to reach \$20 billion by 2010. *Id.*

109. *Id.* As Nicholson observed, “[t]o produce these results, obviously, substantial investment in research and development is necessary, which can only be undertaken if there is the opportunity to gain a return on the investment.” *Id.*

110. *See id.*

111. *See id.*

112. 35 U.S.C. §§ 100-103 (2000). Thus, rather than address the proprietary rights of genetic engineers under a statutory law that is specifically tailored to agricultural innovations, courts were forced to address such issues under the general patent law. That law, however, presents unique problems in the context of agricultural innovations because, although the purpose of intellectual property law is to control access to certain property, plants are self-perpetuating.

113. *Id.* §§ 101, 103.

114. 447 U.S. 303 (1980).

matter.¹¹⁵ The Court thus affirmed the judgment of the United States Court of Customs and Patent Appeals, which had concluded that the United States Patent and Trademark Office erred in denying a patent because the subject matter was a “live organism[].”¹¹⁶ In awarding the patent, the Court declared that patentable subject matter includes “anything under the sun that is made by man.”¹¹⁷ This declaration became “the mantra for the unprecedented expansion in patent-eligible subject matter over the past twenty-plus years.”¹¹⁸

Nevertheless, plants that reproduce through seed have presented “a particularly vexing intellectual property problem because these plants can reproduce through natural processes, in effect providing a free, renewable supply to the farmer.”¹¹⁹ As one scholar has noted, “intellectual property protection is about controlling access to or use of a particular invention, and a self-propagating invention obviously presents unique problems in this context.”¹²⁰ In response to the unique characteristics of such inventions, Congress enacted the Plant Patent Act of 1930 (PPA),¹²¹ which confers patent protection on specified asexually-reproduced plants, and the Plant Variety Protection Act (PVPA),¹²² which Congress originally enacted in 1970 and provides some protection concerning sexually-reproduced or tuber-propagated plants. These Acts, together with trade secret law and utility patents, provide inventors with a variety of legal means to protect plant innovations.¹²³

115. *Id.* at 318.

116. *In re Chakrabarty*, 571 F.2d 40, 41 (C.C.P.A. 1978).

117. *Diamond*, 477 U.S. at 309 (quoting S. REP. NO. 1979, at 5 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399).

118. Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 485 (2003).

119. Nicholson, *supra* note 108, ¶ 14.

120. *Id.*

121. 35 U.S.C. §§ 161-64 (2000). The PPA provides *sui generis* protection to an individual who “invents or discovers and asexually reproduces any distinct and new variety of plant.” § 161. The Act excludes from protection, however, plants that sexually reproduce (through seeds) because “it was believed that they would not breed true, thus rendering them incapable of satisfying the ‘written description’ portion of the patent law.” Cullen N. Pendleton, *The Peculiar Case of “Terminator” Technology: Agricultural Biotechnology and Intellectual Property Protection at the Crossroads of the Third Green Revolution*, 23 BIOTECHNOLOGY L. REP. 1, 8 (2004) (citing *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int’l*, 534 U.S. 124, 134 (2001)).

122. 7 U.S.C. §§ 2321-2582 (2000).

123. *Id.* Sexually propagated plants, although not protected under the PPA, see *supra* note 121, became protected by the PPVA in 1970. See *id.* Under the PPVA, a plant is afforded protection if it is novel, distinct, uniform, and stable. 7 U.S.C. § 2402(a) (2000).

Most recently, the United States Supreme Court in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*¹²⁴ addressed whether utility patents could protect plant inventions or whether only the PPA and PVPA protect such inventions.¹²⁵ The Court held that novel plant breeds were eligible for utility patent protection under the Patent Act and that neither the PPA nor the PVPA limited the scope of such coverage.¹²⁶ Consistent with its earlier pronouncement in *Chakrabarty*, the Court reiterated that courts should construe the Patent Act liberally to evolve with developments in science and technology.¹²⁷

Consequently, the manner in which American courts have shaped intellectual property law has been vital to the rise of biotechnology. And just as early patent decisions fostered the proliferation of genetic innovations, the courts' early decisions with respect to GMO safety will shape the future of biotechnology.

2. *Safety Issues Associated with GMOs*

Public concern about the safety of GMOs can be generally classified into two categories: (1) human health and consumer choice concerns and (2) environmental concerns.¹²⁸ The former set of concerns relates to whether GMOs are safe to consume; the latter to the possible ecological hazards that GMOs present when cultivated.¹²⁹ This section analyzes each concern separately and then draws them together in an examination of *Alliance for Bio-Integrity v. Shalala*¹³⁰—a case in which a judge was called upon to address the cutting edge issue of GMO safety.

a) Human Health and Consumer Choice Concerns with GMOs

With the recent increase of GMOs, the human health and consumer choice issues associated with such foods pose potential safety risks to every nation in the world. To combat these risks, the European Commission in the World Trade Organization blocked the import of bioengineered

124. 534 U.S. 124 (2001).

125. *Id.* at 125-27.

126. *Id.* at 137. The Court concluded that “[i]n short, there is simply no evidence, let alone the overwhelming evidence needed to establish repeal by implication, . . . that Congress, by specifically protecting asexually reproduced plants through the PPA, intended to preclude utility patent protection for sexually reproduced plants.” *Id.* (citing *Matsushita Elec. Indus. Co. v. Epstein*, 516 U.S. 367, 381 (1996)).

127. *J.E.M. AG Supply*, 534 U.S. at 137 n.9 (“[T]hese subject matter terms have been interpreted broadly to evolve with developments in science and technology.”).

128. Bratspies, *supra* note 106, at 70.

129. *Id.*

130. 116 F. Supp. 2d 166 (D.D.C. 2000).

seeds¹³¹—a move that, in addition to costing U.S. corn farmers more than \$200 million a year, prompted a U.S. official to state that he had “strongly considered” filing a lawsuit against the European Commission.¹³²

Through such legal action, the U.S. government might hope to prevent other nations from promulgating unnecessary regulations related to GMOs.¹³³ These initiatives reflect the position that restrictive regulations are not based on verifiable “scientific risk.”¹³⁴ The U.S. policy, in contradistinction to that of the European Commission, is that the GMOs should be permitted to flourish in the absence of proven hazards.¹³⁵

In 1992, the FDA published a “Statement of Policy: Foods Derived from New Plant Varieties” (FDA Statement of Policy).¹³⁶ The FDA Statement of Policy announced that the FDA would presume that foods produced through the rDNA process were “generally recognized as safe” under the Federal Food, Drug and Cosmetic Act¹³⁷ and indicated that labeling for rDNA-developed foods was not necessarily required.¹³⁸ This led to widespread consumer demand for the labeling of GMOs in the late

131. Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 734 (2003). GMOs have been banned in Europe since April 1998. See Deborah J. La Fetra, *Freedom, Responsibility, and Risk: Fundamental Principles Support Tort Reform*, 36 IND. L. REV. 645, 685 n.195 (2003). Further, “the European Union is also pushing for strict controls over the importation of GM foods.” *Id.* (citing *EU to Fight for GM Food Ban*, BBC NEWS, Dec. 13, 1999, available at <http://news.bbc.co.uk/2/hi/business/563579.stm>).

132. When asked about the trade conflict with the Europeans, the U.S. officer—Trade Representative Robert Zoellick—stated, “I personally am of the view that we now need to bring a case.” *Zoellick Calls For WTO Case Against EU Biotechnology Moratorium*, INSIDE U.S. TRADE, Jan. 10, 2003, at 1. The purpose of the lawsuit would purportedly be to enjoin the WTO from blocking the import of U.S. bioengineering seeds. Marden, *supra* note 131, at 734. For a more recent discussion of European views regarding GMOs, see *Biotech Food Tears Rifts in Europe*, N.Y. TIMES, June 6, 2006.

133. Marden, *supra* note 131, at 734 *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 734 (2003).

134. *Id.*; see Ellison, *supra* note 100, at 348.

135. The U.S. Trade Representative’s fact sheet on Agricultural Biotechnology states in its first bulleted point: “The United States government has a coordinated, risk-based system to ensure new biotechnology products are safe for the environment and human and animal health.” U.S. Trade Representative, *Agricultural Biotechnology: The U.S. Regulatory System*, Sept. 2006, http://www.ustr.gov/assets/Trade_Sectors/Agriculture/Biotechnology/asset_upload_file312_8907.pdf; see also Ellison, *supra* note 100, at 348. For a more comprehensive discussion of U.S. policy on GMOs, see generally Ellison, *supra* note 100, at 348.

136. 57 Fed. Reg. 22,984 (May 19, 1992).

137. 21 U.S.C. § 321(s).

138. 57 Fed. Reg. 22,991 (May 29, 1992).

1990s.¹³⁹ The issue promptly reached the Federal Circuit in *Alliance for Bio-Integrity v. Shalala*.¹⁴⁰

b) Environmental Concerns with GMOs

In addition to challenging the decision of the FDA to not require labeling of GMOs, the plaintiffs in *Alliance for Bio-Integrity* alleged that the potential environmental harms of such foods rendered the FDA policy invalid.¹⁴¹ This allegation was based on the three potential environmental harms of GMOs. First, the cross-pollination of wild plants with genetically modified pollen may transfer herbicide resistance to¹⁴² and reduce biodiversity of¹⁴³ such plants.¹⁴⁴ Second, the use of GMOs may kill beneficial insects¹⁴⁵ or cause harmful insects to develop a tolerance to insecticides.¹⁴⁶

139. According to one survey in 1997, “ninety-three percent of Americans wanted the FDA to require labeling of genetically engineered foods. In addition, a *Time Magazine* poll conducted in 1999 found that eighty-one percent of those polled wanted bioengineered foods to be labeled.” Marden, *supra* note 131, at 760.

140. 116 F. Supp. 2d 166 (2000).

141. Ellison, *supra* note 100, at 347.

142. Ke Geng, *Should China Provide Intellectual Property Protection for Genetically Modified Animals?*, 23 NW. J. INT’L L. & BUS. 467, 470 (2003) (explaining that “crops with herbicide resistance genes may transfer these genes to weeds, thus creating a major threat to the environment”). This resistance may in turn “encourage farmers to use more chemicals, with accompanying risks to the environment and pesticide applicators.” Margaret Rosso Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 220 (2002).

143. Kim JoDene Donat, *Engineering Akerlof Lemons: Information Asymmetry, Externalities, and Market Intervention in the Genetically Modified Food Market*, 12 MINN. J. GLOBAL TRADE 417, 456 (2003) (noting that “[e]nvironmentalists argue that GMOs will destroy biodiversity”).

144. The Union of Concerned Scientists has confirmed that genes from modified plants “somehow drift into unmodified ones.” *Keeping Seeds Safe*, *supra* note 105 (noting that two independent labs examined samples of corn, soybean, and canola and “found contamination in half the corn, half the soybean and more than 80 percent of the canola varieties”). These scientists have thus concluded that “[t]o contaminate traditional varieties of crops is to contaminate the genetic reservoir of plants on which humanity has depended for most of its history.” *Id.*

145. Lakshman D. Guruswamy, *Sustainable Agriculture: Do GMOs Imperil Biosafety?*, 9 IND. J. GLOBAL LEGAL STUD. 461, 476 (2002) (“There is also evidence that beneficial insects, ‘unintended targets,’ are killed as a result of GMOs containing pesticides.”).

146. Donat, *supra* note 143 (noting that “[e]nvironmentalists argue that GMOs will . . . create super-insects and weeds that will cause environmental degradation and contamination”).

Finally, the widespread use of GMOs could result in an increased generation rate of new viruses unaffected by current control measures.¹⁴⁷

Similar to the position of the FDA regarding the health concerns of GMOs, the EPA concluded that the existing statutory and regulatory framework adequately addressed the environmental concerns posed by genetic engineering.¹⁴⁸ And, to date, the EPA has not determined that GMOs pose a verifiable “scientific risk” to the environment under this framework.¹⁴⁹ As a result, the legal theory upon which the plaintiffs relied in *Alliance for Bio-Integrity* was not that the FDA Statement of Policy violated an EPA or USDA regulation, but rather that the FDA did not comply with the existing procedures before issuing the policy.¹⁵⁰

c) *Alliance for Bio-Integrity v. Shalala*

In *Alliance for Bio-Integrity*,¹⁵¹ a coalition of groups and individuals brought suit in federal court to invalidate the FDA policy on GMOs.¹⁵² The plaintiffs had two concerns: first, that new breeds of GMOs contained unexpected allergens and toxins; and second, that the religion of some plaintiffs forbade consumption of foods produced by rDNA technology.¹⁵³ In fashioning legal arguments to address these concerns, the plaintiffs challenged the policy on four grounds: (1) the policy was not subjected to notice-and-comment procedures as required by section 553 of the Administrative Procedure Act; (2) the FDA violated the National Environmental Protection Act (NEPA) by not performing an Environmental Assessment or an Environmental Impact Statement in conjunction with the policy; (3) the presumption that GMOs are “generally accepted as safe” was arbitrary.

147. Some scientists, for example, “are concerned that the use of a common gene promoter from the Cauliflower mosaic virus ‘may result in a major source of new viruses arising from recombination.’” Emily Robertson, *Finding a Compromise in the Debate over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 169 (2003) (quoting Richard Caplan & Ellen Hickey, *Weird Science: A Brave New World of Genetic Engineering*, Oct. 31, 2001, <http://www.uspirg.org/home/reports/report-archives/food-safety/food-safety-reports/weird-science-the-brave-new-world-of-genetic-engineering>).

148. Marden, *supra* note 131, at 743-45, 767-77, 776. In contrast to the FDA and the EPA, however, the USDA “initially chose to take a precautionary approach under this existing statutory regime. Instead of presuming that existing regulations were adequate to apply also to GM products, USDA proposed and promulgated regulations specific to GM products.” *Id.* at 768.

149. *Id.* at 778.

150. *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 170 (D.D.C. 2000).

151. *Id.* at 166.

152. *Id.* The coalition was comprised of scientists and religious leaders who were “concerned about genetically altered foods.” *Id.* at 170.

153. *Id.*

trary and capricious; and (4) the policy failed to require labeling of GMOs in violation of the FDCA, the Free Exercise Clause of the United States Constitution, and the Religious Freedom Restoration Act.¹⁵⁴

The district court rejected each of the plaintiffs' arguments and granted a motion for summary judgment in favor of the FDA.¹⁵⁵ The court disagreed that the FDA was required to conduct notice-and-comment procedures because the policy merely created a presumption rather than a substantive rule.¹⁵⁶ The court additionally concluded that the FDA did not violate the NEPA because the FDA Statement of Policy was not a "major federal action" and, therefore, was neither subject to an Environmental Assessment nor an Environmental Impact Statement.¹⁵⁷ Finally, the court determined that scientific applications of statutory law were within the expertise of the FDA and that principles of administrative law prevented the court from second-guessing the decision of the FDA to issue the policy.¹⁵⁸

The court similarly deferred to the FDA's decision not to require the labeling of GMOs.¹⁵⁹ The relevant provision in the FDCA provides that the FDA shall take action for the misbranding of a food if the labeling "fails to reveal facts . . . material with respect to consequences which may result from use of the article."¹⁶⁰ In analyzing this provision, the court de-

154. *Id.*

155. *Id.* at 172-81. In upholding the FDA decision, the court relied on the well-settled proposition that "[t]he rationale for deference is particularly strong when the [FDA] is evaluating scientific data within its technical expertise." *Id.* at 177 (quoting *Int'l Fabricare Inst. v. U.S. Env't'l. Prot. Agency*, 972 F.2d 384, 389 (D.C. Cir. 1992)). On this point, the court elaborated that "[i]n an area characterized by scientific and technological uncertainty . . . [it should avoid] all temptation to direct the agency in a choice between rational alternatives." *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177 (quoting *Env't'l. Def. Fund, Inc. v. Costle*, 578 F.2d 337, 339 (D.C. Cir. 1978)).

156. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 172-73. Unanimity among scientists, the court observed, was not required to preclude a finding that GMOs are "generally accepted as safe"; rather, a plaintiff must show a "severe conflict among experts" to support such a conclusion. *Id.* at 177 (quoting 62 Fed. Reg. at 18,939 (Apr. 17, 1997)).

157. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 173-75.

158. *Id.* at 175-78; Marden, *supra* note 131, at 756.

159. Marden, *supra* note 131, at 756.

160. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 178 (quoting 21 U.S.C. § 321(n) (2000)). In its entirety, section 321(n) of Title 21 provides:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which

terminated that the FDA may only consider consumer demand for such labeling if the FDA first determined that genetically modified food differed “materially” from unmodified food.¹⁶¹ Because the FDA had concluded that genetic modification of a food was not a “material” change in the food, the court deferred to that conclusion, holding that the policy did not violate the FDCA.¹⁶² The court concluded its analysis by noting that the failure of the policy to require such labeling violated neither the Free Exercise Clause nor the Religious Freedom Restoration Act.¹⁶³ In support of the former conclusion, the court reasoned that the policy was neutral and generally applicable; in support of the latter, the court determined that the policy did not substantially burden a religious practice.¹⁶⁴

may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C. § 321(n) (emphasis added).

161. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

162. *Id.* In response to the plaintiff’s argument that consumer demand requires the FDA to require labeling of GMOs, the court cited a district court opinion for the proposition that, if consumer demand was the sole justification for such labeling, the agency would not even have authority to require it. *Id.* (citing *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995) (“In the absence of evidence of a material difference between [milk from cows treated with a synthetic hormone] and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act.”)).

163. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179-81.

164. *Id.* The historical backdrop of these competing tests—whether government action is “neutral and generally applicable” or whether it “substantially burdens” a religious practice—is worth observing. The Free Exercise Clause of the First Amendment provides that “Congress shall make no law . . . prohibiting the free exercise [of religion].” U.S. CONST. amend. I. The United States Supreme Court has established two tests by which to determine whether the government has violated the Free Exercise Clause. The Court enunciated the first test in *Sherbert v. Verner*, 374 U.S. 398, 402-03 (1963). The *Sherbert* test “ask[s] whether [the government action] *substantially burdened* a religious practice, and [if it did], whether the burden was justified by a compelling governmental interest.” *City of Boerne v. Flores*, 521 U.S. 507, 507 (1997) (emphasis added).

Although *Sherbert* provided the Supreme Court with the analytic framework to address free exercise challenges, the Court has been reluctant to apply it in cases involving across-the-board prohibitions of religious conduct. *See, e.g.*, *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520 (1993) (striking down a statute that prohibited animal sacrifices); *Employment Div., Dep’t of Human Res. of Or. v. Smith*, 494 U.S. 872 (1990) (upholding a statute that prohibited the ingestion of peyote). The distinction between such prohibitions and other government action is born of good reason; indeed, virtually *any* criminal prohibition of a religious conduct would “substantially burden” that conduct and, consequently, render the statute presumptively unconstitutional.

To eschew “deeming presumptively invalid . . . every regulation of conduct that does not protect an interest of the highest order,” the Court set forth a new test for determining violations of the Free Exercise Clause in *Employment Division, Department of Human Resources of Oregon v. Smith*, 494 U.S. at 888 (italics omitted). That test stands for the proposition that “[a] law *burdening* religious practice that is *not neutral* or *not of general application* must undergo the most rigorous of scrutiny.” *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546 (1993) (emphasis added). Significantly, the *Smith* test still requires some “burden” on a religious practice before the Court considers whether the law is neutral or generally applicable, but that burden is typically obvious (and thus not expressly analyzed) where the government action at issue is an across-the-board prohibition.

In response to *Smith*, Congress enacted the Religious Freedom Restoration Act (RFRA), codified at 42 U.S.C. § 2000bb (1992), in an attempt to reinstate the *Sherbert* test. *Id.* § 2000bb(a)-(b). The United States Supreme Court, however, held that Congress had surpassed its enforcement authority under section 5 of the Fourteenth Amendment in enacting the RFRA. *City of Boerne v. Flores*, 521 U.S. 507, 507 (1997). Although the Court recognized the authority of Congress to render “its own informed judgment on the meaning and force of the Constitution,” it concluded that “this Court’s precedent . . . must control.” *Id.* at 535-36. Until recently, however, it was unclear whether *Smith* entirely displaced *Sherbert* or whether *Smith* merely provided an alternative test that the Court would apply in cases involving the blanket prohibition of religious conduct. *Compare Smith*, 494 U.S. at 876 (“We held that distinction [between prohibition cases and non-prohibition cases] to be critical”), *with id.* at 883 (noting that the Court had recently “abstained from applying the *Sherbert* test . . . at all”).

In *Locke v. Davey*, 540 U.S. 712, 713 (2004), the Supreme Court appeared to endorse the latter position by strongly implying that the *Smith* test does not apply where the government action “imposes neither criminal nor civil sanctions on . . . [a] religious service or rite.” *Id.* The plaintiff in *Locke* challenged a state program that provided scholarships to qualified college students, but exempted any student who majored in theology. Reasoning that the scholarship program only imposed a “minor burden” on the ability of the student to freely exercise his religion, the Court rejected the argument that the program violated the Free Exercise Clause. *Id.* The Court thus abandoned the *Smith* test for the same reason that it had previously departed from the *Sherbert* test: because to apply the prevailing test in the context of that case would lead to “presumptive unconstitutionality.” *Id.* That is to say, government action that does not impose a blanket prohibition may fail the neutrality or general applicability requirements of *Smith* even though it imposes only a minor burden under *Sherbert*; thus, were the *Smith* test to apply to such a case, the government action would be subject to strict scrutiny and, therefore, would be presumptively unconstitutional.

The relevance of this historical backdrop is to demonstrate that the government action in *Alliance for Bio-Integrity*—the failure of the FDA to require labeling of GMOs—did not impose “criminal [] or civil sanctions on any type of religious service or rite.” *Id.* Consequently, the district court arguably applied the incorrect test to determine whether the FDA policy violated the Free Exercise Clause by inquiring whether the policy was neutral and of general applicability. Nevertheless, the court applied the equivalent of the *Sherbert* test in its “substantial burden” analysis under the Religious Freedom Restoration Act (portions of which the district court concluded were nonetheless constitutional after *Flores*). *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 180-81.

Alliance for Bio-Integrity remains one of the few reported judicial opinions to directly address the growing safety concerns associated with GMOs.¹⁶⁵ Nevertheless, the district court in *Alliance* had the benefit of deferring to an administrative agency with much greater institutional expertise than the Court possessed on the issue of genetic engineering. Courts interpreting subsequent genetic engineering disputes, however, may not have such a benefit. And, indeed, it is useful to reflect on the manner in which courts will approach genetic engineering before “the tidal wave of genetics-related litigation hits.”¹⁶⁶ Mindful of this theme, we turn to the issue of genetic privacy—the final area of biotechnology addressed in this Article and one that has similarly received little judicial attention.

V. GENETIC PRIVACY

The increased use of DNA forensics in criminal and civil cases has raised legal issues surrounding the collection of and access to DNA information. Because genetic information can serve as an important predictor of health, it “has led to concerns that employers and insurers may use this information as a means for limiting [an individual’s] employment opportunities or insurance coverage”—a concern not only of the particular individual but also of his or her family members.¹⁶⁷ To address these concerns, this Part examines (1) privacy issues that arise from the collection and storage of genetic information, (2) current state and federal regulations pertaining to conditions under which researchers and other entities may properly access genetic information, and (3) the manner in which American courts have addressed the issue of genetic discrimination in the workplace.

A. Collection and Storage of Genetic Information

In the area of genetic privacy,¹⁶⁸ the collection and storage of genetic information has received the most judicial and legislative attention.¹⁶⁹ As

165. See Grossman, *supra* note 142, at 239 (suggesting that courts have not had “the opportunity to decide cases involving damages from GMOs”).

166. E. Richard Gold, *Hope, Fear, and Genetics: Judicial Responses to Biotechnology*, 83 JUDICATURE 132, 135 (1999).

167. Mary J. Hildebrand et al., *Toward a United Approach to Protection of Genetic Information*, 22 BIOTECHNOLOGY L. REP. 602, 602 (2003).

168. For a discussion of the manner in which genetic privacy will become a concern to the public at large, see Berrie Rebecca Goldman, *Pharmacogenomics: Privacy in the Era of Personalized Medicine*, 4 NW. J. TECH. & INTELL. PROP. 83 (2005).

169. Some states, such as Illinois, have even passed legislation that allows prosecutors to bring Class A misdemeanor charges against any person who deliberately delays or impedes the collection of DNA from a required offender. See 730 ILL. COMP. STAT. ANN. 5/5-4-3(h)(i)(1) (West Supp. 2006). Similarly, the federal government has criminalized

previously discussed,¹⁷⁰ every state legislature has required convicted sex offenders to provide DNA samples and has authorized the creation of DNA databanks.¹⁷¹ In addition to these efforts at the state level, the federal government recently enacted a statute that provides for mandatory DNA testing of all federal inmates and for the compilation of the DNA samples in a federal database—the Combined DNA Index System (CODIS).¹⁷² These databases serve as “repositor[ies] of genetic records, which law enforcement officials can use for criminal identification purposes.”¹⁷³

Nevertheless, the methods for obtaining DNA samples have been subject to constitutional challenges in virtually every jurisdiction.¹⁷⁴ Litigants have predicated the most common challenges to the involuntary extraction of blood for DNA testing on the right against unlawful searches and seizures under the Fourth Amendment¹⁷⁵ and the right against self-

the failure to cooperate with the statutory collection procedure. 42 U.S.C. § 14135a(a)(5) (2000).

170. See *supra* Section II.B.2.

171. Giannelli, *supra* note 78, at 391-92.

172. Jean Coleman Blackerby, *Life After Death Row: Preventing Wrongful Capital Convictions and Restoring Innocence After Exoneration*, 56 VAND. L. REV. 1179, 1213 (2003).

173. Warren R. Webster, Jr., *DNA Database Statutes & Privacy in the Information Age*, 10 HEALTH MATRIX 119, 125 (2000) (citing Michael J. Markett, *Genetic Diaries: An Analysis of Privacy Protection in DNA Data Banks*, 30 SUFFOLK U. L. REV. 185, 189 (1996)).

174. The notion that advancements in biotechnology can raise constitutional concerns brings to the forefront the ongoing debate—and one of utmost importance—over the proper method of constitutional interpretation. Some originalists—those individuals who interpret the Constitution by its original meaning—contend that the document cannot afford protection against uses of modern technologies because the document was not originally intended or understood to do so. See ANTONIN SCALIA, *A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW* 38 (1997). Other scholars and jurists, including those who believe that the Constitution is a “living” document—one that grows and changes over time to meet the needs of a changing society—believe that the document may indeed provide protection against the use of emerging technologies. *Id.*; see, e.g., *Kyllo v. United States*, 533 U.S. 27, 40-41 (2001) (holding that the use of thermal imaging to measure heat emanating from home was a “search” for purposes of the Fourth Amendment). Still others—preeminently the late John Hart Ely—might, based on Professor Ely’s so-called “middle-ground” theory of constitutional interpretation, assert that the use of such technologies may implicate constitutional rights, but only when that use limits access to the democratic process or denies a minority the protection afforded other groups by representation. See JOHN HART ELY, *DEMOCRACY AND DISTRUST: A THEORY OF JUDICIAL REVIEW* 103 (1980).

175. See, e.g., *Roe v. Marcotte*, 193 F.3d 72, 76-77 (2d Cir. 1999); *Boling v. Romer*, 101 F.3d 1336, 1340 (10th Cir. 1996); *Jones v. Murray*, 962 F.2d 302, 308 (4th Cir. 1992); *People v. Wealer*, 636 N.E.2d 1129, 1136 (Ill. App. Ct. 1994); *Landry v. Attorney*

incrimination under the Fifth Amendment.¹⁷⁶ Appellate courts have generally rejected the former challenge on the basis that, although the extraction of blood implicates privacy interests,¹⁷⁷ the government's interest in preventing future crimes through DNA analysis outweighs a prisoner's lessened expectation of privacy.¹⁷⁸ The United States Supreme Court has all but rejected the latter challenge because the extraction of a blood sample and its chemical analysis do not amount to "testimonial or communicative" evidence and, therefore, are not prohibited by the Fifth Amendment.¹⁷⁹

In addition to these challenges, defendants have asserted that the forcible extraction of genetic information violates the constitutional right to privacy.¹⁸⁰ The Supreme Court has recognized the right to privacy as "created by several fundamental constitutional guarantees."¹⁸¹ Nevertheless, the Court in *Whalen v. Roe*¹⁸² held that a government database containing the names and addresses of people obtaining prescription drugs did not violate the United States Constitution.¹⁸³ That case perhaps presents the most analogous situation to the issue of DNA databank privacy.

Gen., 709 N.E.2d 1085, 1092 (Mass. 1999); *State v. Olivas*, 856 P.2d 1076, 1086 (Wash. 1993).

176. See, e.g., *Schmerber v. California*, 384 U.S. 757, 767 (1966); *In re Cooper v. Gammon*, 943 S.W.2d 699, 705 (Mo. Ct. App. 1997). One court has also rejected the theory that the extraction of DNA was cruel and unusual punishment. See *Kruger v. Erickson*, 875 F. Supp. 583 (D. Minn. 1994).

177. In *Skinner v. Ry. Labor Executives' Ass'n*, 489 U.S. 602, 617 (1989), the Supreme Court recognized that the chemical analysis of blood and urine for medical information about the donor implicates privacy interests. Moreover, "[t]he ensuing chemical analysis of the sample to obtain physiological data is a *further* invasion of the tested employee's privacy interests." *Id.* at 616 (emphasis added).

178. See, e.g., *Patterson v. State*, 742 N.E.2d 4, 11 (Ind. Ct. App. 2000) (holding that the government has a compelling Fourth Amendment interest in promoting DNA testing and creating DNA databases). For a general discussion of constitutional challenges to the involuntary collection of DNA, see Graddy, *supra* note 86, at 228-30.

179. *Schmerber v. California*, 384 U.S. 760 (1966).

180. See, e.g., *Alfaro v. Terhune*, 120 Cal. Rptr. 2d 197 (Ct. App. 2002). See generally Robert S. Peck, *Extending the Constitutional Right to Privacy in the New Technological Age*, 12 HOFSTRA L. REV. 893, 895 (1984).

181. *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965). The Court in *Griswold* held that a state law forbidding the use of contraceptives unconstitutionally infringed upon the right of marital privacy. In so holding, the court recognized that various constitutional guarantees create "zones of privacy." *Id.* at 484. Specifically, the Court declared—in oft-quoted language (although not always favorably)—that "specific guarantees in the Bill of Rights have penumbras, formed by emanations from those guarantees that help give them life and substance." *Id.*

182. 429 U.S. 589 (1977).

183. *Id.* at 602.

Because courts have rejected these constitutional challenges,¹⁸⁴ the involuntary collection of genetic information from convicted inmates is generally permitted in the United States.¹⁸⁵ The unique nature of DNA evidence, however, raises several novel issues that pertain to the collection and storage of genetic information. First, although prisoners have a diminished right to privacy under the Fourth Amendment, their family members—who have a similar DNA composition—should not be affected by that diminished expectation and, therefore, may challenge the retention of such information after the criminal investigation has concluded.¹⁸⁶

Second, a prisoner's lowered expectation of privacy has traditionally permitted the government to conduct a "search" for only a limited period of time—specifically, when the defendant is in prison.¹⁸⁷ DNA information, however, is timeless. Thus, once a sample is collected, it will forever provide information otherwise protected by the Fourth Amendment.¹⁸⁸ One novel issue of genetic privacy, therefore, is whether "an individual who apparently has lost the right to privacy by virtue of having committed a crime, nevertheless [may] be able to regain it after the proverbial debt to society has been paid."¹⁸⁹

184. Notwithstanding the challenges to DNA database laws discussed in this Part, "no court has yet struck down a statute compelling the DNA testing of convicts." Assembly Committee on Public Safety, Committee Analysis of Assembly Bill 673, at 4 (Apr. 3, 2001) (discussing a California bill that would add four new categories of felonious crimes that would require a convicted individual to submit to DNA testing).

185. See Robin Cheryl Miller, *Validity, Construction, and Operation of State DNA Database Statutes*, 76 A.L.R. 5th 239, 239 (2000) (noting that, although statutes that created DNA databases "have frequently been challenged, the challenges usually have been unsuccessful").

186. See Marika R. Athens & Alyssa A. Rower, *Alaska's DNA Database: The Statute, Its Problems, and Proposed Solutions*, 20 ALASKA L. REV. 389, 395 (2003) (noting that although DNA reveals information about every person who shares in that individual's bloodline, a prisoner's reduced expectation of privacy does not extend to the prisoner's family members).

187. See *New Jersey v. T.L.O.*, 469 U.S. 325, 338 (1985) (explaining that the primary rationale behind the notion that prisoners retain no legitimate expectation of privacy is because of "the need to maintain order in a prison").

188. See *Skinner v. Ry. Labor Executives' Ass'n*, 489 U.S. 602, 617 (1989).

189. Mark D. Fox & Chris E. Forte, *Privacy Issues from the Judicial Perspective: Requirements for Protective Orders*, 70 DEF. COUNS. J. 89, 98 (2003). Indeed, genetic databases, biobanks, and population collections are currently available and pose concerns for privacy and discrimination. See Yael Bregman-Eschet, *Genetic Databases and Biobanks: Who Controls Our Genetic Privacy?*, 23 SANTA CLARA COMPUTER & HIGH TECH L.J. 1 (2006).

B. Legislation Governing Discrimination Based On Genetic Data

Once a genetic sample has been collected and catalogued in a DNA database, it serves as an archive of information that may be of interest to a variety of entities—such as insurers, employers, schools, personal physicians, and medical researchers.¹⁹⁰ The increasing collection and use of genetic samples “has many worried about discrimination resulting from inappropriate access to, and use of, private genetic information.”¹⁹¹ To provide adequate safeguards against the systematic misuse of genetic information—which, as some scholars suggest, could lead to the creation of a new underclass of citizens¹⁹²—state and federal legislatures have enacted laws designed to place limitations on the access to such information.¹⁹³

Much of the current debate regarding genetic privacy centers on whether genetic information “should be protected generally, as another component of health data, or by special privacy laws.”¹⁹⁴ Proponents of the former assert that such information is fundamentally no different from other health data.¹⁹⁵ Advocates of the latter contend that the unchanging nature and predictive qualities of genetic information warrant special protection.¹⁹⁶ To fully understand these two schools of thought, the following Section examines the existing laws that govern the use of genetic information.

1. Federal Legislation

“No current federal statute explicitly addresses genetic discrimination in the workplace.”¹⁹⁷ “Although Congress considered fourteen bills protecting genetic privacy in 1996, and an additional seven bills by May of the following year, federal legislation precluding improper use of this sen-

190. Hildebrand et al., *supra* note 167, at 602.

191. *Id.*

192. As other authors have suggested, “[w]ithout adequate safeguards, genetic information could be misused, and, if the practice carried out systematically, such misused genetic information could lead to the creation a new underclass of genetically less-fortunate individuals.” *Id.*

193. *Id.*

194. *Id.* at 603.

195. *Id.*; see, e.g., Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and the Law: An End to Genetics Exceptionalism*, 40 JURIMETRICS J. 21, 24 (1999). Gostin and Hodge examine the approaches that such legislation has taken and argue for a more unified approach to addressing concerns about the use of genetic information.

196. Hildebrand et al., *supra* note 167, at 603.

197. Paul Steven Miller, *Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace*, 3 J. HEALTH CARE L. & POL’Y 225, 237 (2000).

sitive information has consistently failed.”¹⁹⁸ Other federal laws, such as the Americans with Disabilities Act of 1990 (ADA),¹⁹⁹ may provide protection against genetic discrimination.²⁰⁰ The purpose of the ADA is “to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities.”²⁰¹ The ADA defines a disability as “(A) a physical or mental impairment that substantially limits one or more of the major life activities . . . ; (B) a record of such an impairment; or (C) being regarded as having such an impairment.”²⁰² In 1995, the Equal Employment Opportunity Commission (EEOC) issued a statement that subsection (C) “applies to individuals who are subjected to discrimination on the basis of genetic information relating to illness, disease, or other disorders.”²⁰³

In view of the EEOC statement, the ADA arguably provides some protection against employer-based genetic discrimination. The ADA is not clear, however, about “whether this coverage will extend to asymptomatic individuals who are carriers of recessive disorders.”²⁰⁴ Moreover, although the ADA prevents employers from obtaining pre-employment genetic information, employers can require a pre-placement genetic examination after a conditional offer of employment. Thus, “although the ADA prohibits an employer from discriminating because of a disability, the individual will find it hard to prove that he or she did not get a job or promotion because of assumed ‘negative’ genetic information.”²⁰⁵

From the perspective of the individual relying on the ADA, new legislation was needed. In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA). Among other things, the Act safeguarded against health insurers who offer group coverage from discriminating based on private health information.²⁰⁶ This legislation for-

198. Sheri Mezoff, Note, *Forcing a Square Peg into a Round Hole: The Negative Ramifications of Misaligned Protections for Predisposed Individuals Under the ADA*, 85 B.U. L. REV. 323, 324-35 (2005).

199. *Id.* at 237-38; see also 42 U.S.C. §§ 12101-12213 (2000).

200. See Nathalie Smith, *The Right to Genetic Privacy? Are We Unlocking the Secrets of the Human Genome Only to Risk Insurance and Employment Discrimination?*, 2000 UTAH L. REV. 705, 738-39 (2000) (analyzing potential discrimination from health insurers and employers based on genetic information).

201. § 12101(b)(1) (2000).

202. § 12102(2)(A)-(C).

203. U.S. EQUAL EMPLOYMENT OPPORTUNITY COMM’N, 2 EEOC COMPLIANCE MANUAL I § 902.8(a) (2000). To clarify this position, the statement provides an example of an asymptomatic individual who genetically tested positive for colon cancer. *Id.*

204. Smith, *supra* note 200, at 739.

205. *Id.*

206. See 29 U.S.C. §§ 1181-83.

bade health insurers offering group coverage from using genetic information to identify a preexisting condition²⁰⁷ in the absence of a diagnosis of the condition related to such information.²⁰⁸ Further, HIPAA prohibited health insurers offering group health insurance coverage from discriminating against individual participants based on genetic information.²⁰⁹

Although HIPAA provides comprehensive protection in the group health insurance market, it does not extend the same coverage to the individual health insurance market.²¹⁰ Hence, the provisions that prohibit health insurers from using genetic information to identify a preexisting condition and from discriminating based on genetic information do not apply to individuals who seek insurance in the individual or self-employment market. Further, HIPAA applies to insurance discrimination rather than employment discrimination. Thus, HIPAA does not serve as an ADA gap filler.²¹¹ In response to these shortcomings, several state legislatures have enacted laws that provide for greater protection of genetic information.²¹²

One recent development in federal legislation is the Genetic Information Nondiscrimination Act ("GINA").²¹³ GINA is a bill that, if enacted into law, would prohibit discrimination on the basis of genetic information regarding employment and health insurance. Specifically, GINA would prevent employers from discriminating on the basis of predictive genetic information. On January 31, 2007, the Senate Health, Education, Labor,

207. Under HIPAA, "preexisting condition exclusion" is defined as "a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date." 29 U.S.C. § 1181(b)(1)(A) (2000).

208. § 1181(b)(1)(B).

209. § 1182(a)(1)(F).

210. Ashley M. Ellis, Comment, *Genetic Justice: Discrimination by Employers and Insurance Companies Based on Predictive Genetic Information*, 34 TEX. TECH L. REV. 1071, 1072-73, 1078-79 (2003).

211. See Jennifer Chorpening, Comment, *Genetic Disability: A Modest Proposal to Modify the ADA to Protect Against Some Forms of Genetic Discrimination*, 82 N.C. L. REV. 1441, 1467 (2004).

212. Hildebrand et al., *supra* note 167, at 603. For example, several states require a subject to consent before a third party may perform a genetic test or obtain genetic information. See, e.g., ARIZ. REV. STAT. § 20-448.02 (LexisNexis 2006). Other states require written authorization from the subject before a third party may obtain such information. See, e.g., S.C. CODE ANN. § 38-93-30 (West 2006) ("All genetic information . . . must be confidential and must not be disclosed to a third party in a manner that allows identification of the individual tested without first obtaining the written informed consent of that individual.").

213. For more information on GINA, see Chorpening, *supra* note 211, at 1467.

and Pensions Committee approved GINA by a vote of 19 to 2. The House Committee on Education and Labor later approve the bill by a unanimous vote on February 14, 2007.²¹⁴

2. State Legislation

Despite the scant federal legislation regarding access to and use of genetic information, states have enacted an abundance of legislation on the topic.²¹⁵ The legislation has generally taken two approaches. One approach prohibits all uses of genetic information except for therapy, research, and investigation.²¹⁶ Colorado, for example, broadly declares that genetic information is confidential and then carefully defines exceptions for criminal investigations, research, court proceedings, paternity, and public health.²¹⁷ The other approach narrowly enumerates the uses of genetic information that are prohibited and, to the extent that a practice is not enumerated, makes lawful any other use of such information.²¹⁸ Texas, for instance, specifically prohibits small employers from treating genetic information as evidence of a pre-existing condition absent a diagnosis.²¹⁹

Several states, such as Arizona, Maryland, and Montana, generally forbid insurance companies from refusing to consider applicants on the basis of a genetic condition.²²⁰ Further, Arizona and Montana have stated that basing an applicant's rejection or rates on a genetic condition consti-

214. See Nancy King et al., *Workplace Privacy and Discrimination Issues Related to Genetic Data: A Comparative Law Study of the European Union and the United States*, 43 AM. BUS. L.J. 79 (2006).

215. Smith, *supra* note 200, at 732.

216. William F. Mulholland, II & Ami S. Jaeger, *Genetic Privacy and Discrimination: A Survey of State Legislation*, 39 JURIMETRICS J. 317, 318 (1999).

217. *Id.* (discussing COLO. REV. STAT. ANN. § 10-3-1104.7(3) (West 2006)).

218. Mulholland & Jaeger, *supra* note 216, at 318. One commentator has opined that statutes that fall into the second category "leave open the possibility of various forms of discriminatory practices by insurers." *Id.*

219. *Id.* (citing TEX. REV. CIV. STAT. ANN. art. 26.49(c) (Vernon Supp. 1999)). Several states, however, permit insurers to use genetic information to identify a preexisting condition:

For example, Connecticut allows preexisting condition limitations where the condition is substantiated by "medical information other than a genetic test." Arizona allows insurers to engage in such practices if there is "actuarial justification" based on actual or anticipated loss. Arkansas, on the other hand, is more restrictive, allowing preexisting conditions identified through genetic information only where the individual actually exhibits symptoms of the disease.

Mulholland & Jaeger, *supra* note 216, at 319.

220. ARIZ. REV. STAT. § 20-448(D) (LexisNexis 2006); MD. CODE ANN., INS. § 27-909(c)(1) (West 2006); MONT. CODE ANN. § 33-18-206(3) (2005).

tutes unfair discrimination unless the applicant's medical condition and history, and either claims experience or actuarial projections, establish that substantial differences in claims are likely to result from the genetic condition.²²¹ Florida law provides that genetic tests "may be performed only with the informed consent of the person to be tested, and the results . . . are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested." Indiana and Illinois, by contrast, authorize insurance companies to consider "favorable" genetic information that an applicant voluntarily submits.²²² As one scholar has noted, however, these statutes "do not prohibit insurers from inflating insurance premiums for everyone, then reducing these rates for individuals who submit favorable genetic data."²²³

C. Judicial Approaches to Genetic Privacy

Thus, courts will face substantial challenges in dealing with emerging technology issues relating to genetic privacy. Today, case law on the issue of genetic privacy is incipient. Early decisions on this issue will thus be crucial in setting the precedent that shapes how future cases will address issues of genetic privacy. One such case is *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*.²²⁴

1. Genetic Privacy Protection Under the ADA—Norman-Bloodsaw v. Lawrence Berkeley Laboratory

In *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, the Ninth Circuit Court of Appeals addressed whether genetic discrimination in the workplace falls under the protection of the ADA. The employees of Lawrence Berkeley Laboratory (LBL), a government-funded research institution, alleged that LBL tested their blood and urine for certain medical conditions—namely, syphilis, sickle cell anemia, and pregnancy—without their knowledge.²²⁵ The testing occurred in the course of mandatory employment entrance exams and on subsequent occasions.²²⁶ The employees

221. ARIZ. REV. STAT. § 20-448(E) (LexisNexis 2006); MONT. CODE ANN. § 33-18-206(4) (2005).

222. Mulholland & Jaeger, *supra* note 216, at 319 (citing 410 ILL. COMP. STAT. ANN. 513/20(6) (West 1993); IND. CODE ANN. § 27-8-26-9 (West Supp. 1998)).

223. Mulholland & Jaeger, *supra* note 216, at 319.

224. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998).

225. 135 F.3d at 1264.

226. *Id.* With the exception of one plaintiff, who was hired in 1968 and had been subject to an examination thereafter, the employment of each plaintiff was expressly conditioned upon a "medical examination," "medical approval," or "health evaluation." *Id.* at 1264-65.

challenged the testing in federal court under the ADA, Title VII of the Civil Rights Act of 1964, and the right to privacy guaranteed by the constitutions of California and the United States.²²⁷

The employees alleged that LBL violated the ADA by requiring, encouraging, and assisting in medical testing that was “neither job-related nor consistent with business necessity.”²²⁸ The employees further asserted that LBL violated Title VII because it tested only African Americans for the sickle cell trait and tested women for pregnancy.²²⁹ Finally, the employees argued that LBL violated their constitutional right to privacy by conducting the tests, collecting and maintaining the results of the tests, and failing to provide adequate safeguards against disclosure of the results.²³⁰ The district court rejected these challenges primarily on the basis that they were time-barred.²³¹

On appeal, the Ninth Circuit concluded that the claims were not time-barred because the statute of limitations did not commence when the tests

227. *Id.* at 1264.

228. *Id.* at 1265. The relevant portion of the ADA provides:

A covered entity shall not require a medical examination and shall not make inquiries of an employee as to whether such employee is an individual with a disability or as to the nature or severity of the disability, unless such examination or inquiry is shown to be *job-related and consistent with business necessity*.

42 U.S.C. § 12112(d)(4)(A) (2006)(emphasis added).

229. *Norman-Bloodsaw*, 135 F.3d at 1265. Section 703(a) of Title VII of the Civil Rights Act of 1964 makes it unlawful for any employer:

(1) to fail or refuse to hire or to discharge any individual, or *otherwise to discriminate* against any individual with respect to his compensation, *terms, conditions*, or privileges of employment, because of such individual’s race, color, religion, sex, or national origin; *or*

(2) to limit, segregate, or classify his employees or applicants for employment in any way which would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee, because of such individual’s race, color, religion, sex, or national origin.

42 U.S.C. § 2000e-2(a) (2001) (emphasis added). The Pregnancy Discrimination Act further clarifies that discrimination on the basis of “sex” includes discrimination “on the basis of pregnancy, childbirth, or related medical conditions.” *Id.* § 2000e(k).

230. In addition to relying on the federal constitutional right to privacy, the plaintiffs relied upon the privacy protection in Article I, section 1 of the California Constitution. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1265 (9th Cir. 1998). That section provides that “[a]ll people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, and privacy.” CAL. CONST., art. I § 1.

231. *Norman-Bloodsaw*, 135 F.3d at 1266.

were administered.²³² Rather, the court observed that “a limitations period begins to run when the plaintiff knows or has reason to know of the injury which is the basis of the action.”²³³ The court further held that the district court erred in dismissing the claims based on Title VII and on the constitutional right to privacy.²³⁴ Writing for a majority of the court, Judge Reinhart noted that “[o]ne can think of few subject areas more personal and more likely to implicate privacy interests than that of one’s health or genetic make up.”²³⁵

Having concluded that the testing implicated privacy rights, the Ninth Circuit held that LBL violated the employees’ constitutional right to privacy and the Fourth Amendment right against unlawful searches and seizures.²³⁶ The court additionally held that the plaintiff’s assertion that LBL singled out black and female employees for additional non-consensual testing fell “neatly into the Title VII framework.”²³⁷ Nevertheless, the court upheld the district court’s dismissal of the ADA claim because “[t]he ADA imposes no restriction on the scope of the entrance examinations; it only guarantees the confidentiality of the information gathered, and restricts the use to which an employer may put the information.”²³⁸

Some scholars have suggested that the holding in *Norman-Bloodsaw* is limited to its facts because “the decision only applied to entrance examina-

232. *Id.*

233. *Id.* (quoting *Trotter v. Int’l Longshoremen’s & Warehousemen’s Union*, 704 F.2d 1141, 1143 (9th Cir. 1983)).

234. *Id.* at 1269.

235. *Id.* at 1269 (citing *Doe v. City of New York*, 15 F.3d 264, 267 (2d Cir. 1994) (“Extension of the right to confidentiality to personal medical information recognizes there are few matters that are quite so personal as the status of one’s health.”). Significantly, the United States Supreme Court has held that, although certain drug testing of high school students is constitutional, “it is significant that [such tests] look only for drugs, and not for whether the student is, for example, epileptic, pregnant, or diabetic.” *Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646, 58 (1995).

236. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1270-71 (9th Cir. 1998). The Ninth Circuit predicated its constitutional analysis on the proposition that “[t]he constitutionally protected privacy interest in avoiding disclosure of personal matters clearly encompasses medical information and its confidentiality.” *Id.* at 1269 (citing *Roe v. Sherry*, 91 F.3d 1270, 1274 (9th Cir. 1996); *Doe v. City of New York*, 15 F.3d 264, 267-69 (2d Cir. 1994)); *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 577 (3d Cir. 1980).

237. *Norman-Bloodsaw*, 135 F.3d at 1272. In support of its conclusion that LBL violated Title VII, the Ninth Circuit observed that “[p]laintiffs allege that black and female employees were singled out for additional nonconsensual testing and that defendants thus selectively invaded the privacy of certain employees on the basis of race, sex, and pregnancy.” *Id.*

238. *Id.* (quoting 42 U.S.C. §§ 12112(d)(3)(B)-(C) (2000)) (citations omitted).

tions which include only exams conducted after an offer of employment has been made but prior to the employee's start date."²³⁹ Indeed, the ADA provides that non-entrance employment exams must be based on the ability to perform job-related functions or be consistent with business necessity.²⁴⁰ Nevertheless, the holding in *Norman-Bloodsaw* demonstrates that the ADA does not adequately protect employees against certain forms of genetic discrimination.²⁴¹

2. *The Scope of ADA Coverage and its Impact on Genetic Discrimination—Bragdon v. Abbott*

Also in 1998, the United States Supreme Court addressed to whom ADA coverage extends in the case of *Bragdon v. Abbott*.²⁴² The plaintiff, Sidney Abbott, disclosed to her dentist that she was HIV positive.²⁴³ During the course of the dental examination, the dentist discovered a cavity and informed Abbott of his policy against filling cavities of HIV-infected patients in his office.²⁴⁴ Abbott brought suit in federal court under section 302 of the ADA, which provides that "[n]o individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who . . . operates a place of public accommodation."²⁴⁵ Section 302 is limited, however, by a later subsection, which provides that "[n]othing in this subchapter shall require an entity to permit an individual to participate in or benefit from the goods, services, facilities, privileges, advantages and accommodations of such entity where such individual poses a direct threat to the health or safety of others."²⁴⁶

The Court held that an HIV infection is a "disability" under the ADA because it is a "physical or mental impairment that substantially limits one

239. Ellis, *supra* note 210.

240. *Id.* ("According to the ADA, unlike other employment exams, entrance exams do not have to be based on the ability to perform job-related functions or be consistent with business necessity.").

241. *Id.*

242. 524 U.S. 624 (1998).

243. *Id.* at 628-29. The record reflected that, although the patient was HIV-positive, the condition "had not manifested its most serious symptoms" when the incidents in question occurred. *Id.* at 628. The Court concluded the asymptomatic nature of the condition was immaterial to the legal issue of whether she was disabled under the ADA. *See id.*

244. *Id.* at 629. Nevertheless, the dentist offered to perform the work at a hospital. *Id.* Although the patient would have to pay for use of the hospital's facilities, the service itself would have been at no extra charge. *Id.*

245. *Id.* (quoting 42 U.S.C. § 12182(a) (1997)).

246. *Id.* (quoting 42 U.S.C. § 12182(b)(3)).

or more of the major life activities of such individual.”²⁴⁷ The Court based this conclusion on the fact that Abbott was “substantially limited” in her ability to procreate, which the Court considered a “major life activity” within the meaning of the statute.²⁴⁸ In so doing, the Court determined that a person can be disabled under the ADA even though the patient’s infection had not yet progressed to the symptomatic phase.²⁴⁹ The Court remanded the case to the court of appeals to determine if accommodation of Abbott would have posed a direct threat to the health or safety of others.²⁵⁰

Although Abbott’s HIV positive condition fell within the scope of coverage under the ADA, the narrow language of the statute only permits coverage of individuals with conditions that substantially limit a major life activity.²⁵¹ Genetic disorders generally do not fall within this definition for two reasons: first, genetic disorders typically do not substantially limit a “major life activity” before the symptomatic phase;²⁵² and second, genetic information that suggests an individual is “at risk” is not covered under the ADA—rather, an individual must actually have the disorder to receive coverage.²⁵³ As a result, “companies are still conducting genetic tests because there is no clear federal law prohibiting them from doing so.”²⁵⁴

247. *Id.* at 630. The ADA definition of “disability,” at 42 U.S.C. § 12102(2) (2006), is virtually identical to the definition of “disability” (formerly “handicapped individual”) in the Rehabilitation Act of 1973, 29 U.S.C. § 705(9)(B) (2006), and the definition of “handicap” in the Fair Housing Amendments Act of 1988, 42 U.S.C. § 3602(h)(1) (2000). Further, the ADA provides that “nothing [herein] shall be construed to apply a lesser standard than . . . under . . . the Rehabilitation Act . . . or the regulations issued . . . pursuant to [it].” 42 U.S.C. § 12201(a) (1994) Thus, the Court is required to construe ADA to grant at least as much protection as that which is afforded by the Rehabilitation Act. *Bragdon v. Abbott*, 524 U.S. at 632. To determine whether an activity is a “major life activity,” the Rehabilitation Act provides a non-exhaustive list of major life activities, such as “caring for one’s self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.” 45 CFR § 84.3(j)(2)(ii) (2006); 28 CFR § 41.31(b)(2) (1997). Given that reproduction “could not be regarded as any less important than working and learning,” the court held that “the Rehabilitation Act regulations support the inclusion of reproduction as a major life activity. *Bragdon v. Abbott*, 524 U.S. at 639.

248. *Bragdon v. Abbott*, 524 U.S. at 639.

249. *See id.* at 628 (“We granted certiorari to review . . . whether HIV infection is a disability under the ADA when the infection has not yet progressed to the so-called symptomatic phase . . .”).

250. *Id.* at 655.

251. Ellis, *supra* note 210, at 1086.

252. *Id.*; *see, e.g.*, *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998).

253. Ellis, *supra* note 210, at 1086.

254. *Id.* at 1087.

3. *Conclusions*

Notwithstanding the questions that the ADA, HIPAA, and similar state legislation have raised on the issue of genetic privacy, “there has been virtually no case law regarding genetic discrimination in the workplace.”²⁵⁵ The topic of genetic privacy thus stands in marked contrast to DNA forensics—an area of biotechnology that courts have scrutinized for nearly two decades.²⁵⁶ This disparity illustrates two important themes. The first theme is the infancy of legal developments in genetic privacy²⁵⁷—and, as discussed in Part IV, in genetic engineering. As a result, courts are sailing on uncharted waters when attempting to assess the legal issues that these topics inspire.

And this first theme, in turn, makes clear the second: as early judicial decisions shaped the future of DNA forensics, so too will early decisions shape the future of genetic engineering and genetic privacy. Indeed, courts must “fill in the law” when bioethics issues paralyze legislation (the stem cell debate in recent years is but one example). The gravity of this responsibility thus calls for an intricate knowledge of biotechnology and its future implications—one that, at present, the vast majority of courts do not have the resources to acquire. The remainder of this Article is devoted to exploring a response to that problem.

VI. A RESPONSE TO THE GROWING DIVIDE BETWEEN LAW AND BIOTECHNOLOGY

The response of our judicial systems to the legal issues adumbrated in the foregoing Sections will play a significant role in determining whether we are about to enter the promised “enlightened era of genetic marvels” or whether these advancements will go largely unrealized.²⁵⁸ Despite the

255. Miller, *supra* note 197, at 238.

256. *See supra* Parts II and III.

257. Despite the dearth of case law addressing genetic discrimination, “parties have [recently] settled cases involving genetic testing and the ADA outside the courtroom.” Ellis, *supra* note 210, at 1086. In 2001, for example, the Burlington Northern Santa Fe Railway Company and the Equal Employment Opportunity Commission (EEOC) settled a case involving the genetic testing of employees who had developed carpal tunnel syndrome. *Id.* The employees alleged that Burlington Northern threatened to discharge them if they refused to submit to the testing. In the settlement agreement, “Burlington Northern agreed to pay \$2.2 million to the employees who were tested or asked to take genetic tests.” *Id.* Burlington Northern further agreed to refrain from genetic testing in the future and to provide enhanced ADA training to personnel. *Id.*

258. Rothstein, *supra* note 85, at 123. That the resolution of biotechnology disputes will be determined largely by the judge’s decision regarding the admissibility of scientific

weight of this charge, the influx of biotechnology disputes in the *Daubert* era—where trial judges must apply their scientific knowledge to determine the reliability of scientific evidence—has shaped the legal environment into one in which trial judges, who are often not conversant with science, must effectively become “amateur scientists.”²⁵⁹ As one federal judge has observed:

[m]any federal judges believe *Daubert* made their lives more difficult. They are going to have to give a more reasoned statement about why they are letting in evidence. They can't do it on a rubberstamp basis the way some of them did it in the past. . . . After all, we're not scientists. We're in strange territory and we want to do the best we can.²⁶⁰

Federal judges are not alone in this regard. Most state courts have adopted the *Daubert* standard to determine the admissibility of scientific evidence and, consequently, confront the same need for, and suffer from the same lack of, scientific literacy in biotechnology cases. According to one jurist, state judges “tend to have no particular training in statistical analysis as it relates to scientific research, unless they worked through doctoral programs in science before making the career switch to law.”²⁶¹ Indeed, one recent survey indicates that seventy percent of state judges have “limited, and potentially outdated, education or experience with the evaluation of scientific methodology.”²⁶²

evidence—particularly after *Daubert*—is supported by at least some empirical evidence. One survey indicated that judges were “more likely to exclude questionable expert testimony today than they were pre-*Daubert*.” Peter J. Goss et al., *Clearing Away the Junk: Court-Appointed Experts, Scientifically Marginal Evidence, and the Silicone Gel Breast Implant Litigation*, 56 FOOD & DRUG L.J. 227, 231 (2001).

259. One dissenter in *Daubert*, Chief Justice Rehnquist, questioned an interpretation of the Federal Rules of Evidence that required judges to become “amateur scientists.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 600-01 (1993) (Rehnquist, C.J., dissenting).

260. Rorie Sherman, *Judges Learning Daubert: “Junk Science” Rule Used Broadly*, NAT'L L.J., Oct. 4, 1993, at 28 (quoting United States District Judge Jack Weinstein).

261. Alan G. Gless, *Some Post-Daubert Trial Tribulations of a Simple Country Judge: Behavioral Science Evidence in Trial Courts*, 13 BEHAV. SCI. & L. 261, 263 (1995).

262. Cynthia Stevens Kent, *Daubert Readiness of Texas Judiciary: A Study of the Qualifications, Experience, and Capacity of the Members of the Texas Judiciary to Determine the Admissibility of Expert Testimony Under the Daubert, Kelly, Robinson, and Havner Tests*, 6 TEX. WESLEYAN L. REV. 1, 15 (1999). The study revealed that thirteen percent of the state judges received no scientific instruction in high school. *Id.* at 13. Significantly, eighty-nine percent of the judges who reported a science education in high school received that instruction over twenty years ago. *Id.* at 14. The numbers were similar—both in terms of the number of judges that received instruction on the scientific me-

The problem, however, runs deeper than the scientific knowledge of trial judges. Recognizing the multi-faceted impact of *Daubert*, Justice Joseph Walsh of the Delaware Supreme Court has asserted that “[t]here are two factors that hinder the effort to formulate a consistent framework for testing the admissibility of scientific evidence.”²⁶³ The first is that judges’ initial lack of scientific education and training “presents the risk that practitioners of junk science will seek to enter the courtroom to take advantage of the lack of a formalized body of knowledge.”²⁶⁴ The second factor, by contrast (and one not hitherto addressed), is the “highly subjective judgment brought to bear under a gatekeeper construct.”²⁶⁵ Because this latter factor significantly exacerbates the problem at which our response is aimed, we explore it further in the following section.

A. The Problem of Biotechnology Cases After *Daubert*— Subjective Judgment by the Gatekeeper

In addition to the reality that trial judges often fail to possess the scientific acumen necessary to serve as responsible gatekeepers in biotechnology cases,²⁶⁶ two other generalities render the gatekeeper construct problematic: first, the manner in which trial judges apply the construct is highly subjective; and second, that subjective application is afforded considerable deference on appeal.²⁶⁷ The confluence of these two factors has provided the legal community with little ability to predict,²⁶⁸ and appellate judges with little control over, the admission of novel scientific evidence in a particular case.²⁶⁹ As a result, “evidence which achieved admissibility

thod and the number of years ago that such instruction occurred—with reference to the judges’ undergraduate education. *Id.* Only an extremely small number of the surveyed judges received a masters, doctoral, or educational degree in a field related to the scientific method. *Id.* Finally, eighty-three percent of the judges did not report any instruction or educational background in the scientific method received during law school. *Id.*

263. Walsh, *supra* note 16, at 142.

264. *Id.* at 143.

265. *Id.* at 142.

266. *See supra* notes 258-264.

267. *See generally* Walsh, *supra* note 16, at 143.

268. On this point, one scholar has noted that, “[a]lthough [*Daubert*] was intended to improve how courts use science, recent empirical evidence reveals that judges continue to struggle with scientific evidence and that *Daubert* has failed to yield accurate or consistent decisions.” Joëlle Anne Moreno, *Einstein on the Bench?: Exposing What Judges Do Not Know About Science and Using Child Abuse Cases to Improve How Courts Evaluate Scientific Evidence*, 64 OHIO ST. L.J. 531, 531 (2003).

269. *See* Lee Richard Goebes, *The Equality Principle Revisited: The Relationship of Daubert v. Merrell Dow Pharmaceuticals to Ake v. Oklahoma*, 15 CAP. DEF. J. 1, 32 (2002) (noting that “not only do the district courts possess wide discretion in determining whether proffered testimony qualifies as ‘scientific knowledge,’ the appellate courts may

in one court may not be as fortuitous in another court,²⁷⁰ and the decision of the trial judge in that regard is rarely reversed on appeal.

The first factor that renders the gatekeeper construct problematic—the highly subjective nature of an admissibility determination under *Daubert*—comes as no surprise to legal scholars and jurists. To be sure, the majority in *Daubert* recognized this concern when it declared with confidence that “federal judges possess the capacity to undertake this review.”²⁷¹ Nevertheless, “[a]lthough the Court gave the district judges some guidance [by enumerating factors that the trial judge should consider when applying *Daubert*], the ultimate test remained quite subjective.”²⁷² As one scholar notes, “with the subjective nature of the reliability analysis, a judge’s idiosyncrasies or predisposition may affect the admissibility of expert testimony.”²⁷³ Three justices of the Supreme Court (Antonin Scalia,

not reverse the trial courts’ resolution of admissibility issues unless a ruling is ‘manifestly erroneous.’”).

270. Leslie Morsek, *Get on Board for the Ride of Your Life! The Ups, the Downs, the Twists, and the Turns of the Applicability of the “Gatekeeper Function to Scientific and Non-Scientific Expert Evidence: Kumho’s Expansion of Daubert*, 34 AKRON L. REV. 689, 730 n.135 (2001).

271. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993). Indeed, the reason the Supreme Court enumerated the factors that trial judges should consider when determining the admissibility of scientific evidence was precisely to *limit* the discretion of such judges. See Thomas R. Freeman, *Guardians at the Gate*, 24 L.A. LAWYER MAGAZINE, Jul./Aug. 2001, 26, 30 (“[I]n an effort to limit that discretion and provide guidance, the U.S. Supreme Court in *Daubert* and *Kumho* has enumerated several factors that trial courts should consider in making admissibility determinations.”); see also Hyongsoon Him, *Adversarialism Defended: Daubert and the Judge’s Role in Evaluating Expert Evidence*, 34 COLUM. J.L. & SOC. PROBS. 223 (2003) (suggesting that *Daubert* should be interpreted to limit judicial discretion to exclude evidence).

272. Thomas O. McGarity, *Proposal for Linking Culpability and Causation to Ensure Corporate Accountability for Toxic Risks*, 26 WM. & MARY ENVTL. L. & POL’Y REV. 1, 9 (2001). As one scholar has noted:

The *Kumho* Court thus reemphasized the wide latitude granted to the district courts in *Daubert*. A district court, in determining whether proffered testimony qualifies as “scientific knowledge,” can consider any and all factors it deems relevant. This wide latitude was also broadened in *General Electric Co. v. Joiner*, in which the Court held that appellate courts must apply the “abuse of discretion” standard when reviewing a district court’s application of *Daubert*. Thus, not only do the district courts possess wide discretion in determining whether proffered testimony qualifies as “scientific knowledge,” the appellate courts may not reverse the trial courts’ resolution of admissibility issues unless a ruling is “manifestly erroneous.”

Goebes, *supra* note 269, at 32 (citations omitted).

273. Morsek, *supra* note 270, at 739 (noting that it is “unlikely that reversal of these highly subjective decisions . . . would be commonplace with this standard of appellate

Sandra Day O'Connor, and Clarence Thomas) shared this view several years later in *Kumho Tire*.²⁷⁴ The justices observed that the *Daubert* factors “are not holy writ” but rather a proper basis for reversal if the trial court abuses its discretion in applying “one or another of them.”²⁷⁵

Where these justices found solace however, others found trepidation. The second factor that besets the gatekeeper construct—the wide latitude afforded admissibility decisions under *Daubert* on appeal—stems directly from the abuse of discretion standard of review.²⁷⁶ Under this deferential standard of review (applicable to all admissibility determinations under *Daubert*),²⁷⁷ an appellate court may not substitute its judgment for that of the trial court.²⁷⁸ Rather, the appellate court must defer substantially to the judgment of the trial court and reverse that judgment only when it constitutes an “abuse of discretion” as defined by the lenient standards of various federal circuits²⁷⁹ and state courts.²⁸⁰ As a result, the decision of a trial

review”). Other scholars have similarly observed that “whenever a court analyzes admissibility by examining reasonability, reliability, or *Daubert*-type criteria, the court can always exclude the testimony if it chooses. No absolute (that is, non-subjective) constraints seem to exist to prevent a judge from, whether intentionally or unintentionally, determining the result of a case by excluding an expert’s testimony as having been based upon ‘unreasonable’ inductive methodologies.” David M. Malone & Paul J. Zwier, *Epistemology After Daubert, Kumho Tire, and the New Federal Rule of Evidence* 702, 74 TEMP. L. REV. 103, 117-18 (2001).

274. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 158-59 (1999) (Scalia, J., concurring, with whom Justice O’Connor and Justice Thomas joined).

275. *Id.* at 159.

276. See Walsh, *supra* note 16, at 142-43; see also Jean Macchiaroli Eggen, *Clinical Medical Evidence of Causation in Toxic Tort Cases: Into the Crucible of Daubert*, 38 HOUS. L. REV. 369, 429 n.14 (2001). Professor Macchiaroli notes that “[b]etween *Daubert* and *Kumho Tire*, the Supreme Court decided *General Electric Co. v. Joiner*, 522 U.S. 136, 139 (1997), which held that the abuse of discretion standard applied to appellate review of district court admissibility decisions under *Daubert*. *Joiner* thus made it more difficult for appellate courts to reverse exclusion decisions.” 522 U.S. at 139.

277. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141-42 (1997) (concluding that “abuse of discretion is the proper standard of review of a district court’s evidentiary rulings” and that *Daubert* did not change that fact).

278. See, e.g., *Barona Group of the Capitan Grande Band of Mission Indians v. Am. Mgmt. & Amusement, Inc.*, 840 F.2d 1394, 1408 (9th Cir. 1987) (noting that an “appellate court cannot simply substitute its judgment for that of the lower court” under an abuse of discretion standard of review).

279. By way of example, the United States Court of Appeals for the Second Circuit has held that “[a] decision to admit or exclude expert scientific testimony is not an abuse of discretion unless it is ‘manifestly erroneous.’” *Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002) (citing *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1042 (2d Cir. 1995)). The Tenth Circuit, by contrast, will disturb the decision of a lower court under an abuse of discretion standard only when it has “a definite and firm

court in admitting scientific evidence is, in addition to being highly subjective, “fairly well insulated against reversal.”²⁸¹

B. Conventional Efforts to Educate Judges

Given the concomitant rise of biotechnology in legal disputes and the broad deference accorded the highly subjective decisions of trial courts under the *Daubert* standard, the need for scientific acumen in the judiciary is greater now than at any time in our nation’s history.²⁸² To address this need, non-profit organizations, academic institutions, and state bar associations have generally offered two resources: judicial seminars and educational publications.²⁸³ This Section examines each resource and con-

conviction that the lower court made a clear error of judgment or exceeded the bounds of permissible choice in the circumstances.” *United States v. Ortiz*, 804 F.2d 1161, 1164 n.2 (10th Cir. 1986).

280. The Supreme Court of Ohio, for example, has defined the term “abuse of discretion” as “more than an error of law or of judgment; it implies that the court’s attitude is unreasonable, arbitrary, or unconscionable.” *State v. Adams*, 404 N.E.2d 144 (Ohio 1980).

281. Walsh, *supra* note 16, at 143.

282. See generally Gilbert S. Merritt, *From the Scopes Trial to the Human Genome Project: Where is Biology Taking the Law?*, 67 U. CIN. L. REV. 365, 367 (1999) (“Even a cursory understanding of Anglo-American legal history leads to the conclusion that science—physics, astronomy, chemistry, and biology—has played little role in the law and in the disputes courts have had to resolve prior to the middle of the twentieth century.”).

283. See Adam J. Siegel, *Setting Limits on Judicial, Scientific, Technical, and Other Specialized Fact-Finding in the New Millennium*, 86 CORNELL L. REV. 167, 202-03 (2000) (discussing the variety of approaches by which jurists can educate themselves on scientific matters); see also Judith A. Hasko, *Daubert v. Merrell Dow Pharmaceuticals, Inc.: Flexible Judicial Screening of Scientific Expert Evidence Under Federal Rule of Evidence 702*, WIS. L. REV. 479, 505 (1995) (noting that “judges can depend on a variety of educational and informational resources to facilitate their adjustment to th[e] responsibility” of applying *Daubert*).

A third educational resource available to judges is a court-appointed technical expert. See Fed. R. Evid. 706(a). Federal Rule of Evidence 706 grants a trial court the authority to appoint such experts, but requires the experts to advise the parties of their findings and subject themselves to cross-examination. *Id.* Many commentators have suggested that judges avail themselves of Rule 706. Justice Breyer has recommended that courts rely on court-appointed experts who are “recommended to courts by established scientific organizations, such as the National Academy of Sciences or the American Association for the Advancement of Science.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 150 (1997) (Breyer, J., concurring) (quoting Brief of Amici Curiae The New England Journal of Medicine and Marcia Angell at 18-19, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997)). However, “researchers at the Federal Judicial Center discovered that an overwhelming majority of federal district judges responding to a survey reported that they had never appointed a Rule 706 expert.” Siegel, *supra*, at 207 (citing Joe S. Cecil & Thomas E. Willging, *Court-Appointed Experts*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE

cludes that these efforts alone are insufficient to arm judges with the knowledge required to responsibly confront novel issues of biotechnology.

1. *Judicial Seminars on Scientific Matters*

One method by which judges acquire scientific knowledge is through their attendance at judicial seminars.²⁸⁴ Non-profit organizations, such as

535 (Fed. Judicial Ctr. ed., 1994)). This infrequent use of court-appointed experts is at least partially attributable to the fact that “more guidance on appointment procedures and communications with the expert [is needed to] help minimize the risks entailed in this departure from adversary procedures.” Ellen E. Deason, *Court-Appointed Expert Witnesses: Scientific Positivism Meets Bias and Deference*, 77 OR. L. REV. 59, 155 (1998). As one critic has noted, “[t]he potential for abuse under Rule 706 is great, and private communications between judges and technical advisors may have a devastating effect on the adversarial system.” Siegel, *supra*, at 208. Siegel argues that “Congress and the Supreme Court should modify the Code of Conduct, 28 U.S.C. § 455 [the judicial disqualification statute], and Federal Rule of Evidence 104(a) in a way that will restrict the discretion Rule 706 currently affords judges.” *Id.*

According to the Federal Judicial Center, however, “the judges who appointed experts have been ‘almost unanimous in expressing their satisfaction with the expert.’” *Id.* at 208 (quoting Cecil & Willging, *Court-Appointed Experts*, *supra*, at 537). Indeed, all but two of the sixty-five judges [surveyed] indicated that they were pleased with the services provided,” Joe S. Cecil & Thomas E. Willging, *Accepting Daubert’s Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995, 1008 (1994), and “the two judges who did not indicate that they were satisfied remain open to appointing an expert in the future.” *Id.* Such a finding, coupled with the fact that court-appointed experts serve an advisory, case-specific function similar to that of ASTAR resource judges, provides an important clue as to the manner in which the judiciary will receive these institutions’ services.

There are other resources to which judges may refer for scientific education. Two less formal resources include “[v]enturing into cyberspace . . . [and] consult[ing] colleagues off the record.” Adam J. Siegel, *Setting Limits on Judicial, Scientific, Technical, and Other Specialized Fact-Finding in the New Millennium*, 86 CORNELL L. REV. 167, 168 (2000). Yet “the extent to which judges can properly engage in such practices has become a matter of great debate and uncertainty due to the divergent teachings of *Kumho*, the Code of Conduct for United States Judges, 28 U.S.C. §§ 144, 455 (the federal judicial disqualification statutes), and the Federal Rules of Evidence.” *Id.* Because the propriety of such practices remains uncertain, this Section will not address them.

In addition, Justice Breyer noted that the Court has received assistance from amicus briefs written by a variety of health-care professionals and experts in related fields. See Stephen Breyer, *The Interdependence of Science and Law*, 280 SCI., Apr. 24, 1998, at 537. “Such briefs,” he extolled, “help to educate the judges on potentially relevant technical matters, helping to make us, not experts, but moderately educated laypersons, and that education improves the quality of our decisions.” *Id.* at 538. Given that such briefs are typically filed by organizations that have a bias in a case (and that their filings are somewhat unpredictable), they too will not be addressed in this Section.

284. Siegel, *supra* note 283, at 203 (“Of the various educational resources available today, judicial seminars have become a popular means by which judges may acquire

the Federal Judicial Center, sponsor these programs to provide judges with an opportunity to learn fundamental scientific principles.²⁸⁵ One such institution is the Law and Economics Center at the George Mason University School of Law, which provides a series of judicial education programs that focus on science and the law (and, as its name indicates, on law and economics).²⁸⁶ Esteemed scholars from a wide range of academic institutions throughout the nation teach these programs.²⁸⁷ As of 1992, “398 federal judges had attended at least one course sponsored by the Law and Economics Center.”²⁸⁸ Since then, that number has significantly grown.

Another non-profit organization that provides science education to jurists—and one that we more closely examine *infra*—is the Einstein Institute for Science, Health, and the Courts (EINSHAC).²⁸⁹ EINSHAC is a voluntary education and research organization affiliated with the judicial branch of government.²⁹⁰ Organized in the District of Columbia in 1993, EINSHAC’s mission is “to provide judges, courts and court-related personnel with knowledge tools related to criminal and civil justice proceed-

knowledge on timely scientific, technical, or other specialized matters pending in courtrooms nationwide.”). Despite their growing popularity however, judicial seminars are grossly underused. One survey indicates that “only 29 percent of state trial judges in Texas reported having received some type of continuing legal, judicial, or other professional continuing education which provided instruction on the use or analysis of the scientific method.” Kent, *supra* note 262, at 14-15.

285. Jack B. Weinstein, *Limits on Judges Learning, Speaking and Acting—Part I—Tentative First Thoughts: How Many Judges Learn?*, 36 ARIZ. L. REV. 539, 543 (1994). Duke Law School offers a similar program, entitled “Judging Science,” which is a week-long seminar geared toward teaching the scientific method and its various applications to trial and appellate judges. John M. Conley, Forward, 64 LAW & CONTEMP. PROBS. 1, 1 (2001).

286. Weinstein, *supra* note 285, at 546. Judge Weinstein describes the seminars: [T]he three courses offered by the Center were “Basic Economic Institute,” a basic course in economics and on the applicability of economic theory to legal issues; “Basic Course on Science and Public Health,” a course designed to provide judges with a better understanding of scientific evidence; and “Advanced Course on the Economics of Risk, Injury, and Liability,” a course on the economics of the judicial allocation of risks through tort law.

Id. (citation omitted).

287. *Id.* at 546-47 (citation omitted).

288. *Id.* at 547 (citation omitted).

289. See *infra* Part V.C.

290. EINSHAC INFORMATION BOOKLET 1 (2004) (on file with author). Since the issuance of *Daubert* in 1993, EINSHAC has provided scientific courses for judges in the United States, Europe, and Asia. Nicola Nosengo, *Science and Law: Biotechnology at the Bar*, NATURE, Sept. 11, 2003, at 117.

ings involving evidence from the genetic sciences”²⁹¹ Led by its president, Dr. Franklin Zweig, the organization has offered genetic education to more than 3,000 judges and court-related personnel since 1996.²⁹²

Although many non-profit organizations sponsor judicial seminars, “others receive funding directly or indirectly from private corporate interests.”²⁹³ This foray of corporate interests into judicial education has led one non-profit organization, the Alliance for Justice, to suggest that “sponsorship of law and economics seminars by powerful business interests has created a legal system in which justice can be bought and sold just like any other commodity.”²⁹⁴ Other critics similarly cautioned that “seminar sponsors with hidden agendas may successfully bias unwary judges.”²⁹⁵

These allegations have not been taken lightly. In 2000, members of the Senate proposed the Judicial Education Reform Act to regulate the attendance of judges at privately-funded educational seminars.²⁹⁶ Despite such efforts, however, not all agree that the seminars are cause for concern. James Pierson, executive director of an organization that has funded judicial seminars at the Law and Economics Center, has remarked that “judges are perfectly capable of assessing law and economics on their own without being told what to think.”²⁹⁷

The veracity of these charges “remains a matter of great debate.”²⁹⁸ Nevertheless, the mere perception of improper influence on judicial education illustrates the first of two general limitations associated with judicial seminars: the wide variety of seminars offered, coupled with the varying (and often inconspicuous) sponsors upon which such seminars depend for support, often raise misgivings about their objectivity, irrespective of

291. EINSHAC INFORMATION BOOKLET, *supra* note 290.

292. *Id.* Specifically, EINSHAC operates five programs: (1) the Genetics Adjudication Resource Project (GARP); (2) the Law and Science Academy (LSA); (3) Courts and Bioterrorism; (4) Courts International Working Conversations; and (5) the Working Party on Conflict Resolution and Legal System Capacity Enhancement of the United Nations Industrial Development Organization’s Global Biotechnology Forum. It is the first of these programs—GARP—that offers the genetic education courses to judges.

293. Siegel, *supra* note 283, at 205.

294. *Id.* at 204-05. One commentator has likewise argued that judicial integrity may be sacrificed “when private interests are allowed to wine and dine judges at fancy resorts under the pretext of ‘educating’ them.” Abner Mikva, *The Wooing of Our Judges*, N.Y. TIMES, Aug. 28, 2000, at A17.

295. Siegel, *supra* note 283, at 204.

296. Judicial Education Reform Act of 2000, S. 2990, 106th Cong. (2000) (prohibiting judges from accepting “anything of value in connection with a seminar”).

297. Siegel, *supra* note 283, at 205 (citing Henry J. Reske, *Expense-Paid Judicial Seminars Hit*, 79 A.B.A. J., Aug. 1993, at 36).

298. *Id.* at 205-06.

whether as a normative matter one reasonably should question that objectivity.

The second limitation associated with judicial seminars flows from the necessarily abstract nature of the forum.²⁹⁹ That is, judicial seminars are often not intended to, and are perhaps largely incapable of, “speak[ing] to the issues that will come up in any particular case.”³⁰⁰ As a result, one judge has observed that “the real value of these seminars is to encourage the judges to feel comfortable in these types of cases” rather than to educate them on specific points of a pending scientific matter.³⁰¹ Thus, although judicial seminars serve as a valuable and arguably objective resource for educating judges on scientific developments,³⁰² these programs alone fail to adequately prepare judges for the case-by-case demands that novel issues of biotechnology impose upon the legal system.³⁰³

2. *Scientific Publications for Judges*

Publication of scientific manuals and periodicals serves as an additional resource with which to educate judges on scientific matters.³⁰⁴ In 1994, the Federal Judicial Center published the Reference Manual on Scientific Evidence to assist federal judges “in managing expert evidence, primarily in cases involving issues of science or technology.”³⁰⁵ The Judicial Center prepared the Reference Manual to provide judges with “quick access to information on specific areas of science in a form that will be useful in dealing with disputes among experts.”³⁰⁶

299. Roderick R. McKelvie, *Problems of Complex Litigation*, 9 FED. CIR. B.J. 529, 531 (2000) (discussing the “formal and informal methods for getting the judge up to speed on the technology . . . cases”).

300. *Id.*

301. *Id.* Judge McKelvie has noted, “I do not expect that many district court judges have undergraduate degrees in science Very few, if any, trial judges have graduate degrees in science (I do not know of any who do).” *Id.*

302. *See supra* notes 281-292.

303. *Id.*

304. *See* Paul S. Miller et al., *Daubert and the Need for Judicial Scientific Literacy*, 77 JUDICATURE 254, 260 (1994) (discussing science information bench books for judges).

305. REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 1 (Fed. Judicial Ctr. ed., 1994) [hereinafter REFERENCE MANUAL]. The purpose of the manual is to “provide[] judges with a valuable educational resource that poses little threat to the maintenance of an impartial and independent federal judiciary.” Siegel, *supra* note 283, at 203.

306. REFERENCE MANUAL, *supra* note 305, at 3. One scholar has noted that: [t]he bulk of the Reference Manual, Part II, and the novel part in jurisprudential terms, consists of “reference guides” to areas often the subject of scientific expert testimony. . . . These reference guides consist of seven topics: epidemiology, toxicology, survey research, forensic analysis of DNA, statistical inference, multiple regression analysis, and es-

The Reference Manual is not the only such publication. To assist state court judges, the Einstein Program for Law and Judicial Policy Studies at George Washington University's Center for Health Policy Research has developed a series of bench books for state judges, entitled *Science in the Court: Finding Your Way*.³⁰⁷ Perhaps more common—although much less comprehensive—are legal periodicals that devote one or more volumes to the topic of adjudicating biotechnology disputes.³⁰⁸ One example is the November/December 1999 publication of *Judicature*, entitled “Genes and Justice,” which provides scholarly articles for judges about the effects of biotechnology on our legal system.³⁰⁹

Notwithstanding the undeniable value of these publications to the judiciary, legal manuals and periodicals are fraught with a limitation similar to that which afflicts judicial seminars.³¹⁰ Judge William Schwarzer, director of the Federal Judicial Center, emphasized this point best when he noted that the focus of the Reference Manual is not on evidentiary questions of admissibility, but rather on the epistemology of science.³¹¹ As a result, the Reference Manual does not educate judges on the admissibility of specific types of expert evidence or conclusions of specific scientific studies. In-

timation of economic loss. The collection of topics is obviously eclectic, including specific fields of research (epidemiology and toxicology), subjects of study (DNA and economic loss), and particular methodologies (surveys, regression analysis, and statistics).

Laurens Walker & John Monahan, Essay, *Daubert and the Reference Manual: An Essay on the Future of Science in Law*, 82 VA. L. REV. 837, 846-47 (1996) (citing REFERENCE MANUAL, *supra* note 305, at 119).

307. Walker & Monahan, *supra* note 306, at 845 n.36. The project was supported by the State Justice Institute, the National Institute of Justice, the Federal Bureau of Investigation, and the Human Genome Project of the U.S. Department of Energy. *See also* Miller, *supra* note 304, at 260.

308. *See, e.g., Genes and Justice: The Growing Impact of the New Genetics on Courts*, 83 JUDICATURE 1, 97 (1999).

309. *Id.*

310. *See* Daniel W. Shuman & Bruce D. Sales, *The Impact of Daubert and Its Progeny on the Admissibility of Behavioral and Social Science Evidence*, 5 PSYCHOL. PUB. POL'Y & L. 3, 8 (1999) (“Neither legal education nor judicial selection criteria address education and training in scientific methods necessary to provide the expertise to make sophisticated judgments about the reliability or validity of proffered testimony.”); Walker & Monahan, *supra* note 306, at 845.

311. Walker & Monahan, *supra* note 306, at 845 (citing REFERENCE MANUAL, *supra* note 305, at 3). Consistent with the notion that the academic literature is disconnected from the problems faced by judges, one scholar has observed that “although the alleged disjuncture between science and law continues to be fertile scholarly terrain, the academic discourse often ignores practical problems faced by judges, lawyers, and jurors.” Moreno, *supra* note 268, at 532 (citation omitted).

stead, the manual “presents a primer on the methods and reasoning of selected areas of scientific evidence.”³¹² Similar to judicial seminars, therefore, many educational publications fail to educate judges on specific questions of admissibility that may arise in a particular case.

Our point is thus: given the limitations of judicial seminars and educational publications, the legal community must establish new forums that will more effectively mediate between science and the legal environment. To serve their purposes, these forums must improve upon conventional judicial education and at the same time ease the demand on trial judges to serve as gatekeepers. The forums must, in other words, overcome the problematic features of judicial seminars and scientific publications, yet serve their same instructive purpose. The forums must refrain from deferring exclusively to the scientific community on matters of the admissibility of scientific evidence (as the judiciary did under the *Frye* test), yet modify the current practice of exercising the gatekeeper construct without the impartial advice of the scientific community (as the judiciary has done under *Daubert*). The following Section explores one such forum.

C. A Forum to Mediate Between Science and the Legal Environment

At the 150th annual meeting of the American Association for the Advancement of Science in 1998, U.S. Supreme Court Justice Stephen Breyer remarked that scientific advisors may be of great assistance to the judicial community in the twenty-first century.³¹³ Justice Breyer, whose comments echoed those of his concurring opinion in *General Electric Co. v. Joiner*,³¹⁴ observed that, as judges play an increasingly important role in screening scientific experts, advice from neutral parties in the scientific community can be of enormous value to courts.³¹⁵ Justice Breyer suggested that “in this age of science we must build legal foundations that are sound in science as well as in law. Scientists have offered their help. We in the legal community should accept that offer”³¹⁶

One organization in particular has heeded Justice Breyer’s call. EIN-SHAC, the voluntary education and research organization mentioned in

312. Walker & Monahan, *supra* note 306, at 845 (citing REFERENCE MANUAL, *supra* note 305, at 3).

313. *Justice Breyer Calls for Experts to Aid Courts in Complex Cases*, N.Y. TIMES, Feb. 17, 1998, at A17 [hereinafter *Justice Breyer*].

314. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 147-48 (1997).

315. See Stephen Breyer, *The Interdependence of Science and Law*, 280 SCI., Apr. 24, 1998, at 538.

316. *Id.*

the previous Section,³¹⁷ has aided in the recent creation of an institution, ASTAR, that will soon serve as a reference to courts on novel issues of biotechnology and, in so doing, help bridge the gap between the courts and mainstream, independent, and neutral scientific enterprise.

ASTAR is a non-profit agency comprised of the judicial branches of thirty-five states around the nation (the "ASTAR consortium"). Maryland, Ohio, and Washington are serving as the core states that will provide programs for states in their regions. Established in 2003, ASTAR is dedicated to the recruitment, training, evaluation, and certification of judges of state and federal courts who have undertaken specialization in cases involving complex science and technology evidence and issues.³¹⁸ ASTAR's objective is to promote more efficient, public confidence-inspiring adjudication of complex cases involving novel scientific evidence. In 2006, ASTAR received a \$1 million congressional appropriation, administered through the Department of Justice.

1. *The ASTAR Resource Judges*

The ASTAR Consortium endeavors to identify and train judges in the United States and foreign jurisdictions who are conversant in biotechnology to be "resource judges" for their respective jurisdictions. Resource judges are specialized in scientific and technical evidence relevant to novel cases involving evidence of human genetics, agricultural biotechnology, environmental biotechnology, and applied neurobiology. The resource judges share an identified, enumerated group of knowledge foundations expected to be mastered and retained by each resource judge in the course of his or her training. These judges will understand the underlying scientific methodology and technology tests.

The term "resource" refers to reserve skills (a set of performance tasks and knowledge bases that the Consortium has initially defined and described) that each judge will be able to provide his or her respective jurisdiction. Performance tasks include direct adjudication, collegial consultation on procedural matters and novel-evidence gatekeeping, judicial education leadership, and an online case and comment journal.

2. *Training and Certification of the Resource Judges*

The ASTAR Consortium has established an independent non-profit organization, known as the Advanced Science and Technology Adjudication Standards, Credentials, and Accreditation Board ("ASTAboard"), to

317. See Section V.B.1.

318. ASTA News, Volume 1, Issue 2, at 1 (Spring 2005). ASTAR was created by EINSHAC in 2003 and became independent in 2004.

promulgate the standards by which resource judges will be certified. ASTAboard's Chair, the Honorable Eric T. Washington, Judge of the D.C. Court of Appeals, recently presided over the adoption of "The Manual," the principal standards-setting and accreditation instrument to guide ASTAR resource judge preparation.³¹⁹

To qualify as a resource judge, a selected judge must train in three national programs and five state-based workshops. The ASTAboard certifies the judge's completion of basic science and technology training, known as "Platform A." This Platform focuses on the so-called "Four B's"—bioscience, biotechnology, biomedicine, and bioforensics. Upon completion of Platform A, the judge is eligible to be elected as a Fellow of ASTAboard.

Once a resource judge has attained ASTAR Fellow status, the judge may enlist in Platform B. This Platform is an educational workshop that allows resource judges who are interested in one of five more specialized science and technology subjects to obtain more advanced background training. These five subjects are: (1) neuroscience and bio-behavior technologies; (2) environmental biotechnology and bioremediation; (3) health care adjudication and human research subjects disputes; (4) food security and agricultural biotechnology; and (5) synthetic biology, nanoscience, and national security bioforensics. Judges who complete Platform B will earn ASTAR diploma status.³²⁰

Thus, unlike traditional judicial seminars programs, judges certified by ASTAR have completed at least 120 hours of education provided by outstanding faculties at The Ohio State University, the University of North Carolina, and Johns Hopkins. ASTAR has assembled an outstanding group of scientists who are able to impart their knowledge in terms that judges appreciate and can understand. The ASTAR forum therefore provides more intensive training than the traditional one- or two-day judicial

319. ASTA News, Volume 1, Issue 2, at 3 (Spring 2005). The Manual provides a content template that must be met to qualify ASTAR resource judges' eligibility for election as ASTAR Fellows. *Id.*

320. The Honorable Christine M. Durham, Chief Justice of the Supreme Court of Utah, has agreed to Chair ASTAR's Platform B program. *Id.* at 1. Further, the University of Utah President has invited the ASTAR Platform B program in neuroscience and bio-behavioral technologies. *Id.* The Indiana University/Purdue University Health Law Center in Indianapolis will design the Platform B program in Health Care Adjudication. *Id.* These programs are slated to begin in June 2007. *Id.* The Ohio State University will assist with the project.

seminar, which is valuable but does not expose the judges to the intense training ASTAR provides.³²¹

3. *Implementation of the ASTAR Resource Judge Program*

The highest courts of the Consortium states have recently taken measures to implement the ASTAR resource judge program. In Ohio, for example, the trustees of the Judicial College of the Supreme Court of Ohio convened on January 28, 2005 to discuss ASTAR.³²² At that meeting, the trustees accepted responsibility for overseeing the design and implementation of Ohio's ASTAR resource judge program.³²³ The trustees' meeting was a prelude to action on several fronts taken by the Ohio judiciary. On March 2, 2005, letters were sent to each judge in Ohio's jurisdiction inviting application for one of twenty places authorized for the resource judge project's first cycle.³²⁴ By the April 1 deadline, the Judicial College received more than four times that number in applications from Ohio judges.³²⁵

Among the nearly ninety applications ultimately received, the trustees of the Ohio Judicial College selected twenty judges based on diversity of geographical location and geographical jurisdictional status of the court.³²⁶ These resource judges thus represent courts in all major geographic areas in Ohio and at all levels—including the probate courts, the juvenile courts, the courts of common pleas, the courts of appeals, and the Supreme Court of Ohio. The twenty Ohio judges have made a five-year commitment to receive advanced training and to assist other judges presiding over cases that involve scientific matters.

The training and education that Ohio judges received in 2006 included an agricultural science seminar at The Ohio State University in January, a program on the biogenic and environmental causes and treatment of cancer at the University of North Carolina in March, a colloquium on reproductive medicine at The Ohio State University in April, a seminar on computer and internet technologies at the Supreme Court of Ohio in May,

321. This does nothing to prevent a judge from applying Federal Rule of Evidence 706, which permits judges to appoint experts. Because of the ASTAR judge's intense training, he or she will be better able to understand the information provided by the technical expert.

322. *Id.* at 2.

323. *Id.*

324. *See id.*

325. *See id.*

326. The applicants who were not selected will join Ohio's second cycle that begins in January 2007 and have the opportunity to attend the Judges' Science and Medical Schools.

and a case conference on evidence, expert witnesses, and causation at the John Marshall Law School in Chicago, Illinois in October.

Ohio is also in the process of analyzing whether state and local court rules need to be amended to facilitate the use of the ASTAR resource judge. Any necessary changes to the applicable rules are expected to be in place at the beginning of 2008, thus allowing for the first group of ASTAR Fellows to immediately begin serving their respective jurisdictions within Ohio. Several of Ohio's twenty ASTAR judges have already applied their advanced training to cases that have been routinely assigned to them.

Maryland has similarly identified its first group of resource judges. The Honorable Robert M. Bell, Chief Judge of the Maryland Court of Appeals, designated twenty-four Business and Technology Court Judges as ASTAR resource judges. With a strong biotechnology research community, Maryland is one of sixteen states with business and technology specialized courts or judges.³²⁷ The resource judge program thus interfaces well with Maryland's civil and criminal judge priorities.³²⁸ Chief Justice Bell has circulated Judges' Science and Medical School initiations widely among Maryland courts.³²⁹

Maryland recently produced two in-state ASTAR programs, which were attended not only by its ASTAR resource judges, but also by state judges from outside of Maryland, federal judges, and professors from the two accredited law schools in Maryland. The first program, conducted in January 2006 at Johns Hopkins University School of Medicine in Baltimore, was devoted to molecular biology and genetics, stem cell research, and neuro-imaging. The second program was held in April 2006. The first day of the program, conducted at the U.S. Department of Agriculture's Research Service facility in Beltsville, Maryland, was devoted to genetic modification and manipulation of agriculturally important crops and animals. The second and third days were held at Johns Hopkins and addressed the clinical applications of neuro-imaging in assessing competency, evaluating organic brain diseases, cell and gene therapy applications of stem cell research, scientific fraud, scientific peer publications, scientific expert witness qualification assessment, and an exploration of the judicial ethics implications of performing the roles of an ASTAR judge.

327. ASTA News, Volume 1, Issue 2, at 3 (Spring 2005).

328. *Id.* Judges in the Business and Technology Courts have powers to expedite complex cases in each of the State's twenty-four judicial circuits.

329. *Id.*

4. *The Future of ASTAR*

The ASTAR resource judge program is rapidly moving from concept to reality. The initial group of judges identified by Ohio and Maryland commenced their Platform A training,³³⁰ and in October 2006, in Chicago, Illinois, the ASTAboard elected and inducted the group as ASTAR Fellows.³³¹ Approximately forty-five ASTAR resource judges have completed their certified training as of the publication of this Article.³³² In March 2007, ASTAR offered the Advanced Judicial Institute on Nanotechnology, Synthetic Biology, and Environmental Biotechnology to over 200 judges at the Lawrence Berkeley National Laboratory. Numerous regional programs will continue throughout 2007 and beyond.

Resource judges from each state originally in the ASTAR Consortium will provide technical assistance and train resource judges for jurisdictions within the region (the Eastern Region for Maryland and the Central Region for Ohio). Federal courts will be invited to participate in accordance with the plans of the Regional Centers. ASTAR's goal is to train 700 resource judges in the United States and foreign jurisdictions by the end of this decade.

VII. CONCLUSION

The Supreme Court's landmark decision in *Daubert* dramatically changed the role of trial judges in determining the admissibility of scientific evidence. Once passive recipients of scientific data, trial judges must now act as "gatekeepers" to admit reliable science and to screen out "junk science."³³³ U.S. Supreme Court Justice Stephen Breyer emphasized the point further, declaring that judges must do much more than simply reject specious science; they must "aim for decisions that, roughly speaking, approximately reflect the scientific 'state of the art.'"³³⁴

The increased responsibility of trial courts to determine the admissibility of scientific evidence comes as issues of biotechnology are beginning to find their way into the courtroom.³³⁵ This Article has attempted to dem-

330. *Id.* at 1.

331. *Id.*

332. *Id.*

333. Walsh, *supra* note 16, at 141.

334. STEPHEN BREYER, THE INTERDEPENDENCE OF SCIENCE AND LAW, ADDRESS FOR THE ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE ANNUAL MEETING AND SCIENCE INNOVATION EXPOSITION (Feb. 16, 1998), available at <http://aaas.org/spp/yearbook/chap9.htm>.

335. Abrahamson, *supra* note 3 at 102.

onstrate that three areas of biotechnology in particular—DNA forensics, genetic engineering, and genetic privacy—will soon challenge the scientific knowledge of every judicial system in the world. As one scholar predicts, “it will not be long before judges confront issues involving genetics on a regular basis within their courts.”³³⁶

To prepare judges for biotechnology issues in the *Daubert* era, various organizations offer judicial seminars and educational publications. These judicial resources, however, are limited in two respects: first, private corporate sponsors for these resources create an appearance of improper influence; and second, such resources are often not intended to, and are largely incapable of, addressing the specific biotechnology issues that will arise in a particular case.

It is not surprising, therefore, that discussions among jurists and scientists have reached a common conclusion: a new institution is necessary to ease the transition between science and the legal environment as the world adjusts biotechnology to the rule of law. ASTAR, thus realized, will be instrumental to that transition; for biotechnology, in the words of Dr. Franklin Zweig, “push[es] society into a new area where the letter of the law is grey, not black.”³³⁷

336. Gold, *supra* note 166, at 135.

337. Nosengo, *supra* note 290, at 117.

BANKRUPTCY TREATMENT OF INTELLECTUAL PROPERTY ASSETS: AN ECONOMIC ANALYSIS

By Peter S. Menell[†]

TABLE OF CONTENTS

I. INTRODUCTION	734
II. CONTRASTING APPROACHES TO ASSET MANAGEMENT: INTELLECTUAL PROPERTY LAWS VERSUS THE BANKRUPTCY SYSTEM.....	734
A. INTELLECTUAL PROPERTY LAW: THE EX ANTE PERSPECTIVE.....	734
1. <i>The Goals of Intellectual Property Law</i>	734
2. <i>Intellectual Property Transactions</i>	734
a) Patents	734
b) Copyrights.....	734
c) Trade Secrets.....	734
d) Trademarks	734
B. THE BANKRUPTCY SYSTEM: AN EX POST DEBTOR PERSPECTIVE.....	734
1. <i>Overview of the Bankruptcy System</i>	734
2. <i>Characterization of Assets</i>	734
a) Sales, Assignments, and Exclusive Licenses of Intellectual Property Rights	734
b) The Classification of Mode-Specific IP Licenses	734
i) Patent Licenses	734
ii) Copyright Licenses	734
iii) Trade Secret Licenses	734
iv) Trademark Licenses.....	734
v) Software License Agreements	734
3. <i>Resolution of the Bankrupt Estate: Dishonoring of Contract</i>	734
a) Assumption	734
b) Rejection	734
c) Assignment	734
4. <i>Summary</i>	734
III. THE LICENSOR BANKRUPTCY PROBLEM.....	734

© 2007 Peter S. Menell

[†] Professor of Law and Director, Berkeley Center for Law & Technology, University of California at Berkeley (Boalt Hall) School of Law. I would like to thank Jesse Fried, David Nimmer, and Robert Eisenbach for comments and Carol Johns and Tom Fletcher for research assistance.

A.	THE LIMITED SCOPE OF “INTELLECTUAL PROPERTY” UNDER SECTION 365(N).....	734
1.	<i>Trademarks and Bundled IP Licenses</i>	734
2.	<i>Foreign Copyrights</i>	734
3.	<i>Personal Services of Recording Artists</i>	734
B.	LICENSOR OBLIGATIONS	734
C.	MEANING OF “ROYALTY PAYMENTS”	734
D.	ASSESSMENT AND REFORM.....	734
IV.	THE LICENSEE BANKRUPTCY PROBLEM	734
A.	ASSUMABILITY OF LICENSE AGREEMENTS BY REORGANIZING ENTERPRISES	734
B.	MODE-SPECIFIC ANALYSIS OF ASSIGNABILITY OF LICENSE AGREEMENTS	734
1.	<i>Patent Licenses</i>	734
a)	Nonexclusive Licenses.....	734
b)	Exclusive Licenses.....	734
c)	Assumption of Licenses by Reorganized Debtors	734
2.	<i>Copyright Licenses</i>	734
a)	Nonexclusive Licenses.....	734
b)	Exclusive Licenses.....	734
3.	<i>Trademark Licenses</i>	734
4.	<i>Trade Secret Licenses</i>	734
C.	AVOIDING OPPORTUNISM AND PROMOTING DEBTOR ESTATE VALUE IN THE LICENSEE BANKRUPTCY CONTEXT	734
1.	<i>Assignment to Hostile Third Party or Retention by Hostile Debtor</i>	734
2.	<i>Equitable Division of Bilateral Goodwill</i>	734
V.	MANAGING INVESTOR RISK: SECURITIZATION OF IP ASSETS	734
A.	UCC ARTICLE 9: DEFAULT RULES FOR PERFECTING SECURITY INTERESTS	734
1.	<i>Attachment of Security Interests</i>	734
2.	<i>Perfection of Security Interests</i>	734
3.	<i>Federal Preemption</i>	734
B.	INTELLECTUAL PROPERTY STATUTES, PRE-EMPTION, AND ARTICLE 9	734
1.	<i>Copyright</i>	734
2.	<i>Patents</i>	734
3.	<i>Trademarks</i>	734
4.	<i>Trade secrets</i>	734
C.	IMPROVING THE PROCESS FOR PERFECTING SECURITY INTERESTS IN INTELLECTUAL PROPERTY.....	734
VI.	CONCLUSIONS	734

With the rise of intellectual property in the modern economy, bankruptcy treatment of intellectual property assets has taken on ever greater importance. The law in this area must balance different approaches to asset management. Viewing the world from an *ex ante* perspective, intellectual property laws seek to foster investment in research and development. Freedom of contract plays a central role in maximizing the potential value of intellectual property by encouraging a robust licensing market to exploit the value of intellectual creativity. By contrast, the bankruptcy system generally views asset management from an *ex post* standpoint, focusing narrowly on how to maximize the value of a failing or failed enterprise. Thus, bankruptcy law affords trustees and debtors substantial leeway to rescind contracts and reorder the affairs of the failed entity. This Article examines the rather complex rules governing the treatment of intellectual property assets in bankruptcy and suggests various reforms that could better promote economic efficiency.

I. INTRODUCTION

Over the past several decades, intellectual property has taken on an increasingly larger role in the global economy. Today, much of the value of the world's leading companies resides in their portfolios of intangible assets—ranging from the better defined forms of intellectual property (such as patents and copyrights) to the least tangible of the intangibles (trade secrets (know-how) and trademarks (the goodwill associated with a brand)). According to one source, the ratio of the value of hard assets relative to intangible assets among the major industrial companies of the world went from 62%/38% in 1982 to 38%/62% a decade later.¹

In 2000, intangible assets and intellectual property values are clearly the most important assets of most industrial companies given the increased intensity of competition, increased rapidity of technological growth and innovation, increased reliance on legal protection of rights in intellectual property and increased enforcement of ownership rights, and increasingly sharp liability standards for infringement and misappropriation.²

As these assets have appreciated, sometimes becoming a company's most valuable assets, their importance in bankruptcy proceedings has also

1. See William J. Murphy & Thomas Ward, *Proposal for a Centralized and Integrated Registry for Security Interests in Intellectual Property*, 41 IDEA 297, 301 (2002) (citing SWISS REINSURANCE COMPANY, *THE SIGNIFICANCE OF INTELLECTUAL PROPERTY ASSETS, RISKS AND INSURANCE* (2000)).

2. *Id.*

become critical. Sorting out how the bankruptcy system interacts with intellectual property, however, requires understanding many complex areas of law. Besides the sheer complexity of statutes like the Patent Act, Copyright Act, and the Bankruptcy Code, practitioners need to understand how the statutes interact with each other and with various state laws.

From a practical standpoint, intellectual property assets create difficult questions in two areas of bankruptcy law. First, what happens to intellectual property licenses when a company goes through bankruptcy? Many companies' key products and services depend on intellectual property licenses. For example, a pharmaceutical company often needs licenses for patented processes and compounds or its production line halts. A movie studio can only develop and distribute a pre-existing property if it has it under license. How the bankruptcy system preserves—or disrupts—licensing arrangements is critical.

The importance of securitizing intellectual property assets raises the second difficult question: how can parties protect their intellectual property assets in the event of business failure, ensuring that those interests will be honored in bankruptcy? Creating security interests in intellectual property assets is one way to avoid such problems. These security interests act as insurance in the event of bankruptcy. Additionally, security interests allow intellectual property developers to use their assets as collateral to get financing despite their lack of tangible assets. Bankruptcy law touches on security interests as well. One must understand the interaction between bankruptcy and security interests in order to use those interests effectively to protect intellectual property rights in a bankruptcy proceeding.

This Article begins by exploring the friction between the intellectual property laws—which use an *ex ante* perspective to promote efficient levels of investment in the development and exploitation of innovative and creative works—and the bankruptcy system—which views assets from an *ex post* perspective to maximize the value of a debtor's estate. It then examines the three principal tensions at the intersection of intellectual property law and the bankruptcy system: (1) when the licensor of intellectual property goes bankrupt and the trustee of the debtor estate seeks to rescind a license agreement; (2) when an intellectual property licensee enters bankruptcy and the trustee, attempting to maximize the value of the debtor estate, seeks to transfer a license to a third party that may undermine the licensor's desires; and (3) the challenge of securitizing investments in creative enterprises where the main value lies in intangible assets. The Article explains how changes in the law have ameliorated some of the tensions between intellectual property law and the bankruptcy system, but notes several distinct problems that remain. It recommends several changes to

better promote economic efficiency in the bankruptcy treatment of intellectual property assets.

II. CONTRASTING APPROACHES TO ASSET MANAGEMENT: INTELLECTUAL PROPERTY LAWS VERSUS THE BANKRUPTCY SYSTEM

The intellectual property laws and the bankruptcy system reflect very different perspectives on the management of assets. The intellectual property laws are generally concerned with asset creation. Therefore, they encourage conditions that promote investment in research and development, as well as the maximization of value that can be derived from such assets. Much of the value of intellectual property flows from licensing goods and services. Freedom of contract therefore plays a central role in maximizing the potential value of intellectual property by encouraging a robust licensing market to exploit the value of intellectual creativity.

By contrast, the bankruptcy system views economic activity from the standpoint of maximizing the value of a failing or failed enterprise. It seeks to maximize the value of the remaining assets and capacities of the troubled entity. In order to accomplish this, bankruptcy law affords trustees and debtors substantial leeway to rescind contracts and reorder the affairs of the entity. Therein lay the tensions with the intellectual property laws.

As background for the analysis of these tensions, this Part first traces the goals of the intellectual property laws as well as their specific treatment of licensing. It then examines the main contours of the bankruptcy system and its general perspective on honoring (or more appropriately, dishonoring) contractual obligations. The following Sections explore the principal tensions between these two systems.

A. Intellectual Property Law: The Ex Ante Perspective

The intellectual property landscape can be divided into two general areas: those modes of protection focused principally on promoting innovation and creativity and those aimed at protecting the integrity of the marketplace.³ The former purpose provides the impetus and guide for patent and copyright law, and, to a lesser extent, trade secret law. The latter finds expression in trademark and unfair competition law.

3. See generally Peter S. Menell & Suzanne Scotchmer, *Intellectual Property Law*, in HANDBOOK OF LAW AND ECONOMICS (A. Mitchell Polinsky & Steven Shavell eds., forthcoming 2007).

1. *The Goals of Intellectual Property Law*

The Intellectual Property Clause of the U.S. Constitution succinctly and directly expresses the motivation behind patent and copyright law by authorizing Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁴ As the Supreme Court has explained, “[t]he economic philosophy behind [this clause] is the conviction that [it] is the best way to advance public welfare through the talents of authors and inventors in ‘Science and useful Arts.’ Sacrificial days devoted to such creative activities deserve rewards commensurate with the services rendered.”⁵ The Court elaborated further in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*:

The [Intellectual Property] Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the “Progress of Science and useful Arts.” [T]he Clause contains both a grant of power and certain limitations upon the exercise of that power. Congress may not create patent monopolies of unlimited duration, nor may it “authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.” From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.⁶

To understand why the Framers thought exclusive rights in inventions and creations would promote the public welfare, consider what would happen absent any sort of intellectual property protection. Invention and creation often require the investment of resources, such as the time of an author or inventor, expenditures on facilities, prototypes, and supplies. In a private market economy, economically motivated individuals will not invest in invention or creation unless the expected return exceeds the cost—that is, unless they can reasonably expect to make a profit from the endeavor. To profit from a new idea or a work of authorship, the creator

4. U.S. CONST. art. I, § 8, cl. 8.

5. *Mazer v. Stein*, 347 U.S. 201, 219 (1954).

6. 489 U.S. 141, 146 (1989) (citation omitted).

must be able either to sell it to others, or to put it to some use which provides a comparative advantage in the marketplace.⁷

But ideas are notoriously hard to control in the absence of some form of legal protection. Even if the idea is one that the creator can use herself—to boost productivity in her business, for example—she will reap a reward from that idea only to the extent that her competitors do not find out about it. A creator who depends on secrecy for value lives in constant peril of discovery and disclosure. Competitors may steal the idea or learn of it from an ex-employee. They may be able to figure it out by watching the creator's production process or by examining the products sold. Finally, they may come upon the idea on their own or discover it in the published literature. In all of these cases, the secrecy value of the idea is irretrievably lost.

Authors (and publishers) of works of creative expression face a distinct but related problem. Works of creative expression can require substantial amounts of time on research and great expenditures of resources. A novel can take years to conceive, research, and write. A major motion picture can cost tens of millions of dollars or more to produce. In order to derive value from their works, creators must make them available to the public—through publishing, performance, or ancillary means (such as licensing of merchandise derived from the creative work). But once the work is available, others can make copies. Because these others do not incur most of the costs of the production, they can earn a profit by selling the work at substantially lower cost than the creator.

The creator who wants to sell her idea is in an even more difficult position. Selling information requires disclosing it to others. Once the information has been disclosed outside a small group, however, it is extremely difficult to control. Information has the characteristics of what economists call a “public good”—it may be “consumed” by many people without depletion, and it is difficult to identify those who will not pay and prevent them from using the information. For example, once the idea of the intermittent windshield wiper is disclosed, others can imitate its design relatively easily.

Patents and copyrights directly address the problem of appropriating a stream of income from investments in innovation and creative expression. Subject to various exceptions, limitations, and defenses, these modes of protection effectively prohibit the use and sale of protected works without

7. The latter may occur, for example, where an idea for a more efficient machine is used to reduce the cost of producing goods, allowing the owner of the idea to compete more effectively in selling those goods.

the authorization of the intellectual property owner. In this way, innovators (and those who invest in them) can prevent others from directly competing with them for the period that the works receive protection. The creation of exclusive rights can, however, reduce competition. For that reason, patent law and copyright law impose some threshold requirements upon acquisition of rights and limit the scope of protection in various ways. We will examine these attributes below.

Trade secret law also seeks to promote innovation,⁸ although it accomplishes this objective in a very different manner than patent law. Notwithstanding the advantages of obtaining a patent—an exclusive right to practice an invention for a designated period of time—many innovators prefer to protect their innovation through secrecy. They may feel that the cost and delay of seeking a patent are too great or that they can more effectively profit from their investment through secrecy. They might also believe that the invention can best be exploited over a longer period of time than a patent would allow.

Without any special legal protection, however, the secretive inventor runs the risk that an employee (or a thief) will disclose the invention. Once the idea is released, it will be “free as the air.”⁹ Such a predicament would lead any inventor seeking to rely upon secrecy to spend an inordinate amount of resources on building high and impervious fences around their research facilities and greatly limiting the number of people with access to the proprietary information. Although trade secret law does not limit the use of ideas once they have become publicly known, it does significantly reduce the costs of protecting secrets within the confines of the research and commercial environment. An inventor who takes *reasonable* steps to maintain secrecy can obtain strong remedies against individuals within the laboratory or commercial enterprise and those subject to contractual limitations for misappropriation of trade secrets.¹⁰

Trademark law and related unfair competition doctrines flow from a very different primary purpose: protection of the integrity of the marketplace. In fact, the first federal trademark statute (passed in 1870), which grounded protection for trademark rights on the Intellectual Property Clause of the Constitution, was struck down by the Supreme Court be-

8. Trade secret law seeks to promote standards of commercial ethics as well.

9. *See* *International News Serv. v. Associated Press*, 248 U.S. 215, 250 (1918) (Brandeis, J., dissenting) (“The general rule of law is, that the noblest of human productions—knowledge, truths ascertained, conceptions, and ideas—became, after voluntary communication to others, free as the air to common use.”).

10. *See generally* RESTATEMENT (THIRD) OF UNFAIR COMPETITION §§ 38-45 (1995).

cause the statute protected marks regardless of any novelty or originality.¹¹ Congress has since based federal trademark protection on the Commerce Clause, requiring that marks be used in interstate commerce. Trademark law facilitates and enhances consumer decisions by protecting names, logos, words, phrases, symbols, sounds, trade dress, product configuration, and other means of designating the source of commercial products or services. In so doing, trademark law encourages firms to supply quality products and services and invest in building the “goodwill” surrounding a brand name. In this way, it plays some role in encouraging innovation. Nonetheless the protection of a mark turns on its distinctiveness and the extent to which consumers associate it with a source of goods, not its inventiveness.

2. *Intellectual Property Transactions*

In order to understand the tension between intellectual property and bankruptcy law, it is necessary to understand the importance of licensing in markets for creative enterprise. Inventors and creators are often not best situated to commercialize their creativity. Licensing markets allow better situated players to adapt and exploit creative works. The robustness of those markets plays a critical role in encouraging investment in creative activities. Therefore, intellectual property law generally encourages freedom of contract in the licensing of intellectual property. The courts and legislatures have long considered patents, copyrights, and trademarks to be forms of “property” and have characterized them as such.¹²

a) Patents

The Patent Act expressly declares that “patents shall have the attributes of personal property”¹³ and “shall be assignable in law by an instrument in writing.”¹⁴ It states further that the patentee (or his assigns) may

11. *The Trade-Mark Cases*, 100 U.S. 82, 94 (1879).

12. See Justin Hughes, *Copyright and Incomplete Historiographies: Of Piracy, Propertization, and Thomas Jefferson*, 79 S. CAL. L. REV. 993 (2006) (demonstrating a long history of analogizing copyright to property). That intellectual property is characterized as “property” does not mean that it is treated the same as land and other tangible forms of property. See Peter S. Menell, *The Property Rights Movement’s Embrace of Intellectual Property: True Love or Doomed Relationship?*, 34 ECOLOGY L.Q. (forthcoming 2007).

13. See 35 U.S.C. § 261 (2000); see also *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730, 739 (2002) (noting that a patent “is a property right” and that patent rights constitute “the legitimate expectations of inventors in their property”); *Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 642 (1999) (“Patents . . . have long been considered a species of property.”).

14. See 35 U.S.C. § 261 (2000).

“grant and convey an exclusive right” under his patent “to the whole or any specified part of the United States.”¹⁵ As set forth in *Waterman v. Mackenzie*, an agreement is a sale (or assignment) of patent rights only if it conveys “1. the whole patent, comprising the exclusive right to make, use and sell the invention; 2. an undivided share of that exclusive right; or 3. an exclusive right to practice the invention within a specified territory.”¹⁶ Short of an outright assignment, a patent owner is generally free to license rights under the patent as he wishes (subject to competition policy constraints¹⁷). Such licenses can be express or implied. “Unless the writing conveys some or all of the right to exclude others from practicing the invention, it will not convey an interest in the patent, but is a mere license.”¹⁸ It has been well-established under federal common law that non-exclusive licenses cannot be assigned without the authorization of the licensor.¹⁹ There is no definitive ruling dealing with the assignability of exclusive patent licenses without licensor consent. Early on, however, the federal courts held that a patent license is “not assignable unless expressly made so” in the licensing agreement.²⁰

15. *Id.*

16. *In re Access Beyond Techs., Inc.*, 237 B.R. 32, 44 (Bankr. D. Del. 1999) (citing *Waterman v. Mackenzie*, 138 U.S. 252, 255-56 (1891)).

17. *See* 35 U.S.C. § 271(d) (2000) (imposing statutory limitations on patent misuse doctrine to harmonize better with antitrust law); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176 (1980); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 519 (1917) (invalidating license on grounds of anticompetitive patent misuse). *See generally* ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 326-30 (4th ed. 2006).

18. *In re Access Beyond Techs., Inc.* 237 B.R. 32, 44 (Bankr. D. Del. 1999) (citing *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891)).

19. *See* *PPG Indus., Inc. v. Guardian Indus. Corp.*, 597 F.2d 1090, 1093 (6th Cir. 1979); *Unarco Indus., Inc. v. Kelley Co.*, 465 F.2d 1303, 1306 (7th Cir. 1972); *Rock-Ola Mfg. Corp. v. Filben Mfg. Co.*, 168 F.2d 919, 922-23 (8th Cir. 1948).

20. *See* *Hapgood v. Hewitt*, 119 U.S. 226, 233-34 (1886); *Oliver v. Rumford Chem. Works*, 109 U.S. 75, 82 (1883) (declaring that “the instrument of [a patent] license is not one which will carry the right conferred to any one but the licensee personally, unless there are express words to show an intent to extend the right to an executor, administrator, or assignee, voluntary or involuntary”); *Troy Iron & Nail Factory v. Corning*, 55 U.S. 193, 216 (1852) (declaring patent licenses are not assignable without owner’s consent). For more recent affirmation of this doctrine, see *Perlman v. Catapult Entm’t (In re Catapult Entm’t)*, 165 F.3d 747, 750 (9th Cir. 1999); *Institut Pasteur v. Cambridge Biotech Corp.*, 104 F.3d 489, 492 (1st Cir. 1997); *Unarco Indus.*, 465 F.2d at 1306. As noted *infra* note 211, some commentators have raised questions as to whether this invocation of federal common law should prevail in the aftermath of *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938). The U.S. Supreme Court has not had occasion to revisit the viability of this federal common law rule.

The Patent Act establishes a recordation system for “assignment[s], grant[s] or conveyance[s]” of patents.²¹ By recording such instruments with the PTO “within three months from its date or prior to the date of [a] subsequent purchase or mortgage,”²² the acquiring party is protected against an assertion of title by a subsequent purchaser or mortgagee. If the transferee fails to record, however, it risks losing its interest to a subsequent acquirer or mortgagee who paid valuable consideration and lacked notice of the prior transfer of title. Although the PTO permits the recording of licenses,²³ the “bona fide purchaser” defense is available only to licensees holding “‘all substantial rights’ under the patent.”²⁴ This excludes nonexclusive licenses and likely applies to some exclusive licenses as well.

b) Copyrights

Similarly, copyright law generally supports free alienability and licensing. At least with regard to alienability, this was not always so. Under the 1909 Act, a copyright was considered an indivisible property interest which could not be divided through contract. The rationale for the “indivisibility” doctrine was to protect infringers from being harassed by successive law suits by holders of different sticks in the copyright bundle. Therefore, only the owner of the intact bundle could enforce the copyright. This rule did not, however, prevent the copyright from being licensed. Nonetheless, the indivisibility doctrine caused a number of undesirable effects. Some works lost copyright because publishers occasionally used the wrong name on copyright notices, and many copyright interest holders were prevented from enforcing their rights.

The 1976 Act abandoned the indivisibility doctrine. Section 201(d) now provides:

(d) Transfer of Ownership—

- (1) The ownership of a copyright may be transferred in whole or in part by any means of conveyance or by operation of law, and may be bequeathed by will or pass as personal property by the applicable laws of intestate succession.

21. 35 U.S.C. § 261 (2000).

22. *Id.*

23. *See* 37 C.F.R. § 3.11(a)-(b) (2005).

24. *Rhone Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 284 F.3d 1323, 1334 (Fed. Cir. 2002) (quoting *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998)).

(2) Any of the exclusive rights comprised in a copyright, including any subdivision of any of the rights specified by section 106, may be transferred as provided by clause (1) and owned separately. The owner of any particular exclusive right is entitled, to the extent of that right, to all of the protection and remedies accorded to the copyright owner by this title.²⁵

The Copyright Act defines “transfer of copyright ownership” broadly to include:

an assignment, mortgage, exclusive license, or any other conveyance, alienation, or hypothecation of a copyright or of any of the exclusive rights comprised in a copyright, whether or not it is limited in time or place of effect, but not including a nonexclusive license.²⁶

This definition has been interpreted to encompass security interests.²⁷

This broad definition of “transfer of copyright ownership” makes the question of whether licenses are assignable more difficult than in patent law. Where a license agreement limits assignability, such provisions will be enforced. Where an agreement is silent, the courts have imported the federal common law non-assignability doctrine from patent law to hold that a nonexclusive copyright license “is personal to the transferee . . . and the licensee cannot assign it to a third party without the consent of the copyright owner.”²⁸ Courts are split, however, over the assignability of exclusive licenses. As noted above, the 1976 Copyright Act specifically defines the granting of an exclusive license of any of the exclusive rights comprised in copyright as a “transfer of copyright ownership.”²⁹ Furthermore, section 201(d)(1) of the Act states that “ownership of a copyright may be transferred in whole or in part by any means of conveyance or by operation of law.” Section 201(d)(2) provides that “[a]ny of the exclusive

25. 17 U.S.C. § 201(d) (2000).

26. 17 U.S.C. § 101 (2000 & Supp. 2004).

27. See *infra* Section II.B.1.

28. See *Harris v. Emus Records Corp.*, 734 F.2d 1329, 1333-34 (9th Cir. 1984) (based on 1909 Copyright Act); *In re Patient Educ. Media, Inc.*, 210 B.R. 237, 240 (Bankr. S.D.N.Y. 1997) (holding, under the 1976 Copyright Act regime, that the “conclusion and policy analysis in [*Everex*, 89 F.3d at 673] applies with equal force in the analogous area of copyright law”); see also *Michaels v. Internet Entm’t Group, Inc.*, 5 F. Supp. 2d 823, 834 (C.D. Cal. 1998); *Seawind v. Creed Taylor, Inc. (In re Creed Taylor, Inc.)*, 10 B.R. 265, 267-68 (Bankr. S.D.N.Y. 1981) (upholding an anti-assignment clause in an exclusive license to manufacture and distribute sound recordings in part because of the “personal nature of certain licensing arrangements”).

29. 17 U.S.C. § 101 (2000 & Supp. 2004).

rights comprised in a copyright, including any subdivision of any of the rights specified by section 106, may be transferred . . . and owned separately.” Reading these provisions to provide that the holder of an exclusive license is entitled to all the rights and protections of the copyright owner to the extent of the license, including the right to transfer such rights,³⁰ several courts have held that the exclusive licensee may freely transfer his rights.³¹ A recent Ninth Circuit decision, however, reads the Copyright Act to dictate the opposite conclusion.³²

The Ninth Circuit in *Gardner v. Nike* reaffirmed its prior decision that “copyright licenses (whether exclusive or not) were ‘not transferable as a matter of law’” under the 1909 Act.³³ Only an assignment of the entire copyright could be transferred under the 1909 regime based on the doctrine of indivisibility³⁴ and the policy concerns animating that Act. Although recognizing that the 1976 Act introduced the concept of divisibility, the court in *Gardner* read subsection 201(d)(1) narrowly to apply only to owners of the entire copyright, affording them the power to apportion their interest. It read the more specific second sentence of subsection 201(d)(2)³⁵ to limit the rights of exclusive licensees to the “protection and remedies” of the Copyright Act. On this basis, it concluded that the particular transfer right of section 201(d)(1) and the first sentence of subsection 201(d)(2) apply only to copyright owners, not exclusive licensees. The court similarly dismissed the transferability argument based on the definition of “transfer of copyright ownership” in section 101 on the statutory interpretation principle that more specific provisions take precedence over the more general. The court bolstered its arguments by referring to the same policy that favors non-assignability of patent licenses without licensor consent: the promotion of creativity through control of licensing by the intellectual property owner.

30. 17 U.S.C. § 201(d)(2) (2000). See generally 3 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 10.02[A] (2006).

31. See I.A.E., Inc. v. Shaver, 74 F.3d 768, 775 (7th Cir. 1996); *In re Patient Educ. Media*, 210 B.R. at 240.

32. See *Gardner v. Nike, Inc.*, 279 F.3d 774 (9th Cir. 2002).

33. *Id.* at 777-78.

34. The doctrine of indivisibility prohibited a copyright owner from dividing the “bundle of rights.” 3 NIMMER ON COPYRIGHT, *supra* note 30, § 10.01[A].

35. 17 U.S.C. § 201(d)(2) provides:

Any of the exclusive rights comprised in a copyright, including any subdivision of any of the rights specified by section 106, may be transferred as provided by clause (1) and owned separately. The owner of any particular exclusive right is entitled, to the extent of that right, to all of the protection and remedies accorded to the copyright owner by this title.

A transfer of copyright ownership must be in writing and signed by the transferor.³⁶ Section 205 establishes a detailed system for recording copyright transfers and resolving disputes over conflicting transfers:

(a) Conditions for Recordation.—Any transfer of copyright ownership or other document pertaining to a copyright may be recorded in the Copyright Office if the document filed for recordation bears the actual signature of the person who executed it, or if it is accompanied by a sworn or official certification that it is a true copy of the original, signed document.

(b) Certificate of Recordation.—The Register of Copyrights shall, upon receipt of a document as provided by subsection (a) and of the fee provided by section 708, record the document and return it with a certificate of recordation.

(c) Recordation as Constructive Notice.—Recordation of a document in the Copyright Office gives all persons constructive notice of the facts stated in the recorded document, but only if—

(1) the document, or material attached to it, specifically identifies the work to which it pertains so that, after the document is indexed by the Register of Copyrights, it would be revealed by a reasonable search under the title or registration number of the work; and

(2) registration has been made for the work.

(d) Priority Between Conflicting Transfers.—As between two conflicting transfers, the one executed first prevails if it is recorded, in the manner required to give constructive notice under subsection (c), within one month after its execution in the United States or within two months after its execution outside the United States, or at any time before recordation in such manner of the later transfer. Otherwise the later transfer prevails if recorded first in such manner, and if taken in good faith, for valuable consideration or on the basis of a binding promise to pay royalties, and without notice of the earlier transfer.

(e) Priority Between Conflicting Transfer of Ownership and Nonexclusive License.—A nonexclusive license, whether recorded or not, prevails over a conflicting transfer of copyright ownership if the license is evidenced by a written instrument signed by the owner of the rights licensed or such owner's duly authorized agent, and if—

36. 17 U.S.C. § 204(a) (2000). The 1909 Act required that transfers of copyright be in writing, 17 U.S.C. § 28 (1909 Act). Since licenses—exclusive or nonexclusive—were not considered transfers under the indivisibility doctrine, no writing was required. These rules still apply to grants made prior to January 1, 1978.

- (1) the license was taken before execution of the transfer; or
- (2) the license was taken in good faith before recordation of the transfer and without notice of it.

The rules determining priority among conflicting transfers in section 205(d) above apply only where a work has been registered and the transfer duly recorded, the transfer has been made in good faith (i.e., without actual notice of a prior transfer), and valuable consideration has been paid (e.g., not a gift or bequest). Recording the transfer of an unregistered work does not provide a basis for priority of transfer.

c) Trade Secrets

Unlike patent and copyright law, which protect the innovator against the public at large, trade secret law is limited to protecting the *secrecy* of the information and not the information itself. With patents and copyrights, there is a relatively well-defined asset to discuss—the claims of the patent, or the work of authorship. Trade secret law is somewhat less focused on specific assets. There may well be a specific “asset,” such as a formula or a blueprint, but trade secret law covers more amorphous subject matter—information. And the nature of trade secret protection relates as much to the subject matter as to the precautions of the trade secret “owners” and the means by which the defendant acquired the information. Therefore, it is useful to examine the extent to which trade secrets constitute property “assets.”

The Supreme Court appears to have adopted a “property” view of trade secrets in *Ruckelshaus v. Monsanto Co.*³⁷ There, the Court faced the question of whether a federal law that required Monsanto to publicly disclose its trade secrets was a “taking of private property” for which the Fifth Amendment required compensation. The Court found that trade secrets were “property,” reasoning in part that “[t]rade secrets have many of the characteristics of more tangible forms of property. A trade secret is assignable. A trade secret can form the res of a trust, and it passes to a trustee in bankruptcy.”³⁸ Treatment of trade secrets as property rights vested in the trade secret “owner” is consistent with a view of trade secrets law as providing an additional incentive to innovate, beyond those provided in patent law. The Supreme Court has offered some support for this view as well, in cases such as *Kewanee Oil Co. v. Bicron Corp.*³⁹

A powerful alternate explanation for much of trade secret law is what might be described as a “duty-based” theory, or “the maintenance of

37. 467 U.S. 986, 1001-04 (1984).

38. *Id.* at 1002-04.

39. 416 U.S. 470, 481-85 (1974).

commercial morality.”⁴⁰ The Supreme Court adopted this view in a famous early decision in which, unlike *Monsanto*, it was called upon to actually construe the trade secret laws:

The word “property” as applied to trademarks and trade secrets is an unanalyzed expression of certain secondary consequences of the primary fact that the law makes some rudimentary requirements of good faith. Whether the plaintiffs have any valuable secret or not, the defendant knows the facts, whatever they are, through a special confidence that he accepted. The property may be denied, but the confidence cannot be. Therefore the starting point for the present matter is not property or due process of law, but that the defendant stood in confidential relations with the plaintiffs . . .⁴¹

Closely related to this “breach of confidence” theory of trade secrets is a contract perspective. While not always applicable, many trade secret cases arise out of a “duty” that is explicitly stated in a contract, such as a technology license or an employment agreement. The tort-based theory of breach of duty merges in those cases with a standard common-law style action for breach of contract. Whether trade secret law is best understood as a property regime or a tort/contract regime, however, a trade secret is property in bankruptcy.

The Uniform Trade Secrets Act, enacted in forty states and the District of Columbia,⁴² does not provide any special rules for ownership of trade secrets. Therefore, ownership is determined through contract law—typically employment and licensing agreements.

Trade secrets can be freely licensed, although it is essential that such agreements ensure that the information remain secret. The provisions of such agreements generally prohibit assignment of the license (and hence, the trade secret) without the consent of the licensor. There is no specialized process for recording transfers of trade secret rights.

40. 1 MELVIN JAGER, TRADE SECRETS LAW § 1.03, at 1-4 (2002).

41. *E.I. du Pont & Co. v. Masland*, 244 U.S. 100, 102 (1917).

42. *See* RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 39, at 437-38 (1995) (listing state statutes). Some jurisdictions have amended the UTSA in minor ways.

d) Trademarks

Trademarks—words, phrases, logos, and symbols that producers use to identify their goods and services—are protected by both federal law (the Lanham Act⁴³) and state law.⁴⁴

These marks are essential to many business forms. Franchising is perhaps the most vivid example. The McDonald's or Subway restaurant chains are built upon the assurance to consumers that they will receive a particular quality of goods at restaurants bearing the associated trademark. Vast investments are made in developing businesses around particular licensed trademarks. Thus, trademark licenses serve a critical role in investment and consumer welfare.

For these reasons, trademark law has highly developed jurisprudence surrounding trademark licensing. Due to the distinctive nature of trademarks as means for communicating the source of goods and services, trademarks cannot be transferred as simply as a patent or a copyright. As the Supreme Court observed long ago,

There is no such thing as property in a trade-mark except as a right appurtenant to an established business or trade in connection with which the mark is employed. The law of trade-marks is but a part of the broader law of unfair competition; the right to a particular mark grows out of its use, not its mere adoption; its function is simply to designate the goods as the product of a particular trader and to protect his good will against the sale of an-

43. See 15 U.S.C. §§ 1051-1141 (2000 & Supp. 2004). Federal trademark law is often referred to in cases by the original section numbers of the Lanham Act, §§ 1-74.

44. In contrast to the federal patent and copyright acts, the Lanham Act does not preempt state trademark protection. Several provisions refer to the continued effect of state trademark law. See 15 U.S.C. § 1065, 1115(b)(5) (2000 & Supp. 2004); *Golden Door, Inc. v. Odisho*, 646 F.2d 347, 351-52 (9th Cir. 1980); *Mariniello v. Shell Oil Co.*, 511 F.2d 853, 857-58 (3d Cir. 1975); *Nikon, Inc. v. Ikon Corp.*, 803 F. Supp. 910, 925-26 (S.D.N.Y. 1992); *Plasticolor Molded Prods. v. Ford Motor Co.*, 713 F. Supp. 1329, 1346 (C.D. Cal. 1989), *vacated*, 767 F. Supp. 1036 (C.D. Cal. 1991); *Mead Data Cent., Inc. v. Toyota Motor Sales, U.S.A., Inc.*, 702 F. Supp. 1031, 1040-41 (S.D.N.Y. 1988), *rev'd on other grounds*, 875 F.2d 1026 (2d Cir. 1989); *cf. Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156-57 (1989). Some courts, however, hold that state statutes directed at the same types of conduct as the Lanham Act are preempted. See *Three Blind Mice Designs Co. v. Cyrk, Inc.*, 892 F. Supp. 303, 309 (D. Mass. 1995) (holding that state anti-dilution statutes are “wholly preempted” to the extent that they seek to regulate competitive goods directly). *But see* Federal Trademark Dilution Act of 1995, H.R. REP. NO. 104-374 (1995), *as reprinted in* 1996 U.S.C.C.A.N. 1029, 1035 (“It is important to note that the proposed federal dilution statute would not preempt state dilution laws.”). Since federal and state trademark and unfair competition laws follow the same contours, we will focus here on federal law.

other's product as his; and it is not the subject of property except in connection with an existing business.⁴⁵

Therefore, a trademark may only be assigned along with the goodwill of the business in which the mark is used.⁴⁶ Although earlier cases applied this rule quite strictly and required the sale of tangible assets along with the trademark,⁴⁷ more recent cases have relaxed this requirement,⁴⁸ partly in recognition of the increased frequency and importance of trademark licenses. In some contexts, merely relinquishing the right to do business under the trademark to the assignee may be a sufficient transfer of the trademark owner's business.⁴⁹

Similarly, any licenses of trademarks—whether exclusive or nonexclusive—must be supervised by the trademark owner in order to avoid abandoning the mark.⁵⁰ The Lanham Act requires trademark licensors to control “the nature and quality of the goods or services” sold by licensees.⁵¹ Due to the importance of supervising licensees, trademark licenses—whether nonexclusive or exclusive—may not be assigned without the licensor's consent.⁵² As with patent law, the Lanham Act establishes a system for recording assignments, but not licenses, of registered trademarks.⁵³

45. *United Drug Co. v. Theodore Rectanus Co.*, 248 U.S. 90, 97 (1918) (citing *Hanover Star Milling Co. v. Metcalf*, 240 U.S. 403, 412-14 (1916)).

46. *See* 15 U.S.C. § 1060(a) (2000 & Supp. 2004). Assignment of a trademark without the goodwill to which the trademark is attached constitutes an assignment “in gross” and is invalid. *See* *Sugar Busters, L.L.C. v. Brennan*, 177 F.3d 258, 265 (5th Cir. 1999); *Marshak v. Green*, 746 F.2d 927, 929 (2d Cir. 1984); *Greenlon, Inc. of Cincinnati v. Greenlawn, Inc.*, 542 F. Supp. 890, 893 (S.D. Ohio 1982).

47. *See, e.g.*, *PepsiCo, Inc. v. Grapette Co.*, 416 F.2d 285, 290 (8th Cir. 1969).

48. *See, e.g.*, *In re Roman Cleanser Co.*, 802 F.2d 207, 208-09 (6th Cir. 1986); *Glamorene Prods. Corp. v. Procter & Gamble Co.*, 538 F.2d 894, 895-96 (C.C.P.A. 1976).

49. *See, e.g.*, *Greenlon*, 542 F. Supp. at 895; *see also* *Money Store v. Harriscorp Fin., Inc.*, 689 F.2d 666, 670, 675-78 (7th Cir. 1982); *H & J Foods, Inc. v. Reeder*, 477 F.2d 1053, 1055 (9th Cir. 1973).

50. *See* *Gorenstein Enters. v. Quality Care-USA, Inc.*, 874 F.2d 431, 435 (7th Cir. 1989).

51. *See* 15 U.S.C. §§ 1055, 1127 (2000 & Supp. 2004); *Taco Cabana Int'l, Inc. v. Two Pesos, Inc.*, 932 F.2d 1113, 1121-22 (5th Cir. 1991), *aff'd*, 505 U.S. 763 (1992) (noting that licensor exercised adequate control to ensure quality of licensee's product); *Oberlin v. Marlin Am. Corp.*, 596 F.2d 1322, 1327 (7th Cir. 1979); *Dawn Donut Co. v. Hart's Food Stores, Inc.*, 267 F.2d 358, 366-69 (2d Cir. 1959) (Lumbard, J., dissenting in part).

52. A leading trademark law commentator observes that although case law on assignability of marks is sparse, a licensed mark is personal to the licensee and cannot be assigned unless the license states otherwise. *See* 4 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 25.33 (4th ed. rev. 2006); *Miller v. Glenn Miller Prods.*, 318 F. Supp. 2d 923 (C.D. Cal. 2004) (“Although the Ninth Circuit has not

B. The Bankruptcy System: An Ex Post Debtor Perspective

Bankruptcy law seeks to preserve the on-going value of failing enterprises and maximize the economic stake of their creditors.⁵⁴ In order to effectuate these goals, the bankruptcy system generally supports the assignability and fungibility of assets (including executory contracts such as licenses) so as to generate as much value and flexibility as possible to turn around the bankrupt enterprise. Bankruptcy law also constrains freedom of contract by nullifying most agreements that would restrict the trustee's flexibility to maximize the value of the debtor's estate. In so doing, bankruptcy law generally takes an ex post view of economic relationships and values.

1. Overview of the Bankruptcy System

Congress established the modern bankruptcy system with the Bankruptcy Reform Act of 1978 (commonly referred to as the "Bankruptcy Code"), although the Bankruptcy Code has been significantly amended since that time. The Bankruptcy Courts are part of the District Courts of the United States and are governed by the Bankruptcy Rules promulgated by the U.S. Supreme Court.

In the overwhelming majority of business cases, the failing company (as opposed to a creditor) initiates the bankruptcy process by filing a bank-

addressed whether the sub-licensing rule applies to trademark licenses, the courts that have addressed the issue have uniformly held it does, and thus that a trademark licensee may not sub-license a mark without express permission from the licensor."); *Tap Publ'ns, Inc. v. Chinese Yellow Pages (New York), Inc.*, 925 F. Supp. 212, 218 (S.D.N.Y. 1996) (barring assignment of exclusive trademark license that was silent on assignment without trademark owner's consent); *Raufast S.A. v. Kicker's Pizzazz, Ltd.*, 208 U.S.P.Q. 699, 703, 1980 WL 30295 (E.D.N.Y. 1980).

53. Section 1060(a) provides:

(3) Assignments shall be by instruments in writing duly executed. Acknowledgment shall be prima facie evidence of the execution of an assignment, and when the prescribed information reporting the assignment is recorded in the United States Patent and Trademark Office, the record shall be prima facie evidence of execution.

(4) An assignment shall be void against any subsequent purchaser for valuable consideration without notice, unless the prescribed information reporting the assignment is recorded in the United States Patent and Trademark Office within 3 months after the date of the assignment or prior to the subsequent purchase.

(5) The United States Patent and Trademark Office shall maintain a record of information on assignments, in such form as may be prescribed by the Director.

54. See generally H.R. REP. NO. 95-595, at 220 (1977), as reprinted in 1978 U.S.C.C.A.N. 5963, 6179-80.

ruptcy petition with the Bankruptcy Court.⁵⁵ Creditors may, however, force a debtor into bankruptcy.⁵⁶ Filing a petition has two immediate effects. First, it creates a separate legal entity, the “bankruptcy estate,” comprising the debtor’s assets at the moment of filing, as well as the proceeds of such property and any additional property interests the estate may acquire later.⁵⁷ This estate is managed by the bankruptcy trustee as a fiduciary for the creditors of the insolvent enterprise.⁵⁸ Second, it triggers an “automatic stay” to preserve the bankruptcy estate until all of the debtor’s assets can be collected and its creditors brought together to adjudicate their rights in the estate. The automatic stay enjoins creditors from initiating or continuing any action against the debtor or the debtor’s property.⁵⁹ The stay protects the debtor from its creditors, subject to the oversight of the bankruptcy judge. After the stay has been entered, any party wishing to proceed against the debtor must obtain authorization from the bankruptcy court.⁶⁰ This rule can have severe ramifications for intellectual property owners. For example, they cannot pursue a breach of contract action or an infringement action without authorization from the bankruptcy judge presiding over the estate.

The bankruptcy system provides two ways for a debtor to discharge its obligations: liquidation (Chapter 7) and reorganization (Chapter 11).⁶¹ In a Chapter 7 proceeding, the court appoints a trustee to collect the debtor’s nonexempt property, sell it all, and equitably distribute the proceeds to the creditors.⁶² Liquidation can be thought of as the “default” bankruptcy proceeding. A Chapter 11 reorganization provides an alternative to Chapter 7 when preserving the company as a going concern would return more value

55. 11 U.S.C. § 301 (2000); *see* DAVID G. EPSTEIN, STEVE H. NICKLES & JAMES J. WHITE, *BANKRUPTCY* §§ 1-7 (1993).

56. 11 U.S.C. § 303 (2000).

57. 11 U.S.C. § 541(a) (2000).

58. The bankruptcy trustee is generally a private citizen. The trustee is appointed by a United States Trustee, a government official. When no private trustee can be found, a member of the United States Trustee staff can serve as trustee in a Chapter 7 case. The creditors can elect a trustee to replace an appointed trustee. 11 U.S.C. § 702 (2000). A trustee is not automatically appointed in a Chapter 11 case (absent a selection, the debtor itself acts as trustee), but one may be selected if the court so determines.

59. 11 U.S.C. § 362 (2000).

60. Section 362(d) authorizes the bankruptcy court to lift the automatic stay when there is a lack of “adequate protection” of a creditor’s interest in property. *See also* 11 U.S.C. § 361 (2000) (making remedies available to afford adequate protection to an interest in property).

61. Intellectual property issues arise most often in the case of business reorganizations under Chapter 11, which will be the focus of this Article.

62. 11 U.S.C. §§ 507, 701-04 (2000).

to the creditors than a fire sale. In Chapter 11, the “debtor in possession” serves as the bankruptcy trustee, with a fiduciary duty to maximize value for the estate’s creditors. The debtor retains possession of the company’s assets to continue operating the business while developing a plan of reorganization.⁶³

The Bankruptcy Code seeks to provide for the equitable distribution of a debtor’s assets through equal sharing of losses by creditors of equal rank.⁶⁴ Secured claims—those debts for which the debtor posted and perfected specific collateral as security—take priority over unsecured claims. The posting of collateral creates a property interest in the secured property which cannot be “taken” by the government without the payment of “just compensation.”⁶⁵ Therefore, security interests must receive the value of their claim that can be satisfied by the collateral (property of the debtor) on which it is secured before any unsecured claimants can share in any value reflected in that collateral.⁶⁶ After all secured claims have been satisfied to the extent covered by collateral, unsecured creditors are entitled to receive payment from the assets remaining. Section 507 of the Bankruptcy Code sets forth nine levels of priority among the unsecured creditors—beginning with administrative expense claims (money spent administering and preserving the estate) and including wage, pension, tax authorities, and other special classes of claimants. Within each class, all members share on a pro rata basis (in proportion to the size of their claim relative to the magnitude of all claims in the class). All senior priority classes must be paid in full before any money can be distributed to lower ranking classes. After priority claims are paid in full, general unsecured creditors share on a pro rata basis in any remaining assets unless a statutory or contractual subordination provision or inequitable conduct compels a different treatment of these claims.⁶⁷

63. 11 U.S.C. §§ 1107-08 (2000).

64. See 11 U.S.C. § 507 (2000) (establishing claim priorities).

65. U.S. CONST. amend. V; see *In re Gifford*, 669 F.2d 468, 471 (7th Cir. 1982), *rev'd en banc*, 688 F.2d 447 (7th Cir. 1982); *Rodrock v. Sec. Indus. Bank*, 642 F.2d 1193, 1197-98 (10th Cir. 1981), *aff'd*, 459 U.S. 70 (1982).

66. Holders of secured claims can be forced to pay for administrative expenses that the court deems to be “reasonable, necessary costs and expenses of preserving, or disposing of, such property to the extent of any benefit to the holder of such claim,” if the secured creditor is directly benefited by such expenses. 11 U.S.C. § 506(c) (2000).

67. 11 U.S.C. § 510 (2000). Payout rates to general unsecured creditors are typically in the range of thirty to fifty cents on the dollar for reorganized enterprises and five cents on the dollar in liquidations. See Michael J. Herbert & Domenic E. Pacitti, *Down and Out in Richmond, Virginia: The Distribution of Assets in Chapter 7 Proceedings Closed During 1984-87*, 22 U. RICH. L. REV. 303, 315, 316 (1988); Lynn M. LoPucki, *A General*

In order to avoid the risks of bankruptcy, contracting parties commonly include an “ipso facto” clause in their licensing agreements, which provides for the right of a non-defaulting party to terminate or modify an executory contract upon the insolvency of or filing of a bankruptcy petition by the other party. Derived from the Latin for “by the fact itself,” such a clause seeks to resolve the status of the licensing relationship prior to the commencement of the bankruptcy process. To further the policy goal of treating all creditors equally, section 365(e)(1) invalidates any termination or modification clause of an executory contract (or lease) conditioned upon the insolvency or financial condition of a debtor, the filing of a bankruptcy petition, or the appointment of a bankruptcy trustee.⁶⁸

In examining the bankruptcy treatment of intellectual property licenses within the bankruptcy system, it is useful to distinguish between two sets of issues: first, whether intellectual property licenses are characterized as executory contracts (i.e., ongoing contracts) or as sales (i.e., completed transactions); and second, the power of trustees to transfer or rescind executory contracts.

2. *Characterization of Assets*

Assets such as real property or chattels owned by the debtor automatically become part of the bankruptcy estate. Sales of assets completed prior to bankruptcy are outside of the bankruptcy case, and beyond the reach of the bankruptcy court, unless the transaction amounts to a fraudulent transfer.⁶⁹ Most IP licensees fall into a middle ground labeled “executory contracts” that do not automatically enter the bankruptcy estate. Depending on the performance provisions of such contracts, they may constitute net assets or net liabilities of the estate.⁷⁰ In order to promote the maximization of value of the estate and afford the debtor as much flexibility as possible in reorganizing its affairs, the Bankruptcy Code provides the trustee (or “debtor in possession”) with the option to “assume” or “reject” executory

Theory of the Dynamics of the State Remedies/Bankruptcy System, 1982 WIS. L. REV. 311, 311; Lynn M. LoPucki & William C. Whitford, *Bargaining Over Equity's Share in the Bankruptcy Reorganization of Large, Publicly Held Companies*, 139 U. PA. L. REV. 125, 142 (1990).

68. See 11 U.S.C. § 365(e) (2000). *But see* F. Scott Kieff & Troy A. Paredes, *An Approach to Intellectual Property, Bankruptcy, and Corporate Control*, 82 WASH. U. L.Q. 1313 (2004) (proposing use of special purpose entities for holding IP assets to exclude them from bankruptcy estates).

69. See 11 U.S.C. § 548 (2000). See generally EPSTEIN ET AL., *supra* note 55, § 6-47.

70. See generally Jesse M. Fried, *Executory Contracts and Performance Decisions in Bankruptcy*, 46 DUKE L.J. 517 (1996).

contracts,⁷¹ subject to some important exceptions that we explore below and to approval by the Bankruptcy Court.⁷²

The precise definition of the term “executory” contract is somewhat ambiguous. Although not specifically defined in the Code, the majority of courts have encompassed within this category contracts “on which performance remains due to some extent on both sides,”⁷³ a formulation put forth by Professor Vern Countryman in the early 1970s (the “Countryman” test).⁷⁴ This test excludes contracts that are already fully performed (or so nearly performed that failure to complete performance would not constitute a material breach) by either party.⁷⁵ Some courts, however, ap-

71. 11 U.S.C. § 365(a) (2000). In Chapter 7 proceedings, executory contracts that have not been expressly assumed or rejected within 60 days of the filing of a bankruptcy petition are deemed rejected by operation of law. 11 U.S.C. § 365(d)(1) (2000). In Chapter 11 proceedings, the trustee may assume or reject an executory contract at any time before the confirmation of a plan by the court, although parties to the proceeding may request that the court impose a deadline for decision by the trustee. 11 U.S.C. § 365(d)(2) (2000).

72. Section 365, governing the treatment of executory contracts, has been aptly described as “the most convoluted and worst drafted section of the Bankruptcy Code.” Daniel J. Bussel & Edward A. Friedler, *The Limits on Assuming and Assigning Executory Contracts*, 74 AM. BANKR. L.J. 321, 322 n.6 (2000) (citing NAT’L BANKR. REV. COMM’N, BANKRUPTCY: THE NEXT TWENTY YEARS, FINAL REPORT (1997)); see also Michael T. Andrew, *Executory Contracts Revisited: A Reply to Professor Westbrook*, 62 U. COLO. L. REV. 1, 2 (1991) (noting that “behind the deceptively simple prescription of section 365(a) lurks a hopelessly convoluted and contradictory jurisprudence, rendering this one of the most difficult areas of bankruptcy law”).

73. H.R. REP. NO. 95-595, at 347 (1977), quoted in *NLRB v. Bildisco & Bildisco*, 465 U.S. 513, 522 n.6 (1984); see, e.g., *Gloria Mfg. Corp. v. Int’l Ladies’ Garment Workers’ Union*, 734 F.2d 1020, 1022 (4th Cir. 1984); *Fenix Cattle Co. v. Silver (In re Select-A-Seat Corp.)*, 625 F.2d 290, 292 (9th Cir. 1980); *Cottman Transmissions, Inc. v. Holland Enters., Inc. (In re Holland Enters., Inc.)*, 25 B.R. 301, 303 (E.D.N.C. 1982); *In re A.J. Lane & Co., Inc.*, 107 B.R. 435, 436 (Bankr. D. Mass. 1989).

74. Professor Countryman provided a more rigorous definition of “executory contract”: “a contract under which the obligations of both the bankrupt and the other party are so far unperformed that failure of either to complete performance would constitute a material breach excusing the performance of the other.” Vern Countryman, *Executory Contracts in Bankruptcy Law: Part I*, 57 MINN. L. REV. 439, 460 (1973). This test involves an assessment of state law relating to what acts or omissions constitute a material breach.

75. As noted by the court in *In re Access Beyond Techs., Inc.*, 237 B.R. 32 (Bankr. D. Del. 1999) (citing *Enter. Energy Corp. v. United States (In re Columbia Gas Sys.)*, 50 F.3d 233, 240 (3d Cir. 1995)), the test requires a court to determine whether the failure to perform an obligation under the contract would constitute a material breach.

ply a “functional” test which considers a contract “executory” if the bankrupt estate will benefit from such a classification.⁷⁶

Although IP licensing agreements are not automatically classified as executory contracts,⁷⁷ the courts have readily found that many such agreements satisfy the Countryman test. Specific material performance

76. See *Sipes v. Atlantic Gulf Communities Corp. (In re Gen. Dev. Corp.)*, 84 F.3d 1364, 1374 (11th Cir. 1996) (noting that “courts and commentators have consistently expanded the definition of ‘executoriness’ beyond the static definition articulated by Professor Countryman” in order to effectuate the language and legislative purposes of section 365 and the Bankruptcy Code); *Sloan v. Hicks (In re Becknell & Crace Coal Co.)*, 761 F.2d 319, 322 (6th Cir. 1985); *Tonry v. Herbert (In re Tonry)*, 724 F.2d 467, 468 (5th Cir. 1984) (holding a contract to be executory even if only one party has remaining affirmative obligations other than payment of money); *Fox v. Hill (In re Fox)*, 83 B.R. 290, 299 (Bankr. E.D. Pa. 1988); *In re Arrow Air, Inc.*, 60 B.R. 117, 121-22 (Bankr. S.D. Fla. 1986) (noting that the legislative history of section 365 evinces that Congress “considered mutual obligation to be indicative of an executory contract in some, but not all, cases” and that “[e]ven though there may be material obligations outstanding on the part of only one of the parties to the contract, it may nevertheless be deemed executory under the functional approach if its assumption or rejection would ultimately benefit the estate and its creditors”); cf. NAT’L BANKR. REV. COMM’N, *supra* note 72 (recommending deletion of “executory” from the Bankruptcy Code). See generally Jessica L. Kotary & Nicole L. Inman, Note, *Eliminating “Executory” from Section 365: The National Bankruptcy Review Commission’s Panacea for an Ailing Statute*, 5 AM. BANKR. INST. L. REV. 513 (1997); Jay Lawrence Westbrook, *A Functional Analysis of Executory Contracts*, 74 MINN. L. REV. 227 (1989).

77. See *Perlman v. Catapult Entm’t, Inc. (In re Catapult Entm’t)*, 165 F.3d 747, 750 (9th Cir. 1999); *In re Qintex Entm’t, Inc.*, 950 F.2d 1492, 1495 (9th Cir. 1991); *In re Learning Publ’ns, Inc.*, 94 B.R. 763, 765 (Bankr. M.D. Fla. 1988); *In re Stein & Day, Inc.*, 81 B.R. 263, 267 (Bankr. S.D.N.Y. 1988). Some courts, however, presume that intellectual property license agreements are executory without analyzing the nature of the ongoing obligations on both sides of the agreement. See, e.g., *RCC Tech. Corp. v. Sunterra Corp.*, 287 B.R. 864, 865 (D. Md. 2003) (noting without analysis that “there is a long line of authority holding that intellectual property licensing agreements such as the SLA are executory contracts”); *In re Buildnet, Inc.*, 2002 WL 31103235, at *3 (Bankr. M.D.N.C. 2002) (beginning its analysis by asserting that “[a]s a general rule, most patent, trademark, technology and other intellectual property licenses are executory contracts”); *In re Golden Books Family Entm’t, Inc.*, 269 B.R. 300, 308-09 (Bankr. D. Del. 2001); *Novon Int’l, Inc. v. Novamont S.P.A. (In re Novon Int’l, Inc.)*, 2000 WL 432848, at *4 (W.D.N.Y. 2000) (confining its analysis to the assertion that “[g]enerally speaking, a license agreement is an executory contract as such is contemplated in the Bankruptcy Code” and attributing that finding to “each party remain[ing] obligated under the agreement—the licensor not to sue for infringement and the licensee to use the patent in accordance with the terms of the agreement”); *In re Patient Educ. Media, Inc.*, 210 B.R. 237, 241 (Bankr. S.D.N.Y. 1997). Nonetheless, the Bankruptcy Code does not place “intellectual property” licenses in any special class with regard to the determination of whether they are executory. Each case requires the application of either the Countryman or functional test (depending upon the circuit) to the case-specific factors.

obligations, such as a continuing obligation to account for and pay royalties, duties of notice,⁷⁸ responsibilities relating to reporting, labeling, policing, service, and maintenance, refraining from licensing to others (in the context of an exclusive licensing agreement),⁷⁹ and obligations to provide product upgrades, potentially bring one or the other of the parties' activities within the domain of executory contracts. An agreement is not executory, however, simply because one party is obligated to make payments of money to the other party.⁸⁰ Furthermore, some agreements might not clear the executory hurdle because failure to perform the outstanding obligations by one of the parties would not constitute a material breach of the contract.⁸¹ They might also fail where clauses are mere conditions that, if not adhered to, would relieve the other contracting party of continuing performance, but would not amount to breach of the contract.⁸² A critical issue in understanding the meaning of "executory" in the context of intellectual property licensing agreements is whether the licensor's "duty" to forbear from suing the licensee for infringement represents an independent obligation that can support the licensor's responsibilities being deemed executory. Several courts have so held,⁸³ but careful examination of the nature of intellectual property rights suggests otherwise.⁸⁴ We take this issue up in detail below.

Numerous cases have examined whether intellectual property agreements constitute executory agreements or outright transfers of intellectual property rights. As a means of surveying the range of cases, we first explore those cases that have found intellectual property agreements to be sales or assignments rather than executory contracts. We then divide the

78. See *Lubrizol Enters., Inc. v. Richmond Metal Finishers, Inc.*, 756 F.2d 1043, 1045 (4th Cir. 1985).

79. See *Fenix Cattle Co. v. Silver (In re Select-A-Seat Corp.)*, 625 F.2d 290, 292 (9th Cir. 1980).

80. See *Lubrizol*, 756 F.2d at 1046.

81. See, e.g., *Gencor Indus., Inc. v. CMI Terex Corp. (In re Gencor Indus., Inc.)*, 298 B.R. 902 (Bankr. M.D. Fla. 2003) (finding that the obligation of confidentiality was for the unilateral benefit of only one party and that breach of that obligation would not cause a material breach of the overall agreement).

82. *Id.* (finding that the Most Favored Nations Clause and the Patent Defense Clause of a licensing agreement were mere conditions of payment by the licensee (failure of which would excuse further payment) rather than material continuing obligations (failure of which would breach the contract)).

83. See *Everex Sys., Inc. v. Cadtrak Corp. (In re CFLC, Inc.)*, 89 F.3d 673, 673 (9th Cir. 1996); *In re Novon Int'l*, 2000 WL 432848 (W.D.N.Y. 2000); *In re Golden Books Family Entm't, Inc.*, 269 B.R. 300, 309 (Bankr. D. Del. 2001); *In re Access Beyond Techs., Inc.*, 237 B.R. 32, 43 (Bankr. D. Del. 1999).

84. See *In re Gencor Indus.*, 298 B.R. at 902.

cases into the various categories of intellectual property rights to explore what obligations in a license agreement make a contract executory.

a) Sales, Assignments, and Exclusive Licenses of Intellectual Property Rights

A completed sale or assignment of intellectual property rights without further non-severable contractual obligations is not considered “executory.” Unfortunately, the “cases are far from clear as to what is a sale, assignment, or outright transfer (or how a court distinguishes between them).”⁸⁵

A logical starting point is to look at how the intellectual property statutes govern transfers of rights. The Patent Act states that “patents shall have the attributes of personal property” and “shall be assignable in law by an instrument in writing.”⁸⁶ It states further that the patentee (or his assigns) may “grant and convey an exclusive right” under his patent “to the whole or any specified part of the United States.” An agreement is a sale (or assignment) of patent rights only if it conveys: “1. the whole patent, comprising the exclusive right to make, use and sell the invention; 2. an undivided share of that exclusive right; or 3. an exclusive right to practice the invention within a specified territory.”⁸⁷ Similarly, the Copyright Act provides that “[t]he ownership of a copyright may be transferred in whole or in part by any means of conveyance”⁸⁸

An assignment of intellectual property rights constitutes a transfer of the rights and therefore is fully executed upon completion of the transaction. Thus, the court in *Chesapeake Fiber Packaging Corp. v. Sebro Packaging Corp.*⁸⁹ held that an agreement stating that “[patent holder] hereby sells, assigns, transfers and sets over to [alienee] its entire right, title and interest in, to, and under the aforesaid Invention(s) and any and all Letters Patent . . .” amounted to an outright grant of transfer of the intel-

85. David I. Cisar, *Exclusive and Nonexclusive IP Licenses and Executory Contract Assumption and Assignment: Does Exclusivity Matter?*, 22 AM. BANKR. INST. J. 28, 28 (Feb. 2003).

86. 35 U.S.C. § 261 (2000).

87. *In re Access Beyond Techs., Inc.*, 237 B.R. 32, 44 (Bankr. D. Del. 1999) (citing *Waterman v. Mackenzie*, 138 U.S. 252, 255-56 (1891)); see *Wing v. Comm’r*, 278 F.2d 656, 661 (8th Cir. 1960) (“[E]xclusive licenses to manufacture, use, and sell for the life of the patent, are considered to be ‘sales or exchanges’ because, in substantive effect, all ‘right, title, and interests’ in the patent property is transferred”); see also *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1032 (Fed. Cir. 1995) (recognizing exclusive licensee’s right to sue under patent law).

88. 17 U.S.C. § 201(d)(1) (2000).

89. 143 B.R. 360, 363 (Bankr. D. Md. 1992), *aff’d*, 8 F.3d 817 (4th Cir. 1993).

lectual property rights, even though the assignee had a continuing obligation to make royalty payments.⁹⁰

Outright sales of products (including those granting nonexclusive licenses to use the intellectual property embodied in the products) are not executory. For example, a mass-marketed computer software product distributed in conjunction with a “shrink wrap” end user license agreement⁹¹ granting the user nonexclusive rights to use the software is generally not considered executory because only the licensee has any remaining obligations under the purported agreement.⁹²

In a more complex bilateral licensing context, the Ninth Circuit in *In re DAK Indus., Inc.* treated an agreement authorizing a licensee to load copyrighted software onto computer systems as a sale rather than an executory contract.⁹³ Microsoft and DAK Industries, Inc., entered into a “License Agreement” granting DAK nonexclusive, worldwide license rights to distribute Microsoft’s Word for Windows software program on its computer systems. In exchange, DAK agreed to pay a minimum contract fee of \$2,750,000 in five installments and a royalty rate of \$55 per unit for any number of computers sold with the Microsoft software beyond the first 50,000 units. Focusing on what it called the “economic realities” of the agreement, the Ninth Circuit concluded that the minimum commitment contract in question was “best characterized as a lump sum sale of software units to DAK, rather than a grant of permission to use an intellectual property”⁹⁴ based on the following considerations: (1) the pricing and timing of the payments were more consistent with a sale than a lease or license—DAK agreed to pay \$2,750,000 at the outset of the agreement regardless of how many units it sold; (2) the licensee received all of its rights at the beginning of the agreement; (3) the agreement did not simply permit the debtor to use the technology, but also permitted the debtor to sell the technology; and (4) Microsoft delivered the master disk from which the copies were to be made at the time the agreement commenced

90. *Cf.* *Conde Nast Publ’ns, Inc. v. United States*, 575 F.2d 400 (2d Cir. 1978) (holding exclusive trademark and trade name license considered a “sale” for tax treatment purposes and restriction on assignability not inconsistent with a completed sale).

91. A shrinkwrap end user licensing agreement is a license agreement, contained in a plastic wrapping or other packaging surrounding computer software or other media, that states that by opening the packaging, the consumer agrees to the conditions set forth.

92. *See* Raymond T. Nimmer, *Information Law* § 11:161 (2006).

93. *Microsoft Corp. v. DAK Indus., Inc. (In re DAK Indus., Inc.)*, 66 F.3d 1091, 1095-96 (9th Cir. 1995).

94. *Id.* at 1095.

and therefore had substantially completed its performance at the outset of the contract.⁹⁵

The fact that an IP agreement grants exclusive rights to the licensee cuts in favor of the transaction being characterized as a transfer because it represents a more complete conveyance of rights than a nonexclusive license and may have fewer strings (contractual obligations) attached.⁹⁶ However, it may still be characterized as an executory contract if both parties have significant ongoing duties connected to the license of intellectual property rights.⁹⁷ By contrast, a nonexclusive license typically grants a licensee permission to use certain intellectual property—a personal right, but no ownership interest in the intellectual property.⁹⁸ The licensor re-

95. *Id.* at 1095-96.

96. Section 101 of the Copyright Act defines a “transfer of copyright ownership” to include an “exclusive license.” *Cf. Fawick v. Comm’r*, 436 F.2d 655, 662 (6th Cir. 1971) (noting that exclusive license agreements in some instances may constitute a sale for tax purposes). There is some confusion among the courts over the extent to which the granting of an exclusive license constitutes a full transfer of rights. *Compare I.A.E., Inc. v. Shaver*, 74 F.3d 768, 774-75 (7th Cir. 1996) (holding that the licensee under an exclusive license may freely transfer his rights), *with Gardner v. Nike, Inc.*, 279 F.3d 774, 780 (9th Cir. 2002) (reaching contrary result). *See also In re Hernandez*, 285 B.R. 435 (Bankr. D. Ariz. 2002) (holding that the granting of an exclusive patent license did not afford the licensee the right to assign the patent).

97. The cases do not explain what “extra” duties exist to bring these agreements within the ambit of “executory contracts.” For example, in *University of Connecticut Research & Development Corp. v. Germain (In re Biopolymers, Inc.)*, 136 B.R. 28 (Bankr. D. Conn. 1992), the licensor granted an exclusive license (subject to the government’s “march-in” rights for publicly funded innovation under the Bayh-Dole Act, 35 U.S.C. § 203 (2000 & Supp. 2003)) “to make, use and sell” products for the life of the patent, and to grant sublicenses to third parties, subject to the approval of the licensor not to be unreasonably withheld. In exchange, the licensee agreed to make an initial cash and stock payment and to pay defined royalties, provide quarterly business reports, and use its best efforts to produce and sell the products. The court found this agreement to be executory on both sides, although the licensor’s obligations amounted solely to using reasonable standards for approving third party licensees that the licensee brought forward. In another case, the agreement at issue granted an exclusive license but only as to a subset of possible uses. The court concluded that the agreement did not rise to the level of an assignment or sale of the intellectual property at issue, implicitly finding the agreement to be executory. *See In re Supernatural Foods, L.L.C.*, 268 B.R. 759 (Bankr. M.D. La. 2001).

98. “Unless the writing conveys some or all of the right to exclude others from practicing the invention, it will not convey an interest in the patent, but is a mere license.” *In re Access Beyond Techs., Inc.* 237 B.R. 32, 44 (Bankr. D. Del. 1999) (citing *Waterman v. Mackenzie*, 138 U.S. 252, 255-56 (1891)); *see also* Madlyn G. Primoff & Erica G. Weinberger, *E-Commerce and Dot-Com Bankruptcies: Assumption, Assignment, and Rejection of Executory Contracts, Including Intellectual Property Agreements, and Related Issues under Sections 365(c), 365(e) and 365(n) of the Bankruptcy Code*, 8 AM. BANKR. INST. L. REV. 307 (2000).

tains the rights and remedies associated with the intellectual property, and therefore no transfer of property occurs. Even where a licensor grants an exclusive license, however, the agreement may provide for ongoing, reciprocal, non-severable⁹⁹ duties that could conceivably bring the agreement into the realm of executory contracts. Moreover, several courts find that exclusive licenses inherently impose executory obligations upon licensors because they oblige the licensor to refrain from extending further licenses (or selling the product in the exclusive territory themselves).¹⁰⁰

b) The Classification of Mode-Specific IP Licenses

i) Patent Licenses

In the context of patent licenses, courts consider a wide range of continuing contractual obligations to place such agreements in the category of executory contracts. With regard to licensees, an ongoing obligation to account for and pay royalties for the life of the agreement meets the Countryman test for an executory contract.¹⁰¹ Other material ongoing licensee obligations such as sharing of technology with the licensor, reporting on problems with the technology, and marking all products sold under the license with proper statutory patent notice¹⁰² would likely be deemed material and support a finding that the licensee side of the agreement is executory. Turning to licensors, courts have held the following obligations sufficient to bring the licensor's side of the transaction into the executory classification: providing a nonexclusive licensee notice of any patent infringement suit or any other use or licensing of the process,¹⁰³ refraining from licensing the technology to anyone else at a lower royalty rate (a Most Favored Nation clause),¹⁰⁴ approving grants of sublicenses under

99. *Cf. Stewart Title Guar. Co. v. Old Republic Nat'l Title Ins. Co.*, 83 F.3d 735 (5th Cir. 1996) (holding that a license to use certain copyrighted designs in the event an agreement was terminated was a vested (non-executory) right provided to the licensee and was severable from an executory lease provision of the agreement).

100. *Fenix Cattle Co. v. Silver (In re Select-A-Seat Corp.)*, 625 F.2d 290, 292 (9th Cir. 1980); *In re HQ Global Holdings, Inc.*, 290 B.R. 507, 510-11 (Bankr. D. Del. 2003) (finding that a licensor which granted an exclusive territorial license bore a continuing material obligation not to engage in business in that territory).

101. *See Lubrizol Enters., Inc. v. Richmond Metal Finishers, Inc.*, 756 F.2d 1043, 1045 (4th Cir. 1985).

102. *Everex Sys., Inc. v. Cadtrak Corp. (In re CFLC, Inc.)*, 89 F.3d 673, 677 (9th Cir. 1996) (noting because failure to mark deprives the patent holder of damages in an infringement action, the licensee's performance of this duty is material).

103. *See Lubrizol*, 756 F.2d at 1045-46.

104. *Id.*

reasonable standards,¹⁰⁵ indemnifying licensees for losses,¹⁰⁶ and defending claims of infringement.¹⁰⁷

There is controversy over whether a licensor's forbearance from suing a licensee for infringement throughout the duration of the agreement represents in and of itself a material ongoing executory obligation. In *Everex Systems, Inc. v. Cadtrak Corp. (In re CFLC, Inc.)*,¹⁰⁸ the Ninth Circuit held that a licensor's obligation to refrain from suing a nonexclusive licensee cleared the executory hurdle because "a nonexclusive patent license is, in essence 'a mere waiver of the right to sue' the licensee for infringement."¹⁰⁹ Such a rationale, however, is tautological. By licensing the patent to the licensee, the licensor gives up the right to sue the licensee for infringement. The license itself represents a covenant not to sue¹¹⁰ and consequently a continuing obligation not to sue the licensee would appear to be an empty duty. The license itself is a complete defense to the claim. Therefore, this "obligation," standing alone, should not be deemed sufficient to make the licensor's side of the agreement executory.

ii) Copyright Licenses

Copyright licenses vary in their obligations. At one end of the spectrum, an author (or other copyright owner) licenses a completed copyrighted work to a publisher in exchange for either a lump sum payment or an ongoing royalty stream. In this circumstance, the licensor's obligations are complete upon delivery of the work and therefore there is nothing to be executed on that end of the agreement. The licensee may well have material ongoing obligations—such as publishing and distributing the work and paying and accounting for royalties—which would be considered executory in nature. Since both sides of the agreement must be executory,

105. See *Univ. of Conn. Research & Dev. Corp. v. Germain (In re Biopolymers, Inc.)*, 136 B.R. 28, 30 (Bankr. D. Conn. 1992).

106. See *Lubrizol*, 756 F.2d at 1043.

107. See *Biosafe Int'l, Inc. v. Controlled Shredders, Inc. (In re Szombathy)*, 1996 WL 417121 (Bankr. N.D. Ill. 1996), *rev'd in part on other grounds*, *Szombathy v. Controlled Shredders, Inc.*, 1997 WL 189314 (N.D. Ill. 1997).

108. 89 F.3d 673 (9th Cir. 1996).

109. *Id.* at 677; see also *In re Access Beyond Techs., Inc.* 237 B.R. 32, 43 (Bankr. D. Del. 1999) (citing the minimal *Everex* standard with approval while also noting that the license agreement in its case imposed ongoing duties upon each party to provide the other with sub-licenses); *Novon Int'l, Inc. v. Novamont S.P.A. (In re Novon Int'l, Inc.)*, 2000 WL 432848 (W.D.N.Y. 2000).

110. *Gencor Indus., Inc. v. CMI Terex Corp. (In re Gencor Indus., Inc.)*, 298 B.R. 902, 912 (Bankr. M.D. Fla. 2003).

such a contract would fall outside of the class of executory contracts under the Countryman test.¹¹¹ The licensor is merely a creditor.

At the other end of the spectrum, some copyright licenses arise in a context in which a work has yet to be created, or will be edited, revised, or otherwise adapted. Where such efforts are still ongoing, or planned for the future, at the time of the bankruptcy filing, there will likely be material continuing obligations on the side of the creative artist. Where the other party has ongoing commercialization obligations, such as distributing the completed work and accounting for and paying royalties, or where creative responsibility lies on both sides of the agreement, the agreement will satisfy the Countryman test.¹¹² For example, in *In re Qintex Entertainment*,¹¹³ the licensee agreed to pay a fixed sum plus a percentage of gross receipts to the owner of several films in return for the rights to colorize and distribute the films for twenty-four years. The licensee was required to indemnify and defend the licensee in the event of litigation and to exercise creative control over the colorization and marketing of the films.¹¹⁴ The Ninth Circuit found the agreement to be executory.¹¹⁵ Similarly, record

111. See, e.g., Official Unsecured Creditors' Comm. v. Zenith Prods., Ltd. (*In re AEG Acquisition Corp.*), 127 B.R. 34 (Bankr. C.D. Cal. 1991), *aff'd*, 161 B.R. 50 (B.A.P. 9th Cir. 1993) (involving a contract for transfer of films not executory); *In re Learning Publ'ns, Inc.*, 94 B.R. 763, 765 (Bankr. M.D. Fla. 1988) (involving a book contract in which authors had performed their contractual obligations by the time of the bankruptcy filing); *In re Stein & Day, Inc.*, 81 B.R. 263, 267 (Bankr. S.D.N.Y. 1988) (same). As noted by a commentator and quoted in *In re AEG Acquisition*, 161 B.R. at 59-60:

Copyright assignments and licenses should not be treated as executory contracts According to the Copyright Act, assignments and licenses are transfers of copyright ownership; bankruptcy courts should treat them that way. If a debtor has granted an assignment or exclusive license of its copyright rights prior to filing bankruptcy, the assignment or exclusive license should be treated as a completed prebankruptcy transfer of property by the debtor, not as an executory contract Conversely, if a debtor enters bankruptcy with valid copyright assignments or exclusive licenses of copyright rights owned by others, those assignments or exclusive licenses are property of the estate, not executory contracts.

J. Brinson, *The Copyright Act and Bankruptcy: Perfection, Priorities, and Transfers*, 1 J. BANKR. L. & PRACT. 337, 353 (1992) (footnotes omitted).

112. See, e.g., *Viacom Latino Americana, Inc. v. Three Star Corp. (In re Three Star Telecast, Inc.)*, 93 B.R. 310, 312 (D.P.R. 1988) (involving a television program licensing agreement where programs were not yet completed).

113. 950 F.2d 1492, 1494-95 (9th Cir. 1991).

114. *Id.* at 1493-94.

115. *Id.* at 1495. The court's decision rests on a strong foundation in view of the material ongoing responsibilities involved. The court may confuse the analysis, however, by counting among the duties of the licensor the obligation "to refrain from selling the rights

contracts between recording artists and record labels typically have extensive continuing obligations upon both sides of the agreement and hence fall within the domain of executory contracts.¹¹⁶

iii) Trade Secret Licenses

Trade secret licenses often arise in the context of extensive ongoing interaction between contracting parties. Furthermore, such licenses, by their nature, impose particular material obligations upon the parties, such as confidentiality requirements and the exercise of reasonable precautions to maintain trade secrecy. Therefore, such agreements are likely to clear the executory threshold.¹¹⁷

iv) Trademark Licenses

Trademark licenses are almost always executory because the licensor has continuing quality control obligations and the licensee typically has payment, reporting, marketing, and other continuing performance obligations.¹¹⁸ Licensors may also have duties to notify the licensee of any in-

to subdistribute the movies.” As noted above, see *supra* note 110, refraining from licensing to others that which was reserved to the licensee is not a separate obligation but merely an inherent covenant of the licensing agreement. In *Qintex*, the licensor had granted an exclusive license and therefore should not be credited with an affirmative obligation not to license the same rights to others. See also *In re Golden Books Family Entm’t, Inc.*, 269 B.R. 300, 308-09 (Bankr. D. Del. 2001) (concluding that copyright and trademark licenses to various cartoon characters were executory based solely on each party’s presumed “material duty” of “refraining from suing the other for infringement of any of the [intellectual property] covered by the license” (quoting *In re Access Beyond Techs., Inc.* 237 B.R. 32, 43 (Bankr. D. Del. 1999))).

116. See *Cloyd v. GRP Records (In re Cloyd)*, 238 B.R. 328, 335 (Bankr. E.D. Mich. 1999); *In re Taylor*, 103 B.R. 511, 516 (D.N.J. 1989), *aff’d in part and appeal dismissed in part*, 913 F.2d 102 (3d Cir. 1990); *In re Noonan*, 17 B.R. 793, 798 (Bankr. S.D.N.Y. 1982) (stating recording contract is not asset that can be used for its estate’s benefit); Kotary & Inman, *supra* note 76, at 522-29. See generally Jennifer A. Brewer, *Bankruptcy & Entertainment Law: The Controversial Rejection of Recording Contracts*, 11 AM. BANKR. INST. L. REV. 581 (2003). A recording contract is not executory, however, where the parties have terminated the artist’s continuing performance obligations and the record company’s only remaining obligation is to pay royalties to the recording artist-licensor. See *In re Monument Record Corp.*, 61 B.R. 866, 866 (Bankr. M.D. Tenn. 1986).

117. Few reported cases squarely address the question of whether a trade secret agreement is executory. In *In re Matusalem*, 158 B.R. 514, 515 (Bankr. S.D. Fla. 1993), the court presumes that a license for a secret formula for making rum, as well as an associated trademark, is executory without explaining the basis.

118. See, e.g., *In re HQ Global Holdings, Inc.*, 290 B.R. 507, 509 (Bankr. D. Del. 2003); *Blackstone Potato Chip Co., Inc. v. Mr. Popper, Inc. (In re Blackstone Potato Chip Co., Inc.)*, 109 B.R. 557, 560 (Bankr. D.R.I. 1990); *Richard Royce Collection, Ltd. v. N.Y. City Shoes, Inc. (In re N.Y. City Shoes, Inc.)*, 84 B.R. 947, 951 (Bankr. E.D. Pa.

fringements of the licensed trademarks, to enforce the trademark for the benefit of the licensee, and to indemnify the licensee for any damages, expenses, and attorneys' fees.¹¹⁹ Franchise agreements commonly include trademark licenses and easily clear the executory hurdle in both directions due to the many ongoing obligations of the contracting parties.¹²⁰

v) Software License Agreements

With the growth of computer technology, computer software licensing has become a vibrant marketplace. These types of agreements typically embody several modes of intellectual property. It is useful to distinguish between business-to-business software agreements—custom and semi-customized programs for large-scale computers and networks as well as licenses between software developers and computer manufacturers, websites, and other businesses that distribute software—and business-to-consumer licensing agreements.

In the mainframe and minicomputer sectors of the market, many software companies provide software on a customized basis with significant ongoing responsibilities. These companies typically use sophisticated licensing agreements that involve ongoing obligations—including service, support, and upgrades. The licensees are typically bound by ongoing confidentiality, trade secret, use, and copying restrictions as well as reporting and payment schedules. Therefore, these sorts of relationships easily clear the executory threshold.¹²¹

In the microcomputer marketplace, software vendors distribute their products through several marketing channels. It is common for computer manufacturers to pre-install several software products on their machines at the factory. Microsoft and other leading software vendors typically provide these original equipment manufacturers (OEMs) with a master disk

1988); *In re Specialty Foods Pittsburgh, Inc.*, 91 B.R. 364, 374 (Bankr. W.D. Pa. 1988); *In re Chipwich, Inc.*, 54 B.R. 427, 429 (Bankr. S.D.N.Y. 1985).

119. See *In re Chipwich*, 54 B.R. at 429.

120. See, e.g., *Silk Plants, Etc. Franchise Sys., Inc. v. Register (In re Silk Plants, Etc. Franchise Sys., Inc.)*, 100 B.R. 360, 361-62 (M.D. Tenn. 1989); *JRT, Inc. v. TCBY Sys. Inc. (In re JRT, Inc.)*, 121 B.R. 314, 320 (Bankr. W.D. Mich. 1990); *Elec. Realty Assocs., Inc. v. ERA Cent. Reg'l Servs., Inc. (In re ERA Cent. Reg'l Servs., Inc.)*, 39 B.R. 738, 739 (Bankr. C.D. Ill. 1984).

121. See *In re Sunterra Corp.*, 361 F.3d 257, 264 (4th Cir. 2004) ("When the bankruptcy petition was filed, each party owed at least one continuing material duty to the other under the Agreement—they each possessed an ongoing obligation to maintain the confidentiality of the source code of the software developed by the other, i.e., the Software and the Sunterra Enhancements."); *In re Kmart Corp.*, 290 B.R. 614, 617-19 (Bankr. N.D. Ill. 2003).

from which they make copies for each computer system that they sell. These agreements commonly license copyright, trademark, trade secret, and patent rights and may impose service, upgrade, and other obligations on the licensor. The licensee must maintain any trade secrets and account for and pay royalties based on the number of units sold. These licensing relationships generally fall within the executory domain.¹²² Where the licensor grants an exclusive territorial or field license, some courts consider the licensor's implied obligation to refrain from licensing or selling to others to be enough to make the license executory.¹²³ But where the terms and duties of the agreement have the attributes of a sale (i.e., lump sum amount irrespective of the number of units distributed) in which the licensor bears little or no continuing obligations, then the agreement may be treated as non-executory.¹²⁴

Business-to-consumer software licensing agreements have a very different motivation and purpose than the licensing contexts discussed above. Both software pre-loaded onto computer systems and software packages distributed through retail outlets attempt to bind consumers to an "end user licensing agreement" (EULA). This contracting form evolved as a means for augmenting or contracting around various default rules of intellectual property law. For example, by "licensing" the software to consumers, software vendors attempt to avoid the effects of the first sale doctrine of copyright and patent law. In addition, some EULAs prohibit reverse engineering of software products,¹²⁵ which is generally permissible under copyright law.¹²⁶

From the standpoint of the Bankruptcy Code, EULA transactions generally fall within the category of a completed sale. The end user makes a one-time payment and receives the software product. Although the end user may have ongoing responsibilities under license based on the restrictions in the license,¹²⁷ the licensor generally does not have ongoing responsibilities.

122. See, e.g., *In re Logical Software, Inc.*, 66 B.R. 683, 686 (Bankr. D. Mass. 1986) (indicating no dispute as to the executory nature of agreement).

123. See, e.g., *Fenix Cattle Co. v. Silver (In re Select-A-Seat Corp.)*, 625 F.2d 290, 291-92 (9th Cir. 1980).

124. See *Microsoft Corp. v. DAK Indus., Inc. (In re DAK Indus., Inc.)*, 66 F.3d 1091, 1095-96 (9th Cir. 1995).

125. See *Bowers v. Baystate Techs., Inc.*, 320 F.3d 1317, 1323-24 (Fed. Cir. 2003).

126. See *Sega Enters. Ltd. v. Accolade, Inc.*, 977 F.2d 1510, 1527-28 (9th Cir. 1992).

127. See, e.g., *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447 (7th Cir. 1996).

3. *Resolution of the Bankrupt Estate: Dishonoring of Contract*

As discussed, the Chapter 11 debtor must arrange the estate to maximize value for creditors. If a contract is held to be executory, the debtor has three options: (1) assumption of the contractual obligations; (2) rejection of the contract; or (3) assignment (or transfer) of the contract.

a) Assumption

Most assumptions of contracts are approved without objection. The bankruptcy court applies a relatively liberal “business judgment” standard in assessing any disputes over assumptions and rejections of contracts by the debtor.¹²⁸ Upon the court’s approval of the debtor’s assumption of an executory contract, the pre-petition contract is reinstated and becomes fully binding. The debtor cannot assume a contract, however, without first meeting the statutory preconditions of curing outstanding defaults under the contract (or providing “adequate assurance” that it will do so).¹²⁹ In addition, the debtor must “provide adequate assurance of future performance.”¹³⁰ Upon assumption, the contractual obligations become those of the estate and any contract by the debtor after such time will likely result in a post-petition damages claim for breach of contract (treated as a first priority administrative claim,¹³¹ usually at 100 cents on the dollar) rather than a pre-petition claim for damages (which is payable only as set forth in the plan of reorganization).

b) Rejection

Bankruptcy courts similarly apply the deferential business judgment rule in reviewing rejections of executory contracts.¹³² Where the court approves a debtor’s rejection of an executory contract, section 365(g) of the Code provides that the debtor is deemed to have breached the agreement, giving rise to a pre-petition damages claim for breach of contract. That

128. *See Johnson v. Fairco Corp. (In re Johnson)*, 61 B.R. 317, 320 (Bankr. N.D. Ill. 1986) (describing the business judgment standard as a “lax standard” that disturbs a debtor’s actions “[o]nly where [such actions] are in bad faith or in gross abuse of its managerial discretion”).

129. *See* 11 U.S.C. § 365(b)(1)(B) (2000). The debtor must also make whole any third parties who suffered losses as a result of the defaults.

130. *See* 11 U.S.C. § 365(b)(1)(C) (2000).

131. 11 U.S.C. §§ 503, 507(a)(1) (2000).

132. Although the business judgment standard of review is highly deferential, a bankruptcy tribunal may, as a court of equity, restrain a debtor’s rejection of a contract where such an action will needlessly inflict great damage on the licensee, especially if not accompanied by some countervailing benefit to the estate. *See In re Petur U.S.A. Instrument Co.*, 35 B.R. 561, 563 (Bankr. W.D. Wash. 1983).

damages claim, if allowed by the bankruptcy court, is a general unsecured claim, placing the breached party's claim among the pool of general unsecured claims. The Bankruptcy Code bars the remedy of specific performance for a rejected executory contract.

c) Assignment

Once a debtor assumes an executory contract, it may seek to assign that contract to a third party. Bankruptcy law generally authorizes the assignment of executory contracts so as to afford the bankrupt estate the greatest flexibility in reorganizing its business and obtaining value for its creditors, even where the agreement expressly prohibits assignment.¹³³ The Code provides several exceptions and limitations on the assignment of contracts.¹³⁴ Of greatest significance to IP license agreements, section 365(c)(1) prohibits the assignment of an executory contract where "[a]pplicable law excuses a party, other than the debtor, to such contract . . . from accepting performance from or rendering performance to an entity other than the debtor or the debtor in possession, whether or not such contract . . . prohibits or restricts assignment of rights or delegation of duties" and "[s]uch party does not consent to such assumption or assignment." For example, general contract law principles prohibit the assignment of personal service contracts without the promisor's consent. Thus, under section 365(c)(1), an agreement whereby Tony Bennett would perform at a particular arena on a particular night could not be assigned to another promoter or venue without Mr. Bennett's consent.

4. Summary

It is easy to see how the core policies of the intellectual property laws and the bankruptcy system can conflict in action. In a Chapter 11 reorganization, the Bankruptcy Code focuses upon rehabilitating the debtor and providing it with a "fresh start." If the failing enterprise is the licensor of intellectual property, the trustee might seek to rescind licenses in an effort to negotiate better terms. By that point in time, the licensee may have made substantial specific investments in reliance on the continued licensing of intellectual property rights. In a Chapter 7 liquidation, the trustee of the debtor's estate seeks to sell off the assets to the highest bidder. Where the failing enterprise is a licensee of intellectual property, such licenses are

133. Section 365(f)(1) provides that an executory contract may be assigned after it is assumed even though the contract, lease, or applicable law provides otherwise, except as provided in subsection (c) of this section. *See also* 11 U.S.C. § 365(f)(2) (1994) (stating conditions necessary to be satisfied before executory contracts may be assigned); *In re Wash. Capital Aviation & Leasing*, 156 B.R. 167, 175 (Bankr. E.D. Va. 1993).

134. 11 U.S.C. § 365(c) (2000).

placed on the auction block and potentially purchased by entities that could undermine the business strategy of the IP owner—such as unreliable enterprises, or worse, competitors that seek to drive the licensor from the market. From an ex ante perspective, both of these possibilities create risks that reduce the expected value of intellectual property transactions. The inability to contract around this risk (due to the unenforceability of ipso facto clauses) could squelch an otherwise promising transaction or reduce the license-specific investments that would maximize the value of intellectual property licenses. As the following sections explore, bankruptcy law has evolved to ameliorate such concerns, but complexities and problems remain.

III. THE LICENSOR BANKRUPTCY PROBLEM

The risk of bankruptcy can undermine the incentives for parties to license intellectual property and make optimal investments in exploiting those licenses that are consummated. When a licensor of intellectual property rights enters bankruptcy, the Bankruptcy Code's generally permissive attitude toward a debtor's rejection of executory contracts can lead to particularly harsh results for licensees who have built a business or product line upon use of the licensor's intellectual property. As noted above, provisions that contract around the Bankruptcy Code are generally unenforceable, severely limiting licensees' ability to prevent such hardship.¹³⁵ The licensee loses continued use of the licensed intellectual property and is left with a pre-petition claim for contract damages. Due to the exclusivity of intellectual property rights, the licensee cannot go elsewhere to obtain the rights needed to continue its operations built upon such assets.

A 1985 Fourth Circuit decision, *Lubrizol Enterprises, Inc. v. Richmond Metal Finishers, Inc.*,¹³⁶ called attention to this problem. In *Lubrizol*, the debtor, Richmond Metal Finishers (RMF), had granted Lubrizol Enterprises a nonexclusive license to use its patented metal coating process. When RMF entered bankruptcy, it proposed to the bankruptcy court, as part of its reorganization plan, to reject the contract with Lubrizol in order to facilitate sale or licensing of the technology. After determining that the technology licensing agreement was an executory contract, the court approved rejection under the business judgment rule. The court found no evidence to suggest that the debtor's decision was taken in bad faith or reflected a gross abuse of business discretion. The court acknowledged, however, that allowing rejection of such contracts "imposes serious bur-

135. See *supra* text accompanying note 67 (discussion of section 365(e)(1)).

136. 756 F.2d 1043 (4th Cir. 1985).

dens upon contracting parties [and] could have a general chilling effect upon the willingness of [potential IP licensees] to contract at all with businesses in possible financial difficulty.”¹³⁷ Nonetheless, the court concluded that addressing these concerns was beyond its authority and rested with the Congress.

The *Lubrizol* decision produced a strong adverse reaction within the intellectual property, high technology, and investor communities. The protection and ability to make continued use of intellectual property is critical to the formation of many new technology-oriented businesses. In a letter to the Senate Judiciary Committee concerning this issue, the U.S. Department of Commerce complained that the risk of IP licenses being rejected by debtor-licensors would

exacerbate the plight of independent inventors, small businesses, and entrepreneurs in high risk areas, who are often without adequate resources and for whom the availability of risk capital is already a major problem. Even for established enterprises, the financial stability of the licensing partner may introduce unacceptable levels of risk and preclude significant investment in technology that must be acquired by license.¹³⁸

Heeding these admonitions, Congress carved out a special exception to the general bankruptcy law standards applicable to IP licensees for rejecting executory contracts.¹³⁹ The Intellectual Property Bankruptcy Protection Act of 1988 (IPBPA) added the following provision to section 365:

(n)(1) If the trustee rejects an executory contract under which the debtor is a licensor of a right to intellectual property, the licensee under such contract may elect—

(A) to treat such contract as terminated by such rejection if such rejection by the trustee amounts to such a breach as would entitle the licensee to treat such contract as terminated by virtue of its own terms, applicable nonbankruptcy law, or an agreement made by the licensee with another entity; or

(B) to retain its rights (including a right to enforce any exclusivity provision of such contract, but excluding any other

137. *Lubrizol*, 756 F.2d at 1048.

138. S. REP. NO. 100-505 (1988), as reprinted in 1988 U.S.C.C.A.N. 3200.

139. The purpose of this exception was to encourage investment in intellectual property and to protect the right of licensees who contribute financing, research, development, manufacturing or marketing skill by limiting the power of the licensor to reject executory contracts. See *id.*; Patrick Law, *Intellectual Property Licenses and Bankruptcy—Has the IPLBA Thawed the “Chilling Effects” of Lubrizol v. Richmond Metal Finishers?*, 99 COM. L.J. 261 (1994).

right under applicable nonbankruptcy law to specific performance of such contract) under such contract and under any agreement supplementary to such contract, to such intellectual property (including any embodiment of such intellectual property to the extent protected by applicable nonbankruptcy law), as such rights existed immediately before the case commenced, for—

- (i) the duration of such contract; and
- (ii) any period for which such contract may be extended by the licensee as of right under applicable nonbankruptcy law.

(2) If the licensee elects to retain its rights, as described in paragraph (1)(B) of this subsection, under such contract—

- (A) the trustee shall allow the licensee to exercise such rights;
- (B) the licensee shall make all royalty payments due under such contract for the duration of such contract and for any period described in paragraph (1)(B) of this subsection for which the licensee extends such contract; and
- (C) the licensee shall be deemed to waive—
 - (i) any right of setoff it may have with respect to such contract under this title or applicable nonbankruptcy law; and
 - (ii) any claim allowable under section 503(b) of this title arising from the performance of such contract.

(3) If the licensee elects to retain its rights, as described in paragraph (1)(B) of this subsection, then on the written request of the licensee the trustee shall—

- (A) to the extent provided in such contract, or any agreement supplementary to such contract, provide to the licensee any intellectual property (including such embodiment) held by the trustee; and
- (B) not interfere with the rights of the licensee as provided in such contract, or any agreement supplementary to such contract, to such intellectual property (including such embodiment) including any right to obtain such intellectual property (or such embodiment) from another entity.

(4) Unless and until the trustee rejects such contract, on the written request of the licensee the trustee shall—

- (A) to the extent provided in such contract or any agreement supplementary to such contract—
 - (i) perform such contract; or
 - (ii) provide to the licensee such intellectual property (including any embodiment of such intellectual property to

the extent protected by applicable nonbankruptcy law) held by the trustee; and

(B) not interfere with the rights of the licensee as provided in such contract, or any agreement supplementary to such contract, to such intellectual property (including such embodiment), including any right to obtain such intellectual property (or such embodiment) from another entity.

The principal effect of section 365(n) is to enable most IP licensees to retain their rights under rejected license agreements. Congress did not, however, simply override the licensor's power to reject IP licensing agreements. Rather, it carefully crafted the mechanics and rights structure under section 365(n) to satisfy the needs of intellectual property licensees to continue their exploitation of intellectual property while shielding debtor-licensors from any additional burdens associated with the license.

Upon the rejection of a license falling within the Bankruptcy Code's definition of "intellectual property,"¹⁴⁰ the licensee can either treat the rejection as a breach giving rise to a potential claim for money damages under section 365(g), as with other rejected contracts, or retain the rights to the intellectual property covered by the license. Where the licensee elects to retain rights to the intellectual property, the debtor must permit the licensee to exercise its rights and the licensee must continue to pay royalties due under the licensing agreement. The licensee retains rights to the licensed property for the remaining life of the license plus "any period for which such contract may be extended by the licensee as of right under applicable nonbankruptcy law."¹⁴¹ By rejecting the licensing agreement, the debtor is relieved from performing any affirmative duties under the contract. The licensee waives any right of setoff it¹⁴² may have with respect to the licensing agreement and any claim for administrative expenses under the Bankruptcy Code,¹⁴³ although the licensee may file a pre-petition claim under section 365(g) for damages resulting from rejection of the licensing agreement¹⁴⁴ and may seek damages from the debtor for breach of affirmative duties owed under the agreement, but only as a general unse-

140. 11 U.S.C. § 101(35A) (2000).

141. 11 U.S.C. § 365(n)(1)(B)(ii) (2000).

142. A setoff is a settlement of mutual debt between a debtor in bankruptcy and a creditor through cancellation or reduction of a separate financial obligation owed by the creditor to the debtor. *See* 11 U.S.C. § 353 (2000).

143. 11 U.S.C. § 365(n)(2)(C) (2000).

144. *See In re Szombathy*, 1996 WL 417121, at *9 (Bankr. N.D. Ill. 1996), *rev'd in part on other grounds*, *Szombathy v. Controlled Shredders, Inc.*, 1997 WL 189314 (N.D. Ill. 1997).

cured creditor. The debtor is still bound by several passive obligations—such as adhering to confidentiality agreements and, in the case of an exclusive license, not licensing the technology to others—that are necessary for the licensee to enjoy the continued use and exploitation of licensed intellectual property.¹⁴⁵

The IPBPA has proven to be somewhat complicated to apply due to several factors. First, Congress chose a limited definition of “intellectual property” for purposes of section 365(n). Most notably, the definition excludes trademarks. Second, there exists some ambiguity regarding the continuing obligations of licensors following rejection of an IP license and the retention of licensing rights by the licensee. Lastly, questions have arisen concerning the scope of the term “royalties.”

A. The Limited Scope of “Intellectual Property” Under Section 365(n)

Section 365(n) applies only to licenses of “intellectual property” as defined in section 101 of the Bankruptcy Code:

- (35A) “intellectual property” means—
 - (A) trade secret;
 - (B) invention, process, design, or plant protected under title 35;
 - (C) patent application;
 - (D) plant variety;
 - (E) work of authorship protected under title 17; or
 - (F) mask work protected under chapter 9 of title 17.

Several questions have arisen concerning the scope of this provision. First, while including many of the principal forms of intellectual property—patents, copyrights, and trade secrets—this list omits trademarks (and related forms of protection, such as trade dress). As we will see, this omission was intentional, which raises the related question of how licenses which bundle trademark and covered intellectual property rights should be handled. A second issue of scope that has been noted, though not adjudicated, is whether the narrow wording of section 101(35A)(E), which covers U.S. copyrights, also extends to foreign copyrights. A third issue concerns whether a record label (or other content distribution company) can invoke section 365(n)(1) to prevent a recording artist from getting out of an exclusive personal services contract tied to the creation of copyright-protected works.

145. *Id.* at *10 (citing S. REP. NO. 100-505 (1988), as reprinted in 1988 U.S.C.C.A.N. 3200).

1. Trademarks and Bundled IP Licenses

The legislative history behind section 365(n) emphasizes concerns associated with emerging businesses in the computer software and biotechnology industries,¹⁴⁶ for which patent, trade secret, and copyright licenses were of greatest significance. A spokesperson for the National Bankruptcy Conference considered the concerns raised by these industries to be more urgent than the needs of trademark licensees (such as those associated with franchise businesses) and opposed extending the legislation to include trademarks and related forms of intellectual property:

The Conference supports this legislation on a semi-emergency basis in order to further the activities of American research and development companies in the world race for technological leadership. The Conference sees no such emergency for and has no particular interest in, extending such protection to trademarks connected with traditional distributorships and retail businesses at this time.¹⁴⁷

Congress adopted this view and omitted trademarks from the definition of "intellectual property."

Finally, the bill does not address the rejection of executory trademark, trade name or service mark licenses by debtor-licensors. While such rejection is of concern because of the interpretation of section 365 by the *Lubrizol* court and others, see, e.g., *In re Chipwich, Inc.*, 54 Bankr. Rep. 427 (Bankr. S.D.N.Y. 1985), such contracts raise issues beyond the scope of this legislation. In particular, trademark, trade name and service mark li-

146. See Intellectual Property Contracts in Bankruptcy: Hearings on H.R. 4657 Before the Subcomm. on Monopolies and Commercial Law of the H. Comm. on the Judiciary, 100th Cong. 2d Sess. 13-24 (1988) (statement of James Burger, Chief-Counsel - Government, Apple Computer, Inc.); A Bill to Keep Secure the Rights of Intellectual Property Licensors and Licensees Which Come Under the Protection of Title 11 of the United States Code, the Bankruptcy Code: Hearing on S.1626 Before the Subcomm. on Courts and Administrative Practice of the Senate Comm. on the Judiciary, 100th Cong. 1st Sess. 224-34 (1988) (statement of John L. Pickitt, President, Computer and Business Equipment Manufacturers Association).

147. Letter by George A. Hahn on behalf of the National Bankruptcy Conference (July 14, 1988), in THE AM. BANKR. INST. SURVEY: Hearing before the Subcomm. on Courts and Administrative Practice Of the Senate Comm. on the Judiciary on S. 1626, S.1358, S.1863, and S. 2279, 100th Cong., 2d Sess. at 344; see also A Bill to Keep Secure the Rights, *supra* note 146, at 4261 (statement of George A. Hahn on behalf of the National Bankruptcy Conference arguing that Congress need not "bring every retail franchise involving a trademark within the purview of the legislation, thus extending the reach of the bill far beyond what appears necessary").

censing relationships depend to a large extent on control of the quality of the products or services sold by the licensee. Since these matters could not be addressed without more extensive study, it was determined to postpone congressional action in this area and to allow the development of equitable treatment of this situation by bankruptcy courts.¹⁴⁸

Relatively few cases have addressed the rejection of trademark licenses by debtor-licensees. Where the only significant intellectual property right licensed is a trademark, courts have had little difficulty concluding that trademark licenses cannot be retained under the authority of section 365(n).¹⁴⁹ Valid rejection of a trademark licensing agreement extinguishes the licensee's right to use the mark and the licensee is left with only a claim for breach of contract.¹⁵⁰

A 1993 case, *In re Matusalem*,¹⁵¹ however, suggests that the IPBPA's legislative history could be invoked to protect trademark licensees, particularly in circumstances in which the trademark license is bundled with licenses of works that fall within the Bankruptcy Code's definition of "intellectual property." Recognizing that the IPBPA omitted "trademarks" from the definition of "intellectual property," the court nonetheless read

148. S. REP. NO. 100-505, at 5 (1988), as reprinted in 1988 U.S.C.C.A.N. 3200, at 2-3. See generally David M. Jenkins, *Licenses, Trademarks, and Bankruptcy, Oh My!: Trademark Licensing and the Perils of Licensor Bankruptcy*, 25 J. MARSHALL L. REV. 143 (1991) (arguing that trademarks should have been included within the Bankruptcy Code's definition of "intellectual property").

149. See *In re HQ Global Holdings, Inc.*, 290 B.R. 507, 512-513 (Bankr. D. Del. 2003); *Raima UK Ltd. v. Centura Software Corp. (In re Centura Software Corp.)*, 281 B.R. 660 (Bankr. N.D. Cal. 2002); cf. *Blackstone Potato Chip Co., Inc. v. Mr. Popper, Inc. (In re Blackstone Potato Chip Co., Inc.)*, 109 B.R. 557 (Bankr. D.R.I. 1990) (proffering no § 365(n) argument in a case in which the licensee opposed rejection of a trademark license).

150. *Gucci v. Sinatra (In re Gucci)*, 126 F.3d 380, 394 n.1 (2d Cir. 1997) (invoking the maxim that rejection of a contract does not terminate or repudiate a contract but simply relieves the estate from its obligation to perform and citing *Med. Malpractice Ins. Ass'n v. Hirsch (In re Lavigne)*, 114 F.3d 379, 387 (2d Cir. 1997)); see also *Enter. Energy Corp. v. United States (In re Columbia Gas Sys., Inc.)*, 50 F.3d 233, 239 n.8 (3d Cir. 1995) (noting that rejection is equivalent to a nonbankruptcy breach); *Cohen v. Drexel Burnham Lambert Group, Inc. (In re Drexel Burnham Lambert Group, Inc.)*, 138 B.R. 687, 703 (Bankr. S.D.N.Y. 1992) ("Rejection merely frees the estate from the obligation to perform; it does not make the contract disappear."). In *In re HQ Global Holdings*, the licensee argued that it was entitled to continue use of the trademark following a bankruptcy rejection of the licensing agreement so long as the debtor-licensor was relieved of all affirmative duties. The bankruptcy court held that rejection of the license agreement barred continued use by the licensee. 290 B.R. at 513.

151. 158 B.R. 514, 521-22 (Bankr. S.D. Fla. 1993).

the legislative history of the Act to authorize courts to develop equitable standards for determining the treatment of trademark licenses in bankruptcy cases:

[T]he bill does not address the rejection of executory trademark, trade name or service mark licenses by debtor-licensors. While such rejection is of concern because of the interpretation of section 365 by the *Lubrizol* court . . . , such contracts raise issues beyond the scope of this legislation. In particular, trademark, trade name and service mark licensing relationships depend to a large extent on control of the quality of the products or services sold by the licensee. Since these matters could not be addressed without more extensive study, it was determined to postpone congressional action in this area and to allow the development of equitable treatment of this situation by bankruptcy courts.¹⁵²

The court did not, however, reach the question of how such standards would be determined or applied because it ultimately ruled that the debtor-licensor failed to justify its proposed rejection of the licensing agreement under the business judgment test.¹⁵³ The court did note in passing that the harsh effect of rejection—to “utterly destroy” the licensee’s business—would weigh against an overly literal construction of the Bankruptcy Code, but it did not expressly conclude that it would have allowed retention of the trademark license if rejection had been adequately supported, nor did it mention the potential impact of its interpretation of section 365(n) upon trademark law’s quality control requirements.¹⁵⁴

Although commentators have speculated as to what form the equitable test alluded to in *In re Matusalem* might take,¹⁵⁵ no subsequent case has

152. S. REP. NO. 100-505, at 6 (1988), as reprinted in 1988 U.S.C.C.A.N. 3200.

153. The debtor-licensor sought to reject a sub-franchise agreement under which the licensee acquired exclusive rights to the debtor’s secret formula for making rum and exclusive rights to use the debtor’s trademarked rum label in particular territories. Finding that the debtor’s decision to reject the license agreement was motivated by a desire to exact revenge in an ongoing family feud rather than any plausible business purpose, the court turned away the debtor’s proposed rejection of the licensing agreement.

154. *In re Matusalem*, 158 B.R. at 522.

155. See WILLIAM L. NORTON, JR., NORTON BANKRUPTCY LAW AND PRACTICE § 150:18 (2d ed. Supp. 2006); Kenneth A. Klee et al., *The Effect of Bankruptcy on Intellectual Property Rights*, in ALI-ABA COURSE OF STUDY 407, 412 (American Law Institute–American Bar Association Continuing Legal Education ed. 2001); Law, *supra* note 139; Primoff & Weinberger, *supra* note 98; Stuart M. Riback, *The Interface of Trademarks and Bankruptcy*, 387 PLI/PAT 53, 75 (1994); Stuart M. Riback, *Intellectual Property Licenses: The Impact of Bankruptcy*, 672 PLI/PAT 201, 211 (2001), available at http://www.pli.edu/product/book_detail.asp?ptid=503&stid=28&id=EN00000000003935.

developed or applied an equitable standard for addressing the retention of trademark rights under section 365(n), and the one court to address the treatment of bundled trademark and covered intellectual property rights distinguished this case. The court in *In re Centura Software Corp.*¹⁵⁶ expressly declined to consider equitable considerations in adjudicating trademark rights post-rejection, although it suggested that it would have been able to consider such factors if the issue arose prior to court approval of a rejection of the license agreement.¹⁵⁷ In essence, the court determined that section 365(n) has different implications depending upon whether it is invoked pre- or post-rejection.¹⁵⁸ When invoked pre-rejection (as occurred in *In re Matusalem*) the court took the position that the licensee could have argued that the relatedness of the trade name to the protected property should allow it to “bootstrap ongoing trademark rights through an application of the business judgment rule,”¹⁵⁹ notwithstanding the Bankruptcy Code’s exclusion of trademarks. But since it was invoked after rejection had been approved, section 365(n) controlled the adjudication of the licensee’s rights, and because trademarks are excluded from the scope of intellectual property to which section 365(n) applies, the court could not “weigh the equities” in assessing whether to allow the licensee to retain the trademark rights.

The *In re Centura* court both disputes whether *In re Matusalem* reads the Bankruptcy Code to allow for post-rejection consideration of the equities in determining whether trademark rights could be retained and disagrees with the assertion that the legislative history of the IPBPA can be read to authorize a court to engage in such an analysis.¹⁶⁰ To a significant degree, the issue boils down to whether the relatively clear language of the statute—excluding trademarks from the definition of “intellectual property”—allows a court to look to the legislative history at all. The *In re Matusalem* court appears receptive to a more open-ended inquiry concerning the treatment of trademark rights before or possibly even after rejection has been approved, whereas the *In re Centura* court seeks to avoid reading trademarks into the definition of “intellectual property” in the Bankruptcy Code, preferring consideration of equitable factors solely during the rejection determination. Such an approach, while adhering closely

156. *Raima UK Ltd. v. Centura Software Corp. (In re Centura Software Corp.)*, 281 B.R. 660 (Bankr. N.D. Cal. 2002).

157. The parties in *In re Centura* had stipulated to rejection of the trademark license. *Id.* at 672.

158. The court based this interpretation on *NORTON*, *supra* note 155, § 150:18.

159. Quoting *NORTON*, *supra* note 155.

160. *In re Centura*, 281 B.R. at 672-73.

to the letter of the Bankruptcy Code, leaves little leeway for considering equitable factors in view of the deferential nature of the business judgment rule. Where trademark rights are bundled with expressly protected intellectual property rights, the fact that the licensee will be able to continue to exploit the non-trademark rights could well affect the “business judgment” of whether to reject the trademark rights. This approach, however, provides little leeway for courts to balance the equities as between the licensor and the licensee. Rather, it would focus upon whether taking back only the trademark rights would be plausibly advantageous to the debtor. In view of the fact that the licensor might well be able to offer such rights back to the same licensee at a higher price, this legal standard would not appear to effectuate the “equitable treatment” that Congress expressed in the IPBPA’s legislative history. Nor does it provide any basis for considering licensee interests in a pure (non-bundled) trademark situation.

2. *Foreign Copyrights*

The definition of “intellectual property” in section 101(35A) of the Bankruptcy Code covers “works of authorship protected under title 17” of the U.S. Code—the U.S. Copyright Act. The focus on copyrighted works protected by the U.S. Copyright Act raises a question as to the treatment of licenses to exploit foreign-produced works within the United States and licenses to exploit U.S. and foreign-produced works outside of the United States.¹⁶¹ The U.S. Copyright Act does in fact protect “works of foreign authorship” when the U.S. and the work’s country of origin have treaties providing for reciprocal protections or when the work is first published in the United States.¹⁶² For example, works of British origin are protected by copyright in the U.S. under U.S. copyright law, not under British copyright law. Therefore, licenses that grant rights to exploit copyrights of works of foreign authorship in the United States would, assuming the existence of reciprocal treaties and the protectability of the work under U.S. law, fall within the scope of the Bankruptcy Code’s definition of “intellectual property.”

The treatment of licenses of works of foreign or U.S. authorship that grant the right to exploit outside of the United States is not dealt with quite as directly under the Bankruptcy Code. Take, for example, the relatively common case of a license of world-wide rights to a work of foreign or U.S. origin. The question arises whether a licensee would be able to retain exploitation rights outside of the United States under section 365(n) follow-

161. Cf. William M. Goldman, *The Treatment of Intellectual Property in Bankruptcy*, 747 PLI/PAT 461 (2003).

162. See 17 U.S.C. § 104 (2000 & Supp. 2004).

ing a rejection of the license by the debtor-licensor. The debtor-licensor could argue that those rights are not rights under “Title 17” of the U.S. Code and hence fall outside the scope of section 365(n). A licensee seeking to retain such foreign exploitation rights (as well as the U.S. rights, which clearly fall within the ambit of section 365(n)) could counter that the IPBPA defines intellectual property in terms of “works” as opposed to “rights,” and since the license was for a “work” that is protected under Title 17, the IPBPA allows the licensee to retain its foreign (as well as U.S.) rights. Although the rather succinct legislative history of the IPBPA does not address this rather arcane question directly, the more general purposes of the statute—to encourage investment in intellectual property and to protect the right of licensees who contribute financing, research, development, manufacturing, or marketing skill by limiting the power of the licensor to reject executory contracts—clearly support the licensee’s interpretation. There does not appear to be any countervailing policy opposing such an interpretation. Therefore, it would appear that all licensed copyright rights that are protected under the U.S. Copyright Act could be retained under section 365(n).

3. *Personal Services of Recording Artists*

As noted earlier, recording contracts between record labels and recording artists generally fall within the category of executory contracts, and therefore a recording artist can reject the contract in bankruptcy. The question thus arises whether a record label can seek to retain a recording artist’s exclusive services through application of section 365(n) for the duration of the contract.¹⁶³ In *Cloyd v. GRP Records*,¹⁶⁴ the Sixth Circuit held that the definition of intellectual property did not extend to a person. It noted as well that reading the statute to extend that far would implicate the 13th Amendment’s prohibition of involuntary servitude and that preventing the recording artist from performing free from contractual constraints would defeat the Code’s purpose of granting the debtor “a fresh

163. Section 365(n)(1)(B) affords a licensee the option to retain its rights (including a right [to] enforce any *exclusivity provision* of such contract, but excluding any other right under applicable nonbankruptcy law to specific performance of such contract) under such contract and under any agreement supplementary to such contract, to such intellectual property (including any embodiment of such intellectual property to the extent protected by applicable nonbankruptcy law)
(emphasis added).

164. *Cloyd v. GRP Records (In re Cloyd)*, 238 B.R. 328 (Bankr. E.D. Mich. 1999).

start.”¹⁶⁵ Consequently, it concluded that section 365(n) did not apply to the personal services of a performing artist.¹⁶⁶

B. Licensor Obligations

As noted above, section 365(n) relieves debtor-licensors of the responsibility to perform affirmative obligations under rejected contracts but requires that they adhere to certain passive obligations, such as nondisclosure provisions, covenants not to sue, and the like. The source and interpretation of the distinction between unenforceable affirmative duties and enforceable passive obligations, and the scope of these categories, requires a careful consideration of the text and legislative history of the IPBPA.

This issue mainly arises with covenants requiring that a licensor provide licensees with future improvements of licensed technology.¹⁶⁷ These clauses can be particularly important for companies engaged in early stage technological research and those whose products depend on being interoperable. Potential licensees will be reluctant to license such technology if they cannot be assured of continued access to advances. Their choice of one technology provider over another may hinge on whether they can assure their customers of future compatibility with an emerging network technology.¹⁶⁸ Yet, the possibility of such improvement clauses being rejected in bankruptcy places any such agreement under a cloud and could sour an otherwise promising deal. Due to the constraints imposed by bankruptcy law, the parties cannot contract around this situation short of the licensee acquiring the technology and technologists needed to develop it further, which will rarely be the optimal allocation of resources and responsibilities. In many ways, this situation parallels a principal justification for the enactment of section 365(n) in the first place. As noted in the legislative history,

When intellectual property is assigned rather than licensed, the original creator loses his personal stake. The licensee or assignee frequently is interested in the intellectual property for a specific application or geographic market. In order to assure the continued availability of the intellectual property against the contin-

165. See *In re Monument Record Corp.*, 61 B.R. 866 (Bankr. M.D. Tenn. 1986) (citing *Chattanooga Mem'l Park v. Still (In re Jolly)*, 574 F.2d 349 (6th Cir. 1978)).

166. *Cloyd*, 238 B.R. at 335-36. See generally Brewer, *supra* note 116.

167. See Law, *supra* note 139; Robert Canavan, *Unsolved Mysteries of § 365(n)—When a Bankruptcy Technology Licensor Rejects an Agreement Granting Rights to Future Improvements*, 21 SETON HALL L. REV. 800 (1991).

168. See CARL SHAPIRO & HAL VARIAN, *INFORMATION RULES: A STRATEGIC GUIDE TO THE NETWORK ECONOMY* (1998).

gency of the creator's bankruptcy, however, the party seeking the intellectual property for limited use must demand assignment of the property, notwithstanding that a license would otherwise serve his purpose. The creator then is either totally alienated from his creation or, at best, given a license by the assignee. Such circumstances create obvious disincentives to the full development of intellectual property. If the creator is unwilling to assign, in some instances, transactions simply are not completed. In others, the licensee discounts what he will pay to account for the risk now seen as inherent in Section 365. In short, Section 365 is resulting in undercompensation of U.S. inventors. Ironically, the present law, as it is now being interpreted by courts, can result in increased financial distress for the inventor, causing him to be shortchanged to adjust for a risk which under present law cannot be contractually removed if a license format is selected.¹⁶⁹

To date, only one reported bankruptcy case addresses whether a future improvements clause is enforceable following rejection of the IP licensing agreement by the trustee/debtor and an election to retain licensing rights under section 365(n). In *In re Szombathy*,¹⁷⁰ Szombathy licensed the right to manufacture and sell its patented tire shredding machine to Controlled Shredders, Inc. The license agreement extended to any patents which the licensor might later acquire as well as any improvements that the inventor might develop during the term of the patent. The licensor subsequently filed for bankruptcy and the trustee, appointed as part of a Chapter 7 proceeding, rejected the licensing agreement and sought to sell the debtor's intellectual property rights. Pursuant to section 365(n)(1)(B), Controlled Shredders elected to retain its rights to the debtor's patented technology under the licensing agreement and sought access to technological improvements that Szombathy had made following the filing of the bankruptcy petition. Szombathy sought a declaration from the court that neither he, nor any of his successors or any assignee of the Debtor's rights in the intellectual property, bore any affirmative obligations to share post-petition technological developments with Controlled Shredders.

The bankruptcy court found the text of section 365(n) to be clear and unambiguous in limiting a licensee's rights to intellectual property "in existence at the time of the bankruptcy filing." It pointed to a comment in the legislative history stating that the licensee is only "entitled to use the un-

169. S. REP. NO. 100-505 (1988), as reprinted in 1988 U.S.C.C.A.N. 3200.

170. See *In re Szombathy*, 1996 WL 417121, at *9 (Bankr. N.D. Ill. 1996), rev'd in part on other grounds, *Szombathy v. Controlled Shredders, Inc.*, 1997 WL 189314 (N.D. Ill. 1997).

derlying intellectual property in the state that it existed on the day of the bankruptcy filing”¹⁷¹ as well as the reference in section 365(n)(1)(B) affording the licensee such rights as “existed immediately before the case commenced.” The court noted that although the debtor could be held to “certain obligations necessary” to implement the license agreement, such as a covenant not to reveal confidential information, the statute shielded the debtor from performing any affirmative obligations.

The court’s rather literal reading of the statute arguably overlooks the broader policies that Congress sought to effectuate in the IPBPA. As the court recognized, the enforceability of passive obligations, such as the covenant not to reveal confidential obligations, derives from the legislative history.¹⁷² The only express obligation upon debtors in section 365(n) beyond making available the licensed intellectual property is the “right to enforce any exclusivity provision of such contract.” Although not specifically cited by the court, section 365(n)(1)(B) appears to bar specific performance of “any other right under applicable nonbankruptcy law.”

Nonetheless, Congress’s interest in fostering technological innovation affords a basis for allowing bankruptcy courts a modicum of equitable discretion in assessing whether adherence to a future improvements clause amounts to an affirmative duty or a passive obligation necessary to effectuate the licensee’s right to exploit the intellectual property it bargained for.

The bill recognizes that continued affirmative performance of an intellectual property license may be impractical; for instance, a trustee will generally be unable to perform covenants calling for continued research to improve licensed intellectual property. However, performance of covenants requiring no action by the trustee impose no burden on the estate and result in equity to the nonbreaching party and certainty to the economy as a whole.¹⁷³

Thus, requiring a debtor to undertake research efforts that it would not otherwise pursue would clearly impose a significant burden upon the bankrupt estate and is beyond what Congress thought appropriate in balancing the rights of debtor-licensors and licensees. On the other hand, requiring a reorganized debtor to provide improvements it made voluntarily

171. *Id.* at *30 (quoting S. REP. NO. 100-505 (1988), as reprinted in 1988 U.S.C.C.A.N. 3200).

172. The fact that trade secrets are included among the modes of “intellectual property” covered by the Bankruptcy Code provides a textual basis for enforcing confidentiality agreements under section 365(n).

173. S. REP. NO. 100-505 (1988), as reprinted in 1988 U.S.C.C.A.N. 3200.

would not appear, in at least some commercial, technological, and industrial contexts, to impose a substantial or unanticipated burden on the debtor. Thus, an argument can be made on the basis of the legislative history of the IPBPA that bankruptcy courts should adjudicate the enforcement of improvement clauses on a case by case basis.¹⁷⁴

But as the court found in *In re Szombathy*, the language of the statute may be too restrictive to support such an expansive interpretation. Under this view, the only obligations to which debtors may be held are providing access to the licensed intellectual property in the form it “existed immediately before the case commenced,” any nondisclosure agreements, and, in circumstances where the licensee bargained for an exclusive license, refraining from licensing the covered intellectual property to others.

C. Meaning of “Royalty Payments”

Under section 365(n)(2)(B), licensees electing to retain rights under an IP license “shall make all royalty payments due under such contract for the duration of such contract and for any period described in paragraph (1)(B) of this subsection for which the licensee extends such contract.” In practice, license agreements can entail several types of payments, only some of which are labeled “royalty payments.” Although the statute does not define “royalty payments,” the term has been broadly interpreted to include any payment for the use of intellectual property, regardless of nomenclature or whether based on a flat fee or percentage of sales. In *In re Prize Frize, Inc.*,¹⁷⁵ the license agreement distinguished between a “license fee” granting an exclusive license to utilize the proprietary rights and to manufacture, use, and sell a vending machine and “royalty payments” based on a percentage of sales. Following rejection of the contract and retention of rights by the licensee, the licensee sought to pay only what the license agreement designated as royalties and not the license fee (fixed sums payable over a prescribed time). The court held that, regardless of the nomenclature used in the license agreement, the term “royalty payments” in the statute encompassed all license fees to be paid by the licensee to retain its rights to use the intellectual property.

D. Assessment and Reform

Section 365(n) has solved the problem posed by the *Lubrizol* case and many analogous problems relating to bankruptcy of intellectual property

174. In the case of a Chapter 7 liquidation, enforcing an improvements clause as the debtor’s inventors disperse could be difficult and costly.

175. See *Encino Bus. Mgmt., Inc. v. Prize Frize, Inc.* (*In re Prize Frize, Inc.*), 150 B.R. 456, 459-60 (B.A.P. 9th Cir. 1993), *aff’d*, 32 F.3d 426 (9th Cir. 1994).

licensors. As explained above, however, several problems persist. The exclusion of trademark licenses from section 365(n) does not appear to be justified by the distinctive characteristics of trademark protection. The risk of licensor bankruptcy imposes undue and largely unavoidable uncertainty upon trademark licensees that could both discourage licensing and reduce the amount of investment in maximizing the value of licensee activities. Furthermore, the common bundling of trademark and other intellectual property rights exposes the over-inclusiveness of a rule allowing bankrupt licensors unfettered discretion to rescind trademark licenses. The Bankruptcy Code should provide bankruptcy courts discretion to consider a licensee's argument that a trademark license should be retained. The licensee should bear the burden of proving that retention of the license would not unduly impair the debtor-licensor in its fresh start (e.g., due to supervision costs) nor jeopardize the value of the trademark.

A second problem that has emerged under section 365(n) appears to be an overprotective approach to licensor obligations. Rather than relieving debtor-licensors of responsibility to perform any affirmative obligations, there is merit in allowing the bankruptcy court discretion to require performance of those obligations that have little or no cost for the reorganizing licensor that could afford substantial benefit to licensees. The clearest example is future improvement clauses. They can often be satisfied at minimal cost to the licensor. The risk of such obligations being jettisoned in bankruptcy could well impede efficient licensing. Thus, as with trademark licenses, Congress should amend section 365(n) to afford bankruptcy courts discretion to require debtor-licensors to perform relatively modest obligations that have great value to licensees following reorganization.

IV. THE LICENSEE BANKRUPTCY PROBLEM

The inverse of the *Lubrizol* problem can occur when an IP licensee enters bankruptcy. The Bankruptcy Code's policy favoring alienability of assets jeopardizes the licensor's control of its intellectual property rights. The debtor-licensee may seek to assume the IP license and then assign it to a third party in exchange for direct payment or some other economic benefit to the estate. Where the licensee would assign the IP license to a third party that the licensor opposes, the licensor may find itself in a difficult circumstance. Take, for example, the case of an exclusive license to manufacture the licensor's product in exchange for a per unit royalty payment. If that exclusive license were to fall into the hands of a company producing a competing product, the new exclusive licensee might choose to halt production of the licensed product, thereby enhancing the market

for its own product and denying the licensor revenue and consumer exposure. Even if the licensor placed a non-assignment clause in the licensing agreement, such clause would not be enforceable under general Bankruptcy Code provisions.¹⁷⁶

The Bankruptcy Code addresses the assignability of contractual rights through several interrelated provisions. At the most general level, section 365(a) authorizes a trustee to assume or reject executory contracts. Once assumed, an executory contract can be assigned without the consent of the licensor (even if the agreement contains a non-assignment clause)¹⁷⁷ unless the contract is, pursuant to section 365(c), one in which state or non-bankruptcy federal law would excuse the licensor from accepting performance from or rendering performance to an entity other than the debtor.¹⁷⁸ Although general principles of contract law favor the free assignability of contractual rights unless the agreement, a statute, public policy, or principles of equity dictate otherwise,¹⁷⁹ contract law prohibits the

176. *See supra* text accompanying note 68.

177. *See* 11 U.S.C. § 365(f) (2000).

178. The Bankruptcy Code is ambiguous on this issue. Section 365(f)(1) states that “[e]xcept as provided in subsection . . . (c),” the trustee may assign an executory contract notwithstanding “a provision in . . . applicable law, that prohibits, restricts, or conditions the assignment of such contract.” Section 365(c) states that the

trustee may not assume or assign any executory contract . . . if (1) (A) applicable law excuses a party, other than the debtor, to such contract . . . from accepting performance from or rendering performance to an entity other than the debtor . . . , whether or not such contract or lease prohibits or restricts assignment of rights or delegation of duties; and (B) such party does not consent to such assumption or

These sections can be reconciled only by inferring that they refer to different conceptions of “applicable law.” One commentator suggests that the distinction that most closely hews to Congress’ intent reads section (f)(1) to override general legislative provisions that prohibit or restrict assignment entirely while upholding, under subsection (c), general common law doctrines that excuse third parties from accepting or receiving performance from a third party. *See* THOMAS M. WARD, *INTELLECTUAL PROPERTY IN COMMERCE* § 4:93 (2006).

179. *See* 3 RESTATEMENT (SECOND) OF CONTRACTS § 317(2) (1981), which states:

A contractual right can be assigned unless (a) the substitution of a right of the assignee for the right of the assignor would materially change the duty of the obligor, or materially increase the burden or risk imposed on him by his contract, or materially impair his chance of obtaining return performance, or materially reduce its value to him, or (b) the assignment is forbidden by statute or is otherwise inoperative on grounds of public policy, or (c) assignment is validly precluded by contract;

UCC § 2-210(2) (1999); 3 E. ALLAN FARNSWORTH, *FARNSWORTH ON CONTRACTS* §§ 11.2, 11.4, at 61, 82-84 (2d ed. 1998).

assignability of contracts for personal services involving unique skills or talents without the consent of the promisor.¹⁸⁰

The courts have long held that the federal intellectual property policies of promoting innovation and the creative arts favor intellectual property owners having the ability to control the uses of their works.¹⁸¹ These policies disfavor assignability of such rights by licensees without the owner/licensor's consent. Some cases have also noted the personal nature of nonexclusive intellectual property licenses, which reinforces the unassignability of such rights without licensor consent.¹⁸²

The application of section 365(c) to preclude the assignability of intellectual property rights without licensor consent has been most strongly and clearly enunciated with regard to nonexclusive patent and copyright licenses. Nonexclusive licenses are viewed as conferring personal, as opposed to property, rights and hence most directly implicate the policy disfavoring free assignability by licensees. In some cases, courts consider equitable factors, such as the effects of an assignment on the character and profitability of a licensor's business¹⁸³ and the motivations of the transferee,¹⁸⁴ in determining whether a transfer may proceed. The law is less consistent with regard to the assignability of exclusive licenses. Intellectual property law tends to view such licenses as conferring property and not merely personal rights, which would favor greater freedom of transferability by the licensee. But, the one bankruptcy court decision to address the assignability of exclusive patent licenses barred the licensee from assigning the interest.¹⁸⁵ In the copyright area, the law is deeply divided,

180. See, e.g., *Breeden v. Catron* (*In re Catron*), 158 B.R. 624, 627 (Bankr. E.D. Va. 1992), *aff'd*, 158 B.R. 629 (E.D. Va. 1993), *aff'd*, 25 F.3d 1038 (4th Cir. 1994); *In re Taylor*, 103 B.R. 511, 516 (D.N.J. 1989), *aff'd in part and appeal dismissed in part*, 913 F.2d 102 (3d Cir. 1990); *In re McVay*, 169 B.R. 49, 51 (Bankr. W.D. Tenn. 1994).

181. See *infra* Section IV.B.

182. *Id.*

183. See *PPG Indus., Inc. v. Guardian Indus. Corp.*, 597 F.2d 1090, 1096-97 (6th Cir. 1979); *Synergy Methods, Inc. v. Kelly Energy Sys., Inc.*, 695 F. Supp. 1362, 1364-65 (D.R.I. 1988) (examining whether transferee will effectively continue the business of the debtor/licensee); *Nat'l Bank of Canada v. Interbank Card Ass'n*, 507 F. Supp. 1113, 1124 (S.D.N.Y. 1980), *aff'd*, 666 F.2d 6 (2d Cir. 1981) (holding considerably larger size of successor entity justified licensor's objection to transaction); *In re Van Ness Auto Plaza, Inc.*, 120 B.R. 545, 550 (Bankr. N.D. Cal. 1990); *In re Alltech Plastics, Inc.*, 71 B.R. 686, 688-90, *later proceeding at* 5 U.S.P.Q.2d (BNA) 1806, 1810-13 (Bankr. W.D. Tenn. 1987).

184. See *Review Directories, Inc. v. McLeodusa Publ'n Co.*, No.1:99-CV-958, 2001 WL 1946328, at *3-4 (W.D. Mich. July 9, 2001) (holding that acquisition was not made solely to obtain licensed trademark).

185. See *In re Hernandez*, 285 B.R. 435 (Bankr. D. Ariz. 2002).

with a recent Ninth Circuit decision interpreting the Copyright Act to prohibit the assignability of exclusive licenses without licensor consent¹⁸⁶ and other courts interpreting the Copyright Act to allow free assignability of exclusive copyright licenses.¹⁸⁷ The law regarding the assignability of trademark licenses is even less settled. Given the differing policies and doctrines across the modes of intellectual property protection, it is useful to examine each area separately.

Even before turning to the question of assignability of intellectual property licenses under section 365(c) and the non-bankruptcy “applicable law” that it incorporates by reference, however, there exists a rather technical antecedent question of whether a debtor in possession may even assume an intellectual property license that is not assignable under such non-bankruptcy law. The confusion arises as a result of ambiguous and potentially conflicting language in section 365(f).

A. Assumability of License Agreements by Reorganizing Enterprises

Section 365(c)(1) states that “a trustee may not assume *or* assign any executory contract [if applicable non-bankruptcy law excuses the non-bankrupt party] from accepting performance from or rendering performance to an entity other than the debtor or the debtor in possession.”¹⁸⁸ Thus, under a literal reading of this provision, the trustee¹⁸⁹ could not even assume a license if applicable law prohibited assignment.¹⁹⁰ Courts describe this interpretation of the statute as the “hypothetical test” because it bars a debtor in possession from assuming a contract if applicable law would bar assignment by a hypothetical third party.¹⁹¹ By contrast, several courts and commentators believe that this interpretation conflicts with other aspects of the Bankruptcy Code, overlooks the legislative history of the Act, and

186. See *Gardner v. Nike, Inc.*, 279 F.3d 774 (9th Cir. 2002).

187. See *In re Golden Books Family Entm't, Inc.*, 269 B.R. 311, 318-19 (Bankr. D. Del. 2001); *In re Patient Educ. Media, Inc.*, 210 B.R. 237 (Bankr. S.D.N.Y. 1997).

188. 11 U.S.C. § 365(c) (2000) (emphasis added).

189. The courts agree that § 365(c)'s use of the term “trustee” includes Chapter 7 trustees and Chapter 11 debtors in possession. See *Perlman v. Catapult Entm't (In re Catapult Entm't)*, 165 F.3d 747, 750 (9th Cir. 1999), *cert. dismissed*, 528 U.S. 924 (1999); *Institut Pasteur v. Cambridge Biotech Corp.*, 104 F.3d 489, 492 n.7 (1st Cir. 1997); *City of Jamestown v. James Cable Partners, L.P. (In re James Cable Partners, L.P.)*, 27 F.3d 534, 537, *reh'g denied*, 38 F.3d 575 (11th Cir. 1994); *In re W. Elec., Inc.*, 852 F.2d 79, 82 (3d Cir. 1988).

190. The plain language of section 365(c) “link[s] nonassignability under ‘applicable law’ together with a prohibition on assumption in bankruptcy.” EPSTEIN ET AL., *supra* note 55, § 5-15, at 258.

191. See *In re Catapult Entm't*, 165 F.3d at 749.

ignores the practical differences between assumption and assignment.¹⁹² These authorities advocate the use of an “actual test” for determining whether an executory contract may be assumed: the statute bars assumption by the debtor in possession only where the reorganization in question results in the nondebtor *actually* having to accept performance from a third party.

The controversy boils down to disagreement over statutory interpretation. The courts adhering to the hypothetical test conclude that the “statute speaks clearly, and its plain language does not produce a patently absurd result or contravene any clear legislative history.”¹⁹³ In their view, Congress should be held “to its words.”¹⁹⁴ The courts adopting and commentators advocating the actual test find several troubling incongruities in the statute.¹⁹⁵ The legislative history, although imprecise and complicated by the hasty passage of the relevant provisions, tends to buttress the argument that the protection afforded against unconsented assignment was not intended to apply to assumption of executory contracts by debtors in possession.¹⁹⁶

192. See *Institut Pasteur*, 104 F.3d at 492 n.7; *Summit Invest. & Dev. Corp. v. Leroux (In re Leroux)*, 69 F.3d 608, 612 (1st Cir. 1995); *Texaco Inc. v. La. Land & Expl. Co.*, 136 B.R. 658, 668-71 (M.D. La. 1992); *In re Cardinal Indus., Inc.*, 116 B.R. 964, 976-82 (Bankr. S.D. Ohio 1990); EPSTEIN ET AL., *supra* note 55, § 5-15, at 258-59; 3 LAWRENCE P. KING, COLLIER ON BANKRUPTCY § 365.06[1][d][iii] (15th ed. rev. 2006); Bussel & Friedler, *supra* note 72.

194. *In re Catapult Entm't*, 165 F.3d at 754.

194. See *id.*; *In re Sunterra Corp.*, 361 F.3d 257, 262 n.9 (4th Cir. 2004). *But cf. In re Supernatural Foods, L.L.C.*, 268 B.R. 759 (Bankr. M.D. La. 2001) (questioning the analysis in *In re Catapult Entm't*).

195. As articulated by the court in *In re Cardinal Indus.*, 116 B.R. at 977, subsection 365(f)(2)(A) requires that a trustee must first be able to assume an executory contract before it can be assigned. Yet, subsection 365(c)(1) states that a trustee may not “assume or assign” a contract if applicable non-bankruptcy law prohibits an assignment. Given the requirement of subsection 365(f)(2)(A) that a contract be assumed before it can be assigned, it would have been sufficient for Congress to have stated in subsection 365(c)(1) that a trustee may not “assume” a contract, thereby rendering the text “or assign” superfluous. The Ninth Circuit, relying on *Rieser v. Dayton Country Club Co. (In re Magness)*, 972 F.2d 689, 695 (6th Cir. 1992) (finding that subsections (c) and (f) have different scope), downplays any inconsistency in the plain meaning of the statute. *In re Catapult Entm't*, 165 F.3d at 751-53.

196. See H.R. REP. NO. 96-1195, § 27(b) (1980), noting that:

This amendment makes it clear that the prohibition against a trustee’s power to assume an executory contract does not apply where it is the debtor that is in possession and the performance to be given or received under a personal service contract will be the same as if no petition had been filed because of the personal nature of the contract.

As a result of these differing interpretations of the Bankruptcy Code, a significant split exists over whether debtors in possession can even assume executory contracts where applicable law prohibits assignment. The Third,¹⁹⁷ Fourth,¹⁹⁸ Ninth,¹⁹⁹ and Eleventh²⁰⁰ Circuits apply the hypothetical test—essentially barring assumption of executory contracts where assignment to third parties would be prohibited. The First Circuit²⁰¹ and several lower courts²⁰² apply the actual test—which determines whether an executory contract may be assumed based on the particular circumstances of the case:

The disjunctive “or” in § 365(c) is construed as the conjunctive “and.” In applying the actual test, therefore, a court must make a case-by-case inquiry into whether the nondebtor party would be compelled to accept performance from someone other than the party with whom it had originally contracted, and a debtor would not be precluded from assuming a contract unless it actually intended to assign the contract to a third party.²⁰³

The weight of scholarly opinion, emphasizing the purposes of the Bankruptcy Code, the tension between subsections (c) and (f), and the ap-

See generally EPSTEIN ET AL., *supra* note 55, § 5-15, at 258-59. This report was deemed inconclusive on legislative intent by the courts applying a plain meaning interpretation based on several factors, including that it relates to an earlier proposal that was never enacted and reflected the view of only one House of Congress. *See In re Sunterra*, 361 F.3d at 269-70; *In re Catapult Entm't*, 165 F.3d at 753-54.

197. *In re W. Elec., Inc.*, 852 F.2d 79 (3d Cir. 1988); *see also In re Access Beyond Techs., Inc.*, 237 B.R. 32 (Bankr. D. Del. 1999).

198. *In re Sunterra*, 361 F.3d at 262 n.9; *see also In re Travelot Co.*, 286 B.R. 447 (Bankr. S.D. Ga. 2002).

199. *In re Catapult Entm't*, 165 F.3d at 747.

200. *City of Jamestown v. James Cable Partners, L.P.* (*In re James Cable Partners, L.P.*), 27 F.3d 534, 537, *reh'g denied*, 38 F.3d 575 (11th Cir. 1994).

201. *Institut Pasteur v. Cambridge Biotech Corp.*, 104 F.3d 489 (1st Cir. 1997); *Summit Invest. & Dev. Corp. v. Leroux* (*In re Leroux*), 69 F.3d 608, 612 (1st Cir. 1995).

202. *See, e.g., Texaco Inc. v. La. Land & Expl. Co.*, 136 B.R. 658, 668-71 (M.D. La. 1992); *In re GP Express Airlines, Inc.*, 200 B.R. 222, 231-33 (Bankr. D. Neb. 1996); *In re Am. Ship Bldg. Co.*, 164 B.R. 358, 362-63 (Bankr. M.D. Fla. 1994); *In re Fastrax*, 129 B.R. 274, 277 (Bankr. M.D. Fla. 1991); *In re Hartec Enters., Inc.*, 117 B.R. 865, 871-73 (Bankr. W.D. Tex. 1990), *vacated on other grounds*, 130 B.R. 929 (W.D. Tex. 1991); *In re Cardinal Indus., Inc.*, 116 B.R. 964, 976-82 (Bankr. S.D. Ohio 1990).

203. *In re Sunterra*, 361 F.3d at 262 n.9 (citing *Summit Invest. & Dev. Corp. v. Leroux* (*In re Leroux*), 69 F.3d 608, 612 (1st Cir. 1995)).

parent intent of Congress as reflected in the legislative history, favors the application of the actual test.²⁰⁴

A 2002 bankruptcy court decision in a “hypothetical test” jurisdiction suggests that debtors in possession may be able to achieve the effects of the actual test through the application of another bankruptcy doctrine (the “ride through” doctrine), thereby lessening the difference between the two approaches in practice. The court in *In re Hernandez*²⁰⁵ determined that a reorganizing debtor could allow an executory contract that was neither affirmatively assumed nor rejected to pass through the bankruptcy unaffected. This so-called “ride through” doctrine originated in the pre-Bankruptcy Code case of *Consolidated Gas, Electric Light & Power Co. of Baltimore v. United Railways & Electric Co. of Baltimore*,²⁰⁶ and has since been applied by several U.S. Courts of Appeals.²⁰⁷ Since executory contracts that “ride through” the bankruptcy proceeding are not formally assumed or rejected under section 365(a) (nor addressed in a Chapter 11 plan pursuant to section 1123(b)(2)), they are not entitled to the benefits afforded by 11 U.S.C. section 365 such as insulation from ipso facto provisions (§ 365(e)) or the right to cure arrearages within a reasonable period of time (§ 365(b)). The ride through theory requires that the debtor take the benefits of the executory contract with all of the burdens, and failure to

204. See EPSTEIN ET AL., *supra* note 55, § 5-15, at 258-59 (advocating that “Congress should amend section 365(c)(1) to make clear that ‘applicable law’ prohibitions on assignment do not preclude assumption in bankruptcy” and urging courts to permit a trustee or debtor to assume a contract notwithstanding a prohibition on assignment in the “applicable law” so as to ensure a harmony between subsections (c) and (f) of section 365); 3 KING, *supra* note 192, § 365.06[1][d][iii]; Bussel & Friedler, *supra* note 72 (arguing that the “actual test” yields correct results from the point of view of bankruptcy policy and allows results in bankruptcy to effectively mirror the results outside of bankruptcy”).

205. 287 B.R. 795 (Bankr. D. Ariz. 2002).

206. 85 F.2d 799 (4th Cir. 1936).

207. See, e.g., *Stumpf v. McGee (In re O'Connor)*, 258 F.3d 392 (5th Cir. 2001); *Boston Post Rd. L.P. v. FDIC*, 21 F.3d 477, 484 (2d Cir. 1994); *Phoenix Mut. Life Ins. Co. v. Greystone III Joint Venture (In re Greystone III Joint Venture)*, 995 F.2d 1274 (5th Cir. 1991); *In re Public Service Co. of New Hampshire*, 884 F.2d 11 (1st Cir. 1989). It has also been recognized by several commentators and bankruptcy treatises. See, e.g., 3 KING, *supra* note 192, § 365.02[2][d] (“If the debtor fails to either assume or reject the contract by separate order or in its plan, it appears that the contract would continue in existence . . . if the debtor continues operating, arguably the contract passes through the bankruptcy and remains a liability of the reorganized entity.”); *Id.* § 1123.02[2]; Bussel & Friedler, *supra* note 72, at 338 n.48; Mark R. Campbell & Robert C. Haste, *Executory Contracts: Retention Without Assumption in Chapter 11—“Ride-through” Revisited*, 19 AM. BANKR. INST. J. 33 (2000); David G. Epstein & Steve H. Nickles, *The National Bankruptcy Review Commission’s § 365 Recommendations and the “Larger Conceptual Issues”*, 102 DICK. L. REV. 679, 689 (1998).

comply with the burdens results in a breach of contract that cannot be discharged in a Chapter 11 plan. It remains to be seen whether other courts will apply the ride through doctrine in these circumstances in general,²⁰⁸ whether courts will disallow the application of the doctrine where a licensor objects, and what equitable standards will be used to determine whether such “ride throughs” will be allowed in a particular case.²⁰⁹

B. Mode-Specific Analysis of Assignability of License Agreements

Section 365(c)'s exception to the Bankruptcy Code rule supporting assignability of executory contracts turns on whether non-bankruptcy law would excuse the licensor from accepting performance from or rendering performance to an entity other than the debtor. It is therefore necessary to examine mode-specific rules regarding assignability as well as the bankruptcy cases applying these rules under section 365(c).

1. Patent Licenses

As discussed in the overview of intellectual property law, the Patent Act does not expressly prohibit or limit the assignability of patent licenses. The federal courts, however, have for more than a century and a half proscribed assignment of patents without the consent of the patent owner as a matter of federal common law.²¹⁰ Building upon the constitutional principle that a patent affords its owner the right to exclude others from practicing the invention, the federal courts have viewed control of the patent to be a vital means of promoting innovation. This control is enhanced by affording the patent owner the default right to approve any transfer of a patent license. Therefore, the courts hold that the patent license, as a form

208. See Bussel & Friedler, *supra* note 72, at 338 n.48 (2000) (suggesting that utilizing the “ride through” doctrine may “avoid or mitigate the risk of forfeiting valuable rights that might be nonassumable or nonassignable under the hypothetical test construction of §§ 365(c) and (f)”).

209. The court in *In re Hernandez* reasoned that the four part test set out in *Theatre Holding Corp. v. Mauro*, 681 F.2d 102 (2d Cir. 1982), for determining whether a debtor should be permitted to delay the assumption or rejection decision serves as a useful guide for analyzing when ride through of an executory contract should be permitted. These four factors are: (1) the damage that other party to contracts would suffer, beyond compensation available under the Bankruptcy Code; (2) the importance of the contracts to the debtor's business and reorganization; (3) whether the debtor has had sufficient time to appraise its financial situation and potential value of its assets in formulating a plan; and (4) whether the exclusivity period has terminated. 287 B.R. at 806-07.

210. See generally H.H. Henry, *Assignability of Licensee's Rights under Patent Licensing Contract*, 66 A.L.R.2d 606 (2004).

personal property, is “not assignable unless expressly made so” in the licensing agreement.²¹¹

a) Nonexclusive Licenses

The bankruptcy courts have found this rule to apply under section 365(c) to block the assignment of nonexclusive patent licenses without the consent of the patent owner.²¹² While noting that the rationale for a

211. See *Lane & Bodley Co. v. Locke*, 150 U.S. 193, 195-96 (1893); *Oliver v. Rumford Chem. Works*, 109 U.S. 75, 82 (1883) (declaring that “the instrument of [a patent] license is not one which will carry the right conferred to any one but the licensee personally, unless there are express words to show an intent to extend the right to an executor, administrator, or assignee, voluntary or involuntary”); *Hapgood v. Hewitt*, 119 U.S. 226, 233-34 (1886); *Troy Iron & Nail Factory v. Corning*, 55 U.S. 193, 216 (1852) (declaring that patent licenses are not assignable without owner’s consent). For more recent affirmation of this doctrine, see *Unarco Indus., Inc. v. Kelley Co.*, 465 F.2d 1303, 1306 (7th Cir. 1972).

Several commentators have argued that the Supreme Court’s decision in *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938), abrogating the general power of the federal courts to establish common law, overrides these earlier cases. See Aaron Xavier Fellmeth, *Control Without Interest: State Law of Assignment, Federal Preemption, and the Intellectual Property License*, 6 VA. J.L. & TECH. 8 (2001); David R. Kuney, *Intellectual Property Law in Bankruptcy Court: The Search for a More Coherent Standard in Dealing with a Debtor’s Right to Assume and Assign Technology Licenses*, 9 AM. BANKR. INST. L. REV. (2001); Carole A. Quinn & R. Scott Weide, *Violation of the Erie Doctrine: Application of a Federal Common Law to Issues of Patent License Transferability*, 32 CREIGHTON L. REV. 1121 (1999); Daniel A. Wilson, *Patent License Assignment: Preemption, Gap Filling, and Default Rules*, 77 B.U. L. REV. 895 (1997). The *Erie* case itself determined that federal courts must look to state law in construing “contracts or other written instruments and especially to questions of general commercial law.” 304 U.S. at 71. The *Erie* doctrine, however, leaves room for federal courts to apply federal common law rules where a specific showing has been made that applying state law will create conflict or will pose a threat to some federal policy or interest. See *Atherton v. FDIC*, 519 U.S. 213 (1997). On this basis, subsequent federal cases have upheld the long-standing federal common law rule of non-assignability of patent licenses unless expressly provided in the agreement. See *Unarco Indus.*, 465 F.2d at 1306 (concluding that the patent “monopoly conferred by federal statute as well as the policy perpetuating this monopoly, so affects the licensing of patents, and the policy behind such licensing is so intertwined with the sweep of federal statutes, that any question with respect thereto must be governed by federal law” and therefore upholding the federal common law rule relating to the non-assignability of patent licenses); Wilson, *supra*, at 906-08. *But see* *Farmland Irrigation Co. Inc., v. Dopplmaier*, 308 P.2d 732, 740 (Cal. 1957) (applying state law favoring assignability of property interests after observing that the U.S. Supreme Court would be unlikely, in view of the modern tendency in favor of assignability, to uphold the non-assignability rule, and noting that “[n]othing in the nature of patent licenses makes the rights conferred by them necessarily so personal that the parties must have intended that they be nonassignable”).

212. See *Perlman v. Catapult Entm’t (In re Catapult Entm’t)*, 165 F.3d 747, 750 (9th Cir. 1999), *cert. dismissed*, 528 U.S. 924 (1999); *Institut Pasteur v. Cambridge Biotech*

federal common law rule barring assignability of patent licenses without licensor consent is not as strong as prior cases suggest,²¹³ the Ninth Circuit in *Everex* held that federal patent policy justifies the application of a non-assignability rule under section 365(c):

The fundamental policy of the patent system is to ‘encourag[e] the creation and disclosure of new, useful, and non-obvious advances in technology and design’ by granting the inventor the reward of ‘the exclusive right to practice the invention for a period of years’. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51(1989). Allowing free assignability—or, more accurately, allowing states to allow free assignability—of nonexclusive patent licenses would undermine the reward that encourages invention because a party seeking to use the patented invention could either seek a license from the patent holder or seek an assignment of an existing patent license from a licensee. In essence, every licensee would become a potential competitor with the licensor-patent holder in the market for licenses under the patents. And while the patent holder could presumably control the absolute *number* of licenses in existence under a free-assignability regime, it would lose the very important ability to control the *identity* of its licensees. Thus, any license a patent holder granted—even to the smallest firm in the product market most remote from its own—would be fraught with the danger that the licensee would assign it to the patent holder’s most serious competitor, a party whom the patent holder itself might be absolutely unwilling to license. As a practical matter, free assignability of patent licenses might spell the end to paid-up licenses such as the one involved in this case. Few patent holders would be willing to grant a license in return for a one-time lump-sum payment, rather than for per-use royalties, if the license could be assigned to a completely different company which

Corp., 104 F.3d 489, 492 (1st Cir. 1997); *Everex Sys., Inc. v. Cadtrak Corp. (In re CFLC, Inc.)*, 89 F.3d 673, 679-80 (9th Cir. 1996).

213. *Everex*, 89 F.3d at 678-79 (explaining that the holding in *Sola Electric Co. v. Jefferson Electric Co.*, 317 U.S. 173 (1942), that federal law preempted any state law which would estop a patent licensee from challenging a provision of the license as a violation of the Sherman Act, could better be attributed to the broad sweep of federal anti-trust policy than federal patent policy, and that the rationale of *Unarco Industries*, 465 F.2d at 1306, that the “monopoly conferred by federal statute as well as the policy perpetuating this monopoly, so affects the licensing of patents, and the policy behind such licensing is so intertwined with the sweep of federal statutes, that any question with respect thereto must be governed by federal law,” seems insupportably broad given the general rule that most questions with respect to the construction of patent licenses are governed by state law).

might make far greater use of the patented invention than could the original licensee.²¹⁴

The court further recognized that nonexclusive patent licenses are personal in nature and not property interests.²¹⁵

b) Exclusive Licenses

The assumability and assignability of exclusive patent licenses in bankruptcy is still largely an open question.²¹⁶ The underlying patent law regarding assignability of exclusive licenses has never been definitively established. And the application of such law in the bankruptcy context is as yet undeveloped.

Focusing first on the non-bankruptcy “applicable law” bearing on assignability of exclusive licenses, no authoritative federal court decision directly states whether exclusive licenses are assignable without the consent of the licensor.²¹⁷ It has long been established that unlike general questions of contract interpretation relating to patent licenses, which are governed by state law,²¹⁸ patent license assignability questions are governed by federal law in order to promote federal policies and national uniformity in the interpretation of patent law.²¹⁹

As noted previously, the federal law is clear that nonexclusive licenses cannot be assigned without consent of the licensor and that assignments of patents—the transfer of substantially all rights under the patent—generally include the right to transfer the patent to third parties. Exclusive licenses lie somewhere in between. Although not in a case directly addressing the

214. *Id.* at 679.

215. *Id.* at 679; *see also In re Alltech Plastics, Inc.*, 71 B.R. 686, 689 (“Given that the rights pursuant to a patent license are personal and nonassignable, it seems logical to conclude that the duties thereunder are also personal and nondelegable.”), *later proceeding* at 5 U.S.P.Q.2d (BNA) 1806, 1810-13 (Bankr. W.D. Tenn. 1987).

216. *See* JAY DRATLER, JR., LICENSING OF INTELLECTUAL PROPERTY § 1.06[2], at 1-55 (2001). The Ninth Circuit expressly stated in *In re Catapult Entm’t*, 165 F.3d at 750 n.3 (citing *Everex*, 89 F.3d at 679), that “we express no opinion regarding the assignability of exclusive patent licenses under federal law, and . . . we expressed no opinion on this subject in [the] *Everex* [case].”

217. Whatever the rule might be, the cases are clear that “[q]uestions with respect to the assignability of a patent license are controlled by federal law.” *PPG Indus., Inc. v. Guardian Indus. Corp.*, 597 F.2d 1090, 1093 (6th Cir. 1979). In so holding, courts generally have acknowledged the need for a uniform national rule that patent licenses are personal and non-transferable in the absence of an agreement authorizing assignment, contrary to the state common law rule that contractual rights are assignable unless forbidden by an agreement.

218. *See Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979).

219. *PPG Indus.*, 597 F.2d at 1093.

assignability of exclusive licenses, a recent Federal Circuit decision observes:

courts generally have acknowledged the need for a uniform national rule that patent licenses are personal and non-transferable in the absence of an agreement authorizing assignment, contrary to the state common law rule that contractual rights are assignable unless forbidden by an agreement.²²⁰

Authority can be found to support treating exclusive patent licenses like either nonexclusive licenses or full assignments depending upon the purpose that the law seeks to further. The most significant area in which the classification of exclusive patent licenses has arisen relates to the right to enforce patents against third party infringers, i.e., standing to sue. Patent law has traditionally limited the right to sue for infringement to the “patentee” (and successors in title to the patentee)²²¹ in order to spare potential infringers from multiple suits by several nonexclusive licensees.²²² In this limited context, courts have long held that exclusive licensees are more akin to assignees (or successors in title to a patent) and therefore have standing (jointly with the patentee) to sue alleged infringers.²²³

th[e] so-called exclusive licensee, while only licensee, comes so close to having truly proprietary interests in the patent, that the courts have held he is equitably entitled to sue on the patent, provided he joins the true proprietor of the patent in the suit.²²⁴

Since there is only one entity that may practice the invention in a particular geographic region or in a particular field of use, such a rule does not expose alleged infringers to multiple enforcement actions and protects the exclusive licensee’s substantial interest in patent enforcement, even where the patent owner is reluctant to pursue actions. In this respect, then, the assignee and the exclusive licensee are treated in similar fashion (and differently from the nonexclusive licensee).²²⁵

220. Rhone Poulenc Agro, S.A. v. DeKalb Genetics Corp., 284 F.3d 1323, 1328 (Fed. Cir. 2002).

221. 35 U.S.C. §§ 281, 100(d) (2000).

222. A.L. Smith Iron Co. v. Dickson, 141 F.2d 3, 6 (2d Cir. 1944).

223. See *Waterman v. Mackenzie*, 138 U.S. 252 (1891); *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1032 (Fed. Cir. 1995); *Phila. Brief Case Co. v. Specialty Leather Prods. Co.*, 145 F. Supp. 425 (D.N.J. 1956), *aff’d*, 242 F.2d 511 (3d Cir. 1957).

224. *Phila. Brief Case*, 145 F. Supp. at 428.

225. Some older cases treat exclusive patent licenses as “assignments” when they extend for the life of the patent. See *Heywood-Wakefield Co. v. Small*, 96 F.2d 496, 499 (1st Cir. 1938) (holding “license contract” in which patentee granted exclusive right un-

It would be a mistake, however, to carry the analogy between the assignee and the exclusive licensee beyond this limited context of standing to sue without careful consideration of the terms of the licensing agreement. The classification of patent agreements depends on the extent to which rights are granted and not the labels attached to the documents. The Federal Circuit recognizes that an exclusive licensee holds some “of the proprietary sticks from the bundle of patent rights, albeit a lesser share of rights in the patent than for an assignment and standing to sue alone [i.e., without bringing in the patent owner as a co-party].”²²⁶ The court notes elsewhere that “[a]lthough our precedent has recognized that in some circumstances an exclusive patent license may be tantamount to an assignment of title to the patent, this is so only when “the licensee holds ‘all substantial rights’ under the patent.”²²⁷ In fact, the Federal Circuit expressly recognizes limits on the assignability of rights in a license agreement as a factor weighing in favor of finding a transfer of fewer than all substantial rights.²²⁸ From this it can reasonably be inferred that the Federal Circuit perceives non-assignability (without consent) to be an attribute of exclusive licenses.

In a particular situation, the licensor might provide separate exclusive territorial licenses to hundreds or thousands of separate entities. It might also limit the duration of such licenses to months or divide the rights up across dozens of separate fields of use. Therefore, the extent to which an exclusive license mirrors an assignment of substantially all rights under

der patent to make, use, and sell invention during term of patent was an assignment); *Am. Type Founders v. Dexter Folder Co.*, 53 F. Supp. 602, 604 (S.D.N.Y. 1943) (construing an agreement granting an exclusive license for the term of the patent and reserving royalties to the patentee as an assignment and not a license); *Lamar v. Granger*, 99 F. Supp. 17, 36 (W.D. Pa. 1951) (same).

226. *Ortho Pharm.*, 52 F.3d at 1031.

227. *Rhone Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 284 F.3d 1323, 1334 (Fed. Cir. 2002) (quoting *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998)); see also *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001) (observing that an exclusive licensee receives more substantial rights in a patent than a nonexclusive licensee, but receives fewer rights than an assignee of all substantial patent rights).

228. See *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1380 (Fed. Cir. 2000); see also *Pfizer Inc. v. Elan Pharm. Research Corp.*, 812 F. Supp. 1352, 1373 (D. Del. 1993) (reasoning that express prohibition on assignment of patent license without patent holder’s consent, among other factors, precluded finding that agreement was an “assignment”); *Raber v. Pittway Corp.*, 23 U.S.P.Q.2d 1313, 1314-15 (N.D. Cal. 1992) (same). *But cf.* *Aluminum Co. of Am. v. Norton Co., Inc.*, 27 U.S.P.Q.2d 1317, 1318-19 (W.D. Pa. 1993) (holding that express prohibition on assignment of an exclusive patent license does not prevent a finding of a grant of “all substantial rights” in the subject patent thus allowing licensee to sue infringers).

the patent (geographically, temporally, and fields of use) depends very much on the actual situation.

Thus far, only one bankruptcy court has been called upon to address the assignability of exclusive patent licenses.²²⁹ In *In re Hernandez*, the licensing agreement authorized three different entities to manufacture and sell products produced using the patented process. Although it prohibited outright assignment of the license, the agreement allowed each of the licensees to sub-license others to practice the invention. The agreement allowed the licensor to grant additional licenses (two per year), but only after an initial five year moratorium on further licensing. Although the agreement certainly grants more rights than a mere covenant not to be sued for infringement, it is somewhat of a stretch to characterize the agreement as “exclusive.” Several entities were authorized to practice the invention in the same time period and territory and the licensor could, after five years, authorize additional licensees.

That being said, the court concluded that this agreement created an “exclusive license,” requiring it to address whether exclusive licenses can be assigned in bankruptcy without the consent of the licensor. The court held that the granting of an exclusive patent license, while vesting the licensee with standing to enforce the patent, did not afford the licensee the right to assign the patent. The court provided only cursory analysis of the complex issues in play and ultimately based its decision on the federal patent policy interest in affording the patentee broad control over the identity of its licensees. Going beyond the prior cases, the court seems to have acknowledged that licensors of exclusive rights may have a special interest in determining the identity of their licensees.

The court’s decision can be justified on grounds quite similar to those relied upon by the court in *Everex*.²³⁰ The Patent Act has been interpreted to afford the patentee broad discretion in the means of exploiting such right. A manufacturing patentee may choose to exploit such right entirely on its own and forgo any licensing. Inversely, a smaller inventor may choose to divide up the patent into several pieces by territory or field of use by extending several, limited exclusive licenses. For example, the patentee of a widget might grant licensee A, a well-known regional distribution company, an exclusive license to serve the northeastern states in ex-

229. See *In re Hernandez*, 285 B.R. 435 (Bankr. D. Ariz. 2002); cf. *In re Supernatural Foods, L.L.C.*, 268 B.R. 759, 798-802 (Bankr. M.D. La. 2001) (finding that any transaction that does not fit squarely within the statutory and judicial requirements for an assignment is presumptively a license, whether exclusive or not, and, that all licenses are essentially covenants not to sue).

230. 89 F.3d 673, 679 (9th Cir. 1996).

change for a sales-based royalty; licensee B, the southern states; licensee C, the Midwest; and licensee D, the West. Providing each with an exclusive license for its region enhances its incentives to exploit the market for the patented invention. Suppose that licensee A goes into bankruptcy and seeks to assign its license. If the highest bidder were the developer of a competing product, the patentee would risk losing a large share of its market if A's trustee could unload the license to this purchaser. The licensor's inability to block such an assignment would seriously jeopardize its plan to get the most out of its patented technology, undermining the overarching policy goal of the patent system. Therefore, the case for finding a federal common law of non-assignability for exclusive licenses parallels the case for nonexclusive licenses. Unless the patentee has transferred so much of the patent bundle to an exclusive licensee as to constitute an assignment, it seems appropriate for a bankruptcy court to read the non-assignability of patent license rule to apply whether or not the license agreement granted exclusive or nonexclusive rights.

c) Assumption of Licenses by Reorganized Debtors

In the First Circuit and other jurisdictions applying the "actual test" for determining whether a debtor may assume an executory contract,²³¹ the bankruptcy court must inquire into whether the licensor actually would be "forced to accept performance under its executory contract from someone other than the debtor party with whom it originally contracted."²³² In essence, the court must assess whether a debtor-in-possession that seeks to assume the contract is a legal entity materially distinct from the pre-petition debtor with whom the licensor contracted. In view of the extensive realignment of interests that occur in many Chapter 11 proceedings, this inquiry can raise complex questions.

In the most prominent such case to be decided,²³³ Institut Pasteur, a research and development company which owns various patented procedures for diagnosing HIV Virus Type 2, and Cambridge Biotech Corp. (CBC), a company that manufactures and sells HIV diagnostic kits, entered into mutual cross-license agreements whereby each acquired a non-

231. See *Summit Invest. & Dev. Corp. v. Leroux* (*In re Leroux*), 69 F.3d 608, 612 (1st Cir. 1995); *Texaco Inc. v. La. Land & Expl. Co.*, 136 B.R. 658, 668-71 (M.D. La. 1992); *In re GP Express Airlines, Inc.*, 200 B.R. 222, 231-33 (Bankr. D. Neb. 1996); *In re Am. Ship Bldg. Co.*, 164 B.R. 358, 362-63 (Bankr. M.D. Fla. 1994); *In re Fastrax*, 129 B.R. 274, 277 (Bankr. M.D. Fla. 1991); *In re Hartec Enters., Inc.*, 117 B.R. 865, 871-73 (Bankr. W.D. Tex. 1990), *vacated on other grounds*, 130 B.R. 929 (W.D. Tex. 1991); *In re Cardinal Indus., Inc.*, 116 B.R. 964, 976-82 (Bankr. S.D. Ohio 1990).

232. *Leroux*, 69 F.3d at 612.

233. *Institut Pasteur v. Cambridge Biotech Corp.*, 104 F.3d 489 (1st Cir. 1997).

exclusive perpetual license to use some of the technology patented or licensed by the other. In particular, CBC acquired the right to incorporate Institut Pasteur's HIV2 procedures into any diagnostic kits sold by CBC in the United States, Canada, Mexico, Australia, New Zealand, and elsewhere. Each cross-license prohibited the licensee from assigning or sublicensing to others, but authorized them to "extend to its Affiliated Companies the benefits of this Agreement so that such party shall remain responsible with regard [to] all [license] obligations."²³⁴

CBC filed a Chapter 11 petition and continued to operate its retroviral diagnostic testing business as debtor in possession. Its reorganization plan proposed that CBC assume the cross-licenses and continue to operate its retroviral diagnostics division utilizing Pasteur's patented HIV2 procedures, and sell all CBC stock to a large biotechnology corporation that was a direct competitor of Institut Pasteur. Institut Pasteur objected to the plan and specifically sought to block the assumption of the license, contending that the proposed sale of CBC's stock to Institut Pasteur's competitor amounted to a de facto "assignment" to a third party without its consent.

The bankruptcy court, district court, and ultimately the First Circuit ruled that the proposed sale of CBC stock to Institut Pasteur's competitor did not constitute a de facto "assignment" under the actual test, but rather was merely an assumption of the cross-licenses by the reorganized debtor under new ownership. Looking at the nature of the dealings leading up to the bankruptcy, the courts determined that the pre-petition licensing relationship between Institut Pasteur and CBC was neither "unique" nor "something in the category of a personal services contract." This analysis appears to run counter to most courts' recognition that nonexclusive patent licenses are "personal" in nature. Perhaps more importantly, the court's decision directly contradicts the primary policy purpose underlying the patent non-assignment doctrine: that the patentee should be able to control who acquires rights under its patent. Given the fact that the patentee's direct competitor gained effective legal control over the entity that assumed the license, the practical effect was that the competitor gained control of the license, precisely what patent law does not allow.²³⁵ The result in this case may also be an artifact of Massachusetts corporate law, under which

234. The agreements define an "Affiliated Company" as "an organization which controls or is controlled by a party or an organization which is under common control with a party." *Id.* at 490.

235. The courts might have been more sympathetic to Institut Pasteur had it insisted upon a provision in the cross-licensing agreements limiting or terminating CBC's rights in the event its stock ownership were to change hands. The record reveals that the parties had contracted for such a provision in other licenses between themselves. *Id.* at 494-95.

stock sales do not trigger a change in outright title and ownership of a licensee-corporation's assets (including its patent licenses).²³⁶

2. *Copyright Licenses*

a) Nonexclusive Licenses

When the assignability of nonexclusive copyright licenses first arose in a bankruptcy context, the courts could not find any direct authority on whether copyright law requires consent by the licensor. Invoking the principle that “where precedent in copyright cases is lacking, it is appropriate to look for guidance to patent law ‘because of the historic kinship between patent law and copyright law,’”²³⁷ the courts have imported the federal common law non-assignability doctrine from patent law to hold that a nonexclusive copyright license “is personal to the transferee . . . and the licensee cannot assign it to a third party without the consent of the copyright owner.”²³⁸ Therefore, a licensee cannot assign a nonexclusive copyright license without the consent of the licensor.

Without such a rule, copyright owners face many of the same risks and pitfalls as patent owners in devising a licensing regime. The risk of licensing rights being assigned without consent would undoubtedly discourage

236. *See* Seagram Distillers Co. v. Alcoholic Beverages Control Comm'n, 519 N.E.2d 276, 281 (Mass. 1988) (treating the corporation as a legal entity distinct from its shareholders). By contrast, California courts “have consistently recognized that an assignment or transfer of rights does occur through a change in the legal form of ownership of a business.” *SQL Solutions*, 1991 WL 626458, at *3 (finding that a change in stock ownership by which the licensee became a wholly-owned subsidiary of another company effected an assignment of an intellectual property license); *see also* *Trubowitch v. Riverbank Canning Co.*, 30 Cal.2d 335, 344-45 (Cal. 1947); *People ex rel. Dep't of Pub. Works v. McNamara Corp. Ltd.*, 28 Cal. App.3d 641 (Cal. Ct. App. 1972); *Sexton v. Nelson*, 228 Cal. App.2d 248, 259 (Cal. Ct. App. 1964).

237. *Harris v. Emus Records Corp.*, 734 F.2d 1329, 1333 (9th Cir. 1984) (quoting *Sony Corp. of Am. v. Universal City Studios*, 464 U.S. 417, *reh'g denied*, 465 U.S. 1112 (1984)). The historic kinship between patent and copyright law may well be appropriate in addressing the common “asset” qualities of these modes of intellectual property, but it is deeply flawed in addressing liability issues. *See* Peter S. Menell & David Nimmer, *Unwinding Sony*, 95 CALIF. L. REV. (forthcoming 2007).

238. *See Emus Records*, 734 F.2d at 1333-34 (based on 1909 Copyright Act); *In re Patient Educ. Media, Inc.*, 210 B.R. 237, 240 (Bankr. S.D.N.Y. 1997) (holding, under the 1976 Copyright Act regime, that the “conclusion and policy analysis in [*Everex*] applies with equal force in the analogous area of copyright law”); *SQL Solutions, Inc. v. Oracle Corp.*, 1991 WL 626458, at *6 (N.D. Cal. 1991); *see also* *Michaels v. Internet Entm't Group, Inc.*, 5 F. Supp. 2d 823, 834 (C.D. Cal. 1998); *Seawind v. Creed Taylor, Inc. (In re Creed Taylor, Inc.)*, 10 B.R. 265, 267-68 (Bankr. S.D.N.Y. 1981) (upholding an anti-assignment clause in an exclusive license to manufacture and distribute sound recordings in part because of the “personal nature of certain licensing arrangements”).

some efficient licensing relationships from being formed. Copyright owners sensitive to the identity of their licensees would be biased against licensing to entities that faced any significant risk of bankruptcy for fear that the works would simply wind up in the hands of the highest bidder.

b) Exclusive Licenses

Unlike the patent area, several courts have directly confronted the assignability of exclusive copyright licenses. Unfortunately, they are deeply split over their treatment.

The 1976 Copyright Act, unlike the Patent Act, specifically defines the granting of an exclusive license of any of the exclusive rights comprised in copyright as a “transfer of copyright ownership.”²³⁹ Furthermore, section 201(d)(1) of the Act states that “ownership of a copyright may be transferred in whole or in part by any means of conveyance or by operation of law.” Section 201(d)(2) provides that “[a]ny of the exclusive rights comprised in a copyright, including any subdivision of any of the rights specified by section 106, may be transferred . . . and owned separately.” Reading these provisions to provide that the holder of an exclusive license is entitled to all the rights and protections of the copyright owner to the extent of the license and the right to transfer such rights,²⁴⁰ several courts have held that the licensee under an exclusive license may freely transfer his rights.²⁴¹ A recent Ninth Circuit decision, however, reads the Copyright Act to dictate the opposite conclusion.²⁴²

The Ninth Circuit in *Gardner v. Nike* reaffirmed its prior decision that “copyright licenses (whether exclusive or not) were ‘not transferable as a matter of law’” under the 1909 Act.²⁴³ Only an assignment of the entire copyright could be assigned under the 1909 regime based on the doctrine of indivisibility²⁴⁴ and the policy concerns animating that Act. Although recognizing that the 1976 Act introduced the concept of divisibility into the Copyright Act, the court in *Gardner* read subsection 201(d)(1) narrowly to apply only to owners of the entire copyright, affording them the power to apportion their interest. It read the more specific second sentence

239. 17 U.S.C. § 101 (2000 & Supp. 2004).

240. 17 U.S.C. § 201(d)(2) (2000). *See generally* 3 NIMMER ON COPYRIGHT, *supra* note 30, § 10.02[A] (2006).

241. *See* I.A.E., Inc. v. Shaver, 74 F.3d 768, 775 (7th Cir. 1996); *In re Patient Media Educ.*, 210 B.R. at 240.

242. *See* *Gardner v. Nike, Inc.*, 279 F.3d 774 (9th Cir. 2002).

243. *Id.* at 777-78 (citing *Harris v. Emus Records Corp.*, 734 F.2d 1329, 1333 (9th Cir. 1984)).

244. The doctrine of indivisibility prohibited a copyright owner from dividing the “bundle of rights.” 3 NIMMER ON COPYRIGHT, *supra* note 30, § 10.01[A].

of subsection 201(d)(2)²⁴⁵ to limit the rights of exclusive licensees to the “protection and remedies” of the Copyright Act. On this basis, it concluded that the particular transfer right of section 201(d)(1) and the first sentence of subsection 201(d)(2) apply only to copyright owners, not exclusive licensees. The court similarly dismissed the transferability argument based on the definition of “transfer of copyright ownership” in section 101 on the statutory interpretation principle that the more specific provisions should take precedence over the more general. The court bolstered its arguments by reference to the same policies that have been found to favor non-assignability of patent licenses without licensor consent: the promotion of creativity through control of licensing by the intellectual property owner.

The upshot of this decision is that at least in the Ninth Circuit, the “applicable law” prohibits the assignment of exclusive copyright licenses without the licensor’s consent. Therefore, licensors can, under section 365(c), block the assignment of exclusive copyright licenses by debtor-licensees. Whether this decision attracts a wide following across the circuits remains to be seen.²⁴⁶ It should be noted, though, that a Second Circuit decision preceding the Ninth Circuit’s opinion construes subsection 201(d)(2) and the section 101 definition of “transfer of copyright ownership” quite similarly to *Gardner v. Nike*, although in a case resolving a dispute over the ownership of a copyright rather than assignability.²⁴⁷ In the bankruptcy context, however, the Delaware Bankruptcy Court in *In re Golden Books Family Entertainment*²⁴⁸ expressly rejected the line of rea-

245. Section 201(d)(2) provides:

Any of the exclusive rights comprised in a copyright, including any subdivision of any of the rights specified by section 106, may be transferred as provided by clause (1) and owned separately. The owner of any particular exclusive right is entitled, to the extent of that right, to all of the protection and remedies accorded to the copyright owner by this title.

17 U.S.C. § 201(d)(2).

246. The leading copyright treatise concludes that an exclusive licensee, “having acquired ‘title’ or ownership of the rights conveyed, may reconvey them absent contractual restrictions.” 3 NIMMER ON COPYRIGHT, *supra* note 30, § 10.01[B][4].

247. See *Morris v. Bus. Concepts, Inc.*, 259 F.3d 65 (2d Cir. 2001) (holding that an exclusive licensee of a certain copyright right is not a “copyright owner” under the Act).

248. 269 B.R. 311 (Bankr. D. Del. 2001). It should be noted that the court in *In re Golden Books* makes several errors in stating the Copyright Act provisions—adding an “s” to “protection” in subsection 201(d)(2) and suggesting the right to freely assign copyrights can be found in § 106. The former error may have affected its understanding of the rather nuanced statutory construction followed by the *Gardner* court, and the latter error

soning and result reached in *Gardner v. Nike*.²⁴⁹ The court found on very similar facts that the debtor-exclusive licensee of copyright rights could assign those rights without the consent of the licensor because the “applicable law” (copyright) did not excuse the licensor from accepting performance from or rendering performance to an entity other than the debtor.

3. Trademark Licenses

As with patent and copyright law, no federal or state trademark statutes expressly bar assignment or sub-licensing of trademark licenses without the licensor’s consent. Analogizing between trademark and other intellectual property regimes is perilous because trademark law is premised on preventing consumer confusion and unfair competition, not promoting innovation.²⁵⁰ The promotion of innovation may flow indirectly from protecting the association between goods and their source by building goodwill to support investment, but trademark law finds its constitutional and jurisprudential basis in ensuring the marketplace’s integrity.²⁵¹ The only court to squarely address the issue of whether a trademark can be assigned by a debtor-licensee recognized this distinction, and developed an independent rationale for barring assignment.²⁵²

Despite this different motivation, the *NCP Marketing* court noted a key similarity between trademark licenses and patent and copyright licenses, namely that a licensor has a significant interest in a licensee’s identity.²⁵³ In trademark law, this interest flows from the trademark owner’s need to protect its mark’s goodwill, value, and distinctiveness.²⁵⁴

may have based the alleged transfer right on the main rights provision of the Copyright Act rather than the more ambiguous provisions in subsections 201(d)(1) and (2).

249. The Delaware case was resolved after the lower court decision in *Gardner*, but before the Ninth Circuit affirmance (on substantially the same grounds). Therefore, the Delaware Bankruptcy Court was able to consider fully the reasoning that ultimately prevailed in the Ninth Circuit case.

250. *The Trade-Mark Cases*, 100 U.S. 82, 94-95 (1879).

251. *See generally* RESTATEMENT (THIRD) OF UNFAIR COMPETITION (1995).

252. *N.C.P. Mktg. Group, Inc. v. Blanks* (*In re NCP Mktg. Group, Inc.*), 337 B.R. 230, 235-36 (Bankr. D. Nev. 2005). An appeal in this matter is pending before the Ninth Circuit. *N.C.P. Mktg. v. BG Star Prods.*, *appeal docketed*, No. 05-17384 (9th Cir. Dec. 20, 2005). A few other bankruptcy courts had suggested trademark licenses could not be assigned without consent, but based their holdings on other grounds. *See In re Travelot Co.*, 286 B.R. 447 (Bankr. S.D. Ga. 2002); *In re Luce Indus., Inc.*, 14 B.R. 529 (Bankr. S.D.N.Y. 1981).

253. *In re NCP Mktg.*, 337 B.R. at 236 (citing *Miller v. Glenn Miller Prods.*, 318 F. Supp. 2d 923, 933 (C.D. Cal. 2004)).

254. *In re NCP Mktg.*, 337 B.R. at 236.

Nonetheless, the result is the same—“trademark rights are personal to the assignee and not freely assignable to a third party.”²⁵⁵

Trademark law’s core purpose provides a more direct basis for limiting assignability than either patent or copyright law. Whereas those innovation-focused bodies of intellectual property law support limitations on assignment through a somewhat indirect logical chain (as a means of bolstering the licensor’s control, which in turn is thought to enhance incentives to innovate), trademark law’s express doctrines prohibiting “naked licenses,” invalidating assignments of trademarks in gross (i.e., without accompanying goodwill), and requiring the policing of licensing agreements, provide direct rationales for precluding the unauthorized assignment of trademark licenses. As Professor McCarthy, author of the leading treatise on trademark and unfair competition law, observes, “Since the licensor-trademark owner has the duty to control the quality of goods sold under its mark, it must have the right to pass upon the abilities of new potential licensees.”²⁵⁶

Despite this justification for barring licensees from assigning trademarks without consent, the case law prior to *NCP Marketing* does not uniformly reach this conclusion. A smattering of cases held that a trademark license could be assigned.²⁵⁷ The case *In re Rooster, Inc.*²⁵⁸ concerned the licensing system developed by the owner of the “Bill Blass” trademark. The licensor selected a group of fifteen sublicensees—based upon extensive investigations of financial status, physical plant, key personnel, existing products, channels of distribution and marketing, “taste level,” and reputation in the industry—with whom it developed a cohesive menswear fashion line through a back-and-forth process of design and review. The licensor prepared an initial “clothing package” that included the tone and color pallet for the coming season. The sublicensees then developed a collection based upon that package and coordinated across their various choices. After the line had been approved, the sublicensees produced various items and sold them in the marketplace, providing a 7% royalty on gross sales to the licensor.

Rooster, one of the fifteen sublicensees, handled the tie collection. Although it had responsibility for researching libraries of patterns maintained by Italian silk producers to identify patterns reflecting the colors and tone

255. *Id.* (citing 4 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS § 25.33 (4th ed. rev. 2006)).

256. 4 MCCARTHY, *supra* note 255, § 25.33.

257. *See, e.g., In re Sunrise Rests.*, 135 B.R. 149 (Bankr. M.D. Fla. 1991); *In re Rooster, Inc.*, 100 B.R. 228, 231-33 (Bankr. E.D. Pa. 1989).

258. 100 B.R. 228 (Bankr. E.D. Pa. 1989).

set by the licensor, the licensor approved any pattern before it could go into production. Rooster would then manufacture and sell approved patterns with the Bill Blass trademark. After Rooster filed for bankruptcy, it sought to sell its rights under the licensing agreement to another fashion industry company. Blass objected, asserting its right to approve any such transfer. While recognizing the applicability of section 365(c) to the assignment of this contract, the court narrowed its focus to whether the licensing agreement constituted “a contract for personal services, which applicable Pennsylvania law holds as unassignable.”²⁵⁹ Notwithstanding the clear trademark license in the agreement, the court did not look to the trademark law as an independent basis for blocking the assignment of the contract. Upon concluding that the debtor’s performance under the licensing agreement did not draw “upon any special personal relationship, knowledge, unique skill or talent,”²⁶⁰ the court ruled that the license could be assigned. Because “[a]ll parties concede[d] the applicability of Pennsylvania law to this dispute,” the court never addressed whether federal trademark law would block the unconsented assignment of a license.²⁶¹

The bankruptcy court in *In re Sunrise Restaurants* followed the same reasoning, holding that Burger King could not block the assignment of a number of the debtor-licensee’s franchises because the Burger King franchise agreement was not a “personal services contract.”²⁶² The trustee proposed transfer of the agreement to a third party, to which the licensor, the holder of the Burger King trademark, objected. The franchise agreement contained a strict anti-assignment clause. In analyzing the licensor’s objection to the assignment, the court focused solely on whether the agreement was “personal” in nature—i.e., whether it was based on special knowledge, skill, or talent of the licensee. The court did not consider the assignability of the trademark. The court approved the assignment on the grounds that the franchise did not involve special confidence or trust between the parties, or any special judgment, task, skill, or ability on the part of the licensee.²⁶³

The entire franchise operation is based on the strict rules and conditions imposed by the contract, and no retail operator is permitted to utilize his own independent culinary skills to cook hamburgers or to serve any other food items which are not generally served in Burger King establishments according to their

259. *Id.* at 232.

260. *Id.* at 233-35.

261. *Id.* at 232 n.8.

262. *In re Sunshine Rests.*, 135 B.R. at 153.

263. *Id.*

standard. This being the case, the objection by [Burger King Corporation] of the Debtor's right to assume or assign the franchise agreements and other contractual rights is without merit and must be rejected.²⁶⁴

A recent case directly analyzed section 365(c) with regard to the assignability of trademarks, but its discussion ultimately turned out to be dicta because the court ruled that no trademark license was ever granted.²⁶⁵ Travelot, the developer of a hybrid travel agency service that combined web-based travel bookings with the customized services of a pre-screened, high quality travel agent in the destination locality, entered into an agreement with CNN to provide access to its service on CNN's website. The agreement involved several stages in which the parties were to find a technology partner who could provide the technical expertise needed to connect CNN.com visitors with Travelot's service providers and local travel agents, review marketing plans, and approve the functioning of the reservation system and the web content on an agreed-upon timetable. Travelot made substantial investments based on the expectation that it would be able to introduce its service through the CNN website. When it looked as though the agreement was destined to fall through on CNN's end, Travelot filed a bankruptcy petition seeking to assume the contract in a reorganization of the venture. CNN opposed the plan, arguing that under section 365(c) it was entitled to block the assumption of the contract because it would amount to an assignment (under the hypothetical test applied in the Eleventh Circuit)²⁶⁶ without its consent in violation of applicable trademark law. After reviewing trademark law authority on assignability, the court concluded that a "licensor need not accept performance from or render performance to an entity other than the licensee."²⁶⁷ Nonetheless, the court ultimately permitted the assumption of the contract on the ground that the licensing agreement did not in fact grant Travelot a license to use the CNN trademark.²⁶⁸

The case that comes closest to actually applying the background principles of trademark law to block an assumption of a trademark involved a license to manufacture and sell products under the well-known "Fruit of the Loom" mark by a debtor-licensee.²⁶⁹ Under the license, Fruit of the

264. *Id.*

265. *In re Travelot Co.*, 286 B.R. 447 (Bankr. S.D. Ga. 2002).

266. *See City of Jamestown v. James Cable Partners, L.P. (In re James Cable Partners, L.P.)*, 27 F.3d 534, 537, *reh'g denied*, 38 F.3d 575 (11th Cir. 1994).

267. 286 B.R. at 455.

268. *Id.* at 455-58.

269. *In re Luce Indus., Inc.*, 14 B.R. 529 (Bankr. S.D.N.Y. 1981).

Loom reserved the right to approve any subcontractors and to inspect the quality of goods manufactured under its license. Prior to the bankruptcy, the licensee had subcontracted to a manufacturer approved by the licensor. As part of its plan to reorganize, the debtor sought to assume the license and subcontract the manufacturing and sale of the goods to a different subcontractor that was neither approved nor consented to by Fruit of the Loom. These goods would be sold directly by the subcontractor, which would first recoup the money spent on manufacturing, remit the license fees directly to Fruit of the Loom, and reserve the remaining profit, if any, for the debtor. At Fruit of the Loom's request, the court rejected this plan on the grounds that the arrangement amounted to a "court-directed assignment of a non-assignable license agreement" and that the licensor would not be "adequately assured of future performance" because the licensee would maintain no office, showroom, sales staff, or "leadership," and because the licensor would have no direct enforcement rights against the subcontractor.²⁷⁰ While reflecting the principles underlying section 365(c), the court did not actually apply this provision or section 365(f) relating to the continued enforceability of an anti-assignment clause. Rather, the court viewed the case through the lens of section 365(b) and based its decision on the licensee's inability to provide "adequate assurance of future performance under the contract."

A line of cases addressing the transfer of automobile dealership franchise agreements also overlooks the role of trademark law in deciding whether to allow assignment,²⁷¹ although most of these cases can be distinguished on the ground that state dealership transfer statutes prohibit an automobile manufacturer from unreasonably withholding consent to a transfer.²⁷² Trademark licenses obviously serve a core function in the au-

270. *Id.* at 531-32; *see also In re W. Elec., Inc.*, 852 F.2d 79, 82-84 (3d Cir. 1988) (holding that assumption of license agreement by bankrupt contractor as debtor-in-possession was not permitted, due to contractor's changed circumstances).

271. *See, e.g., Leonard v. Gen. Motors Corp. (In re Headquarters Dodge, Inc.)*, 13 F.3d 674, 683 (3d Cir. 1993); *In re Pioneer Ford Sales, Inc.*, 729 F.2d 27, 30 (1st Cir. 1984) (refusing to approve transfer because Ford had a reasonable basis for objecting to proposed transferee); *Ford Motor Co. v. Claremont Acquisition Corp. (In re Claremont Acquisition Corp.)*, 186 B.R. 977, 991 (Bankr. C.D. Cal. 1995) (reversing order compelling assignment of GM franchise but affirming order compelling assignment of Ford franchise), *aff'd*, 113 F.3d 1029 (9th Cir. 1997); *In re Tom Stimus Chrysler-Plymouth, Inc.*, 134 B.R. 676, 679 (Bankr. M.D. Fla. 1991); *In re Van Ness Auto Plaza, Inc.*, 120 B.R. 545, 550 (Bankr. N.D. Cal. 1990) (upholding manufacturer's withholding of consent to transfer dealership).

272. *See, e.g., CAL. VEH. CODE* § 11713.3(e) (West 2000). Such statutes seek to protect the licensors'/car manufacturers' interest in controlling their brand while maximizing the value of the bankrupt licensee's estate. *Ford Motor Co. v. Claremont Acquisition*

tomobile dealership business. Many consumers consider the brand of automobile for which they are shopping to be a primary factor in choosing where to shop. Therefore, a strict application of section 365(c) would allow the licensor to block the transfer of a dealership to another entity to the extent that the manufacturer's trademark was part of the transfer. In some states, however, statutes specifically address the transferability of automobile dealership franchises,²⁷³ although this raises the question of which law—the trademark law or the state dealership transfer laws—takes precedence under section 365(c).

In summary, trademark law generally bars the assignment of licenses without the licensor's consent. Nevertheless, several bankruptcy courts have applied alternative standards to determine whether assignments involving trademark licenses should be allowed. Two justifications drive these cases. The first set of cases analyzes assignability only under the law of personal service contracts and fails to consider trademark law principles.²⁷⁴ The second set of cases appears to stem from a concern that the trademark license is but one aspect of the debtor's business and that blocking assignment could impose particularly harsh effects upon the bankruptcy estate. This second justification leads the courts to apply general equitable standards.²⁷⁵ The opinions appear to be trying to determine the

Corp. (*In re Claremont Acquisition Corp.*), 186 B.R. 977, 983-84 (Bankr. C.D. Cal. 1995), *aff'd*, 113 F.3d 1029 (9th Cir. 1997); *In re Van Ness Auto Plaza*, 120 B.R. at 548-49. Not all of the cases dealing with this issue arise in states with such statutes, however. See *In re Bronx-Westchester Mack Corp.*, 20 B.R. 139, 143 (Bankr. S.D.N.Y. 1982) (permitting the assignment of a "Mack" truck dealership over the licensor's objection).

273. See, e.g., CAL. VEH. CODE § 11713.3(d)(1) (West 2000); FLA. STAT. ANN. § 320.643(1)(a) (West 2007); IND. CODE § 9-23-3-11 (2007); R.I. GEN. LAWS § 31-5.1-4(c)(7) (2006); ARK. CODE ANN. § 4-72-205 (West 2007); N.J. STAT. ANN. § 56:10-6 (West 2007); see also Michelle Morgan Harner, Carl E. Black & Eric R. Goodman, *Debtors Beware: The Expanding Universe of Non-Assumable/Non-Assignable Contracts in Bankruptcy*, 13 AM. BANKR. INST. L. REV. 187, 226-31 (2005); Elaine D. Ziff, *The Effect of Corporate Acquisitions on the Target Company's License Rights*, 57 BUS. LAW. 767, 782 (2002); Gary Michael Brown, Note, *State Motor Vehicle Franchise Legislation: A Survey and Due Process Challenge to Board Composition*, 33 VAND. L. REV. 385 (1980); STEWART MACAULAY, LAW AND THE BALANCE OF POWER: THE AUTOMOBILE MANUFACTURERS AND THEIR DEALERS (1966).

274. See *In re Lil' Things, Inc.*, 220 B.R. 583, 587-88 (Bankr. N.D. Tex. 1998) (explaining why courts initially misunderstood the scope of "applicable law" under section 365(c)); *In re Sunrise Restaurants, Inc.*, 135 B.R. 149 (Bankr. M.D. Fla. 1991); *In re Tom Stimus Chrysler-Plymouth, Inc.*, 134 B.R. 676 (Bankr. M.D. Fla. 1991); *Varisco v. Oroweat Food Co. (In re Varisco)*, 16 B.R. 634 (Bankr. M.D. Fla. 1981); *In re Taylor Mfg., Inc.*, 6 B.R. 370 (Bankr. N.D. Ga. 1980).

275. See Celia F. Rankin, *Intellectual Property Licenses and Bankruptcy*, 32 COLO. LAW. 63, 65 (2003); Neil S. Hirshman, Michael G. Fatall & Peter M. Spingola, *Assigna-*

extent to which the trademark license is truly personal in nature—i.e., whether there are objective standards for ensuring that the trademark owner will not be hurt by a third party acquiring the license.²⁷⁶ If such standards exist, then the court can assure itself that the licensor will not be unduly injured by a change in the identity of the licensee. Given the structure of section 365(c) and the applicable trademark law, however, it is difficult to square these cases with the Bankruptcy Code.

4. Trade Secret Licenses

Trade secret licenses, by their very nature, specify clearly the parties with whom information may be shared and preclude disclosure of information to others. Since disclosure by the licensee would destroy the secrecy essential to this form of intellectual property, the licensor necessarily gives careful consideration to the risks posed by sharing the information with a particular potential licensee, and the licensee receives the secret information under conditions of trust and confidence. This agreement is highly personal in nature, so it seems likely that trade secret law would bar assignment of trade secret licenses without the consent of the licensor.²⁷⁷ Perhaps not surprisingly, there are no cases applying section 365(c) to know-how licenses.²⁷⁸

bility of Intellectual Property Licenses in Bankruptcy: Navigating the Murky Waters of Section 365, INTELL. PROP. LAW NEWSL., Fall 2002, at 15; Ziff, *supra* note 273, at 779-83.

276. The court in *Bronx-Westchester* permitted the assumption of a truck dealership on the following reasoning:

[Section] 365(c)(1)(A) bars a debtor from assigning an executory contract if applicable law excuses a party from accepting performance from or rendering performance to the debtor. This provision relates to executory contracts that are personal in nature. A distributorship or franchise agreement which does not depend upon a special relationship between the parties is not within the reach of this exception. *In re Varisco*, 16 B.R. 634 (Bankr. M.D. Fla. 1981). In the instant case, as in the *Varisco* case, the original distributorship agreement with Mack Trucks, Inc. was entered into with the debtor's predecessor. The debtor acquired the dealership by purchase. There is no special personal relationship between the parties to the contract in question other than the dealer's ability to sell Mack Trucks and support the operations called for under the contract.

In re *Bronx-Westchester Mack Corp.*, 20 B.R. at 142.

277. See RAYMOND T. NIMMER, 2 INFORMATION LAW § 11:163 (2004). In a California Supreme Court decision from a half century ago, however, Justice Traynor emphasized California's strong public policy favoring the free assignability of contracts (including licenses) and held that such public policy should apply to trade secret and patent licenses notwithstanding federal cases to the contrary. See *Farmland Irrigation Co. v.*

C. Avoiding Opportunism and Promoting Debtor Estate Value in the Licensee Bankruptcy Context

From an economic standpoint, licensee bankruptcy poses two opportunism problems. First, the trustee or debtor estate may be able to obtain an unjustified elevated price for an IP license by selling it to an unsuitable third party. Second, a licensor might unreasonably withhold consent to a wealth-enhancing assignment of an IP license in order to extract goodwill associated with the debtor's business.

1. *Assignment to Hostile Third Party or Retention by Hostile Debtor*

Following bankruptcy, the trustee or debtor estate seeks to maximize the value of the remaining assets or prospective value of the reorganized enterprise. Where the estate holds intellectual property licenses, the goal will be to assign or deploy the licenses in such a way to maximize its value from the standpoint of the estate. At auction, the intellectual property license may be of most value to a less scrupulous enterprise than the debtor, and quite possibly an entity that the licensor would not have contracted with or would have demanded more favorable terms from. In the worst case scenario, the licensee might sell an exclusive license to the licensor's prime competitor. The competitor might suppress or shut down sales of the licensed product as part of its business strategy to push the licensor from the market. Alternatively, a reorganizing debtor might retain the license but shift its business strategy in such a way as to erode or destroy the value of the intellectual property (from the intellectual property owner/licensor's perspective). The *Institut Pasteur* case arguably falls into this category.²⁷⁹ In each of these scenarios, the debtor's use of the intellectual property will likely result in an overall loss of economic value because the loss to the intellectual property owner will exceed the benefit to the bankrupt estate.

Section 365(c) provides a critical safety valve to prevent these undesirable outcomes. Unfortunately, the application of section 365(c) is confused by two ambiguities: (1) whether the hypothetical or actual test ap-

Dopplmaier, 48 Cal. 2d 208 (Cal. 1957). The aspect of the decision relating to assignability of patent licenses has since been overruled, *see* *Everex Sys., Inc. v. Cadtrak Corp. (In re CFLC, Inc.)*, 89 F.3d 673, 679 (9th Cir. 1996), discussed *supra* note 215, but the trade secret ruling has never been withdrawn or reversed. Since trade secret licenses are governed solely by state law, it is conceivable that a bankruptcy court applying California law could find trade secret licenses to be assignable even without licensor consent.

278. *See* Hirshman et al., *supra* note 275, at 16.

279. *See supra* text accompanying notes 233-236.

plies, and (2) what the interaction is between subsection (f)(1)'s nullification of anti-assignment "applicable law" and subsection (c)'s excuse under "applicable law." Congress should clarify the Bankruptcy Code to address the ex post opportunism threat to the intellectual property laws by establishing that subsection (f)(1) does not stand in the way of background applicable law that affords intellectual property owners discretion to block unauthorized assignments of licenses.²⁸⁰ Furthermore, the Code should allow IP licensors to object to retention of licenses by reorganizing debtors that pose a risk to the value of the intellectual property. To prevent this power from being used to extract greater value from the debtor-licensee than the costs imposed on the licensor, courts should approve assumption of a license when the reorganized entity will continue to operate within the circumstances under which the license was made. The courts should only disapprove when the reorganization plan so changes the use of the intellectual property as to constitute an effective assignment to an entity that the licensor would have reasonable grounds to oppose. These changes would prevent unjust enrichment by debtor estates and needless erosion or destruction of intellectual property value. In so doing, they promote the purposes of the intellectual property system without undermining the bankruptcy system.

2. *Equitable Division of Bilateral Goodwill*

The second problem is more subtle and reveals a fundamental tension between the goals of intellectual property laws (or at least trademark law) and the goals of the bankruptcy system. It is well illustrated by the automobile franchisee bankruptcy scenario discussed earlier.²⁸¹ Suppose that the Bailey family becomes a franchisee for Potter Motor Company in Bedford Falls.²⁸² Over several decades, Bailey Potter Motors develops a great reputation for its products, sales, civic responsibility, and fair dealing. Bailey Potter Motors sponsors various youth sports leagues, contributes to park clean-up efforts, and generally earns the respect of the local marketplace. Unfortunately, George Bailey's Uncle Billy, who handles accounting for the franchise, misplaces a large bank deposit, forcing the Bailey Potter Motors into bankruptcy. The trustee in bankruptcy seeks to assign

280. The Supreme Court could also provide clarity by interpreting section 365(f)(1) so as not to negate section 365(c).

281. *See supra* text accompanying note 273.

282. Old movie fans may recognize some of these parties from Frank Capra's classic film, *IT'S A WONDERFUL LIFE* (Liberty Films 1946), starring Jimmy Stewart, Donna Reed, and Lionel Barrymore.

the Potter Motors license to a reputable successor who is willing to pay top dollar to continue the Bailey Potter Motors tradition.

Even though this assignment does not pose any significant economic threat to Potter Motors Company, and would likely result in continued strong sales for the licensor in Bedford Falls, Potter Motors could block the assignment of the Bailey Potter Motors dealership on the ground that the Potter Motors trademark cannot be assigned without its consent.²⁸³ By blocking the deal, Potter Motors would be able to deprive the debtor estate of goodwill that it established over its many years in operation. It could then license another party (perhaps even the same one that the Bailey Potter Motors trustee was considering) and derive some or all of the Bailey goodwill.

This scenario seems to be part of the motivation behind the federal and state laws that protect automobile dealers against overreaching by motor vehicle manufacturers.²⁸⁴ By prohibiting manufacturers from blocking assignment of dealerships unless they can establish good cause (such as a bad credit record or lack of experience on the part of proposed assignee), the law effectively allows the goodwill earned by the franchisee to remain an asset of the estate.

This rule avoids ex post opportunism on the part of the intellectual property licensor while affording safeguards (an opportunity to question the ability of the proposed assignee) against erosion of their intellectual property interests. This rule could be generalized beyond the automobile franchise context. Whenever the debtor estate has established goodwill that an intellectual property licensor seeks to extract through unreasonable withholding of consent, a bankruptcy court should be able to allow the assignment to go forward so long as safeguards are in place to protect the intellectual property. It should be noted, however, that this dual goodwill scenario is unlikely to arise commonly. Were Congress to bestow such power to bankruptcy courts—essentially, to allow them to determine whether consent to the assignment of intellectual property licenses is being unreasonably withheld—then courts should ensure that the proposed assignee amply satisfies the licensor's criteria. Courts should be reluctant to second guess the licensor unless its own patterns of licensing suggest that it is withholding consent unreasonably.

283. *See* *Miller v. Glenn Miller Prods.*, 318 F. Supp. 2d 923, 933 (C.D. Cal. 2004) (“[A] trademark licensee may not sub-license a mark without express permission from the licensor.”); *N.C.P. Mktg. Group, Inc. v. Blanks (In re NCP Mktg. Group, Inc.)*, 337 B.R. 230, 235-36 (Bankr. D. Nev. 2005).

284. *See supra* text accompanying note 273.

V. MANAGING INVESTOR RISK: SECURITIZATION OF IP ASSETS

Investors in creative enterprises—whether they are biotechnology start-ups or Hollywood productions—face special problems in protecting their investments against business failure. In more conventional investments, the proceeds may well be devoted to the acquisition of tangible assets—such as real estate, buildings, or chattels. The investors can condition their investments on those assets being put up as collateral. Should the entity fail, the investors will at least have protection up to the value of the collateral so long as they have “perfected” their security interest under applicable state or federal law.²⁸⁵ If the claim exceeds the value of the collateral, then the remaining balance becomes part of the pool of general unsecured claims.

Although intangible assets can serve as collateral, they are typically much more difficult to identify, trace, and liquidate. In addition, they can change as a project progresses. For example, a research project may begin as a trade secret and mature into a patented invention. Uncertainty surrounding the rules for perfecting security interests in intellectual property creates problems in securing investments in creative enterprises. This Part begins with an overview of the general rules for perfecting security interests. It then examines the specific challenges of perfecting security interests in intellectual property. It concludes with several proposals for simplifying, integrating, and harmonizing the process for perfecting IP collateral.

A. UCC Article 9: Default Rules for Perfecting Security Interests

Article 9 of the Uniform Commercial Code (“UCC”) provides the primary governance regime for protecting consensual security interests in personal property. This code, which was substantially revised in the late

285. Perfecting a lien refers to the process of recording the lien pursuant to applicable law. An unperfected security interest may be valid between the contracting parties, but does not bind those who later acquire a security interest if they lack actual knowledge of the prior lien. A perfected interest serves notice on all subsequent creditors.

The bankruptcy estate honors the principle of derivative title and therefore takes property subject to all liens—perfected and unperfected. *See generally* EPSTEIN ET AL., *supra* note 55, § 3-18. The trustee can, however, avoid unperfected liens under its avoiding powers. Under section 544 of the Bankruptcy Code, the trustee in bankruptcy obtains the rights and powers of a “hypothetical lien creditor” who obtains a judicial lien as of the date of filing the bankruptcy petition. This judicial lien takes priority over the unperfected lien, thereby enabling the trustee to avoid any transfer of property of the debtor that is avoidable by such a judicial lien creditor. *See* 11 U.S.C. §§ 544(a), 545(2) (2000). Under § 547(b), the trustee can avoid perfected security interests that constitute preferential transfers.

1990s, has been adopted by every state.²⁸⁶ It seeks to provide a uniform, inexpensive, reliable, and effective process for protecting security interests.

1. *Attachment of Security Interests*

In a conventional secured transaction, a debtor borrows money in exchange for a promise to repay the loan. The lender, as a means of ensuring repayment, obtains a security agreement from the debtor by “attaching” particular assets of the debtor to serve as collateral for the debt.²⁸⁷ Article 9 permits lenders to attach not only existing tangible assets, such as inventory or equipment, but also intangibles, such as the debtor’s stream of income and intellectual property.²⁸⁸ Article 9 also allows lenders to attach future assets of the debtor, also known as “after-acquired collateral.” Secured creditors often claim all of a debtor’s assets as collateral.

The purpose of the security interest is to provide a means to satisfy the debt should the borrower default. Rather than first having to go to court to obtain a judgment, the secured creditor can simply repossess the collateral, sell it, and keep the proceeds (up to the amount due on the debt). The secured creditor also typically moves to the front of the line in a bankruptcy proceeding. This greatly disadvantages unsecured creditors, some of whom are incapable of securing their claims against the debtor (e.g., tort victims and other involuntary creditors).

2. *Perfection of Security Interests*

Sections 9-310 through 9-316 describe the steps needed to perfect a security interest. In general, the creditor must file a financing statement recording the security interest under the debtor’s name in the designated

286. The revised Article 9 became effective on July 1, 2001. All references are to the revised version of Article 9.

287. Article 9 uses the term “attach” to describe the point at which property (collateral) becomes subject to a security interest. The security interest attaches to the collateral as soon as it becomes enforceable against the debtor. UCC § 9-203(a) (2002). A security interest becomes enforceable against the debtor when value has been given by the creditor, the debtor has rights in the collateral (or power to transfer rights in the collateral to the secured creditor), and the debtor has authenticated a security agreement adequately, provided the collateral to the secured creditor (pursuant to a security agreement), or otherwise delivered a certificate (in the case of certificated security) or control of accounts (in the case of deposit accounts, electronic chattel paper, investment property, or letter-of-credit rights) to the secured creditor. UCC § 9-203(b) (2002).

288. A security interest in designated collateral also extends to proceeds received upon sale or other disposal of the collateral. UCC § 9-203(f) (2002).

state recording office.²⁸⁹ This allows subsequent prospective lenders to verify whether the property they seek to attach as collateral has already been attached by a prior creditor. The first entity to properly record a security interest generally has priority in resolving conflicting claims.²⁹⁰

3. *Federal Preemption*

Federal law can preempt state recording statutes either expressly or by implication.²⁹¹ Implied preemption can arise as either (1) conflict preemption—where compliance with both the state and the federal law is impossible or where state law frustrates the achievement of federal objectives;²⁹² or (2) field preemption—where “the scheme of federal regulation is ‘so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.’”²⁹³

The federal intellectual property statutes do not expressly preempt any state laws protecting security interests. However, the various registration and transfer recordation provisions of the federal intellectual property laws may preempt Article 9 under conflict or field preemption doctrines. To the extent the federal intellectual property laws do preempt Article 9, their provisions materially differ based on where and how they permit recordation and how they resolve priority disputes. For example, only Article 9 authorizes a secured creditor to attach present as well as future (“after-acquired”) assets, whereas the federal intellectual property recording systems protect only specifically identified, i.e., existing, property.²⁹⁴ Another

289. See UCC § 9-310(a) (2002). Form UCC-1 is used for filing a security interest with a state’s central filing office. Under the revised code, central filing is required in most situations. UCC § 9-501 (2002).

Certain security interests do not require a filing statement if they are perfected automatically upon attachment (UCC §§ 9-309, 9-315 (2002)), the occurrence of another event, (UCC §§ 9-308(d)-(g), 9-313(e)-(g), 9-315 (2002)), perfection under the law of another jurisdiction, (UCC § 9-316 (2002)), or the secured party’s taking possession or control of the collateral, (UCC §§ 9-311(a), 9-312(d)(1)-(2), 9-312(e)-(g), 9-313 (2002)). UCC § 9-310(b) (2002).

290. UCC § 9-322 (2002).

291. UCC § 9-109(c)(1) provides that Article 9 does not apply to the extent that “a statute, regulation, or treaty of the United States preempts this article.” Of course, the Supremacy Clause of the U.S. Constitution invalidates any state laws that “interfere, or are contrary to the laws of Congress.” *Gibbons v. Ogden*, 22 U.S. 1, 211 (1824).

292. See *Hillsborough County v. Automated Med. Lab., Inc.*, 471 U.S. 707, 713 (1985); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979); *Kewanee Oil v. Bicron Corp.*, 416 U.S. 470, 479 (1973); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

293. *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

294. See 17 U.S.C. § 205(c)(1) (2000) (holding recordation of a document in the Copyright Office gives notice only if “the document . . . specifically identifies the work

important difference is that the federal intellectual property statutes do not follow a strict first-to-file rule for determining priority among conflicting claimants. The Copyright Act contains a “relation-back” provision that gives a transferee a grace period for recording its interest. Under section 205 of the Copyright Act, the first (in time) transferee has priority over a second transferee (who records first) if the first transferee ultimately files within a month after execution of the transfer in the United States.²⁹⁵ Similarly, the Patent Act and the Lanham Act both afford assignees thirty days to record. These provisions expose subsequent purchasers to the risk that their title will be invalidated by a transfer that they could not have found through a diligent search of public files.

B. Intellectual Property Statutes, Pre-emption, and Article 9

Because implied preemption depends on the scope of the federal statute and regulations, whether a given federal intellectual property regime preempts Article 9 depends on each regime’s particular nuances. Therefore, we turn to an analysis of the protection of security interests on a mode-specific basis. Since the Copyright Act provides the most extensive recordation regime among the modes of federal intellectual property protection, it raises the most significant and complex questions with regard to federal preemption. We begin our analysis there and then move on to patent, trademark, and trade secret law.

1. Copyright

Although the Copyright Act does not expressly address security interests in copyrights, it does provide for a detailed system for recording transfers of copyright ownership and resolving priority disputes. As discussed earlier, the Copyright Act includes within the definition of “transfer of copyright ownership” any “assignment, mortgage, exclusive license, or any other conveyance, alienation, or hypothecation of a copyright or of any of the exclusive rights comprised in a copyright, whether or not it is limited in time or place of effect, but not including a nonexclusive license.”²⁹⁶ Section 205 creates the system for recording transfers of registered copyrights and resolving disputes.

The leading case on the preemptive interaction between the Copyright Act and Article 9 held that the Copyright Act’s recordation system pre-

to which it pertains”); *Nat’l Peregrine, Inc. v. Capitol Fed. Sav. & Loan Ass’n (In re Peregrine Entm’t, Ltd.)*, 116 B.R. 194, 203 n.10 (C.D. Cal. 1990); Paul Heald, *Resolving Priority Disputes in Intellectual Property Collateral*, 1 J. INTELL. PROP. L. 135 (1993).

295. 17 U.S.C. § 205 (2000).

296. 17 U.S.C. § 101 (2000 & Supp. 2004).

empties Article 9's with respect to registered copyrights.²⁹⁷ On the other hand, because the Copyright Act's recordation system cannot record interests in unregistered copyrights, Article 9's system for recording security interests remains intact for unregistered copyrights.²⁹⁸ In so holding, the Ninth Circuit Bankruptcy Appellate Panel explicitly overruled a series of lower court decisions that held that unregistered copyrights could not be perfected under Article 9.²⁹⁹ The only wrinkle under this bright-line rule occurs when the copyright owner (who is not the party with the security interest) chooses to register the work. At that point, the Article 9 filing no longer serves to perfect the interest and must be replaced by a recordation in the Copyright Office.³⁰⁰ While this could create disastrous gaps in the status of a security interest, the panel believed that prudent claimants will police their debtors or require registration upfront.³⁰¹ An implication of the panel's decision is that security interests in yet-to-be-created works of authorship—as would be created under “blanket liens”—can be perfected under Article 9 until their owner registers them. The court emphasized the important role that the use of security interests in works in progress can play in financing new ventures;³⁰² by permitting perfection under Article 9 for yet-to-be-created and unregistered copyrights, the court arrived at the most efficient legal regime for perfecting security interests in copyrights.³⁰³

Copyright receivables, that is, income streams derived from copyrights, present a different problem for perfecting security interests. The court in *In re Peregrine Entertainment* implicitly held that copyright law preempts state law with regard to the perfection of security interests in copyright receivables.³⁰⁴ Although the Copyright Act does not have any specific re-

297. *In re World Auxiliary Power Co.*, 303 F.3d 1120, 1128 (B.A.P. 9th Cir. 2002).

298. *Id.*

299. *Id.* at 1129-30.

300. *Id.* at 1131-32.

301. *Id.*

302. *Id.* at 1132.

303. Commentators have long criticized the inefficiencies of the Copyright Act recording system and the Copyright Office's delay in placing recorded interests into a publicly accessible database. Unlike the state recording systems established pursuant to Article 9, which indexes filings by debtor, the Copyright Office arranges records by work of authorship. Therefore, a lender seeking to perfect security interests against several works owned by the debtor must make separate filings against each work separately. Where libraries of works are taken as collateral, this can amount to hundreds of separate filings. By contrast, a single filing under Article 9 would suffice to perfect security interests against all of the works.

304. *See Nat'l Peregrine, Inc. v. Capitol Fed. Sav. & Loan Ass'n (In re Peregrine Entm't, Ltd.)*, 116 B.R. 194 (C.D. Cal. 1990).

cordation provision for proceeds of copyrights, Judge Kozinski based his decision on the ground that “a copyright entitles the holder to receive all income derived from the display of the creative work [under § 106(5)].”³⁰⁵ Following *In re Peregrine Entertainment*, the court in *In re Avalon Software Inc.* expressly held that the Copyright Act governed perfection of security interests in the proceeds of copyrights, including licenses and proceeds from licenses.³⁰⁶

Commentators have observed that these holdings reach beyond the stated purpose of Copyright Office recordation (which deals solely with transfers of property rights and not contract rights)³⁰⁷ and makes it difficult for lenders to secure debts to vendors of copyrighted works.³⁰⁸ Fortunately, a 1997 Ninth Circuit case undercuts, if not overrules, *In re Peregrine*'s holding with regard to receivables.³⁰⁹ In *Broadcast Music, Inc. v. Hirsch*, a songwriter received performance right royalties from BMI.³¹⁰ As a means of covering his debts, he assigned his rights to future royalty income to his creditors. The creditors did not record these security interests with the Copyright Office or perfect them under Article 9. The Internal Revenue Service later executed a tax lien on this same income stream. It argued that it had priority over unperfected security interests because tax liens are perfected upon assessment. The Ninth Circuit ruled, however, that no recording in the Copyright Office was required because the assignment of royalties did not constitute an assignment or transfer of an interest in copyright. The court distinguished *In re Peregrine* on the ground that *Hirsch* did not involve an assignment of a security interest in copyright, but rather “outright assignments of a right to receive royalties for the purpose of satisfying a debt.”³¹¹

Jordan, Warren, and Walt characterize the distinction that the Ninth Circuit draws between these two cases as “too glib.” They also question the accuracy of *Broadcast Music, Inc. v. Hirsch*'s interpretation of a “se-

305. *Id.* at 199.

306. See *In re Avalon Software Inc.*, 209 B.R. 517 (Bankr. D. Ariz. 1997).

307. See Raymond T. Nimmer, *Revised Article 9 and Intellectual Property Asset Financing*, 53 ME. L. REV. 287, 345 (2001).

308. See Patrick R. Barry, *Software Copyrights as Loan Collateral: Evaluating the Reform Proposals*, 46 HASTINGS L.J. 581, 594-98 (1995); ROBERT L. JORDAN, WILLIAM D. WARREN & STEVEN D. WALT, *SECURED TRANSACTIONS IN PERSONAL PROPERTY*, 443-44 (5th ed. 2000).

309. *Broad. Music, Inc. v. Hirsch*, 104 F.3d 1163, 1166 (9th Cir. 1997).

310. BMI is a performance rights organization which grants licenses to entities like television and radio stations, dance halls, hotels, and restaurants to the right to publicly perform works within its library.

311. *Broad. Music*, 104 F.3d at 1166 (9th Cir. 1997).

curity interest,” noting the rather broad definition under Article 9.³¹² Nonetheless, they opine that the implication of the decision—that security interests in copyrights would be perfected through filings pursuant to the Copyright Act and that security interests in receivables would be governed by Article 9—would represent an improvement over *In re Peregrine*’s conclusion that security interests in both copyrights and copyright receivables must be perfected in accordance with the Copyright Act from a purely administrative perspective focused on lowering the costs of recording security interests. Nevertheless, at this point it is unclear which regime applies to the perfection of security interests in receivables. Prudent lenders wishing to secure such income streams should perfect such interests through both systems in order to assure protection.³¹³

2. Patents

The Patent Act does not contain any language expressly preempting Article 9. It does, however, create a recording system, although it is substantially narrower in scope than the Copyright Act’s. While the Copyright Act system applies to “transfers” broadly defined, the Patent Act’s recording system is limited to “assignments, grants, and conveyances.”³¹⁴

It was not until 2001 that the question of whether the Patent Act preempted Article 9 reached an appellate court. In *In re Cybernetic Services, Inc.*,³¹⁵ the Ninth Circuit ruled unequivocally that because the Patent Act recording system was limited to ownership interests in patents, and not mortgages, licenses, or hypothecations, the Act does not preempt Article 9’s framework for recording security interests.³¹⁶ Therefore, at least in the Ninth Circuit, Article 9 governs the perfection of security interests in patents.³¹⁷ Outside of the Ninth Circuit, it continues to be prudent for credi-

312. JORDAN ET AL., *supra* note 308, at 444-45.

313. See generally Alice Haemmerli, *Insecurity Interests: Where Intellectual Property and Commercial Law Collide*, 96 COLUM. L. REV. 1645 (1996).

314. 35 U.S.C. § 261 (2000).

315. 252 F.3d 1039 (B.A.P. 9th Cir. 2001).

316. One commentator contends that the Ninth Circuit’s decision in *In re Cybernetic Servs., Inc.* went too far in characterizing security interests as “mere licenses” falling completely outside of section 261’s transfer protection system. See Thomas M. Ward, *The Perfection and Priority Rules for Security Interests in Copyrights, Patents, and Trademarks: The Current Structural Dissonance and Proposed Legislative Cures*, 53 ME. L. REV. 391 (2001). Based on the “subsequent purchaser or mortgagee” language of section 261, Ward argues that partial preemption should apply to enable the lien creditors who record their interest with the PTO, but fail to file under Article 9, to obtain protection against subsequent transferees.

317. See *Pasteurized Eggs Corp. v. Bon Dente Joint Venture (In re Pasteurized Eggs Corp.)*, 296 B.R. 283, 290 (Bankr. D.N.H. 2003) (adopting the *In re Cybernetic Servs.*

tors to file security interests with both the PTO and the appropriate state UCC office.³¹⁸

3. Trademarks

The Lanham Act closely parallels the Patent Act with regard to recordation, creating a system limited to assignments of ownership interests. Due to the paramount importance of protecting the link between a mark and the source of the goods or services, the assignment of a trademark may only occur along with the transfer of the goodwill associated with the mark. In other respects, the Lanham Act assignment regime mirrors the Patent Act.³¹⁹

As in the patent area, courts view the recordation provisions of the Lanham Act as limited to assignment of ownership interests. Therefore, they hold that the Lanham Act does not preempt Article 9 with regard to the perfection of security interests.³²⁰ Therefore, a security interest in a trademark must be perfected under state law, and a filing in the Patent and Trademark Office will not substitute for compliance with Article 9. The Lanham Act only governs recordation of “assignments” of trademark

analysis and concluding that filing of a security agreement with the PTO was insufficient to perfect creditor's security interest in debtor's patent, which was therefore subject to avoidance in exercise of debtor's strong-arm powers). Several lower courts reached similar conclusions prior to the Ninth Circuit's ruling. *See* City Bank & Trust Co. v. Otto Fabric, Inc., 83 B.R. 780, 782 (D. Kan. 1988); *In re* Transp. Design & Tech., Inc., 48 B.R. 635, 639 (Bankr. S.D. Cal. 1985).

318. *See* Haemmerli, *supra* note 313, at 1659.

319. *Compare* 15 U.S.C. § 1060 (2000 & Supp. 2004), with 35 U.S.C. § 261 (2000).

320. *See* Trimarchi v. Together Dev. Corp., 255 B.R. 606, 610 (Bankr. D. Mass. 2000); Joseph v. 1200 Valencia, Inc. (*In re* 199Z, Inc.), 137 B.R. 778 (Bankr. C.D. Cal. 1992) (reasoning that because the Lanham Act refers only to assignments and not to “pledges, mortgages, or hypothecations of trademarks,” a PTO filing did not perfect the creditor's security interest in a trademark); *In re* Chattanooga Choo-Choo Co., 98 B.R. 792 (Bankr. E.D. Tenn. 1989) (reasoning that the Lanham Act provides only for registration of ownership, not notice of security interests, and therefore Article 9 governs perfection of a security interest in a trademark); *In re* C.C. & Co., Inc., 86 B.R. 485, 487 (Bankr. E.D. Va. 1988) (reasoning that Congress did not intend Lanham Act to provide method for perfection of security interest in trade names, and lender had properly perfected its security interest in a trade name by filing financing statement under Virginia's UCC); *In re* Roman Cleanser Co., 43 B.R. 940 (Bankr. E.D. Mich. 1984), *aff'd*, 802 F.2d 207 (6th Cir. 1986) (interpreting only the Lanham Act); *In re* TR-3 Indus., 41 B.R. 128, 131 (Bankr. C.D. Cal. 1984) (reasoning that the omission by Congress of a registration provision for security interests in trademarks was purposeful and the recordation provision of the Lanham Act does not preempt Article 9).

rights and the attachment of a security interest is not an assignment of rights.³²¹

4. *Trade secrets*

Since trade secrets exist only under state law, there is no question of federal preemption, and therefore security interests in such assets must be perfected under state law with a UCC-1 filing. One caveat, however, is in order. As recognized by the court in *In re Avalon Software Inc.*,³²² trade secret materials often include works of authorship protected by the Copyright Act, like source code. As discussed previously, the Copyright Act preempts Article 9 with regard to registered copyrights.³²³ However, registering copyrights that contain trade secrets could present practical difficulties because the act of recording could disclose the trade secrets. This added complication reveals an additional benefit of the Ninth Circuit's decision in *In re World Auxiliary Power Co.* that the Copyright Act does not preempt Article 9 with regard to the perfection of security interests in unregistered copyrights.³²⁴ Creditors seeking to secure claims to the intellectual property embodied in source code can avoid any possible disclosure risk by simply recording the interest in a general Article 9 filing.

C. **Improving the Process for Perfecting Security Interests in Intellectual Property**

Improving the ability to securitize investments in creative ventures against intellectual property assets would reduce the risks of investment and, in so doing, promote innovation. More than a decade ago, the ABA Task Force on Security Interests in Intellectual Property observed that

The current state of the law governing security interests in intellectual property is unsatisfactory. There is uncertainty as to where and how to file, what constitutes notice of a security interest, who has priority, and what property is covered by a security interest. This area of the law is further complicated by the fact that both federal and state laws impact on these issues.³²⁵

321. *Trimarchi*, 255 B.R. at 610-11; *In re Roman Cleanser Co.*, 43 B.R. at 946.

322. 209 B.R. 517 (Bankr. D. Ariz. 1997).

323. *See supra* notes 296-313 and accompanying text.

324. 303 F.3d 1120 (9th Cir. 2002).

325. TASK FORCE ON SECURITY INTERESTS IN INTELLECTUAL PROPERTY, BUSINESS LAW SECTION, AMERICAN BAR ASSOCIATION, PRELIMINARY REPORT 1 (1992).

In March 1999, the Task Force proposed the “Federal Intellectual Property Security Act,”³²⁶ which sought to “facilitate commercial financing of enterprises based upon the security of their intellectual property” by creating a centralized federal filing system for all federally created intellectual property rights. This proposal remains on the shelf.

Several problems raise the costs and limit the efficacy of using intellectual property as collateral: confusion about whether state or federal law applies; long grace periods between registration of intellectual property and recording transfers; the morphing of intellectual property from state protection (trade secrets, unregistered copyrights) to federal protection (patents, registered copyrights). Many of these problems can be addressed through the passage of federal legislation requiring that security interests in all forms of intellectual property be centralized and integrated within a federally-administered, online, searchable database.³²⁷ The emergence of the internet along with advances in search technology³²⁸ have brought about the capacity to leapfrog over antiquated state and federal recording systems (and overlapping and sometimes conflicting rules) to a universal security interest database for all forms of intellectual property. Such a system better comports with the inherently intangible and dynamic nature of intellectual property—unlike real property or chattels, intellectual property does not typically reside in any one state and it can change over the course of its development. This approach would reduce transaction costs, enhance accessibility, and move beyond the present fragmented system.

VI. CONCLUSIONS

The intersection of intellectual property laws with the Bankruptcy Code and Article 9 produces a daunting mix of challenging and potentially conflicting legal rules. These complexities, however, can be dissected and broken down into logical decision-making frameworks. Unfortunately, several important questions remain subject to conflicting precedent or are unresolved. Nonetheless, a structured analysis with due regard to the underlying policy values of both the Bankruptcy Code and the intellectual

326. The draft legislation can be found at <http://www.abanet.org/intelprop/106legis/fipsa.html> (last visited Apr. 28, 2007).

327. One such proposal has been put forward by William J. Murphy and Thomas Ward, *supra* note 1.

328. The Patent and Trademark Office as well as the Copyright Office have moved some of their databases online. In addition, some private enterprises—LexisNexis, Westlaw, and Google (with its patent search database) have shown that the costs of assembling and making available large, online searchable databases for intellectual property have come within reach.

property law provides the basis for coherent resolution of these challenging questions. The time is ripe for Congress to revisit several of these issues in order to bring intellectual property laws and the bankruptcy system into greater harmony.

PATENT DAMAGES AND REAL OPTIONS: HOW JUDICIAL CHARACTERIZATION OF NONINFRINGEMENT ALTERNATIVES REDUCES INCENTIVES TO INNOVATE

By Jerry A. Hausman,[†] Gregory K. Leonard[‡] & J. Gregory Sidak^{‡‡}

TABLE OF CONTENTS

I. INTRODUCTION	827
II. THE CALCULATION OF PATENT DAMAGES	831
A. REASONABLE ROYALTY	831
B. LOST PROFITS	833
III. THE <i>GRAIN PROCESSING</i> DECISION	836
IV. OPTIONS AND PATENTS	839
A. FINANCIAL OPTIONS AND REAL OPTIONS	840
B. REAL OPTIONS AND <i>GRAIN PROCESSING</i>	842
C. AN EXAMPLE OF THE CHANGE IN OPTION VALUE DUE TO <i>GRAIN PROCESSING</i>	845
D. CHANGES IN THE INCENTIVES OF FIRMS TO ENGAGE IN RESEARCH AND DEVELOPMENT	846
V. LOST PROFITS IF THE INFRINGER ADOPTS A NONINFRINGEMENT ALTERNATIVE TECHNOLOGY IN THE BUT-FOR WORLD	846
A. NASH-BERTRAND COMPETITION WITH DIFFERENTIATED PRODUCTS	847
B. COURNOT COMPETITION WITH HOMOGENEOUS PRODUCTS	851
VI. CONCLUSION	852

© 2007 Jerry A. Hausman, Gregory K. Leonard, and J. Gregory Sidak

[†] MacDonald Professor of Economics, Massachusetts Institute of Technology, jhausman@mit.edu.

[‡] Vice President, NERA Economic Consulting, gregory.leonard@nera.com.

^{‡‡} Visiting Professor of Law, Georgetown University Law Center, jgsidak@aol.com.

We thank Farrell Malone, Ketan Patel, and Kelly Paulson for valuable research assistance.

The legal framework under which courts calculate patent damages changed substantially after the Federal Circuit decided *Grain Processing Corp. v. American Maize-Products Co.* in 1999. Perhaps the most important question in the typical lost profits analysis is determining the fraction of the infringing sales that constitutes lost sales to the patent holder. The answer usually depends on the set of noninfringing substitute products to which the customers of the infringing product could have turned in the but-for world, where the infringing product was not available to them. Before *Grain Processing*, the case law as a legal matter generally restricted the set of noninfringing substitute products to include only products that were actually sold in the marketplace. For example, an infringer could claim that it would have continued to sell a noninfringing product that it had actually been selling and that this product would have captured some of the infringing sales. This argument would tend to limit the patent holder's lost sales. However, the infringer could not claim that it would have developed and introduced some new noninfringing product in the but-for world and that this product would have captured some of the infringing sales. *Grain Processing* eased this restriction, allowing an infringer to claim that it would have offered a noninfringing product that, although not actually sold in the marketplace, was technically feasible at the time and could have been made commercially available relatively quickly. The *Grain Processing* decision went even further and concluded that, in the particular case at issue, the plaintiff was not entitled to lost profits because the infringer's noninfringing product would have been identical from the point of view of customers (though more costly to the infringer). Damages were therefore calculated on a reasonable royalty basis only. Although *Grain Processing* has generated much scholarly commentary, we are unaware of any article considering the factor that we see as the decision's most important economic ramification: the grant of a "free option" to the infringer. By "free option," we mean that a firm may keep its options open by using potentially infringing technology rather than technology that definitely does not infringe. Under *Grain Processing*, such a firm has the opportunity to later claim that it would have used the noninfringing technology had it known the patent was valid and infringed. Thus, by choosing the patented technology, the firm keeps its options open, although at the risk of having to pay damages once the uncertainty regarding validity and infringement is resolved. *Grain Processing* substantially decreases this risk because it diminishes the size of the damages award. If the patent is found to be valid and infringed, the firm can argue under *Grain Processing* that it would have switched to the noninfringing technology in the but-for world, effectively making the switch retroactively. *Grain Processing* thereby makes the option essentially free. By providing potential infringers with increased option value if they use the patented technology, *Grain Processing* reduces the deter-

rent effect of litigation and therefore encourages infringement. Consequently, it reduces the returns to research and development, and so also the incentives to innovate.

I. INTRODUCTION

Patent damage awards have become an increasingly important feature of business strategy in the United States over the past 20 years. Jury awards exceeding \$100 million were relatively rare before 1990 but now are common.¹ These large awards usually arise when damages have been calculated using a lost profits approach. A patent holder can lose profits to an infringer in several ways. By far the most important source of lost profits is the sales that the patent holder lost to the infringer.² Absent the infringement (often termed the “but-for” world³), the patent holder would have made some or all of the sales that the infringer made. The damages associated with these lost sales are the incremental profits that the patent holder would have made on the sales.⁴ A second important source of lost profits is what is often called “price erosion.”⁵ Here, the increased competition from the infringer can lead to decreased prices and thus decreased profits. These two sources of lost profits can both occur in a given situation and often interact with each other.⁶ Other sources of lost profits damages include the patent holder’s lost “convoyed sales” (sales of unpatented products sold in conjunction with the patented product) and lost “learning by doing” opportunities that would have led to lower marginal costs and

1. See Paul McDougall, *How to Avoid the Patent Trap*, INFORMATIONWEEK, Oct. 30, 2006, at 23 (“Before 1990, only one patent damage award larger than \$100 million had been awarded; in the past five years there have been at least 10 judgments and settlements of that size and at least four that topped \$500 million, the Coalition For Patent Fairness says.”).

2. Lost profits are at issue in every patent infringement case. Other types of damages, as described below, constitute only some fraction of lost sales because of the infringement.

3. See, e.g., *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc) (“To recover lost profits damages, the patentee must show a reasonable probability that, ‘but for’ the infringement, it would have made the sales that were made by the infringer.”).

4. See *id.*

5. See, e.g., *Vulcan Eng’g Co. v. FATA Aluminium, Inc.*, 278 F.3d 1366, 1377 (Fed. Cir. 2002) (“For price erosion damages the patentee must show that, but for the infringement, it would have been able to charge and receive a higher price It is not required that the patentee knew that the competing system infringed” (internal citations omitted)).

6. See, e.g., *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc.*, 976 F.2d 1559, 1577-80 (Fed. Cir. 1992). In the but-for world absent price erosion, a decreased quantity would be sold at the higher price.

thus higher profits for the patent holder in the absence of the infringement.⁷

By statute, a patent holder whose patent has been infringed is entitled to at least a “reasonable royalty” as damages.⁸ Thus, if the court does not award lost profits damages, it calculates damages using a reasonable royalty approach.⁹ Damages calculated under a reasonable royalty approach are typically, but not always, less than the damages calculated under a lost profits approach.¹⁰ Part II of this Article discusses the traditional methods of calculating patent damages.

The legal framework under which patent damages are calculated changed substantially after the U.S. Court of Appeals for the Federal Circuit decided *Grain Processing Corp. v. American Maize-Products Co.* in 1999.¹¹ Perhaps the most important question in the typical lost profits analysis is determining the fraction of the infringing sales that constitutes lost sales to the patent holder. The answer usually depends on the set of noninfringing substitute products to which the customers of the infringing product could have turned in the but-for world where the infringing product was unavailable to them. Before *Grain Processing*, the case law as a legal matter generally restricted the set of noninfringing substitute products to include only products that were actually sold in the marketplace. For example, an infringer could claim that it would have continued to sell a noninfringing product that it had actually been selling and that this product would have captured some of the infringing sales, which would tend to limit the patent holder’s lost sales. However, the infringer could not claim that it would have developed and introduced some new noninfringing product in the but-for world and that this product would have captured some of the infringing sales. *Grain Processing* eased this restriction on the

7. See Peter E. Strand, *Back to Bedrock: Constitutional Underpinnings Set ‘New’ Standards for Patent Infringement Causation*, 8 B.U. J. SCI. & TECH. L. 375, 449-50 (2002).

8. 35 U.S.C. § 284 (2000) (“[T]he court shall award [the patentee] damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer.”).

9. A hybrid approach is often used as well in situations where not all of the infringing sales represented lost sales to the patent holder. In that case, a lost profits approach is used to calculate damages on the infringing sales that represent lost sales to the patent holder and a reasonable royalty approach is used to calculate damages on the remaining sales.

10. This follows because the reasonable royalty is merely a fee for use of the patented item or technology, while lost sales include the market value of the final good produced with the patented item or technology.

11. See *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341 (Fed. Cir. 1999).

set of noninfringing substitutes available in the but-for world by allowing an infringer to claim that it would have offered a noninfringing product that, although not actually sold in the marketplace, was technically feasible at the time and could have been made commercially available relatively quickly. Indeed, the *Grain Processing* decision went further to conclude that, in the particular case at issue, the plaintiff was not entitled to lost profits because the infringer's noninfringing product would have been identical from the point of view of customers (though more costly to the infringer). Damages were therefore calculated on a reasonable royalty basis only. Part III of this Article describes the *Grain Processing* decision.

The *Grain Processing* decision has led to considerable law review commentary. Most of the analysis is conjecture regarding the decision's implications for future infringement cases.¹² Though some commentators note the adverse impact that *Grain Processing* could have on the incentives of would-be infringers and the likelihood of litigation,¹³ much of the commentary that evaluates *Grain Processing* applauds the decision.¹⁴ No-

12. See Mark Chretien, *The Question of Availability: Grain Processing Corp. v. American Maize-Products Co.*, 38 HOUS. L. REV. 1489, 1516 (2002) (discussing the practical impact of the decision); Susan Perng Pan, *Patent Damage Assessments After Rite-Hite and Grain Processing*, 42 J.L. & TECH. 481 (2002) (same); Margaret E. M. Utterback, *Substitute This! A New Twist on Lost Profits Damages in Patent Infringement Suits: Grain Processing Corp. v. American Maize-Products Co.*, 2000 WIS. L. REV. 909, 922-40 (2000) (discussing the opinion and potential implications on patentees and potential defendants); see also Peter E. Strand, *Back To Bedrock: Constitutional Underpinnings Set 'New' Standards for Patent Infringement Causation*, 8 B.U. J. SCI. & TECH. L. 375 (2002) (discussing the likely impact of the decision within a broader discussion of causation in infringement cases).

13. See, e.g., Michael Lambe, *Going Against the Grain?: The "Maize" of Lost Profits Awards in Grain Processing Corp. v. American Maize-Products Co.*, 79 N.C. L. REV., 1189, 1199 (2001) (arguing that *Grain Processing* gives competitors an "incentive to test the boundaries of [a] patent" and will increase litigation as a result); Kelsey I. Nix & Nicholas Vogt, *Revisiting the Test for Calculating Patent Lost Profits: Federal Circuit Cases Expand Infringer's Ability to Rebut Inference on Causation*, N.Y.L.J., Feb. 3, 2003, S7, at S14 (describing the decision as giving infringers "more flexibility to reconstruct the market to negate claims of lost profits" but arguing that the Federal Circuit set a high standard for available substitutes).

14. See, e.g., Roger D. Blair & Thomas F. Cotter, *Rethinking Patent Damages*, 10 TEX. INTELL. PROP. L.J. 1, 19 (2001) (describing the decision as consistent with the Federal Circuit's decisions in the area over the previous decade); Liane M. Peterson, *Grain Processing and Crystal Semiconductor: Use of Economic Methods in Damage Calculations Will Accurately Compensate for Patent Infringement*, 13 FED. CIR. B.J. 41, 42 (2003) (cataloguing methods of damages calculations and applauding the Federal Circuit's "openness to new methodologies"); John W. Schlicher, *Measuring Patent Damages by the Market Value of Inventions—The Grain Processing, Rite-Hite, and Aro Rules*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 503, 532 (2000) (describing *Grain Processing* as

tably, no commentary addresses what we consider to be the decision's most important economic feature: *Grain Processing*'s grant of a "free option" to the infringer—by which we mean that the infringer benefits from being able to use the patented invention without forgoing any profits or other rights to obtain the option.¹⁵

As we explain in Part IV, free options can have large economic incentive effects on rational economic decisions. We find that the grant of a free option is contrary to the basic framework of the patent system in the United States. Although it is widely appreciated how *Grain Processing* has made it more difficult for patent holders to claim lost profits damages, it is less well understood how *Grain Processing* has affected the incentives of companies to risk litigation by using patented technology (without a license) rather than to avoid infringement by using an economically inferior noninfringing technology. Whether the patent is valid and infringed is unknown until the litigation occurs. A patent only provides the patent holder with the right to sue for infringement. A court decides whether the patent is valid and infringed.

Consider a firm facing a decision between these two alternatives. If it chooses to risk litigation and use the patented technology, it retains the option to switch to the noninfringing technology if the patent is later found to be valid and infringed. Of course, the firm will be liable for damages for the period of infringement. If, on the other hand, the firm chooses to use the noninfringing technology, it will not have the opportunity to learn whether the patent is valid and infringed.¹⁶ Thus, the firm that uses the patented technology keeps its options open, although at the risk of having to pay damages once a court resolves the uncertainty regarding validity and infringement.

The *Grain Processing* decision substantially decreases the risk of litigation because it diminishes the size of the damages award. If a court finds the patent valid and infringed, the firm can argue under *Grain Processing* that it *would have switched* to the noninfringing technology in the but-for world, thereby effectively making the switch retroactively. *Grain Process-*

"achiev[ing] more sensibly the fundamental goal of the patent system"); Utterback, *supra* note 12, at 937-38 (stating that *Grain Processing* "ultimately furthers the purposes of patent law"). *But see* Chretien, *supra* note 12, at 1512-14 (criticizing *Grain Processing* and offering an alternative).

15. For a non-technical explanation of how legal rules can confer free options, see Jerry A. Hausman & J. Gregory Sidak, *A Consumer-Welfare Approach to the Mandatory Unbundling of Telecommunications Networks*, 109 YALE L.J. 417, 458 (1999).

16. It is possible that the patent holder would sue some other infringer, and the validity of the patent would be determined in that litigation. However, the question of infringement would often still remain.

ing thereby makes the option essentially free.¹⁷ This option reduces the deterrent effect of litigation and therefore encourages infringement. As a consequence, the returns to research and development fall, as do the incentives to innovate.

We also address the conclusion of the *Grain Processing* decision that lost profits were inappropriate because the infringer could have offered an essentially equivalent noninfringing product in the but-for world, albeit at a higher cost of production. As we demonstrate below, this conclusion is not economically correct because the infringer would have had economic incentives to increase its price in this situation. As a result, the patent owner would have had greater sales and profits in the but-for world than in the actual world. We conclude that lost profits should not necessarily be precluded even if the infringer could have provided a noninfringing version of its product in the but-for world.

II. THE CALCULATION OF PATENT DAMAGES

A. Reasonable Royalty

Under American law, one method used to determine the appropriate reasonable royalty for patent infringement is an analysis of the outcome of a “hypothetical licensing negotiation” between the patent owner as a willing licensor and the infringer as a willing licensee, which is assumed to have taken place at the time of the first infringement.¹⁸ Thus, one assumes that a license would always result from the hypothetical negotiation.¹⁹

17. Two possible costs of this option—switching costs and litigation expense—do not change the analysis. First, to the extent they exist, the costs would be factored into the value of the option. It is extremely unlikely that attorneys’ fees would exceed the value to the infringer of using the patented technology. Second, one can view switching costs as the infringer’s marginal cost of using the new, noninfringing technology. By assumption, the infringer has made no sunk investment to be able to exploit the patented technology; so, even setting to one side the fallacy of sunk costs, the infringer would have no abandonment of sunk investment to dissuade him from switching to the noninfringing technology.

In many cases, there are no switching costs. Technology is typically adopted during the product design process; adopting the patented technology at that point does not require a switch from another technology because no technology has been previously adopted (the product is only now being designed).

18. *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002) (“A ‘reasonable royalty’ contemplates a hypothetical negotiation between the patentee and the infringer at a time before the infringement began.” (citing *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075 (Fed. Cir. 1983))).

19. *See id.*

An economic approach to analyzing the hypothetical negotiation is to determine the bounds of the Edgeworth Box²⁰—that is, the minimum royalty that the patent holder would accept (while still being better off than without a license) and the maximum royalty the infringer would be willing to pay (while still being better off than without a license). A negotiated royalty necessarily must fall between these upper and lower bounds, which define the “bargaining range.”

The maximum royalty rate that the infringer would have been willing to pay is a function of the incremental profits that it would expect to earn by licensing the patents at issue as compared to not licensing. An important consideration is whether there exist any noninfringing “design-arounds” and the costs of implementing and using those design-arounds as compared to using the patented technology. For example, suppose that a design-around exists but would cost a certain amount to implement, would require greater ongoing marginal costs of production as compared to what could be achieved with the patented technology, and would lead to a lower quality product (and thus lower sales and a lower price) as compared to what could be achieved with the patented technology. In that case, the infringer would be willing to pay a royalty up to the increase in profits associated with the cost savings, the increased sales, and the increased price (but no more) in order to license the patented technology.

The minimum royalty that the patent holder would be willing to accept to grant a license is a function of the losses that it would sustain by licensing as compared to not licensing. For example, if the patent owner would lose other licensing opportunities when it licensed the infringer, the patent owner would demand a royalty that at least replaced the profits that these lost licensing opportunities would have generated. If the patent owner would lose sales to the infringer, the patent owner would demand a royalty that at least compensated for the loss of profits on those sales.

Once the bargaining range has been established, economic factors are used to estimate where within the bargaining range an agreement would result.²¹ In addition, American courts have adopted a list of economic and business factors, called the *Georgia Pacific*²² factors, that are used to aid in determining the amount of the reasonable royalty.

20. See HAL VARIAN, MICROECONOMIC ANALYSIS 314-15 (3d ed. 1992).

21. In principle, the Edgeworth Box can be empty, in which case the infringer cannot pay the amount lost by the patent holder and still be profitable. This situation can occur, for example, when the patent holder is a significantly lower cost producer than the infringer.

22. *Georgia-Pac. Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (setting forth fifteen evidentiary factors for consideration).

B. Lost Profits

From an economist's point of view, the purpose of a lost profits damages award in a patent case is to compensate the patent holder for the profits on sales that it lost as a result of the infringement. This economic approach comports with the Supreme Court's view that damages for patent infringement should equal "the difference between [the patent owner's] pecuniary condition after the infringement, and what his condition would have been if the infringement had not occurred."²³ To determine the amount of profits that the patent holder lost, the first step is to determine the level of profits that the patent holder would have achieved had the infringement not occurred—that is, in the world as it would have been absent the infringement. This scenario is often called the "but-for" world. Damages are equal to the difference between the but-for profits and the actual profits of the patent holder.

As discussed in Section II.A, higher profits for the patent holder in the but-for world could have resulted from, among other things, greater sales or a higher price. In calculating the but-for profits, it is important to account for any additional costs the patent holder would have incurred to make the additional sales. For example, the incremental costs required to produce and sell the additional units (including the cost of capacity expansion if needed) must be accounted for when calculating the but-for profits.

In attempting to ascertain whether to award lost profits, American courts often refer to the "*Panduit* factors," all of which must be satisfied for an award of lost profits: (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) manufacturing and marketing capability to exploit the demand, and (4) the amount of profit that would have been made.²⁴ Although the second *Panduit* factor is the primary focus of this Article, we will first discuss the other three factors.

To satisfy the first *Panduit* factor, courts require a demonstration that customers of the infringing product would have bought the patented product if the infringing product were unavailable. In many situations, the patented product will not capture all of the sales of the infringing product because some demand will go to competing noninfringing products. If the necessary data are available, one can estimate the amount of substitution using econometric methods that measure the cross elasticity of demand. The basic economic idea is that the price of the infringing product is in-

23. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 480 (1964) (quoting *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 536, 552 (1886)).

24. *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978); *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995).

creased to its “virtual price” where its demand is zero, and the econometric model is used to determine the share of its sales relative to the patent owner’s product and other competing products.²⁵

The third *Panduit* factor, which involves determining whether the patent holder had sufficient manufacturing and marketing capability to make the additional sales, usually comes down to the ability of the patent holder to expand its current operations by adding a work shift at an existing manufacturing plant to expand output or to invest in additional manufacturing capacity.²⁶ Of course, this factor may be less significant in industries such as software and other products where an output increase is relatively easy to undertake, as compared to manufacturing industries such as chemicals.

Satisfying the fourth *Panduit* factor requires the estimation of the patent holder’s incremental profit on the additional sales. As mentioned above, it is important to consider all of the potential incremental costs associated with the additional sales. Typically, one can calculate the incremental costs based on existing cost data from the patent holder.

We now consider the second *Panduit* factor, which concerns the absence of noninfringing substitutes. In principle, this factor comprises both a demand-side consideration (substitute noninfringing products already on the market) and a supply-side consideration (substitute noninfringing technologies that the infringer could have used). On the demand side, however, we know of no instance where U.S. courts have required the absence of noninfringing substitutes for an award of lost profits. Especially in an economic situation consisting of differentiated products, the relevant economic (and legal) question is not whether any noninfringing substitute product exists, but instead how much demand of the infringing product would shift to the patent holder’s product as opposed to the noninfringing substitute products. We discussed above, in the context of the first *Panduit* factor, econometric techniques that permit estimation of the substitution among these competing products.

The more difficult economic question arises on the supply side. If the use of the patented technology was not available to the infringer, what techniques could it have substituted in place of using the patent holder’s technology? In the but-for world, making this determination may be quite difficult because often no real world observations of production exist absent infringement. At one extreme, the infringer would have exited the

25. See, e.g., Jerry A. Hausman & Gregory K. Leonard, *Competitive Analysis Using a Flexible Demand Specification*, 1 J. COMPETITION L. & ECON. 279, 299 (2005).

26. See, e.g., *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 276-77 (Fed. Cir. 1985) (holding that reasonable probability that manufacturing efforts are adequate is enough).

market in the but-for world since no substitution would have been possible. This situation sometimes arises in the pharmaceutical industry because a patent may cover the chemical compound that causes a given drug to work. In this situation, it may be impossible for the infringing firm to manufacture a competing drug without violating the patent.

At the other extreme, an infringer would claim that it would have costlessly “invented around” the patented technology and produced the identical product at the same cost as using the patented technology. Whether this claim is economically rational is questionable because the infringer rationally should have shifted to the alternative technology rather than risking having to pay patent damages. This question aside, a further problem exists in ascertaining whether the alternative technology could have been used at all, since it often was not actually used in real world operations. Courts are often reluctant to credit the use of an alternative technology by the infringer when the infringer did not actually use or actively investigate the substitute technology. Otherwise, it may be extremely difficult to determine whether claimed behavior in the but-for world has a factual basis.

However, two situations do exist where it may be reasonable to assume use of an alternative noninfringing technology in the but-for world. First, the infringer may claim that in the but-for world it would have adopted the same technology used in an existing noninfringing substitute product. Where the patent is a production process patent, the cost of production using the noninfringing technology is typically higher than using the patented technology, so that lost profits would still likely result because of less price competition. We discuss this fact further below. Alternatively, where the patent involved product features, use of noninfringing technology would likely lead to a product without all of the features of the patented product. Here, both lost profits from lost sales and price erosion may occur, leading to lost profits by the patent holder.

A second and closely related situation may occur when the infringer has previously used a noninfringing technology and subsequently adopted the infringing technology. In the but-for world, the infringer can claim that it would have continued to use the noninfringing technology. However, since the infringer would adopt the infringing technology only if it led to increased profits, again the older noninfringing technology would either be higher cost or lack some of the features of the infringing product. In either situation, lost profits would arise from either lost sales or price erosion or both.

III. THE GRAIN PROCESSING DECISION

The *Grain Processing* case lasted eighteen years and went to the Federal Circuit three times—a story worthy of a latter day Dickens. Grain Processing and its infringing competitor America Maize sold large quantities of maltodextrins, which are food additives that give treated foods properties such as binding and viscosity and preserve food properties at low temperatures.²⁷ Food processors use maltodextrins in products such as drinks, cereals, and frozen foods.²⁸ Grain Processing began manufacturing and selling maltodextrins in 1969 and owned a patent, “Low D.E. Starch Conversion Products,” (“the ’194 patent”) that covered maltodextrins with particular attributes and processes for their production.²⁹

American Maize began selling maltodextrins in 1974 and sold a particular maltodextrin, Lo-Dex 10, over the entire period that Grain Processing owned the rights for the ’194 patent.³⁰ However, American Maize used four different production processes over the time period to produce Lo-Dex 10.³¹ From 1974 to 1982, American Maize used a particular process for maltodextrin production that the Federal Circuit held to infringe Grain Processing’s patent.³² In 1982, American Maize changed its process, but Grain Processing claimed that the new process also infringed its patent.³³ The Federal Circuit agreed and enjoined American Maize from continuing to use either of the infringing processes.³⁴

American Maize developed a third process to manufacture Lo-Dex 10, which it used from 1988 to 1991.³⁵ However, in 1990, Grain Processing once again claimed infringement. Overruling the district court, the Federal Circuit held that this third process infringed the ’194 patent as well.³⁶ American Maize tried a fourth time and, in only two weeks, developed yet another Lo-Dex 10 manufacturing process, albeit one with a higher cost

27. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1343 (Fed. Cir. 1999).

28. *Id.*

29. *Id.* at 1344 (citing U.S. Patent No. 3,849,194 (filed Sept. 17, 1971)).

30. *Id.*

31. *Id.* at 1344-45.

32. *Id.* The original district court decision found that American Maize did not infringe. The Federal Circuit reversed that decision. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 911 (Fed. Cir. 1988).

33. *Grain Processing Corp.*, 185 F.3d at 1345.

34. *Grain Processing Corp.*, 840 F.2d at 911.

35. *Grain Processing Corp.*, 185 F.3d at 1345.

36. *Id.* at 1346 (citing *Grain Processing Corp.*, 21 U.S.P.Q.2D (BNA) 1474 (Fed. Cir. 1991) (unpublished)).

than the preceding processes.³⁷ Grain Processing did not challenge it, and American Maize used it for six months in 1991 until the '194 patent expired.³⁸

Regarding American Maize's third process, Grain Processing claimed lost profits based on "lost sales, price erosion, and American Maize's accelerated market entry after the patent expired."³⁹ The district court denied lost profits and instead granted a reasonable royalty of 3 percent, rather than the 28 percent Grain Processing sought.⁴⁰ The court based its decision to deny lost profits on Grain Processing's failure to satisfy the second *Panduit* factor, which requires the absence of acceptable noninfringing substitutes.⁴¹ The district court ruled that American Maize could have produced a noninfringing substitute using the fourth process that it developed in 1991.⁴² Although American Maize did not actually manufacture and sell the noninfringing product until the final six months before the '194 patent expired, the district court decided that its availability in the last six months of the patent's lifetime "scotches [Grain Processing's] request for lost-profits damages."⁴³ The district court ruled that buyers found that the infringing and noninfringing products were "indistinguishable from customers' standpoint," stating that "no one argues that any customer cared a whit about the product's descriptive ratio."⁴⁴ Thus, the court set the 3 percent reasonable royalty rate on the basis of an estimate of the cost difference between the noninfringing process and the third (infringing) process.⁴⁵

Grain Processing appealed, claiming that it should have received lost profits, which presumably would have considerably exceeded the royalty based on the 3 percent rate.⁴⁶ Grain Processing's primary argument was that the district court's decision was based on "a non-infringing substitute that did not exist during, and was not developed until after, the period of

37. *Id.*

38. *Id.* at 1346-47.

39. *Id.* at 1347.

40. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 893 F. Supp. 1386, 1393 (N.D. Ind. 1995). This was a bench trial decided by Judge Frank Easterbrook of the Seventh Circuit, sitting by designation.

41. *See id.* at 1391-93.

42. *See id.* at 1391-92.

43. *See id.* at 1392. The noninfringing product was sold starting in May 1991, whereas the patent expired in November 1991. *See id.* at 1388, 1396.

44. *Id.* at 1390.

45. *Id.* at 1393.

46. *See Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1347 (Fed. Cir. 1999).

infringement.”⁴⁷ The Federal Circuit reversed the district court’s decision, ruling that, to qualify as an acceptable noninfringing substitute, the product or process must be “available or on the market at the time of infringement.”⁴⁸ The Federal Circuit remanded the case to the district court for further determination of lost profits.⁴⁹

On remand, the district court again denied lost profits to Grain Processing, holding that the noninfringing process was actually available during the period of infringement.⁵⁰ The court held that American Maize could have adopted the noninfringing process in 1979 but did not do so because it was more expensive.⁵¹ Because the products were equivalent apart from the manufacturing process, Grain Processing could not prove the *Panduit* factors, which the court interpreted as requiring “economically significant demand for a product having all . . . attributes” of the patented product.⁵² Such a demand did not exist because the noninfringing process hypothetically could have met market demand.⁵³ Since Grain Processing and American Maize were the only two manufacturers of such maltodextrins, Grain Processing would have gained most of the sales made by American Maize if American Maize was not in the market. Thus, lost profits likely would have been substantial if calculated based on lost sales.

The Federal Circuit affirmed the district court’s opinion, holding that the noninfringing product was an “acceptable substitute for the claimed invention”:⁵⁴

[A] fair and accurate reconstruction of the “but for” market also must take into account, where relevant, alternative actions the infringer foreseeably would have undertaken had he not infringed. Without the infringing product, a rational would-be infringer is likely to offer an acceptable noninfringing alternative, if available, to compete with the patent owner rather than leave the market altogether. The competitor in the “but for” marketplace is

47. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 1997 U.S. App. LEXIS 2885, at *3 (Fed. Cir. 1997) (unpublished opinion).

48. *Id.* at *5.

49. *Id.* at *7-8.

50. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 979 F. Supp. 1233, 1234-35 (N.D. Ind. 1997).

51. *Id.*

52. *Id.* at 1237.

53. *Id.*

54. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999).

hardly likely to surrender its complete market share when faced with a patent, if it can compete in some other lawful manner.⁵⁵

Reflecting on the twelve years it took American Maize to develop a noninfringing manufacturing process, the Federal Circuit held that if an alleged alternative is not on the market during the period in which the patent owner claims damages, “a trial court may reasonably infer that it was not available as a non-infringing substitute at that time.”⁵⁶ The burden then switches to the infringer who must demonstrate that the noninfringing substitute was in fact available during the infringement period.⁵⁷ “[M]ere speculation or conclusory assertions will not suffice to overcome the inference. After all, the infringer chose to produce the infringing, rather than non-infringing, product.”⁵⁸ The Federal Circuit agreed with the district court that the lower cost of the infringing process was the “sole reason” that American Maize used it.⁵⁹ Further, the Federal Circuit affirmed the district court’s ruling that the “substantial profit margins” on Lo-Dex 10 were sufficient to conclude that American Maize would have used the more costly noninfringing process without increasing its prices.⁶⁰ The Federal Circuit decided that American Maize could have used the higher cost noninfringing process throughout the period beginning in 1979, even though it actually did not use the process until 1991.⁶¹

Grain Processing marked a substantial change in the availability of lost profits as a form of patent damages. An infringer no longer has to rely on noninfringing alternatives actually sold in the marketplace, but instead the infringer can claim it could have feasibly offered a noninfringing alternative in the but-for world. As in *Grain Processing* itself, if the hypothetical noninfringing alternative that the infringer proposes is a close substitute in the eyes of consumers, the plaintiff may lose any claim to lost profits entirely.

IV. OPTIONS AND PATENTS

The U.S. patent system confers upon the patent holder the property right to exclude the use of its patented product or process for a specified period of time for the purpose of providing incentives for research and in-

55. *Id.* at 1350-51.

56. *Id.* at 1353.

57. *Id.*

58. *Id.*

59. *Id.* at 1354-55.

60. *Id.* at 1354.

61. *Id.* at 1354-55.

novation. Strictly speaking, a patent gives the holder the right to *sue* to exclude an infringer. A court, of course, may find that the patent is invalid.

One who uses the patented technology without a license to do so is subject to monetary damages to compensate the patent holder for the use of its property. In *Grain Processing*, American Maize infringed Grain Processing's patent from its issuance until six months before its expiration. Since both the district court and the Federal Circuit found "substantial profit margins" on the American Maize product,⁶² it is reasonable to conclude that a duopoly situation likely existed with no close substitute for the products at issue. Thus, if American Maize were absent from the market, it is likely that Grain Processing would have enjoyed even greater profit margins, as it would have been in a position of considerable market power (presumably monopoly power) with no close substitutes to constrain the price. In our view, the *Grain Processing* decision gives infringers such as American Maize a "free option" that discounts the optimal price for infringement and thus decreases incentives for innovation.

A. Financial Options and Real Options

Options are a significant factor in financial markets and in economic decision-making. An option gives the right, but not the obligation, to engage in the purchase or sale of a financial instrument or real property.⁶³ A call option on a stock gives the owner the right to buy a share of the stock at a specified exercise price on or before the option's expiration date.⁶⁴ A put option gives the owner the right to sell a share of the stock at a specified exercise price on or before the expiration date.⁶⁵ For example, an Intel call option for \$25 might give the owner the right, but not the obligation, to purchase 100 shares of Intel stock at \$25 per share on or before the expiration date—say, December 31, 2006. If Intel's stock exceeds \$25 on the expiration date, the owner will exercise the option. Otherwise, the option will expire without being exercised. Options are valuable. For example, on May 12, 2006, with Intel stock at about \$19, a call option with an exercise price of \$17.50 and an expiration date of June 30, 2006, sold in the market at a price of \$1.80; a call option with an exercise price of \$20 and the same expiration date sold for only \$0.35.

62. *See, e.g., id.* at 1355; *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 893 F. Supp. 1386, 1392 (N.D. Ind. 1995).

63. *See, e.g.,* RICHARD BREALEY, STEWART MYERS & F. ALLEN, *PRINCIPLES OF CORPORATE FINANCE* 597 (8th ed. 2005); JOHN C. HULL, *OPTIONS, FUTURES, AND OTHER DERIVATIVES* 6 (5th ed. 2003).

64. HULL, *supra* note 63, at 6.

65. *Id.*

Real options, which involve “real” assets instead of financial assets, are similar to and closely associated with financial options. Real options involve the opportunity, but not the obligation, to modify a project. Some common examples are the option to expand a project, to abandon a project, or to modify a technology used in a project. Real options are valuable because having an option increases flexibility if circumstances change. Thus, a firm making an investment decision will often spend extra funds to maintain flexibility because the future is always uncertain. A greater ability to adapt to future uncertain outcomes is often worth the extra expenditure. Indeed, a leading finance textbook discusses the flexibility inherent in real options under the name of “production options.”⁶⁶

Although we have stressed the value of options, government regulation can often grant free options to certain firms. For example, the Federal Communications Commission’s (FCC) application of the Telecommunications Act of 1996 required incumbent owners of telecommunications networks to rent their networks elements (for example, local loops) to new entrants on the basis of a monthly contract.⁶⁷ Although the investment in a telecommunications network is typically very long-lived and irreversible, often called a sunk and irreversible investment, the FCC permitted the new entrant to stop renting the network at any time without advance notice.⁶⁸ Thus, the FCC gave the new entrant the right, but not the obligation, to continue to rent the network elements. The FCC conferred this benefit upon new entrants often for free, since the new entrants were not required to sign a long-term contract or take on any obligation to continue renting the network element.⁶⁹ Since a free option is the transfer of value from one party to another, it will affect economic incentives. Specifically, the incumbent provider has less of an incentive to invest because the grant of a free option means that a portion of the value of its investment has been transferred to the new entrant. The telecommunications industry in the United States endured this negative effect on investment, and the FCC eventually changed its policy so as not to require incumbents to rent net-

66. BREALEY, MYERS & ALLEN, *supra* note 63, at 262.

67. *See* Telecommunications Act of 1996, 47 U.S.C. § 251(c)(3).

68. *See* Jerry A. Hausman, *The Effect of Sunk Costs in Telecommunication Regulation*, in THE NEW INVESTMENT THEORY OF REAL OPTIONS AND ITS IMPLICATIONS FOR TELECOMMUNICATIONS ECONOMICS (James Alleman & Eli Noam eds., 2002); Jerry A. Hausman, *Valuing the Effect of Regulation on New Services in Telecommunications*, 1997 BROOKINGS PAPERS ON ECON. ACTIVITY: MICROECONOMICS 1, 28-35 (1997); Hausman & Sidak, *supra* note 15.

69. *See* Telecommunications Act of 1996, 47 U.S.C. § 251(c).

work elements from their new investment in broadband telecommunications networks.⁷⁰

B. Real Options and *Grain Processing*

We now apply real options analysis to the *Grain Processing* case. To simplify the analysis, we will ignore the last six months before patent expiration, when American Maize adopted a noninfringing production process, and assume that American Maize used a production process that infringed Grain Processing's patent throughout the patent term. We further assume that American Maize never used a noninfringing process, even though such a process was known and available throughout the period of infringement. When Grain Processing sues for patent infringement and claims lost profits for damages, American Maize can claim that it could have used the noninfringing process throughout the period. We also assume, as actually happened, that the courts will deny lost profits because Grain Processing did not satisfy the second *Panduit* factor, the absence of acceptable noninfringing substitutes. Instead, Grain Processing will only receive a reasonable royalty in the event that the courts find the patent is valid and infringed. Thus, if the court finds the patent to be either invalid or not infringed, American Maize need pay no damages to Grain Processing. Alternatively, if the court holds that the patent is valid and infringed, American Maize must pay no more than a reasonable royalty.

We analyze this situation in the context of a stylized model. A firm can choose between two technologies: technology 1, which may infringe a patent, and technology 2, which is noninfringing. The firm's per period profits are π_1 if it uses technology 1 and π_2 if it uses technology 2, with $\pi_1 \geq \pi_2$. There are two periods. If the firm has chosen technology 1, at the end of period 1 it is determined whether the patent is valid and whether technology 1 infringes the patent (we assume that the costs of this determination, that is, litigation costs, are zero).⁷¹ The probability that the patent is valid and infringed by the first technology is θ . If the patent is found to be valid and infringed, the firm must switch to technology 2 in period 2 and it must pay damages in the amount D . For the purposes of this model, we assume that there is no discounting.

70. For a discussion of this outcome, see Jerry A. Hausman & J. Gregory Sidak, *Did Mandatory Unbundling Achieve Its Purpose? Empirical Evidence from Five Countries*, 1 J. COMPETITION L. & ECON. 173, 194-203 (2005).

71. Litigation costs can be included by deducting them from profits.

If the firm chooses technology 2, its total expected profits over the two periods are $2\pi_2$.⁷² If the firm chooses technology 1, its total profits are $\pi_1 + \pi_2 - D$ if the patent is found to be valid and infringed and $2\pi_1$ if the patent is found invalid or noninfringed. Thus, if the firm chooses technology 1, its total expected profits are

$$\theta(\pi_1 + \pi_2 - D) + (1 - \theta)2\pi_1 = 2\pi_1 - \theta(\pi_1 - \pi_2) - \theta D. \quad (1)$$

The firm will choose technology 1 if its expected profit from infringing is greater than its expected profit from not infringing—that is, if

$$2\pi_1 - \theta(\pi_1 - \pi_2) - \theta D \geq 2\pi_2 \quad (2)$$

or, rearranging, if

$$\frac{2 - \theta}{\theta}(\pi_1 - \pi_2) \geq D. \quad (3)$$

Thus, if the damages award D is sufficiently large, (that is, larger than the expected profit from potentially infringing), it will deter the firm from choosing the potentially infringing technology 1.

This model has the economic characteristics of a real option. In the investment context, real options considerations arise when the investment decision is at least partially irreversible (that is, some investment costs are sunk) and the decision to invest can be delayed until uncertainties are resolved.⁷⁴ Under these conditions, there is a value in waiting to sink costs until the uncertainties are resolved. This value derives from retaining flexibility (an option) to avoid sinking costs if the uncertainties resolve in an adverse fashion. In the model described above, by choosing technology 1, the firm retains the flexibility to switch to technology 2 if, when the uncertainty is resolved, the patent is found to be valid and infringed. This option is lost if the firm chooses technology 2 at the outset, a decision assumed to be irreversible.

72. We assume that the firm cannot choose technology 2 in period 1 and then switch to technology 1 in period 2 since, in a more general model, the firm would be continuously subject to an infringement lawsuit.

73. That is, (probability of infringing) * (profits if infringing) + (probability of not infringing) * (profits if not infringing).

74. AVINASH K. DIXIT & ROBERT S. PINDYCK, INVESTMENT UNDER UNCERTAINTY 6 (1994).

One cost of retaining the option is that the firm will have to pay the damages award D in the event that the patent is found to be valid and infringed. Indeed, as seen above, in principle D can be sufficiently large to make maintenance of the option unprofitable. We now turn to the question of how the *Grain Processing* decision affected the value of using technology 1 and retaining the option.

As discussed above, *Grain Processing* has made it more difficult to prove lost profits damages, which are typically larger than reasonable royalty damages. Suppose that $D = \pi_1$. Before *Grain Processing*, a damages award of this magnitude was a possible outcome in the situation where the potentially infringing firm and the patent owner were the only suppliers of the product in question. In that case, the patent owner would argue that, in the but-for world where the infringing product was not on the market, it would have made all of the infringing sales itself. If the patent owner's price was essentially the same as the potentially infringing firm's price, the patent owner's profits on these additional sales (that is, its lost profit damages) would be equal to the potentially infringing firm's profits on these sales and damages would be $D = \pi_1$.⁷⁵ With the damages award at this level, the firm may or may not choose technology 1, depending on whether inequality (3) is satisfied. For a relatively small profit differential $\pi_1 - \pi_2$ and relatively high patent strength value θ it is likely that inequality (3) will not be satisfied and the firm will be deterred from choosing potentially infringing technology 1.

After *Grain Processing*, the potentially infringing firm could claim that an award of lost profits damages is inappropriate because it could have switched to technology 2 at the outset to avoid infringement. In that case, damages would be calculated on a reasonable royalty basis. As discussed in Section II.A, the largest the reasonable royalty could be is the upper end of the Edgeworth Box, or the infringing firm's maximum willingness to pay. The maximum royalty that the infringing firm would be willing to pay each period to obtain a license to use the patented technology is $\pi_1 - \pi_2$ because for any royalty greater than this amount, the infringing firm would prefer to switch to technology 2 rather than take a license to the patent. Thus, under *Grain Processing*, $D \leq \pi_1 - \pi_2$. But, this inequality implies

$$D \leq \frac{2-\theta}{\theta}(\pi_1 - \pi_2) \quad (4)$$

75. The patent owner might additionally claim price erosion damages. In that case, $D > \pi_1$ is possible.

since $0 \leq \theta \leq 1$. Inequality (4) therefore implies that the firm will necessarily choose technology 1. In other words, the firm will not be deterred from choosing technology 1 by the prospect of having to pay the reasonable royalty damages award resulting from application of *Grain Processing*. Put another way, *Grain Processing* increases the value of the option inherent in choosing technology 1 to the point where it becomes essentially “free”—the firm would be irrational to reject it.

C. An Example of the Change in Option Value Due to *Grain Processing*

To illustrate how much of a difference *Grain Processing* makes to the value of choosing the potentially infringing technology, we performed calculations that approximate the case facts in *Grain Processing*. We assume that it takes 13 years for the patent to expire. The infringer’s revenue each year is \$100 and the profit margin when using the patented technology is 50 percent. Each year there is some probability that a finding of patent validity and infringement will occur, conditional on it not having occurred already. We assume that this “hazard rate” will be constant each year at 0.1, so that there will be an exponential density function.⁷⁶ If a finding of validity and infringement occurs, the infringer must pay damages for past infringement and switch to the alternative noninfringing technology for the remaining years; the profit margin for these years is reduced to 47 percent (to reflect the cost increase associated with using the noninfringing technology). The infringer discounts the future at a 6 percent rate.

We calculate the expected present discounted value as of year 0 of the infringer’s cash flow stream under two scenarios. In the first scenario, damages after a finding of validity and infringement are calculated under a lost profits approach. We assume in this case that the patent holder’s lost profits damages are equal to the profits that the infringer actually made. This assumption is reasonable if, in the but-for world, the patent holder would have made all of the infringing sales at the same price and profit rate as the infringer. In this scenario, the expected present discounted value of the cash flows to the infringer would be \$325.

In the second scenario, we assume that damages after a finding of validity and infringement are calculated under a reasonable royalty approach because of the application of the second *Panduit* factor under *Grain Processing*. In particular, damages are assumed to equal 3 percent of the in-

76. We could change the constant probability assumption to allow an increasing or decreasing hazard over time using a Weibull distribution. Other distributions would allow for a non-monotonic hazard. However, the general form of the results does not depend on the particular distribution chosen.

fringing revenues. In this scenario, the expected present discounted value of the infringer's cash flows is \$425. Thus, *Grain Processing* causes the value to the infringer for using the patented technology to increase by 31 percent. One would expect this change in values to have a significant effect on an infringer's decision whether to use the patented technology or avoid infringement through use of the noninfringing technology.

D. Changes in the Incentives of Firms to Engage in Research and Development

We have demonstrated how *Grain Processing* has substantially increased the incentives of firms to choose potentially infringing technologies rather than noninfringing technologies. In principle, this change in incentives can lead to greater amounts of litigation as patent owners are faced with more frequent cases of potential infringement.

Grain Processing also has changed the incentives of firms to engage in research and development (R&D). The smaller damages awards and the increased incentives on the part of potential infringers to infringe dampen the returns to R&D. As a consequence, the incentives to invest in R&D are weaker. This outcome may undermine the original goals of the U.S. patent system.⁷⁷

V. LOST PROFITS IF THE INFRINGER ADOPTS A NONINFRINGEMENT ALTERNATIVE TECHNOLOGY IN THE BUT-FOR WORLD

Until now, we have taken as given one of the underlying assumptions of the *Grain Processing* decision: that, having adopted the noninfringing alternative technology in the but-for world, American Maize would have retained its sales and the patent owner Grain Processing would have made no additional sales. This assumption underlies in part the conclusion in *Grain Processing* that damages should depend on a reasonable royalty approach rather than lost profits.

However, the assumption that American Maize would have retained all of its sales in the but-for world is inconsistent with well-established economic theory. If American Maize had switched to the noninfringing process, its marginal costs in the but-for world would have been higher by an amount approximately equal to 3 percent of the price. The *Grain Processing* decision assumes that American Maize would have absorbed the addi-

77. For a discussion of how economic returns to patents interact with the U.S. patent system's goal of increasing innovation, see Jerry A. Hausman & Jeffrey K. MacKie-Mason, *Price Discrimination and Patent Policy*, 19 RAND J. ECON. 253 (1998).

tional marginal costs and held its price at the same level it charged in the actual world. But, this course of action would not be optimal in most models of competition. Instead, American Maize's optimal response to an increase in its marginal costs would be to increase its price, which would lead to increased sales, an increased price, and increased profits for Grain Processing.

In other words, contrary to the conclusion of the *Grain Processing* decision, Grain Processing did sustain lost profits damages even under the assumption that American Maize would have turned to the alternative non-infringing process in the but-for world. We will demonstrate the extent of lost profits that the patent owner sustained in the context of two basic models of competition: Nash-Bertrand competition with differentiated products and Cournot competition with homogeneous products.⁷⁸

A. Nash-Bertrand Competition with Differentiated Products

For simplicity, we assume the case of two firms, each selling one product, although the results generalize to N firms, with each selling multiple products. The patent owner is firm 1 and the infringer is firm 2. The demand faced by firm i ($i = 1, 2$) is $Q_i(p_1, p_2)$. The marginal cost faced by firm i is c_i . (We assume that the marginal costs are constant over the relevant range of output.) The firms simultaneously set prices in a one-shot game. Firm i chooses p_i to maximize profits

$$(p_i - c_i)Q(p_i, p_j)^{79} \quad (5)$$

taking p_j as given.

We examine the resulting Nash equilibrium. Differentiating to maximize profits, the first order condition for firm i is

$$(p_i - c_i) \frac{\partial Q_i(p)}{\partial p_i} + Q_i(p) = 0. \quad (6)$$

78. See generally Jeremy I. Bulow & Paul Pfleiderer, *A Note on the Effect of Cost Changes on Prices*, 91 J. POL. ECON. 182 (1983) (showing how a monopolist optimally changes its price in response to a marginal cost change); Jerry A. Hausman & Gregory K. Leonard, *Efficiencies from the Consumer Viewpoint*, 7 GEO. MASON L. REV. 707 (1999) (showing how marginal cost efficiencies resulting from a merger lead to lower prices in the context of several models of competition). For an overview of the Nash-Bertrand and Cournot models of competition, see JEAN TIROLE, *THE THEORY OF INDUSTRIAL ORGANIZATION* 209-21 (1998).

79. That is, (price – cost) * (quantity sold at that price).

The system of two equations of form (6) (that is, one equation for each firm) implicitly define the Nash equilibrium prices as functions of the costs of both firms.

Suppose now the cost of the infringing firm 2 increases because it has to adopt the more costly alternative noninfringing process. By differentiating first order condition (6) for firm 2 with respect to c_2 (while holding p_1 constant), we can obtain the derivative $\left. \frac{\partial p_2}{\partial c_2} \right|_{p_1}$, that is, the change in firm

2's optimal choice of price resulting from the decrease in its marginal cost:

$$\left. \frac{\partial p_2}{\partial c_2} \right|_{p_1} = \frac{\frac{\partial Q_2}{\partial p_2}}{(p_2 - c_2) \frac{\partial^2 Q_2}{\partial p_2^2} + 2 \frac{\partial Q_2}{\partial p_2}}. \quad (7)$$

The numerator is negative (because demand is downward sloping) and nonzero, and the denominator is negative by firm 2's second order condition. Thus, $\left. \frac{\partial p_2}{\partial c_2} \right|_{p_1} > 0$, which establishes that firm 2 would have the in-

centive to increase its price in response to the increase in its marginal cost rather than hold its price constant.

Equation (7) describes the change in firm 2's pricing incentives holding constant the price of firm 1. However, the increase in the marginal cost of firm 2 also gives firm 1 the incentive to increase its price. Thus, in equilibrium both prices change due to the increase in the marginal cost of firm 2. The change in the equilibrium price of firm 2 can be determined by differentiating the first order condition (6) for firm 2 with respect to c_2 without holding firm 1's price constant.⁸⁰ We obtain

$$\left(\frac{\partial p_2}{\partial c_2} - 1 \right) \frac{\partial Q_2}{\partial p_2} + (p_2 - c_2) \left[\frac{\partial^2 Q_2}{\partial p_2^2} \frac{\partial p_2}{\partial c_2} + \frac{\partial^2 Q_2}{\partial p_2 \partial p_1} \frac{\partial p_1}{\partial c_2} \right] + \frac{\partial Q_2}{\partial p_2} \frac{\partial p_2}{\partial c_2} + \frac{\partial Q_2}{\partial p_1} \frac{\partial p_1}{\partial c_2} = 0. \quad (8)$$

80. For a general approach to comparative statics in this type of situation, see Avinash Dixit, *Comparative Statics for Oligopoly*, 27 INT'L ECON. REV. 107 (1986).

Note that equation (8) includes the term $\frac{\partial p_1}{\partial c_2}$, which is the change in the equilibrium price of firm 1 caused by a change in firm 2's cost. Equation (8) can be rearranged to take the following form:

$$\frac{\partial p_2}{\partial c_2} \left(2 \frac{\partial Q_2}{\partial p_2} + (p_2 - c_2) \frac{\partial^2 Q_2}{\partial p_2^2} \right) + \frac{\partial p_1}{\partial c_2} \left(\frac{\partial Q_2}{\partial p_1} + (p_2 - c_2) \frac{\partial^2 Q_2}{\partial p_2 \partial p_1} \right) = \frac{\partial Q_2}{\partial p_2}. \quad (9)$$

The term inside the first parentheses on the left-hand-side of (9) is negative by the second order conditions for firm 2's maximization problem. The second term on the left-hand-side of (9) is positive if the firm's products are strategic complements. Thus, the equilibrium prices are increasing in c_2 . The magnitude of the increase in price for a given increase in c_2 depends on the slope and curvature of the two demand curves.

The change in the profits of firm 1 as a result of the increase in c_2 can be determined to first order by differentiating firm 1's equilibrium profit function

$$\pi_1(c_2) = (p_1(c_2) - c_1) Q_1(p_1(c_2), p_2(c_2)) \quad (10)$$

with respect to c_2 (where we have suppressed the additional dependence of the equilibrium profit function on c_1). This differentiation yields

$$\frac{\partial \pi_1}{\partial c_2} = \frac{\partial p_1}{\partial c_2} Q_1 + (p_1 - c_1) \frac{\partial Q_1}{\partial p_1} \frac{\partial p_1}{\partial c_2} + (p_1 - c_1) \frac{\partial Q_1}{\partial p_2} \frac{\partial p_2}{\partial c_2} \quad (11)$$

The first two terms are zero due to the envelope theorem. The third term demonstrates that firm 1's equilibrium profits increase when c_2 increases, and that, to first order, this increase in profits is equal to the increase in firm 1's quantity sales resulting from the increase in firm 2's price, multiplied by firm 1's pre-existing per unit profit margin.

As a concrete example, consider the case of linear demand where the demand functions take the form

$$Q_i = \alpha - \beta p_i + \gamma p_j \quad (12)$$

where $\beta \geq \gamma > 0$. In that case, equation (9) simplifies to

$$\frac{\partial p_2}{\partial c_2}(-2\beta) + \frac{\partial p_1}{\partial c_2}\gamma = -\beta \quad (13)$$

and the corresponding equation derived from differentiating the first order condition (6) for firm 1 with respect to c_2 is

$$\frac{\partial p_1}{\partial c_2}(-2\beta) + \frac{\partial p_2}{\partial c_2}\gamma = 0 \quad (14)$$

Solving these two equations for $\frac{\partial p_i}{\partial c_2}$ yields

$$\frac{\partial p_2}{\partial c_2} = \frac{2\beta^2}{4\beta^2 - \gamma^2}, \quad \frac{\partial p_1}{\partial c_2} = \frac{\beta\gamma}{4\beta^2 - \gamma^2}. \quad (15)$$

Thus, in the boundary case where $\beta = \gamma$, for each \$1 increase in c_2 , p_2 would increase by \$0.67 and p_1 would increase by \$0.33. The fact that p_2 increases more than p_1 implies that firm 1 would gain market share after an increase in c_2 .

We will now calibrate the parameters to approximate the *Grain Processing* case facts and calculate the lost profits that firm 1 sustains as a result of firm 2's infringement, assuming that in the but-for world firm 2 would use the alternative noninfringing technology (that is, under the assumptions of the *Grain Processing* decision). When both firms are using the patented technology, we assume equal costs ($c_1 = c_2 = 50$). The parameters are chosen ($\alpha = 100$, $\beta = 2$, and $\gamma = 2$) so that each firm sells $Q_i = 100$ at a price of $p_i = 100$. The firms therefore split the market evenly when both use the patented technology. Each firm has profit $\pi_i = 5000$.

If the infringer, firm 2, is forced to use the noninfringing technology, its costs rise to $c_2 = 53$. In that case, the equilibrium prices are $p_1 = 101$ and $p_2 = 102$ and the equilibrium quantities are $Q_1 = 102$ and $Q_2 = 98$. The profits of the patent holder, firm 1, increase to $\pi_1 = 5202$. Thus, the patent holder sustained lost profits even if the infringer would have used the noninfringing technology in the but-for world.

Damages in these circumstances would be calculated using a hybrid lost profits-reasonable royalty approach. In addition to the lost profits of \$202, a reasonable royalty of \$3 (3 percent of the \$100 selling price) would be applied to the 98 infringing units that did not represent lost sales to the patent owner. Thus, total damages would be \$496. This damages

award would substantially exceed the reasonable royalty-only damages award of \$300 (\$3 royalty on 100 infringing units).

B. Cournot Competition with Homogeneous Products

We now analyze lost profits under a model of Cournot competition with homogeneous products. Inverse market demand is denoted by $P(Q_1 + Q_2)$, where Q_i is the quantity supplied by firm i . Again we assume constant marginal costs c_i . The first order condition for firm i is

$$\frac{\partial P}{\partial Q} Q_i + (P(Q_1 + Q_2) - c_i) = 0. \quad (16)$$

The two first order conditions implicitly define the equilibrium quantities, which are functions of the marginal costs. To determine the effect of a change in c_2 on the equilibrium quantities, we differentiate (16) with respect to c_2 and rearrange to obtain

$$\frac{\partial Q_1}{\partial c_2} = - \frac{\frac{\partial Q_1}{\partial c_2} \frac{\partial P}{\partial Q} + Q_1 \frac{\partial^2 P}{\partial Q^2}}{2 \frac{\partial P}{\partial Q} + Q_1 \frac{\partial^2 P}{\partial Q^2}}. \quad (17)$$

Because the numerator and the denominator of the second term of equation (17) are both negative, we have: $\text{sign}\left(\frac{\partial Q_1}{\partial c_2}\right) = -\text{sign}\left(\frac{\partial Q_2}{\partial c_2}\right)$, and un-

der the usual conditions $\frac{\partial Q_1}{\partial c_2} > 0$. Thus, an increase in the infringer's cost will cause the patent holder to expand its output although the infringer contracts its output.

In the case with linear demand $P = \alpha - \beta Q$, we have $\frac{\partial Q_1}{\partial c_2} = \frac{1}{3\beta}$. We now

calibrate the linear demand case to the facts of the *Grain Processing* case. As before, we assume that, when both firms are using the patented technology, they have equal costs ($c_1 = c_2 = 50$). The parameters are chosen ($\alpha = 200$ and $\beta = 0.5$) so that each firm sells $Q_1 = 100$ at a price of $P = 100$. The firms therefore split the market evenly when both use the patented technology. Each firm has profit $\pi_1 = 5000$.

If the infringer, firm 2, is forced to use the noninfringing technology, its costs rise to $c_2 = 53$. In that case, the equilibrium price increases to $P = 101$ and the equilibrium quantities are $Q_1 = 102$ and $Q_2 = 96$. The profits of the patent holder, firm 1, increase to $\pi_1 = 5202$. Thus, again, the patent holder sustained lost profits even if the infringer would have used the noninfringing technology in the but-for world. Also, the total (hybrid) damages award of \$490 (the \$202 lost profits damages plus the \$288 reasonable royalty damages on the 96 infringing units that the patent holder would not have made in the but-for world) again substantially exceeds the \$300 damages award that would result from a reasonable royalty-only approach.

VI. CONCLUSION

The patent system allows firms to exclude competitors, thereby creating incentives for innovation. Firms enforce their right to exclude via infringement suits with attendant damage awards and injunctions. Damage awards in patent litigation are supposed to compensate the patent owner for economic harm that the infringement created. The *Grain Processing* decision has decreased the expected value of damages from infringement because it has conferred a free option on the infringer. Under *Grain Processing*, courts permit an infringer to claim that in the but-for world it would have adopted an existing noninfringing technology despite the fact that the infringer had never done so. This free option transfers economic value to the infringer and transfers economic value away from the patent holder. Thus, it decreases the economic incentives to innovate, which is one of the primary goals of the U.S. patent system.

We also demonstrate that standard models that economists use to analyze firm behavior and profit maximization contradict the conclusion of the district court in *Grain Processing* with respect to the absence of lost profits. When a firm's marginal costs increase, it typically will increase its price. Thus, if the infringer were to adopt the higher cost noninfringing technology, prices would typically increase and the patent holder would both increase its price and gain greater sales. Calculation of lost profits in most economic models, plus a reasonable royalty on those infringing units that do not represent lost sales to the patent holder, will then exceed the cost difference between the infringing low cost technology and the noninfringing high cost technology multiplied by the sales made by the infringer. From this calculation, the hybrid lost profits and reasonable royalty damages award will typically exceed a reasonable royalty-only damage award by a substantial margin. Thus, the district court's conclusion in

Grain Processing that no lost profits existed if the infringer were assumed to have adopted the noninfringing technology is at odds with standard economic theory.

A BURKEAN PERSPECTIVE ON PATENT ELIGIBILITY

By Thomas F. Cotter[†]

TABLE OF CONTENTS

I. INTRODUCTION	855
II. PATENT ELIGIBILITY	859
III. SOME BURKEAN-INSPIRED OBJECTIONS TO THE CONTEMPORARY TREND	874
IV. SOME MODEST STEPS TOWARD REFORM.....	884
A. TECHNOLOGICAL ARTS AND MENTAL STEPS	884
B. PHYSICAL TRANSFORMATION DOCTRINE	894
V. CONCLUSION	895

I. INTRODUCTION

I doubt that the Anglo-Irish statesman and political theorist Edmund Burke devoted a great deal of attention to patent law.¹ To be sure, patents

© 2007 Thomas F. Cotter

[†] Professor of Law, University of Minnesota Law School. I presented this Article at the George Washington University Law School/Oracle Corporation symposium, titled “What’s Ahead on Highway 101?” held at the George Washington University Law School on November 3, 2006. I thank Oracle Corporation for its generous financial support; the conference organizers for their graciousness in inviting me to participate in the conference; and the conference participants and attendees, in particular Martin Adelman, Shannad Basheer, Chris Cotropia, John Duffy, the Honorable Michael Fleming, Sean O’Connor, Kristen Osenga, the Honorable Randall Rader, Joshua Sarnoff, Richard Stern, and John Witherspoon, for their comments and criticism. I also thank, for their comments and criticism, Kevin Collins and Alan Durham; Sharada Devarasetty, for research assistance; and Dale Carpenter, for his helpful insights into the thought of Edmund Burke. All opinions expressed herein, as well as any errors, are mine alone.

1. The only evidence I have seen thus far of Burke’s thoughts on patents is a citation to an unpublished manuscript of Burke’s that is said to be in the National Library of Ireland. See David L. Cohen, *Article 69 and European Patent Integration*, 92 NW. U. L. REV. 1082, 1095 n.63 (1998) (citing KEITH DUTTON, EDMUND BURKE 23 (1979) (quoting Edmund Burke for the proposition that “[m]onopoly is an odious term . . . [but patent] is

for new inventions were part of the legal environment during Burke's lifetime (1729-1797), both within the United Kingdom and in several other countries, including (from 1790 on) the United States.² But Burke had many other matters to occupy his attention, among them the American colonists' revolt (Burke favored a conciliatory approach), Catholic emancipation (which Burke also favored), and the mismanagement of the East India Company (the governor of which Burke unsuccessfully prosecuted for corruption). Burke is probably best remembered today, however, for his passionate defense of traditional conservatism, most prominently in his famous work *Reflections on the Revolution in France*.³

Written following the deposition of Louis XVI and the establishment of the French Republic, but before Louis's execution and the Reign of Terror, *Reflections* casts the revolution in a sinister light, arguing that the radical changes convulsing France at the time were likely to bring considerable misery in their wake. In making his case against the revolution, Burke presents an eloquent defense of tradition and custom that has attracted many adherents to the present day. In what is probably the most oft-quoted passage from the book, Burke expresses fear over "put[ting] men to live and trade each on his own private stock of reason; because we suspect that this stock in each man is small, and that the individuals would do better to avail themselves of the general bank and capital of nations and

not making a monopoly of what was common. It is the direct reverse, for the condition of the patent, compelling a discovery, makes that common which was private before"); cf. Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287, 291 (1988) (speculating that Burke would have objected to the "egalitarian" nature of intellectual property, which empowers "the talented upstarts Burke sought to restrain").

2. As explained by historian Christine MacLeod, however, to refer to English practice during Burke's day as a patent "system" may be "something of a misnomer." CHRISTINE MACLEOD, *INVENTING THE INDUSTRIAL REVOLUTION: THE ENGLISH PATENT SYSTEM, 1660-1800* 1 (1988). Although "[p]atents for invention have been granted regularly since the middle of the sixteenth century . . . it was not until 1852 that the first major legislation on patents was enacted by parliament and the Patent Office established." *Id.* Prior to that time, the inventor had to endure a circuitous ten-stage procedure involving several different government offices. *See id.* at 40-41. For discussion of the early U.S. patent system, see EDWARD C. WALTERSCHEID, *TO PROMOTE THE PROGRESS OF USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION 1798-1836* (1998).

3. *See* EDMUND BURKE, *REFLECTIONS ON THE REVOLUTION IN FRANCE* (Frank M. Turner ed., Yale Univ. Press 2003) (1790). Burke actually was a member of the Whig Party, not the Tories, and at least some of his modern day admirers depict him as something of a moderate liberal within the context of his time and place. *See* CONOR CRUISE O'BRIEN, *THE GREAT MELODY: A THEMATIC BIOGRAPHY AND COMMENTED ANTHOLOGY OF EDMUND BURKE* xxxii-xli, lxi-lxiv (1992); Carl Bogus, *Rescuing Burke*, 72 MO. L. REV. (forthcoming 2007) (distinguishing Burke from modern-day religious conservatives, neoconservatives, and libertarians).

of ages.”⁴ In other words, for Burke, tradition and custom embody practices that incorporate the collective insights of many people and that have proven successful over time; they are therefore likely to reflect more wisdom and foresight than any one individual is likely to possess. Indeed, much of the value of tradition and custom may not even be apparent to any single individual or subgroup. The many are indeed smarter than the few.

Burkean conservatism nevertheless labors under some obvious limitations. More than a few traditional practices, such as slavery or torture, surely strike most of us as downright repellent.⁵ Moreover, the extent to which tradition reflects the perspectives of elites clearly presents a bone of contention for thinkers more inclined towards egalitarianism. On a more practical level, one might question whether tradition can respond adequately to emergencies or to novel, long-term challenges such as environmental degradation. But Burke himself recognized that change is sometimes necessary to respond to changing circumstances, and that mindless conformity to tradition is no virtue. As Burke put it, “A state without the means of some change is without the means of its conservation.”⁶ Burkean conservatives nevertheless clearly prefer gradual, incremental change to radical change, anticipating that radical change can give rise to unforeseeable negative consequences and erode the unappreciated benefits embodied in tradition.⁷ For Burkeans, changes to laws and social practices should be based whenever possible on experience, as opposed to abstract ideas, and should be proportionate to the perceived change in circumstances.⁸

4. BURKE, *supra* note 3, at 74.

5. See ROGER SCRUTON, *THE MEANING OF CONSERVATISM* 34 (1999) (stating that the traditions which conservatives uphold, unlike torture, “engage the loyalty of their participants, in the deep sense of moulding their idea of what they are and should be”); Cass Sunstein, *Burkean Minimalism*, 105 MICH. L. REV. 353, 371 (2006) (arguing that Burkeanism fails when custom is based on collective action or other problems, and thus fails to reflect latent wisdom). Burke himself was opposed to slavery. See O’BRIEN, *supra* note 3, at 91-92; Bogus, *supra* note 3.

6. BURKE, *supra* note 3, at 19.

7. See *id.* at 51-52, 133, 143.

8. There are, to be sure, many (sometimes conflicting) interpretations of Burkean conservatism. Some self-professed Burkeans, such as Russell Kirk and Roger Scruton, emphasize tradition’s role in affirming the meaning of individual lives within the context of civil and religious society. See RUSSELL KIRK, *THE CONSERVATIVE MIND: FROM BURKE TO ELIOT* 28-47 (7th ed. 1986); SCRUTON, *supra* note 5, at 8, 30-36, 157-63. By contrast, Friedrich Hayek admired Burke’s appreciation of tradition as an aggregator of individual wisdom, and identified Burke as a classical “liberal” in the sense of a defender of free markets and limited government. See F.A. Hayek, *Why I Am Not a Conservative*, in *THE CONSTITUTION OF LIBERTY* 397, 407-08 (1960); see also F.A. HAYEK, *THE FATAL CONCEIT: THE ERRORS OF SOCIALISM* 7 (1988) (arguing that free markets aggregate in-

It would be strange, no doubt, to argue that Burke's views on such specific and weighty matters as the French Revolution, the British Constitution, or the relationship of church to state have any direct bearing on, of all things, patent law. What I will argue in this Article, however, is that some of the general themes found in Burke's writing—his preference for gradual, incremental, organic social change, as opposed to top-down, grandly theoretical social engineering, as well as his concomitant appreciation for the unarticulated wisdom that is sometimes embodied in tradition—may shed some light on some contemporary debates about the scope of patentable subject matter. To be sure, the content of these contemporary debates may pale in comparison with the political and social upheavals that motivated Burke to record his thoughts for posterity. But the scope of patent law is hardly a trivial matter either, and a well-functioning patent system can play a crucial role in either fostering or impeding the innovation upon which human survival may depend. I will argue that a Burkean-inspired approach to patent law—one that respects, though it does not worship, tradition and that generally prefers gradual to radical change—suggests that we consider again some traditional, but now dormant, restraints on patentable subject matter that may have embodied a degree of wisdom. More specifically, I argue that some of the traditional limitations on patentable subject matter, as embodied in the technological arts, mental steps, and physical transformation doctrines, may yet have much to recommend them. Reintroduction of these requirements, suitably reformed to reflect changing times, into U.S. law would permit the patenting of soft-

formation concerning consumer demand much more efficiently than any central planner ever could). Michael Oakeshott, on the other hand, found affinity in Burke's admiration of custom as embodying practical wisdom that cannot be reduced to mere technique, and dismissed Hayek's rationalist politics as the mirror image of the trend it sought to counter. See MICHAEL OAKESHOTT, *RATIONALISM IN POLITICS AND OTHER ESSAYS* 26 (Liberty Press 1991). To the extent my discussion above emphasizes tradition as the embodiment of unappreciated wisdom, it may have more in common with the Hayek and Oakeshott interpretations than with those of Kirk and Scruton.

There are also different ways that Burkeans might define and use tradition. As Sunstein notes, with particular emphasis on the application of Burkeanism to constitutional adjudication, some Burkeans might stress adherence to social practices while others might emphasize adherence to judicial precedent (and Burke himself tended to conflate the two); some might look to tradition at a high level of abstraction while others might focus more narrowly on the content of specific traditions. See Sunstein, *supra* note 5, at 368. For present purposes, my modest claim is simply that certain patent law doctrines such as technological arts, mental steps, and physical transformation, embodied a tradition loosely understood as a general or common understanding of the limited scope of patentable subject matter; and that that general or common understanding, whatever its flaws may have been, may also have embodied a degree of wisdom that is too easily shunted aside in the quest for an all-encompassing approach to patentable subject matter.

ware-related inventions and business methods, as is arguably required under the TRIPs Agreement.⁹ But, it might go a long way toward screening out patents that read on laws of nature or that threaten to interfere with important liberty interests.

Part II of this Article presents an overview of patent eligibility and discusses the courts' and the U.S. Patent and Trademark Office's (USPTO) retreat from the technological arts, mental steps, and physical transformation doctrines. Part III argues that these traditional limitations may have embodied some underappreciated wisdom. Part IV suggests some possible ways in which these doctrines might be revived and reformed to be of use today. Part V concludes.

II. PATENT ELIGIBILITY

The current version of the Patent Act explicitly refers to four broad categories of patentable subject matter, namely processes, machines, articles of manufacture, and compositions of matter.¹⁰ Earlier versions, though worded slightly differently,¹¹ were interpreted for the most part to include these same four categories, although until the mid-nineteenth century it was unclear whether processes were patentable to the extent they read on embodiments not disclosed within the patent description.¹² No version of the Act, however, has ever defined these terms or stated what types of inventions or discoveries fall outside the scope of statutory subject matter.¹³ Courts and commentators nevertheless have traditionally agreed upon three general categories of nonpatentable subject matter, namely laws of nature, abstract ideas, and naturally-occurring physical

9. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPs Agreement].

10. 35 U.S.C. § 101 (2000).

11. See, e.g., Patent Act of 1870, ch. 230, § 24, 16 Stat. 198, 201 (“[A]ny person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter . . . may . . . obtain a patent therefor.”); Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 319 (stating the same language as the Patent Act of 1870).

12. See, e.g., 1 R. CARL MOY, MOY’S WALKER ON PATENTS §§ 5.21-22 (4th ed. 2006) (discussing doctrinal developments).

13. Case law has sometimes provided definitions of the terms “machine,” “composition of matter,” “manufacture,” and “process.” See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 182-84 (1981) (discussing processes); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (discussing articles of manufacture and compositions of matter). For present purposes, not much hangs on the distinctions among machines, compositions of matter, and manufactures. As for processes, see *infra* note 39 and accompanying text.

phenomena.¹⁴ These three exclusions from the scope of patentable subject matter persist, but several other doctrines that courts once employed to exclude yet other inventions from patent eligibility have in recent years been narrowed or jettisoned altogether. Prominent among these other exclusions have been the mental steps doctrine, the technological arts doctrine, and (though it is not the principal focus of this Article) the exclusion of business methods, though there have been others.¹⁵

The basic intuition behind the mental steps doctrine—that patent claims should not “read on” (cover) activity that takes place within the human mind—appears to underlie several decisions dating back to the early twentieth century.¹⁶ But the doctrine has always been somewhat am-

14. See *Diehr*, 450 U.S. at 185; *Chakrabarty*, 447 U.S. at 309. Some critics have argued, however, that the U.S. Supreme Court has never squarely held that laws of nature are not patentable, and that cases that assert, or have been cited as having asserted, this principle do so only in dicta. See, e.g., Brief for Franklin Pierce Law Center as Amicus Curiae Supporting Respondents at 6-11, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 304561. It is nevertheless fair to state that the vast majority of observers, including the Patent Office itself, have long interpreted laws of nature, abstract ideas, and naturally-occurring physical phenomena as unpatentable. Products of nature that have been isolated and refined from their naturally-occurring state, however, have been viewed as patentable at least since *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911), *aff'd in part, rev'd in part on other grounds*, 196 F. 496 (2d Cir. 1912). The Supreme Court established the patentability of human-created bacterium in *Chakrabarty*, 447 U.S. at 310. Although critics of *Chakrabarty* contend, with some force, that this interpretation of the Patent Act departed from the traditional understanding of the scope of patentable subject matter, my principal focus in this Article is on departures involving inventions other than life forms.

15. For example, beginning in the mid-nineteenth century, the USPTO and the courts began rejecting applications claiming purportedly novel types of business forms under the “printed matter” doctrine. By most accounts, the doctrine was intended to preserve the boundary between patent and copyright law. See, e.g., MOY, *supra* note 12, §§ 5.10-5.11. As the doctrine exists today, it renders unpatentable an invention that is distinct from the prior art only by virtue of printed matter that is not “functionally related to the underlying object.” See *In re Ngai*, 367 F.3d 1336, 1338 (Fed. Cir. 2004). Construed more broadly, the printed matter doctrine might pose a serious threat to the patentability of many software-related inventions, but few observers, even among those most critical of software patents, argue for revival of a strengthened printed matter doctrine.

16. See *Don Lee, Inc. v. Walker*, 61 F.2d 58, 67 (9th Cir. 1932) (rejecting a claim directed toward a method of computation); *Ex parte Meinhardt*, 1907 Comm'n Dec. 238, 239 (stating that methods for solving mathematical problems are unpatentable); Warren T. Jessup, *Patentability of Mental Processes*, 40 J. PAT. OFF. SOC'Y 482, 482 (1958) (describing the doctrine as having evolved during the preceding fifty years, though in the author's opinion on the basis of a misreading of case law as requiring that processes effect physical transformations); Norman D. McClaskey, *The Mental Process Doctrine: Its Origin, Legal Bases, and Scope*, 55 IOWA L. REV. 1148 (1970) (similar); Katharine P.

biguous in its interpretation. A very broad interpretation of the doctrine would render unpatentable a process that contains any steps that *can* be performed mentally, regardless of whether (1) the process also contains steps that are incapable of being performed mentally, or (2) the steps that can be performed mentally also can be performed non-mentally. It does not appear that any courts or commentators have ever interpreted the doctrine quite this expansively, although some appear to have taken the position that subject matter is unpatentable if the novelty or nonobviousness of the invention is attributable entirely to the mental step or steps (the so-called “point of novelty” test).¹⁷ Some observers also expressed the view that a process that can be performed *entirely* by mental steps is unpatentable, even if the process also can be performed by means of a machine or apparatus.¹⁸ The narrowest interpretation of the doctrine would limit patent exclusion to processes that are incapable of being performed by a machine or apparatus—that is, to processes which, if they are to be performed at all, *must* be performed exclusively by mental steps.¹⁹

Ambrose, Comment, *The Mental Steps Doctrine*, 48 TENN. L. REV. 903, 903 (1981) (referring to the doctrine as “the product of some unclear thinking in the 1940s”). Interestingly, though, Ambrose concludes her critical analysis of the mental steps doctrine by proposing that a process would lack novelty if it attempted “to remove from the public domain any abstract idea, law of nature, or physical phenomenon that is presumed to have always existed.” *Id.* at 917. This is not very different from Professor Collins’ proposal, discussed *infra* notes 186-191 and accompanying text, that the mental steps doctrine be revived to preclude patenting of claims which depart from the prior art only by virtue of their inclusion of a mental step, on the ground that such claims *do* remove subject matter from the public domain.

17. See *In re Abrams*, 188 F.2d 165, 169 (C.C.P.A. 1951); *In re Heritage*, 150 F.2d 554, 556-57 (C.C.P.A. 1945); see also 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.03[6] (2006) (describing the “basic idea” of the mental steps doctrine as being “that no patent can be obtained for a method an essential component of which consists of human mental participation”).

18. See *In re Mahony*, 421 F.2d 742, 745 (C.C.P.A. 1970) (noting that “both sides . . . have assumed that if a claim reads on both mental and non-mental implementation of a process, the claim is drawn to non-statutory subject matter,” but expressly declining to decide whether that interpretation of the doctrine was correct); MOY, *supra* note 12, § 5.40 (stating that “[i]nventions claimed so narrowly as to cover only implementation by machine are exempt” from the mental steps doctrine).

19. To cite a completely hypothetical example, presumably a claim could be drafted in such a way as to specify that some or all of its steps *must* be performed mentally by a human being, such as a method for performing a mind-reading illusion. A claim that permits too much individual discretion or variability in its performance, however—for example, a claim that depends upon the exercise of subjective aesthetic judgment—probably would fail for lack of definiteness, regardless of the existence or not of a mental steps doctrine. See *Datamize, L.L.C. v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005); *In re Prater*, 415 F.2d 1393, 1402 n.22 (C.C.P.A. 1969).

In *In re Musgrave*,²⁰ the inventor sought to patent a method for more accurately mapping subsurface formations in the earth's crust. Some of the steps of the method involved correcting for errors attributable to the presence of topsoil and the distance from shotpoint to measuring stations.²¹ The patent examiner had rejected the claims at issue on the ground that they included steps that could be performed mentally, but the Court of Customs and Patent Appeals reversed.²² In so holding, the court rejected the point of novelty test, reasoning that "novelty and advancement of an art are irrelevant to a determination of whether the nature of a process is such that it is encompassed by the meaning of 'process' in 35 U.S.C. 101."²³ In addition, the court rejected all but the narrowest interpretation of the mental steps doctrine²⁴ and called into doubt even this interpretation by stating that "[a]ll that is necessary . . . to make a sequence of operational steps a statutory process within 35 U.S.C. 101 is that it be in the technological arts so as to be in consonance with the Constitutional purpose to promote the progress of 'useful arts.'"²⁵ As predicted by the concurring judge in *Musgrave*, who accused the majority of a radical break with precedent,²⁶ the mental steps doctrine has become largely a dead letter ever since.²⁷

Yet, while the *Musgrave* court narrowed the mental steps doctrine to near oblivion, it nevertheless referred, in the portion of the opinion quoted above, to the necessity for a patentable process to "be in the technological arts so as to be in consonance with the Constitutional purpose to promote the progress of 'useful arts.'"²⁸ But this "technological arts" doctrine too

20. 431 F.2d 882 (C.C.P.A. 1970).

21. *See id.* at 882-85.

22. *See id.* at 885-93.

23. *Id.* at 889; *see also In re Bernhart*, 417 F.2d 1395, 1399 (C.C.P.A. 1969) (rejecting point of novelty).

24. *See Musgrave*, 431 F.2d at 893.

25. *Id.*

26. *See id.* at 893-94 (Baldwin, J., concurring). Judge Baldwin concluded, however, that the claims at issue either read only on machine-implemented steps, or included steps that were not "purely mental," and therefore they did not violate the mental steps doctrine. *See id.* at 895.

27. *See* Kevin Emerson Collins, *Propertizing Thought* 53 (unpublished manuscript, on file with author).

28. *Musgrave*, 431 F.2d at 893. The author of the majority opinion in *Musgrave*, Judge Giles Rich, was one of the drafters of the 1952 Patent Act. *See* A. Samuel Oddi, *Regeneration in American Patent Law: Statutory Subject Matter*, 46 IDEA 491, 546 (2006). He was also the author of the majority opinions in *Alappat* and *State Street Bank*, discussed *infra* at text accompanying notes 44-69. It is notable therefore that, even for Judge Rich, the scope of patentable subject matter was not necessarily coextensive with

has recently fallen by the wayside, as a consequence of the expansion of patentable subject matter over the last twenty-five years—an expansion that in large part has been driven by the evolving standards relating to the patentability of computer-related art.

The first two times the U.S. Supreme Court took up the issue of the patentability of computer-related art, in *Gottschalk v. Benson*²⁹ and *Parker v. Flook*,³⁰ it appeared to take a relatively hardline position against the patentability of these inventions. In both cases, the majority noted that one can characterize computer programs as mathematical algorithms, and suggested that such algorithms are akin to laws of nature and therefore non-patentable.³¹ Both cases also purported *not* to hold, however, that computer-related art is *per se* unpatentable,³² and (whether wittingly or not) suggested several ways in which future courts might limit their holdings. For example, in *Gottschalk* the Court noted that the claims at issue “were not limited to any particular art or technology, [or] to any particular apparatus or machinery, or to any particular end use”; and that the claims “purported to cover any use of the claimed method,” for converting binary-

merely the “useful, concrete, and tangible,” unless the latter two opinions illustrate a change in his views. For Judge Rich, patentable subject matter must pertain to the “useful” or “technological” arts, in contrast with the “liberal arts” or “fine arts.” See John R. Thomas, *The Post-Industrial Patent System*, 10 *FORDHAM INTELL. PROP. MEDIA & ENTER. L.J.* 3, 9 n.35 (1999) (explaining that not every invention is patentable because “[i]nvaluable though it may be to individuals, the public, and national defense, the invention of a more effective organization of the materials in, and the techniques of teaching a course in physics, chemistry or Russian is not a patentable invention” and noting further that “[a]lso outside that group is one of the greatest inventions of our times, the diaper service” (quoting Giles S. Rich, *Principles of Patentability*, 28 *GEO. WASH. L. REV.* 393, 393-94 (1960))).

29. 409 U.S. 63 (1972). Justice Douglas authored the opinion of the Court. There were no dissents, but three justices (Stewart, Blackmun, and Powell) did not participate in the case.

30. 437 U.S. 584 (1978). Justice Stevens authored the majority opinion. Justice Stewart dissented, and was joined by Chief Justice Burger and by Justice Rehnquist. See *id.* at 599 (Stewart, J., dissenting) (arguing that the process at issue did not “lose[] its status of subject-matter patentability simply because *one step* in the process would not be patentable subject matter if considered in isolation”).

31. See *id.* at 589 (stating that “an algorithm, or mathematical formula, is like a law of nature”); *Gottschalk*, 409 U.S. at 65, 67-68 (describing the invention at issue as an “algorithm,” that is, “a [p]rocedure for solving a given type of mathematical problem,” and likening algorithms to nonpatentable “phenomena of nature, . . . mental processes, and abstract intellectual concepts”).

32. See *Flook*, 437 U.S. at 590 (“[A] process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.”); *Gottschalk*, 409 U.S. at 71 (“It is said that the decision precludes a patent for any program servicing a computer. We do not so hold.”).

coded decimal numerals into pure binary numbers, using a general purpose digital-purpose computer.³³ As a result, “the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”³⁴ Similarly, in *Flook* the Court stated that “a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.”³⁵ But the Court in *Flook* nevertheless held that the invention at issue, a method for updating “alarm limits” in connection with catalytic conversion, *was* unpatentable—despite the fact that a patent would not have precluded all uses of the underlying algorithm and that the claims included the post-solution step of adjusting the alarm value to the updated number calculated by use of the algorithm (because the post-solution step was “conventional or obvious”).³⁶

Four years later, however, the Court reversed course in *Diamond v. Diehr*.³⁷ At issue in *Diehr* was the patentability of a process for curing rubber, using a computer to repeatedly calculate an algorithm, the Arrhenius equation, that is useful for determining the appropriate cure time and that had long been known in the art.³⁸ This time, the Court viewed the invention at issue as unequivocally a statutory (i.e., potentially patentable) “process.” Quoting the Court’s 1877 decision in *Cochrane v. Deener*, the Court defined a process as “a mode of treatment of certain materials to produce a given result,” “an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.”³⁹ (As we shall see, the question of whether a statutory process *must* effect a physical transformation—and if so, exactly what this means—or whether the quotation from *Cochrane* is merely illustrative of one type of statutory process, remains controversial.) The Court reasoned that the in-

33. *Gottschalk*, 409 U.S. at 64.

34. *Id.* at 72.

35. *Flook*, 437 U.S. at 590.

36. *Id.* The Court noted the Patent Board of Appeals’ application of a “point of novelty” test, under which the patent eligibility of a process depends on the patentability of the step or steps that are distinct from the prior art. *See id.* at 587-88. It purported not to apply that test itself, stating that the Court’s approach is “not at all inconsistent with the view that a patent claim must be considered as a whole,” but rather reflects the fact that there was no inventive concept in the application other than the algorithm. *Id.* at 593-94.

37. 450 U.S. 175 (1982). Justice Rehnquist authored the 5-4 majority opinion of the Court. Justice Stevens dissented and was joined by Justices Brennan, Marshall, and Blackmun. *See id.* at 193.

38. *See id.* at 177-78.

39. *Id.* at 183 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)); *see also id.* at 184 (describing the invention at issue as “a physical and chemical process for molding precision synthetic rubber products,” involving the transformation of raw materials into a different state or thing).

vention was not rendered non-statutory merely by virtue of the fact that several of its steps employed a mathematical equation and a computer, and noted that those claims did not preempt all uses of the Arrhenius equation.⁴⁰ And while the Court restated the *Flook* propositions that mathematical principles by themselves are unpatentable, and that “insignificant post-solution activity will not transform an unpatentable principle into a patentable process,”⁴¹ the Court chastised the examiner for concluding that the invention at issue was unpatentable because all of the steps other than the use of the computer were known in the art⁴²—thus arguably laying to rest the point of novelty test.

In the years immediately following *Diehr*, the fledgling United States Court of Appeals for the Federal Circuit struggled to interpret the standards announced in *Diehr* with respect to the patentability of computer-related art.⁴³ In the landmark case of *In re Alappat*, the Federal Circuit, sitting en banc, articulated an expansive scope of patent eligibility for computer-related art.⁴⁴ In *Alappat* the inventor claimed as his invention a machine that, when programmed to perform an algorithm he had developed, would improve the electronic waveform displayed on a digital oscilloscope.⁴⁵ The USPTO had rejected the claims, reasoning that an invention claiming a computer programmed to perform a series of calculations and output data was indistinguishable from an unpatentable mathematical algorithm.⁴⁶ The Federal Circuit, however, reversed on the ground that *Alappat*’s invention fell within the statutory category of a “machine.”⁴⁷ In so holding, the court cited the Supreme Court’s opinion in *Diamond v. Chakrabarty*—which held that human-created life forms constitute patentable subject matter—for the proposition that Congress intended § 101 to encompass *any* new and useful process, machine, manufacture, or composition of matter that satisfied all of the other statutory criteria.⁴⁸ The court did not read the Supreme Court’s trilogy of computer-related art

40. *See id.* at 187.

41. *Id.* at 191-92.

42. *See id.* at 188-89. The Court stated that the questions of whether the invention was novel and whether it was nonobvious were separate from the question of whether the invention fell within the scope of patentable subject matter. *See id.* at 190.

43. *See, e.g.,* Arrhythmia Res. Tech., Inc. v. Corazonix Corp., 958 F.2d 1053 (Fed. Cir. 1992); *In re Iwahashi*, 888 F.2d 1370 (Fed. Cir. 1989); *see also In re Abele*, 684 F.2d 982 (C.C.A.P. 1982).

44. *In re Alappat*, 33 F.3d 1526, 1542 (Fed. Cir. 1994) (en banc).

45. *See id.* at 1537.

46. *See id.* at 1539.

47. *See id.* at 1544.

48. *See id.* at 1542.

cases as establishing an “overly broad, fourth category of subject matter excluded from § 101,”⁴⁹ and instead interpreted those cases as standing for the proposition that “certain types of mathematical subject matter, standing alone, represent nothing more than *abstract ideas* until reduced to some type of practical application.”⁵⁰ Thus, the proper focus is on whether the claim as a whole recites patentable subject matter, and not whether it contains some elements that would be unpatentable by themselves.⁵¹ Applying these criteria to *Alappat*’s invention, the court concluded that the claimed machine was not a “disembodied mathematical concept,” but rather a specific machine that produced a “useful, concrete, and tangible result.”⁵²

In the wake of *Alappat*, the USPTO in 1996 issued new Examination Guidelines for Computer-Related Inventions to assist examiners in determining whether applications reciting such inventions satisfy the criteria for patentability.⁵³ Those Guidelines have been amended in light of *Ex parte Lundgren*, a case discussed below,⁵⁴ and are now incorporated in the Manual of Patent Examining and Procedure as part of the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility.⁵⁵ Following *Alappat*, the general criterion set forth in the Guidelines for distinguishing patentable from nonpatentable subject matter is whether the invention carries out a useful, concrete, tangible result.⁵⁶ In a nod to *Gottschalk*, a factor that remains useful in making this determination is whether use of the claimed invention would preempt all uses of an idea.⁵⁷

49. *Id.* at 1543.

50. *Id.*

51. *See id.* at 1544.

52. *Id.*

53. 61 Fed. Reg. 7478 (1996), available at <http://www.uspto.gov/web/offices/pac/-compexam/examcomp.htm>. The USPTO subsequently incorporated the Guidelines into section 2106 of the Manual of Patent Examining and Procedure, and it has periodically amended them, most recently in response to *Ex parte Lundgren*. 76 U.S.P.Q.2D 1385 (B.P.A.I. 2005). *See* MANUAL OF PATENT EXAMINING AND PROCEDURE § 2106 (8th rev. ed. Aug. 2006) [hereinafter MPEP].

54. *See infra* text accompanying notes 79-104.

55. *See* MPEP, *supra* note 53, § 2106, at 2100-06.

56. *See id.* at 2100-06, 2100-09.

57. *See id.* at 2100-09. Until the August 2006 revision, the Guidelines also suggested, in a nod to *Flook* and *Diehr*, that claims reciting only insignificant pre- or post-solution steps might be unpatentable. *See* MANUAL OF PATENT EXAMINING AND PROCEDURE § 2106, at 2100-15 to -16 (8th ed. rev. Aug. 2005) [hereinafter, August 2005 MPEP].

The culmination of the Federal Circuit's broad interpretation of *Diehr* has been its decisions in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*⁵⁸ and *AT&T Corp. v. Excel Communications, Inc.*⁵⁹ At issue in *State Street Bank* was an issued patent directed toward a data processing system for implementing an investment structure developed for use in the business of administering mutual funds.⁶⁰ The district court held that the claims were unpatentable as either mathematical algorithms or business methods, but the Federal Circuit reversed.⁶¹ Construing the Supreme Court trilogy as standing for the proposition "that mathematical algorithms are not patentable subject matter to the extent that they are merely abstract ideas,"⁶² the court held that "to be patentable an algorithm must be applied in a 'useful' way."⁶³ Notably, the court concluded that "the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price" constituted a "practical application of a mathematical algorithm, formula, or calculation, because it produces a 'useful, concrete, and tangible result'—a final share price momentarily fixed for recording and reporting purposes."⁶⁴ Thus, "[t]he question of whether a claim encompasses statutory subject matter should not focus on which of the four categories a claim is directed to . . . but rather on the essential characteristics of the subject matter, in particular, its practical utility."⁶⁵

In addition, the court laid to rest what it described as the "ill-conceived" business methods exception, noting that despite widespread belief⁶⁶ that case law dating back to the nineteenth century had established

58. 149 F.3d 1368 (Fed. Cir. 1998).

59. 172 F.3d 1352 (Fed. Cir. 1999).

60. *State Street Bank*, 149 F.3d at 1370.

61. *Id.* at 1372-73.

62. *Id.* at 1373 ("Unpatentable mathematical algorithms are identifiable by showing they are merely abstract ideas constituting disembodied concepts or truths that are not 'useful.'").

63. *Id.*

64. *Id.*

65. *Id.* at 1375.

66. See, e.g., Robert A. Kreiss, *Patent Protection for Computer Programs and Mathematical Algorithms: The Constitutional Limitations on Patentable Subject Matter*, 29 N.M. L. REV. 31, 85 (1999) (referring to "the repeated comments made by courts, commentators, and the PTO over the years to the effect that business methods are not patentable subject matter"); Leo J. Raskind, *The State Street Bank Decision: The Bad Business of Unlimited Patent Protection for Methods of Doing Business*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 61, 61-62 & n.2 (1999) (noting that many of the earlier decisions rejecting claims to business methods could be explained on other grounds, but

that business methods were unpatentable, neither the Federal Circuit nor its predecessor Court of Customs and Patent Appeals had ever specifically invoked that exception so as to render an invention unpatentable.⁶⁷ Instead, the court characterized each of the cases that appeared to rely on the business methods exception as explainable on some other ground, such as the rule against patenting abstract ideas.⁶⁸ According to the court, at least since the enactment of the 1952 Patent Act, “business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.”⁶⁹ The following year, the court in *AT&T* confirmed and extended *State Street Bank* by upholding the patentability of a process for generating a message record for interexchange telephone calls.⁷⁰ Although the end result of the process was the creation of a “signal useful for billing purposes,”⁷¹ the court rejected the argument that *Diehr* stood for the proposition that process claims containing algorithms are patentable “only if there is a ‘physical transformation’ or conversion of subject matter from one state into another.”⁷² According to the court, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm may bring about a useful application”;⁷³ the only requirement is that the algorithm-containing process “as a whole, produces a tangible, useful, result.”⁷⁴

Notwithstanding these developments in the law accommodating computer-related art, and their extension to business methods, the USPTO until recently continued to cite *Musgrave* in its Examination Guidelines for Computer-Related Inventions for the proposition that “[o]nly when the claim is devoid of any limitation to a practical application in the technological arts should it be rejected under 35 U.S.C. 101.”⁷⁵ The Guidelines themselves did not define the term “technological arts,” however, giving examiners wide latitude to interpret patentable subject matter. Several pat-

nevertheless describing *State Street Bank*’s wholesale rejection of the business methods exception as “startling”).

67. *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998).

68. *Id.* at 1375-76.

69. *Id.* at 1375.

70. *See AT&T Corp. v. Excel Commc’ns, Inc.*, 172 F.3d 1352, 1353 (Fed. Cir. 1999). Judge Plager authored the opinion; there were no dissenting opinions.

71. *Id.* at 1358.

72. *Id.*

73. *Id.*

74. *Id.* at 1361.

75. August 2005 MPEP, *supra* note 57, § 2106, at 2100-7.

ents that issued in the 1990s and early 2000s—including not only such notorious examples as a method for exercising a cat⁷⁶ and a method for swinging on a swing,⁷⁷ but also to non-computer related business methods⁷⁸ and even the occasional sports move⁷⁹—appeared to bear little if any relationship to what most people would think of as “technology.”

It therefore came as little surprise to many observers when in a recent administrative law decision, *Ex parte Lundgren*,⁸⁰ the USPTO’s Board of Patent Appeals and Interferences put to rest the technological arts exception.⁸¹ The invention at issue in *Lundgren* was a method for compensating

76. See U.S. Patent No. 5,443,036 (filed Nov. 2, 1993).

77. See U.S. Patent No. 6,368,227 (filed Nov. 17, 2000).

78. See, e.g., U.S. Patent No. 6,058,941 (filed June 18, 1999) (patenting a method of taping and cutting hair); U.S. Patent No. 5,851,117 (filed Apr. 23, 1997) (patenting a method for training a janitor); U.S. Patent No. 6,014,975 (filed June 6, 1995) (patenting a shaving method); U.S. Patent No. 6,607,389 (filed Dec. 3, 2001) (patenting a method for selecting a jury).

79. See, e.g., U.S. Patent No. 5,993,336 (filed Mar. 31, 1998) (patenting a method of executing a tennis stroke); U.S. Patent No. 5,616,089 (filed Mar. 29, 1996) (patenting a method of putting). To be sure, many of the aforementioned patents and others falling into the same categories have little if any commercial value, and therefore are a social waste only to the extent they clutter up the system. But one cannot assume a priori that all non-technological inventions are so trivial as to never be enforced, or that enforcement would never interfere with other important interests. To my knowledge, for example, no one has yet sought to patent a new baseball pitch, but it may be only a matter of time before someone attempts to do so. See HAROLD SEYMOUR, *BASEBALL: THE EARLY YEARS* (1960) (discussing the debate over which nineteenth century pitcher invented the curveball); Posting of Brett Bull to SI.com, *Unwinding the Gyroball*, http://sportsillustrated.cnn.com/2007/writers/the_bonus/01/25/matsuzaka.gyroball/index.html (Jan. 30, 2007, 9:07 am) (reporting on a purportedly devastating pitch, the “gyroball,” invented in Japan in the 1990s).

80. 76 U.S.P.Q.2D 1385 (B.P.A.I. 2005) (per curiam).

81. In so holding, however, the Board ruled contrary to an earlier non-precedential opinion, *Ex parte Bowman*, 61 U.S.P.Q.2D 1669, 1671 (B.P.A.I. 2001), which held an invention “which is not tied to any technological art, environment, or machine” to be an unpatentable abstract idea.

Recently, an apparently contradictory but non-precedential opinion of the Board of Patent Appeals and Interferences has come to light. See *Ex parte Bilski*, Appeal No. 2002-2257 (B.P.A.I. 2006), available at <http://www.uspto.gov/web/offices/dcom/bpai/its/fd022257.pdf>. Like *Lundgren*, *Bilski* involved a business method that was not tied to any particular technology and did not effect a physical transformation. See *Bilski*, *supra*, at 2. The Board, in an opinion authored by Judge Barrett (one of the *dissenting* judges in *Lundgren*, see *infra* text accompanying notes 89-96), purported to apply Judge Barrett’s analysis and held that the method did *not* constitute patentable subject matter. See *Bilski*, *supra*, at 11, 41-53. The case is currently on appeal to the Federal Circuit. See Patent Law Blog (Patently-O), BPAI ‘Informative’ Opinion on Business Method Patents, http://www.patentlyo.com/patent/2007/02/bpai_informativ.html (Feb. 16, 2007); see also

a firm manager for reducing the firm's exposure to the risk of antitrust liability; none of the steps of the invention required the use of a computer or other equipment.⁸² The examiner had rejected the application on the ground that the claims read on subject matter "outside the technological arts, namely an economic theory expressed as a mathematical algorithm without the disclosure or suggestion of computer, automated means, apparatus of any kind"⁸³ In a brief per curiam opinion, however, the Board reversed, citing *AT&T* for the proposition that "a process claim that applies a mathematical algorithm to 'produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle, on its face comfortably falls within the scope of Section 101."⁸⁴ The Board rejected the examiner's determination "that there is a separate test for determining whether claims are directed to statutory subject matter, i.e., a 'technological arts' test."⁸⁵ In the board's view, "there is currently no judicially recognized separate 'technological arts' test to determine patent eligible subject matter under Section 101."⁸⁶

Lundgren nevertheless elicited two strong dissents among the five administrative law judges. In the first dissenting opinion, Judge Smith argued that "the term 'technological arts' should be construed to mean nothing more than a threshold nexus to some field of technology," and that such a requirement is implicit within the "constitutional mandate authorizing Congress to grant patents in order to promote the progress of the useful arts."⁸⁷ In Judge Smith's view, "if the claims recite that the steps were performed by a computer . . . the claimed invention would at least have met the constitutional 'technological arts' standard, although [it] would still need to be analyzed under 35 U.S.C. Section 101 for conventional compliance with that section of the statutes."⁸⁸ In a much lengthier separate opinion, Judge Barrett expressed agreement with the majority's view

Patent Prospector, Transformation,
http://www.patenthawk.com/blog/2007/02/transformation_1.html (Feb. 19, 2007, 5:13 pm) (quoting Harold C. Wegner asking, "[I]n the absence of any intervening judicial precedent to the contrary, on what basis can a new panel simply abrogate the 'precedential' *Lundgren* opinion?").

82. See *Lundgren*, 76 U.S.P.Q.2D at 1385-86.

83. *Id.* at 1386.

84. *Id.* (quoting *AT&T Corp. v. Excel Commc'ns, Inc.*, 172 F.3d 1352, 1358 (Fed. Cir. 1999)).

85. *Id.*

86. *Id.* at 1388.

87. *Id.* (Smith, J., dissenting).

88. *Id.*

“that there is no separate and distinct ‘technological arts’ test.”⁸⁹ He also saw no difficulty with permitting patents to issue on processes the steps of which are completely performed by humans.⁹⁰ Judge Barrett nevertheless dissented from the majority’s implication that “the sole test for statutory subject matter is the ‘useful, concrete and tangible result’ test.”⁹¹ He distinguished *State Street Bank* and *AT&T* on the ground that both of these cases “involved transformation of data by a machine, such as a computer,” whereas the claim at issue was “broad enough to read on performing the steps without any machine or apparatus.”⁹² In Judge Barrett’s view, a rule that would conform both to the constitutional mandate to limit patents to the “useful arts” and to the Supreme Court and Federal Circuit case law would define patentable processes as processes that effect “a physical transformation of subject matter (matter or energy) to a different state or thing if it is not tied to a particular machine.”⁹³ In light of the Federal Circuit cases, however, “the ‘subject matter’ transformed does not need to be a physical (tangible) object or article or substance, but can be physical, yet intangible, phenomena such as electrical signals or electromagnetic waves.”⁹⁴ Under this test, a process would not be patentable if it is abstract, in the sense of not serving a useful purpose, *or* if it does not transform matter or energy.⁹⁵ Processes that can be implemented by human effort without the use of any device and without transforming matter or energy external to the human actor would, on this view, be unpatentable, even if useful.⁹⁶

Judge Barrett’s test therefore would incorporate the old mental steps doctrine, but it would permit computer-related art to be patented as long as the invention carries out a useful purpose, because computer-related art necessarily involves the transformation of matter or energy. Further, this test would permit human implemented processes to be patented as long as

89. *Id.* at 1389, 1390 (Barrett, J., concurring in part and dissenting in part) (concluding that a technological arts test would be unworkable and unfair).

90. *See id.* at 1428-29.

91. *Id.*

92. *Id.* at 1392.

93. *Id.* at 1401.

94. *Id.* at 1398. Judge Barrett’s revision of the traditional “physical transformation” test therefore would recognize many, perhaps most, computer-related inventions as falling within the domain of patentable subject matter. *See also* Alan L. Durham, “*Useful Arts*” in the Information Age, 1999 BYU L. REV. 1419, 1464-65, 1513 (arguing that “any ‘useful arts’ distinction based on *physicality* is disturbingly superficial,” and that many software inventions “have little or no physical effects, yet are equally utilitarian”).

95. *See Lundgren*, 76 U.S.P.Q.2D at 1399 (Barrett, J., concurring in part and dissenting in part).

96. *See id.*

they transform matter or energy and are useful.⁹⁷ Process claims that are drafted so as to read on either machine or human implementation would have to satisfy both tests.⁹⁸ Judge Barrett's proposed test did not carry the day, however. In conformity with the majority opinion, the new Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility neither make reference to a technological arts requirement, nor do they view physical transformation as a *sine qua non*.⁹⁹ Consistent with the position apparently taken by the Federal Circuit in cases such as *Alappat*, *State Street Bank*, and *AT&T*, the USPTO now purports to apply only the three criteria of useful (meaning that the claim is limited to a practical application), tangible (defined to mean "not abstract"), and concrete (defined to mean "substantially repeatable").¹⁰⁰

But perhaps the most anticipated development in the law of patent eligibility in recent years turned out to be something of a non-event. In February 2005, the United States Supreme Court surprised many observers by inviting the Solicitor General to file a brief setting forth the views of the United States on the question of whether the patent claim at issue in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, was invalid by reason of the rule that laws of nature, natural phenomena, and abstract ideas are unpatentable.¹⁰¹ Contrary to the Solicitor General's ad-

97. *See id.* Judge Barrett's dissent may have a good deal to recommend it. *See infra* text accompanying note 193.

98. *See id.*

99. *See* MPEP, *supra* note 53, § 2106, at 2100-11.

100. *See id.* How far the Federal Circuit is willing to go with respect to patentable subject matter may be tested in the pending case of *In re Nuijten*. In *Nuijten*, the USPTO rejected a claim to a "signal with embedded supplemental data, the signal being encoded in accordance with a given encoding process and selected samples of the signal representing the supplemental data, and at least one of the samples preceding the selected samples is different from the sample corresponding to the given encoding process," on the ground that a signal is not an article of manufacture or composition of matter. *See* John F. Duffy, *In re Nuijten: Patentable Subject Matter, Textualism and the Supreme Court*, available at <http://www.bustpatents.com/sec101/nuij-duf.pdf> (last visited Feb. 12, 2007); Harold Wegner, 35 *USC* § 101 "Electrical Signal" Patent-Eligibility Test Case, IPFRONTLINE, Aug. 9, 2006, <http://www.ipfrontline.com/depts/article.asp?id=12151&deptid=4>. Professor Duffy argues that the claim does recite patentable subject matter because the terms "composition of matter" and "manufacture" mean anything that is neither imaginary nor spiritual. *See* Duffy, *supra*. On the other hand, the claim at issue in *Nuijten* seems more clearly than the claim at issue in *Lundgren* to fall within the everyday meaning of "technological arts" or, as Professor Duffy puts it, "clever engineering." *Id.* A reversal in *Nuijten* therefore might not require calling *Lundgren* into question. The Federal Circuit heard oral argument in *Nuijten* in February 2007. *See id.*

101. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2925 (2006) (Breyer, J., dissenting).

vice, the Court then granted certiorari on the question of whether the patent claim at issue was invalid on the ground that it resulted in “a monopoly over a basic scientific relationship . . . such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.”¹⁰² The inventors in *Metabolite* had discovered a naturally-occurring correlation between the level of homocysteine, an amino acid, in human bodily fluid, and deficiencies of folate and cobalamin.¹⁰³ They then obtained a patent which, in relevant part, claimed a method for diagnosing whether a subject suffers from a folate or cobalamin deficiency, comprising (1) testing for the presence of an elevated level of homocysteine; and (2) correlating an elevated level of homocysteine with a folate and cobalamin deficiency.¹⁰⁴ The assignee of the ensuing patent filed suit against LabCorp for inducing physicians to infringe the patent. The district court entered judgment for the assignee, and the Federal Circuit affirmed. The court, however, failed to address whether the claim, construed to read on a physician’s use of any test for homocysteine and subsequent correlation, impermissibly covered a law of nature, i.e., the relationship between elevated homocysteine levels and vitamin deficiencies.¹⁰⁵

The parties presented oral argument before the Court in early 2006, but the Court thereafter dismissed the writ as improvidently granted.¹⁰⁶ In dissent, however, Justice Breyer, joined by Justices Stevens and Souter, argued against dismissing the writ, despite the fact that LabCorp had not pressed the law of nature argument at trial and the Federal Circuit had expressed no opinion on the matter.¹⁰⁷ Justice Breyer then argued that, despite the occasional difficulty of distinguishing between natural phenomena and their applications, the present case was “not at the boundary”: the patent claim at issue, in other words, was indistinguishable from the natural phenomenon of the correlation between high levels of homocysteine and folate or cobalamin deficiency.¹⁰⁸ Justice Breyer also noted that the claim did not involve any “physical transformation of matter,” though without deciding whether patentable processes must involve such transformations.¹⁰⁹ He also expressed doubt on *State Street Bank*’s implication that processes are patentable as long as they produce a “useful, concrete,

102. *See id.* at 2925.

103. *See id.* at 2922.

104. *See id.* at 2924.

105. *See id.* at 2924-25.

106. *Id.* at 2921. As is often the case, the Court offered no reason for its decision to dismiss the writ as improvidently granted.

107. *See id.* at 2925 (Breyer, J., dissenting).

108. *Id.* at 2927.

109. *See id.*

tangible result,” suggesting that this test would have been met in *Gottschalk* and *Flook*, as well as in the famous *Morse* case.¹¹⁰

Given the Court’s apparent interest in the issues raised in *Metabolite*, however, it may not be long before the Court grants certiorari in a similar case that more carefully preserves those issues for appellate review. Doing so would allow for some probing of whether the standards developed by the Federal Circuit and the USPTO in the years following *Diehr* have extended the scope of patentable subject matter too far. For the time being, however, neither the Federal Circuit nor the USPTO appears motivated to step back from the principles that patentable subject matter may pertain to non-technological arts, may read on mental steps, and need not effect any conventional physical transformation.¹¹¹ This trend has extended patentable subject matter beyond the boundaries that most observers would have considered proper a generation ago, as well as beyond the boundaries followed today by other jurisdictions such as the European Patent Office (EPO).

III. SOME BURKEAN-INSPIRED OBJECTIONS TO THE CONTEMPORARY TREND

On one level, all of the preceding developments—the elimination of the mental steps and technological arts doctrines, as well as any requirement that there be a physical transformation of matter—seem reasonable. After all, the Patent Act makes no mention of these doctrines, and courts may be correct in inferring that Congress intended the scope of patentable

110. *See id.* at 2928. In *O’Reilly v. Morse*, the Supreme Court rejected claim 8 asserted by Samuel F.B. Morse, inventor of the telegraph, directed to “the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances.” 56 U.S. 62, 112-20 (1854). The case is sometimes read as implicating the principle that laws of nature are unpatentable, though others believe that a better rationale for the result is that the inventor could not enable others to practice unforeseeable embodiments of claim 8’s inventive principle. *See Oddi, supra* note 28, at 514.

111. Only the *Nuijten* case so far appears contrary to the trend, but as noted above it turns more on the question of whether signals are compositions of matter or manufactures than on their relation to technology. *See supra* note 100. Note also that the Supreme Court, or at least some members of the Court, may find reason to express an opinion on the patentability of software-related art in the pending case of *Microsoft Corp. v. AT&T Corp.*, No. 05-1056 (argued Feb. 21, 2007). Although the case hinges on the Court’s interpretation of 35 U.S.C. § 271(f), during oral argument three justices raised the question of whether software itself is patentable subject matter. *See* Transcript of Oral Argument, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056, available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/05-1065.pdf, at 13 (question of Justice Scalia); *id.* at 22 (question of Justice Breyer); *id.* at 26 (question of Justice Stevens).

subject matter to be broad.¹¹² The doctrines themselves may appear arbitrary and subject to capricious interpretation. Who is to say what counts as a physical transformation? In a material universe, every process will cause *some* sort of physical transformation, if only at the microscopic level or within the human body, including the brain. As noted above, courts never had a clear understanding of the mental steps doctrine,¹¹³ and reasonable minds may well differ on the subject of what falls within the technological arts.¹¹⁴ One may also question whether these now-disfavored doctrines really were part of any firmly-rooted patent law tradition. The mental steps doctrine, as noted above, does not appear in any reported case prior to the twentieth century.¹¹⁵ In *State Street Bank*, the Federal Circuit was able to distinguish earlier cases rejecting patents on business methods on some other ground or grounds.¹¹⁶ The Supreme Court may not have intended the dictum in *Cochrane v. Deener* that processes must involve physical transformations to provide a definitive, limiting definition of what constitutes a patentable process.¹¹⁷

Moreover, to the extent that one can read the old doctrines as closing off entire new fields, such as computer-related arts, from the scope of patent protection, they seem arbitrary and short-sighted. Investment in new areas of endeavor may benefit humankind.¹¹⁸ On this view, the modern, rational step was to eliminate these archaic doctrines altogether, and to focus on encouraging the invention and disclosure of any and all subject matter so long as it is useful, practical, and sufficiently predictable in its

112. Some observers have argued that the constitutional text authorizing Congress to enact patent laws to “promote the progress of . . . the useful arts,” U.S. CONST. art. I, §8, cl. 8, might require that patentable subject matter be limited to the technological arts, as being synonymous with “useful arts.” See *Ex parte Lundgren*, 76 U.S.P.Q.2D 1385 (B.P.A.I. 2005) (Smith, J., dissenting); Malla Pollack, *The Multiple Unconstitutionality of Business Method Patents: Common Sense, Congressional Consideration, and Constitutional History*, 28 RUTGERS COMP. & TECH. L.J. 61, 90 (2002). But see Edward Walterscheid, “*Within the Limits of the Constitutional Grant*”: *Constitutional Limitations on the Patent Power*, 9 J. INTELL. PROP. L. 291, 350, 354 (2002) (arguing that the useful arts are not limited to the technological arts, but rather to any functional subject matter).

113. See *supra* notes 22-28 and accompanying text.

114. See *Ex part Lundgren*, 76 U.S.P.Q.2D 1385, 1389-90 (B.P.A.I. 2005) (per curiam) (Barrett, J., concurring in part and dissenting in part).

115. See *supra* note 16 and accompanying text.

116. See *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1375-77 (Fed. Cir. 1998).

117. See 1 CHISUM, *supra* note 17, §1.03[6].

118. Accord Durham, *supra* note 94, at 1514 (arguing, for example, that search engine and virus detection algorithms are “tools for the analysis, manipulation, and transformation of data” and “should be considered at the core of patentable subject matter”).

effects. Indeed, some advocates of an expansive view of patentable subject matter have argued that even the current rules may not be expansive enough. The amicus brief filed by the Franklin Pierce Law Center in *Metabolite* argued in favor of eliminating the “law of nature” exclusion.¹¹⁹ In a related vein, John Schlicher—a practitioner and scholar whose work has greatly influenced my own—has questioned the need for a utility requirement, reasoning that patents on useless inventions would have no value and therefore would impose little social cost.¹²⁰ For all we know, they may be right: the social benefits of these doctrines may be minimal, and the costs of continuing with them may be high, if they discourage, at the margin, some researchers from conducting the sort of basic research that might lead to the discovery of new laws of nature lacking any immediate practical application. On this view, a rational system would permit patentable subject matter to expand into every nook and cranny of human endeavor, and would rely exclusively upon other patent doctrines, such as nonobviousness, to weed out the trivial.

And yet there are reasons to question whether this rational, orderly scenario is entirely correct. Arguments that there is no textual basis within the Patent Act for mental steps or other limiting doctrines only go so far, even if we put aside contrary arguments that there is a constitutional basis for some or all of these limitations.¹²¹ Much of patent law traditionally has been judge-made: consider, for example, the evolution of the nonobviousness doctrine prior to its codification in 1952;¹²² the first sale doctrine;¹²³ the exclusion of laws of nature and naturally-occurring physical phenomena;¹²⁴ the doctrine of non-statutory double patenting;¹²⁵ or the Federal

119. See Brief for Franklin Pierce Law Center as Amicus Curiae, *supra* note 14, at 6-11.

120. See 1 JOHN W. SCHLICHER, PATENT LAW: LEGAL AND ECONOMIC PRINCIPLES § 3.3 (2d ed. 2005); 2 JOHN W. SCHLICHER, PATENT LAW: LEGAL AND ECONOMIC PRINCIPLES § 13.22 (2d ed. 2005).

121. See *supra* note 112.

122. See *Graham v. John Deere & Co.*, 383 U.S. 1, 5-16 (1966) (discussing the evolution of the “inventiveness” doctrine prior to the codification of the nonobviousness doctrine in 1952, though also suggesting that inventiveness or nonobviousness may be a constitutional requirement).

123. The first-sale doctrine entitles the owner of a lawfully-made article embodying the patented invention to use and resell the article, without permission of the patent owner, unless the patent owner has validly conditioned the sale of that article in some relevant respect. See, e.g., *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 706-08 (Fed. Cir. 1992). It has never been explicitly codified in the Patent Act.

124. See *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

Circuit's "useful, concrete, and tangible" test, the latter two portions of which have neither a textual basis nor are interpreted to mean what those terms mean in ordinary discourse.¹²⁶ And while doctrines such as technological arts or mental steps may lack a long pedigree as measured by explicit statements in the case law, the absence of such statements may simply reflect a widespread, unchallenged understanding that patentable subject matter did not extend so far.¹²⁷

125. Under the doctrine of non-statutory double patenting, one may not patent an obvious variation of one's own patented invention, absent the filing of a terminal disclaimer under which the second patent covering the obvious variation expires on the same date as the first patent. See *Geneva Pharms., Inc. v. Glaxosmithkline PLC*, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003).

126. See *supra* text accompanying note 100.

127. See, e.g., 1 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 66, at 101 n.2 (1890) (citing with approval *Morton v. N.Y. Eye Infirmary*, 17 F. Cas. 879 (C.C.S.D.N.Y. 1862) (holding invalid a patent on "a method of rendering patients insensible to pain during surgical operations," despite the fact that the invention "conferred inestimable benefits upon the whole race of man")); Robert I. Coulter, *The Field of the Statutory Useful Arts, Part II*, 34 J. PAT. OFF. SOC'Y 487, 494, 505 (1952) (arguing that, in historic context, the "useful arts" are distinct from the liberal and fine arts, and also that "mental operations *per se* . . . are not patentable," although "practical technological methods which provide modes or means linking elemental agencies (including the human mind) to produce the useful result" are); Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Computer Software*, 39 EMORY L.J. 1025, 1036 n.34 (1990) (noting little explanation, in judicial opinions, for the mental steps doctrine, but proposing that "this lack of explanation instead may be a sign of how far outside the bounds of the patent system mental processes are perceived to be"); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139, 1142, 1145-47, 1164 (1999) (referring to "our long-held sense of the reach of the patent system" as "somehow cabin[ing] the scope of patentable subject matter," and citing nineteenth and twentieth century case law articulating a physical instantiation requirement). To be sure, even if such an understanding existed relatively early on, it would not necessarily bind modern-day courts; arguments for tradition always beg the question concerning the level of generality at which the tradition should be considered binding. See Sunstein, *supra* note 5, at 381. Many observers today might disagree, for example, with the specific holding of *Morton v. N.Y. Eye Infirmary*, 17 F. Cas. 879 (C.C.S.D.N.Y. 1862) (though even today medical methods, though patentable, are not generally enforceable, see 35 U.S.C. § 287(c)), to say nothing of other patent-limiting cases (including *Parker v. Flook*, 437 U.S. 584 (1978)) that rest upon what John Duffy and Robert Merges refer to as the "nature's library" fallacy, i.e., that applications of a newly discovered law of nature may be obvious if the law of nature itself is considered part of the prior art. See ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 108 (3d ed. 2002). But as I argue above, courts also should consider the possibility that the assumptions underlying some of the now-disfavored doctrines embodied a degree of underappreciated wisdom that we should not be too quick to jettison entirely.

To the extent there *was* some such common understanding, by the mid-twentieth century and quite possibly much earlier, regarding the limited scope of patentable subject matter, a Burkean perspective might suggest that we should not be too quick to discard that understanding altogether absent some compelling need. As I suggested in the Introduction, I am speaking here not of Burke's specific views on the political and social issues of his day, but rather of the Burkean attitude of prudence: the idea that traditional practices may embody the unarticulated and underappreciated wisdom of many people and many times, and that changes from tradition should be undertaken, when necessary, with due regard to that wisdom. Taking a page from Oakeshott,¹²⁸ I also do not contend that any specific results *necessarily* flow from traditional conservatism; practical wisdom cannot be reduced to mere technique. What I will suggest, more in the nature of a conversation or discussion, are some ways in which a Burkean-inspired appreciation for the latent wisdom of tradition and custom might be useful in approaching some of the recent controversies over patentable subject matter. To the extent that old limitations embodied a degree of wisdom—and to the extent no one has yet articulated a compelling policy reason, such as a perceived underinvestment in the production of non-technological processes, in favor of the wholesale jettisoning of these traditional rules—courts might be well-advised to reconsider some of these rules.¹²⁹ At the same time, nothing in this Burkean-inspired approach suggests that the law of patents ought to be frozen at the time of some mythical golden age. Patent law must keep pace with the times, and it probably would be inadvisable—as well as a likely violation of the TRIPs

128. *See supra* note 3.

129. Put another way, no one is sufficiently well-informed to know how to craft the patent eligibility requirement so as to maximize the surplus of social benefits over social costs. Although it is conceivable that defining the scope of patentable subject matter very broadly—even doing away with the requirement altogether—might induce more invention, discovery, and disclosure, it also may induce more transaction, monopoly, and rent-seeking costs. The marginal payoff may well be negative, in light of other incentives to discovery (such as fame, prizes, and direct or other indirect subsidies) and the potentially exponential increase in transaction costs in particular. Unfortunately, this observation does not tell us precisely how to differentiate patentable from unpatentable subject matter; indeed, the question may defy empirical analysis. One must rely in large part upon non-verifiable assumptions concerning the likely consequences, including unintended consequences, of legal rules. The Burkean perspective suggests that tradition provides a set of such assumptions, departures from which should be based upon evidence that modifications are necessary to adapt the law to changing times, rather than upon some perceived need to conform patent law to some model of Cartesian rationality.

Agreement¹³⁰—to exclude computer and business-related art from the scope of patent eligibility altogether. Reintroducing some of the traditional limitations on patent eligibility, though subject, as we shall see, to appropriate reforms, might restore some needed balance to the system. In particular, one may view the physical transformation, mental steps, and technological arts requirements as embodying principles which still merit respect, even if not absolute fidelity. Among these principles are the following.

Laws of nature and basic research should remain unpatentable, and efforts should be made to ensure that clever patent drafting does not eviscerate this principle. As suggested above, even this time-honored principle is not completely unassailable from a utilitarian standpoint. Allowing patents to issue on laws of nature or other tools of basic research—which currently fall outside the scope of patentability, both as a matter of patentable subject matter doctrine and under the current understanding of the utility doctrine¹³¹—might conceivably encourage some additional investment in their discovery. Nevertheless, the principle that laws of nature and basic research should remain outside the patent system is also clearly rational, in light of both the potential for a contrary rule to generate enormous social costs and the availability of other time-honored means, such as direct government subsidies, for inducing basic discoveries. Indeed, a rule forbidding the patenting of laws of nature and basic research rests comfortably within a web of traditional limitations on patentability, including not only utility but also the inherency doctrine,¹³² which rests in part upon similar assumptions concerning the value of a more limited role of the patent system in facilitating basic research. Patents on laws of na-

130. See TRIPs Agreement, *supra* note 9, art. 27 (subject to certain permissible exceptions, “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application”). Note, however, that the TRIPs Agreement does appear to permit restricting patents to “fields of technology.”

131. See *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). Indeed, the best response to Schlicher’s argument against the utility doctrine is precisely this: by requiring basic research tools and other fundamental building blocks to remain in the public domain, the utility doctrine performs a function more important than merely discouraging investment in useless, and presumably valueless, invention.

132. The inherency doctrine forbids the patenting of discoveries which are inherently present in the prior art, regardless of whether the benefits of the discovery have been previously appreciated, as long as the public has been deriving the benefits of the discovery all along. Although the case law has long been marked by confusion, the more recent Federal Circuit decisions have reconciled the competing strands along these lines. See, e.g., *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320-21 (Fed. Cir. 2004); Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371 (2005).

ture would also lead to administrative difficulties and would intrude upon personal autonomy in troubling ways. Had Sir Isaac Newton been able to patent the law of gravity, for example, how exactly would he have been capable of excluding others from using it, and should society have let him try? Perhaps patent eligibility standards can be one tool for ensuring against clever “drafting around” that claims as one’s invention all or most practical applications of such a physical law.

When possible, the patent system should strive to avoid conflicts with free speech, copyright, privacy, and other important competing interests. As other scholars have noted, an overly expansive eligibility standard may result in the granting of patents that threaten to invade free speech, privacy, or other constitutionally-protected rights. Dan Burk, for example, has noted that, to the extent that software embodies expression that is entitled to a degree of First Amendment protection, patents that read on competing software products—that is, that render competing products infringing and thus potentially subject to an injunction—raise potentially disturbing constitutional issues.¹³³ These issues may be more problematic in the context of patent than copyright law, insofar as copyright only protects original expression (or selection or arrangement), and not its functional equivalents.¹³⁴ The famous idea/expression dichotomy¹³⁵ helps to ensure that copyright rights do not intrude too far upon the First Amendment guarantee of freedom of speech.¹³⁶ A patent claim that is drafted broadly enough, by contrast, will read on a functionally-equivalent invention, ei-

133. See Dan L. Burk, *Patenting Speech*, 79 TEX. L. REV. 99, 150 (2000).

134. See 17 U.S.C. § 102(a), (b) (2000).

135. The basic principle is that copyright subsists in an author’s original expression of ideas or fact, or in her original selection or arrangement of those ideas or facts, but not in the ideas or facts themselves. See Thomas F. Cotter, *Memes and Copyright*, 80 TUL. L. REV. 331, 354 (2006) (citing sources).

136. See *Eldred v. Ashcroft*, 537 U.S. 186, 219 (2003); *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 560 (1985). This is not to say that copyright doctrine necessarily makes sufficient accommodations to freedom of speech; the point is arguable, to say the least. See, e.g., Neil Weinstock Netanel, *Locating Copyright Within the First Amendment Skein*, 54 STAN. L. REV. 1, 13 (2001); Jed Rubenfeld, *The Freedom of Imagination: Copyright’s Constitutionality*, 112 YALE L.J. 1, 5 (2002). Determining precisely where expression leaves off and idea begins is not easy, because copyright covers not only exact copying but also substantially similar copying. See, e.g., *Arnstein v. Porter*, 154 F.2d 464, 468 (2d Cir. 1946). But copyright at least makes an effort to reconcile property rights with free speech rights. Because patent rights are generally broader in scope than copyrights, however, and because patent law lacks anything resembling a fair use defense, there is no obvious way to address the potential conflict of patent law and the First Amendment in cases in which that conflict arises.

ther literally or under the doctrine of equivalents.¹³⁷ When patents covered only traditional forms of technology, the broader scope of patent rights rarely presented a conflict with other bodies of law; now that patents and copyrights sometimes both read on the same subject matter, however, the potential for patent law to negate the public's right to incorporate non-copyrightable ideas into competing software products can present formidable difficulties in accommodating the competing interests.¹³⁸ Burk therefore suggests that "[t]he introduction of expressive subject matter into patent law may require revival or reformation" of either the mental steps or printed matter doctrine, "in order to re-establish the line between function and expression in patentable subject matter."¹³⁹ In a related vein, Kevin Collins argues that strict liability for patents that would render infringing the (possibly involuntary) act of thinking raises constitutional problems, although for Collins the principal problem is that such patents effectively remove subject matter from the public domain. That is, if the point of novelty subsists only in the mental step, as in the claim at issue in *Metabolite*, a patent effectively renders it impossible to use subject matter (e.g., a naturally-existing correlation between two phenomena) that itself is nonpatentable subject matter.¹⁴⁰

But John Thomas has pointed to what is perhaps the most serious problem posed by the expansion of patentable subject matter, namely its potential impact upon personal liberties.¹⁴¹ As Thomas notes, patents in recent years have claimed among other things methods for terminating

137. The defendant's product or process infringes under the doctrine of equivalents if that product or process contains each element found in the patented invention, or the substantial equivalent thereof; an element is the substantial equivalent of another if a person of ordinary skill in the art would know that the substituting element is interchangeable with the substituted element. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997).

138. At least in some contexts, the U.S. Supreme Court has been reluctant to interpret federal intellectual property laws in such a way as to negate rights that it views as being conferred upon the public under other federal intellectual property laws. *See, e.g., Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 34-35 (2003); *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 32 (2001). Enforcement of the printed matter doctrine remains one way of trying to keep patent and copyright separate. *See supra* note 15 (discussing the printed matter doctrine). However, ascertaining the boundaries of that doctrine can be quite difficult. *See Burk, supra* note 133, at 141-45.

139. Burk, *supra* note 133, at 161.

140. *See* Kevin Emerson Collins, *The Problem of Insufficient Thought Control: Reflexive Thought and Constructive Nonvolition in Patent Law* 54-56 (unpublished manuscript, on file with author).

141. *See* John R. Thomas, *Liberty and Property in Patent Law*, 39 HOUS. L. REV. 569, 570 (2002).

pregnancy, for advising clients with respect to tax and regulatory compliance, and for various methods of communication (including, but not limited to, methods of advertising).¹⁴² In many instances, constitutional principles would almost certainly preclude the government from directly prohibiting the practices that comprise the subject matter of these patents, and yet the owner of an enforceable patent on a method for inducing abortion, providing tax advice, or advertising a product could obtain an injunction forbidding others from the unauthorized practice of the very same conduct.¹⁴³ Whether constitutional law itself should play a role in constraining the courts from enforcing patents that implicate personal liberty interests presents difficult questions concerning the interpretation of the state action doctrine, among other things.¹⁴⁴ Thomas himself argues that “the fashioning of a subconstitutional restraint seems the best way” to accommodate the competing interests,¹⁴⁵ and in other work has argued in favor of retaining the technological arts and physical transformation doctrines as a way to stem the tide of liberty-intrusive patents.¹⁴⁶ To some extent, these traditional limitations on patentable subject matter may have implicitly recognized the value in protecting liberty interests from being undermined by the patent system.¹⁴⁷ The liberty-intrusive patents Thomas decries have little to do with technological arts or physical transformations, at least not within the conventional meaning of those terms.

The virtue of redundancy. Many of the legal standards that have grown up around patent eligibility make use of concepts that one can already find in other patent doctrines, most notably utility and inherency. As noted above, like patent eligibility one can understand the utility requirement as a tool for ensuring that basic research remains in the public domain.¹⁴⁸ So too can inherency, which properly understood prevents inventors from

142. *See id.* at 580-90.

143. *See id.* at 592 (characterizing as a “disturbing question” the issue of whether patents may “restrict personal liberties in ways that legislation cannot”).

144. *See id.* at 592-619.

145. *Id.* at 609.

146. *See* Thomas, *supra* note 127, at 1143, 1175.

147. To be sure, modern-day Burkeans may disapprove of constitutional doctrine that recognizes, among other things, a penumbral constitutional right to privacy and free speech rights that permit flag-burning and the distribution of pornographic materials—or they may not, to the extent that these rights, whether legitimate or not in their inception, have become long-settled artifacts of the constitutional landscape. *See* Sunstein, *supra* note 5, at 368-69, 392-94. My point is merely that, to the extent our legal traditions embrace a degree of respect for personal autonomy, freedom of speech, and other liberty interests, however one interprets them, the potential for patent law of all things to interfere with these interests ought to be a matter of concern.

148. *See supra* note 132 and accompanying text.

claiming inventions the benefits of which the public has been enjoying, albeit unwittingly, prior to the inventor's discovery of the natural principle at issue.¹⁴⁹ Although this observation might lead one to conclude that a rational patent system could rely exclusively upon these other doctrines to weed out inventions which, for policy reasons, should remain unpatentable, the existence of other doctrines that embody common assumptions on the limited role of the patent system may provide greater confidence in the value of restraint. Moreover, redundancy provides some assurance that, even if one doctrine is misapplied in a given instance, another will serve as a backup to attain the correct outcome.¹⁵⁰

All of this reasoning leads me to conclude that, despite some potential drawbacks, the technological arts, mental steps, and physical transformation doctrines may have possessed some underappreciated virtues. Abandoning them entirely, in the interest of attaining a more rational, logical patent system, may well have been precipitate. And yet to state that these doctrines may have possessed some latent merit does not necessitate that they be revived in their original state. Times do change, after all, and legal doctrines must change with them. In particular, an expansive reading of the mental steps and physical transformation doctrines would render a broad swath of computer-related art unpatentable, to the extent that the art makes use of mathematical algorithms which, in theory, one could perform mentally, or transforms one set of data into another set of data. Although some opponents of software patents might not mind seeing such changes, in my view a radical return to the status quo ante would be just as imprudent as staying the present course. Software-related inventions, after all, can and do add substantial value to the economy. Moreover, such a return might be difficult to reconcile with the TRIPs Agreement, which for better or worse requires all member nations to make patents "available for all inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."¹⁵¹ Reversing *State Street Bank's* rule in favor of business method patents might involve similar problems, at least to the extent some such methods relate to a "field[] of technology," and would

149. See *supra* note 133 and accompanying text.

150. At the same time, policymakers must recognize that satisfaction of the patent eligibility standard is only one of many requirements for patent protection. Many of the common complaints concerning the patenting of computer-related art, for example, may be better directed at problems involving nonobviousness and disclosure, rather than subject matter. See *supra* note 122 (discussing nonobviousness); Julie E. Cohen & Mark A. Lemley, *Patent Scope and the Software Industry*, 89 CALIF. L. REV. 1, 13-14 (2001) (discussing disclosure).

151. TRIPs Agreement, *supra* note 9, art. 27.1.

require legislative action insofar as Congress, in the wake of *State Street Bank*, to enact a new provision to the Patent Act that makes specific reference to business method patents.¹⁵² A more fruitful avenue for further analysis therefore would be to investigate more carefully the circumstances under which these doctrines might play a useful, albeit altered, role in the modern patent system.

IV. SOME MODEST STEPS TOWARD REFORM

I have chosen to focus my attention on three specific doctrines, namely technological arts, mental steps, and physical transformation, as candidates for a possible revival. Yet I have not said much to this point about precisely how I envision these doctrines could be grafted back into existing law. None of these doctrines were clearly defined in the past, and in any event a mindless return to past practice would probably, as I suggested above, be unwarranted. At the same time, however, to try to define their future contours definitively now would be arrogant; the wisdom of the many is greater than that of any individual participant, including me. I will, however, set forth some tentative observations on the ways in which the law might incorporate some of the wisdom of the past, in the hope that this exercise will stimulate others to build on this work and the work of other scholars who have recently contributed to this ongoing discourse. I first discuss technological arts and mental steps; I then, briefly, discuss physical transformation.

A. Technological Arts and Mental Steps

An initial difficulty in implementing a technological arts requirement lies in defining the term “technological arts,” but those difficulties may be exaggerated. Although there may never be a definition of technology that everyone can agree upon completely, there are some serious candidates for an adequate definition that would likely resolve the vast majority of cases. Professor Thomas, for example, having canvassed the works of historians and philosophers of technology as well as the case law of several other countries, proposes as a working definition “the production or transforma-

152. See 35 U.S.C. § 273(b)(1) (1999) (exempting from liability a person who would otherwise infringe a method patent, “if such person had, acting in good faith, actually reduced the subject matter to practice at least one year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent”); *id.* § 273(a)(3) (defining the relevant method covered by this provision to be “a method of doing or conducting business”).

tion of artifacts through the systematic manipulation of physical forces.”¹⁵³ Alternatively, one version of an (ultimately defeated) European Council Directive on computer-related patents would have defined technology as “the use of controllable forces of nature to achieve predictable results.”¹⁵⁴ And Professor Durham, arguing that software engineering should be viewed as a branch of technology, would nevertheless limit patentability to inventions which “reflect the *programmer’s art* rather than the non-technological art in whose service the programmer’s art is employed.”¹⁵⁵ Thus, while there will undoubtedly be some cases at the margin, and not everyone will agree precisely where the boundary lies, it is hard to believe that if more attention were focused on the matter, a workable definition would lie forever beyond our reach. The need to apply some sort of “technological arts” criterion has hardly led other countries’ and regions’ patent systems to grind to a halt; it is hard to see why it should be an insurmountable obstacle for ours.¹⁵⁶

Assuming that we can agree upon a definition, a second problem, relating also to mental steps, is to determine whether the USPTO should apply that definition to the invention as a whole or whether the USPTO

153. See Thomas, *supra* note 127, at 1142, 1178-80 (drawing upon definitions of “capable of industrial application” in other nations’ laws).

154. See European Parliament legislative resolution on the proposal for a directive of the European Parliament and of the Council on the patentability of computer-implemented inventions (COM(2002) 92–C5-082/2002–2002/0047(COD)), art. 2(c) (Sept. 24, 2003), available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P5-TA-2003-0402+0+DOC+XML+V0//EN>. As noted above, the EPO—not to be confused with the European Council or the European Union—requires patentable inventions to demonstrate a “technical effect,” but as far as I can tell the term is not defined in the European Patent Convention or regulations. See Case No. T 0931/95 - 3.5.1, at 16 (noting that “the meaning of the term ‘technical’ or ‘technical character’ is not particularly clear,” but that this is also true of the term “invention”; that “the fact that the exact meaning of a term may be disputed does in itself not necessarily constitute a good reason for not using that term as a criterion”; and finally that “case law may clarify the issue”).

155. Durham, *supra* note 94, at 1521-22 (emphasis added).

156. There is clearly some force, however, to the argument that the doctrines discussed in the text above can lead to unnecessary formalistic distinctions; for example, a technological arts requirement might distinguish between (potentially patentable) systems and (potentially unpatentable) methods, even if the underlying inventive principle is identical. See John A. Squires & Thomas S. Biemer, *Patent Law 101: Does A Grudging Lundgren Panel Decision Mean that the USPTO Is Finally Getting the Statutory Subject Matter Question Right?*, 46 IDEA 561, 567 (2006). Be that as it may, if a technological arts requirement in general serves a beneficent purpose, some formalism may be an unintended but manageable byproduct thereof. It is hardly obvious that a rule favoring systems over methods will have any significant impact on patent incentives, particularly if method claims can often be drafted as system claims, and vice versa.

should apply some variation on the point of novelty approach instead. In the present context, an “invention as a whole” approach would screen out claims, such as the method claims at issue in *Lundgren*, that have no technological purpose and that can be performed by non-technological means. If merely automating any process necessarily removes any technological arts or mental steps impediment, however, the reform would not screen out much else. It might be easy to evade such a rule without sacrificing much claim breadth by simply drafting the claims so that the invention must be performed technologically, for example by computer means.¹⁵⁷ The invention as a whole approach also would do little, if anything, to revive the mental steps doctrine; surely most process claims can be drafted to include at least one step that need not, or must not, be performed mentally. For that matter, claims not so drafted might run afoul of whatever remains of the mental steps doctrine today after *Musgrave*, without any further reform.

All of this reasoning leads me to suggest that if technological arts and mental steps are to perform a modest but non-negligible function in preventing patents from intruding upon liberty and other important interests, it might be more fruitful to reconsider application of a point of novelty approach. To be sure, and as discussed in Part II, the Court of Customs and Patent Appeals disapproved of the point of novelty approach in *Musgrave*,¹⁵⁸ while the U.S. Supreme Court appears to have dispensed with it in *Diehr*.¹⁵⁹ The arguments against the point of novelty approach appear in many ways compelling. For one thing, the point of novelty approach appears to depart from standard concepts of novelty and nonobviousness, which depend upon an evaluation of the subject matter as a whole in relation to the prior art, and not upon individual claim elements.¹⁶⁰ Courts can,

157. Depending on how one defines technology, even pencil and paper might provide sufficient technological means. See Case T 0258/03 – 3.5.1, *Hitachi* (EPO Bd. App., Apr. 21, 2004), ¶4.6, available at <http://legal.european-patent-office.org/dg3/pdf/t03-0258ep1.pdf>. Requiring the invention as a whole to have a technological *purpose*, rather than merely technological means, would avoid this problem but might still cover a vast territory.

158. See *In re Musgrave*, 431 F.2d 882, 891 (C.C.P.A. 1970).

159. See *Diamond v. Diehr*, 450 U.S. 175, 204-05 (1981). Note, however, that Professor Collins defends his point of novelty approach, discussed *infra* notes 187-192 and accompanying text, against the charge that it cuts against the grain of considering the patent claim as a whole, on the grounds, inter alia, that *Diehr*'s apparent disapproval of the point of novelty approach can be interpreted narrowly. See Collins, *supra* note 27, at 55.

160. A claimed invention lacks novelty if, inter alia, another invention contains *all* of the “elements” or “limitations” of the claimed invention, arranged in the same order. 35 U.S.C. § 103 (stating it is obvious if “the difference between the subject matter sought to

and frequently do, find a combination of elements, each one of which is found in the prior art, to be both novel and nonobvious when considered as a whole.¹⁶¹ And as the court suggested in *Musgrave*, the point of novelty approach seems illogical in the sense that it contemplates that the very same invention may fall within the scope of patentable subject matter at one point in time, when the prior art is more limited in scope and thus does not anticipate the non-mental or non-technological steps, but not at another point when the prior art embraces those steps.¹⁶²

And yet as Holmes said and Burke might have said, “[t]he life of the law has not been logic; it has been experience.”¹⁶³ Experience suggests that a point of novelty test is not unworkable. For one thing, the USPTO

be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art”); see *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

161. See, e.g., *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1095 (Fed. Cir. 1985).

162. See *In re Musgrave*, 431 F.2d 882, 889 (C.C.P.A. 1970). Consider too the claim at issue in *Metabolite*. If (Case 1) that claim comprised only the single limitation of testing for the presence of an elevated level of homocysteine, it would constitute patentable subject matter (but would be unpatentable for lack of novelty). If instead (Case 2) the claim comprised the two steps of testing and correlating (as the actual claim at issue in *Metabolite* did), then under a point of novelty test that would render the subject matter unpatentable unless the point of novelty resides in steps other than the mental step. The addition of the extra element would render the subject matter unpatentable. Addition of a third step (Case 3)—for example, instructing the patient regarding the diagnosis of cobalamin deficiency, or administering treatment for the deficiency—might bring the claim back into patentable subject matter territory. This series of results—moving from patentable subject matter in Case 1 to unpatentable subject matter in Case 2, then back to patentable subject matter in Case 3—seems bizarre if one views patentable subject matter as an ontological state. If on the other hand patentable subject matter is perceived as simply a legal conclusion, a label reflecting certain underlying policy determinations, the conclusion is less odd. The relevant policies may counsel against patentability only in Case 2 (though again, other policies, those reflected in the novelty doctrine, surely would counsel against patentability in Case 1). But I concede that the result is inelegant and untidy.

163. OLIVER WENDELL HOLMES, JR., *THE COMMON LAW* 1 (Dover Publications 1991) (1881). Holmes was not a respecter of tradition in the sense that Burke was. See Oliver Wendell Holmes, *The Path of the Law*, 10 HARV. L. REV. 457, 469 (1897) (“It is revolting to have no better reason for a rule of law than so it was laid down in the time of Henry IV.”); Sunstein, *supra* note 5, at 398 (comparing and contrasting Holmes and Burke); cf. BURKE, *supra* note 3, at 81 (describing jurisprudence as “the pride of human intellect, which, with all its defects, redundancies, and errors, is the collected reason of ages, combining the principles of original justice with the infinite variety of human concerns”). Neither Burke nor Holmes, however, as I understand them, had much patience with efforts to conform law or other institutions to some grand, a priori theory.

has continued to apply point of novelty in two limited contexts.¹⁶⁴ And the European Patent Office (EPO) continues to apply a variation on the point of novelty test to the present day to determine the patentability of computer-related art. At issue in a recent EPO case on point, *Hitachi*,¹⁶⁵ was an automatic auction method carried out by means of a computer. The examiner had concluded that the method was a “business method as such,” rather than an “invention,” and thus fell outside the scope of patentable subject matter under article 52(1) of the European Patent Convention.¹⁶⁶ Under a version of the point of novelty test, known as the “contribution approach,” that the EPO had articulated in some earlier cases, this conclusion appeared correct. That approach advised the examiner to isolate the “‘new features’ of an invention and features of that invention which are known from the prior art,”¹⁶⁷ and then determine whether the new features, as opposed to the invention as a whole, exhibited a “technical char-

164. First, as noted above, the printed matter doctrine renders an invention unpatentable if the only distinction between the invention and the prior art is nonfunctional descriptive material. *See In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004). Second, U.S. courts continue to apply a point of novelty approach with respect to design patents. *See Lawman Armor Corp. v. Winner Int'l, L.L.C.*, 437 F.3d 1383, 1384-85 (Fed. Cir. 2006), *as clarified*, 449 F.3d 1190, 1192 (Fed. Cir. 2006). Moreover, if the words “point of novelty” set off too many alarms among the patent bar, maybe it would help to call it something else. In conversation, Richard Stern has suggested the use of the alternative term “departure from the prior art.”

165. Case T 0258/03 – 3.5.1, *Hitachi* (EPO Bd. App., Apr. 21, 2004), *available at* <http://legal.european-patent-office.org/dg3/pdf/t030258ep1.pdf>; *see also* Case T 0931/95 – 3.5.1, *Pension Benefit Systems Partnership* (EPO Bd. App. Sept. 8, 2000), ¶ 6, *available at* <http://legal.european-patent-office.org/dg3/pdf/t950931eu1.pdf> (rejecting also the “contribution” approach, though not as definitively as in *Hitachi*). For a recent British case declining to follow *Hitachi*, and instead applying a test that would exclude more software and business-related inventions from the scope of patentable subject matter, see Lord Justice Jacob’s opinion in and appendix to *Aerotel Ltd. v. Telco Holdings Ltd* (U.K. Ct. App. Oct. 27, 2006), *available at* <http://www.bailii.org/ew/cases/EWCA/Civ/2006/1371.html>. Lord Justice Jacobs also appears to read another recent EPO Board of Appeals decision, Case T 0424/03 – 3.5.1, *Microsoft Corp.*, (EPO Bd. App. Feb. 23, 2006), as *not* requiring an inventive step that is technical in character. *See Aerotel, supra*, at ¶¶ 26, 113-14. I am not convinced that this is the result the Board intended in *Microsoft*, though the Board’s discussion of inventive step and technical character perhaps could be clearer. *See Microsoft, supra*, ¶¶ 5.2, 7. If Lord Justice Jacobs’s interpretation is correct, however, and if the EPO were to follow that interpretation in future cases, the EPO standard arguably would differ from the current U.S. approach only in requiring some relation to technological arts—and only a minimal relation at that. *See infra* note 174 and accompanying text.

166. *See* Case T 0258/03, Summary of Facts and Submissions ¶ III.

167. *Id.* ¶ 3.3.

acter.”¹⁶⁸ In other words, the question was whether “the invention involves some contribution to the art in a field not excluded from patentability.”¹⁶⁹ In *Hitachi*, however, the Board of Appeals reversed this earlier case law, holding “any comparison with the prior art . . . to be inappropriate for examining the presence of an invention”;¹⁷⁰ “a mix of technical and non-technical features may be patentable.”¹⁷¹ As far as subject matter is concerned, all that matters “is the presence of technical character which may be implied by the physical features of an entity or the nature of an activity, or may be conferred to a non-technical activity by the use of technical means.”¹⁷² The only “activities falling within the notion of a non-invention ‘as such’ would typically represent purely abstract concepts devoid of any technical implications.”¹⁷³

One might conclude that the Board was overthrowing point of novelty in its entirety, opting for the USPTO’s approach of finding patentable subject matter as long as the inventor does not claim a computer program per se. That conclusion would be premature, as the Board then went on to conclude that the auction method at issue was unpatentable because it did not “represent a nonobvious technical solution to a technical problem.”¹⁷⁴ In other words, in assessing the “inventive step” requirement—the analogue to the U.S. Patent Act’s nonobviousness requirement—the examiner should take “account of only those features which contribute to a technical character.”¹⁷⁵ Applying that standard to the auction method, the Board noted first that the “overall aim of the claimed method” was to identify a successful bidder, and therefore that the aim lacked a technical character.¹⁷⁶ The dispositive question would therefore be whether the inventive steps themselves were technical in nature. The Board concluded, however, that the technical steps of the invention, such as those involving data transmission and storage, were not inventive, but rather standard in the field.¹⁷⁷ The inventive steps, by contrast, involving “using the stored information to arrive at the successful bidder,” concerned only prices and thus lacked any technical character. The prominent inventive feature “is

168. *See id.* ¶¶ 3.1, 3.2.

169. *Id.* ¶ 3.2.

170. *Id.* ¶ 3.3.

171. *Id.* ¶ 3.4.

172. *Id.* ¶ 4.5.

173. *Id.*; *see also id.* ¶ 4.6 (suggesting that even the “act of writing using pen and paper” involves technical character).

174. *Id.* ¶ 4.6.

175. *Id.* ¶ 5.3.

176. *Id.* ¶ 5.4.

177. *See id.*

fundamentally independent of the computer arrangement for performing the auction” and “could just as well be used for conducting a Dutch auction without computer support.”¹⁷⁸ In short:

The invention can therefore be regarded as a mere automation of the non-technical activity of performing a Dutch auction in the absence of bidders. Any ingeniousness required to develop the rules for the hypothetical auction cannot be considered for inventive step The technical part of the invention is thus essentially limited to instructing the server computer to apply the given conditions and perform any necessary calculations.¹⁷⁹

The EPO’s approach as evidenced in *Hitachi*, therefore, appears to be one in which the patentable subject matter requirement provides few obstacles to patentability, but which denies patent protection to subject matter which fails to demonstrate at least one “step” that is *both* inventive and technical. In a sense, it merely moves the relevant point of novelty inquiry from the patentable subject matter to the inventive step (obviousness) stage of the analysis. If the inventive step is one that can be performed by a human being, the invention fails the inventive step criterion. This approach clearly differs from the current U.S. approach, under which both patentable subject matter *and* nonobviousness (the latter in accordance with section 103 of the Patent Act) are considered with respect to the invention “as a whole,” and not with respect to individual “steps” or elements.¹⁸⁰ Incorporating this approach into U.S. law, however, might be difficult in light of the aforementioned language of section 103.

The works of Alan Durham and Dan Burk suggest two other possible point of novelty approaches. Durham ultimately recommends an approach that resembles the EPO’s discarded contribution approach, under which

178. *Id.* ¶¶ 5.4, 5.7.

179. *Id.* ¶ 5.7. The Board went on to state that, “if a step of a method has been designed in such a way as to be particularly suitable for being performed on a computer, it has arguably a technical character. Suggesting such a step might require technical considerations.” *Id.* ¶ 5.8. But the Board nevertheless concluded that the subject matter at issue did not contain any feature “which does not correspond to what a human being would do if performing the auction without computer support.” *Id.*

180. *See* 35 U.S.C. § 103(a) (2000). This section states:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the difference between the subject matter sought to be patented and the prior art are such that the *subject matter as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art.

Id. (emphasis added).

one inquires whether the point of novelty or inventive step pertains to the technological arts,¹⁸¹ which Durham conceives as including software engineering.¹⁸² This approach would exclude inventions that couple standard programming techniques with non-technological steps, on the ground that “[a] patent claim that, in substance, describes only a non-technological advancement should be held beyond the scope of the ‘useful arts,’ even if it makes general references to existing technology.”¹⁸³ Alternatively, if Burk is correct that we should be concerned about software patents that read on First Amendment-protected speech, perhaps an approach that requires the point of novelty to comprise something *other* than the software is preferable.¹⁸⁴ Suppose, for example, that a claim comprises five elements, A, B, C, D, and E, where A, B, C, and D are prior art and E, the only point of novelty, necessarily reads on speech that is both functional and expressive and therefore, arguably, entitled to some degree of First Amendment protection. In such a case, a patent precludes others from engaging in otherwise lawful activity (practicing A, B, C, and D), based upon the content of the speech (E) that accompanies the activity. If Burk is right that much software is like E, this result comes uncomfortably close to a content-based restriction on speech. To be sure, a patent might not preempt all uses of E, but it would preempt otherwise lawful conduct when coupled with the performance of E. A point of novelty approach that focused on the non-software steps would preclude a patent in such a case, unless there was some other step F that distinguished the invention from the prior art, in which case an injunction would not be based on the presence of E. In some instances this solution might be hard to square with the Durham proposal, however. A fruitful ground for future scholarly inquiry might center on the fundamental question of whether, or when, software patents embody elements such as the hypothetical “E” that qualify as protected First Amendment speech.¹⁸⁵

181. Cf. Durham, *supra* note 94, at 1518-19 (arguing that the problem with some inventions is that “the part that is new is not technological, and the part that is technological is not new,” and that in such cases “[e]ither the black letter rules of patent law must give a little, or we must resign ourselves to patents on some essentially non-technological inventions”).

182. *See id.* at 1522-25.

183. *Id.* at 1525.

184. Though possibly neither will accommodate the First Amendment interest sufficiently. Perhaps patent law needs a fair use doctrine, as Burk suggests. *See* Burk, *supra* note 133, at 150-54.

185. Burk himself is not sure that software *should* qualify as protected speech; he notes only that, in some contexts, courts have held that it is. *See id.* at 102 (“I believe the long-term implications of holding software to be protected speech could be more trouble-

Professor Collins has proposed a reformulated mental steps doctrine that is structurally similar to the Durham and Burk proposals relating to technological arts. Under Collins' proposed version of the mental steps doctrine, an invention would be unpatentable if it met four criteria: (1) the claim recited "at least one act of information processing that can be performed by the human mind"; (2) the mental step is more than merely "a necessary accessory to real-world human action"; (3) the step is not merely one that recites an act of observation, but rather processes information; and (4) "the non-thought-based steps do not constitute a patentable method (and therefore are not a useful, novel and nonobvious method) in and of themselves."¹⁸⁶

Inversely, in a claim that does not propertize thought, any recited thought-based steps are technically superfluous steps in an otherwise valid claim that are added to make the utility of the claim more intuitively self-evident . . . In these latter claims, the thought-based steps are harmless to the public because they do nothing more than restrict the scope of a patentee's rights to exclude.¹⁸⁷

In addition to his proposal that is specific to the propertization of thought, the claim at issue in *Metabolite* would be unpatentable, because "the only recited non-thought based step in the claim," that is, the one involving assaying homocysteine, was known to the prior art.¹⁸⁸ Collins argues that, because thought is often non-volitional, a claim that combines prior art with possibly non-volitional thought "may prevent the public from performing actions that, prior to the issuance of the patent, the public had the right to perform."¹⁸⁹ Moreover, this approach might serve to vin-

some than the immediate folly such a holding might rectify."). His paper was published before the Supreme Court's decision in *Eldred v. Ashcroft*, however, and it might be useful to consider whether the Court's relative lack of concern over the effect of copyright extension on protected speech would translate into an analogous lack of concern in the patent realm—or not, given patent law's lack of equivalents to fair use or the idea/expression dichotomy.

186. Kevin Emerson Collins, *Propertizing Thought, Syllogistic and Other*, at 16-18, available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers2/Collins.doc>; see also Collins, *supra* note 27, at 16-24.

187. Collins, *supra* note 186, at 18.

188. See *id.* at 19.

189. *Id.* at 27. Collins justifies his proposal in part on the ground that strict liability for claims that "propertize" reflexive thought, using his terminology, unconstitutionally removes subject matter from the public domain. See Collins, *supra* note 140, at 54-56. He therefore suggests that, in *Metabolite*, a third step consisting of "delivering a diagnosis of a B vitamin deficiency or a normal B vitamin level to the patient," might resolve the con-

dicating personal autonomy interests by holding unpatentable inventions that otherwise would render conduct infringing merely because of the perhaps involuntary operation of the mind.¹⁹⁰ As the Court of Customs and Patent Appeals suggested in an earlier time and place, “It is self-evident that thought is not patentable.”¹⁹¹

stitutional overbreadth problem. *See id.* at 69-70. The addition of the third step, however, would not cure the constitutional defects of the *Metabolite* claim if it is an interference with self-ownership interests that underlies the objection to the propertization of thought. *See Collins, supra* note 186, at 61-66.

190. Presumably the doctrine would not target so-called “ministerial” mental steps, such as merely observing a phenomenon, but rather only information-processing steps. *See* 1 CHISUM, *supra* note 17, § 1.03[6][a] (noting that courts applying the mental steps distinguished between ministerial and evaluative mental steps); *Collins, supra* note 27 (manuscript at 16) (making a similar distinction).

191. *In re Abrams*, 188 F.2d 165, 168 (C.C.P.A. 1951). On balance, Collins’ recommended reform to address the problem created by the confluence of strict liability and the reflexiveness of some acts of thinking would appear fairly modest in its effects. In terms of the *Metabolite* case, for example, the claim at issue would constitute patentable subject matter as long as some third element, such as “instructing the patient regarding the diagnosis of cobalamin deficiency” or “administering treatment for the deficiency” was added to the first two. *See supra* note 189. But if it would be easy to add such a step in most such cases, the reform makes no sweeping change to existing law. One might also note that patent owners are not likely to haul people into court for merely thinking. Someone who infringes the claim at issue in *Metabolite* by testing and then doing nothing more than making a mental correlation is unlikely to be detected. And even if he were detected, it is doubtful there would be any effective remedy for the infringement. What would be the benefit of an injunction, and what lost profits or royalties could be attributed to a merely mental correction? Hence there would be little incentive to sue. Looked at from the other direction, however, the modesty of the reform may be one of its virtues. Requiring the addition of a third step to claims such as the claim at issue in *Metabolite* would appear to have little disincentive effect upon medical research, if indeed the third step is easy to conceive and if few infringement claims would ever be premised upon purely mental correlations without more. Moreover, the reform would have the modest benefit of reducing the potential for unscrupulous or vindictive patent owners to use claims like the one at issue in *Metabolite* as a tool for harassment, by making clear that no one is even technically or theoretically liable for purely unavoidable behavior such as thinking. In an analogous context, a question under debate today is whether a real property owner is liable for infringement if a patented seed blows onto her property and begins propagating there, through no affirmative act whatsoever on the part of the real property owner. Patent infringement is a strict liability regime, to be sure, but arguably even strict liability usually contemplates some volitional act on the part of the alleged tortfeasor. If this latter line of reasoning is correct, however, it would also suggest that no one should be liable for the mere act of thinking, which is similarly often nonvolitional. *See Collins, supra* note 140, at 36-39 (distinguishing purposive and reflexive acts of thinking). In other words, I may have as little control over the memes that propagate within my brain as I do over the seeds that propagate within my real property. Finally, even if it would be rare for an infringement claim to be premised on the mere thinking of patentable thoughts, why

In summary, if the technological arts and mental steps doctrines are to have even a modest impact, they may require the reintroduction of some sort of point of novelty test. Although the EPO's approach, which defers the relevant inquiry until the inventive step stage, may have much to recommend it, it is likely to be difficult to incorporate such a standard into U.S. law without amending section 103. By contrast, one could apply the approaches of Durham, Burk, and Collins at the subject matter stage, screening out inventions whose novelty and nonobviousness in relation to the prior art either (1) pertain to a non-technological art or (2) depend upon a step that can be performed mentally. Perhaps other commentators might further improve upon these proposals. Further, in the case of the Durham and Burk proposals, commentators would need to draw some conclusion as to whether an element comprising software is more like speech or engineering. All three proposals, however, might have the salubrious consequence of screening out patents that would otherwise intrude upon laws of nature and human liberty interests, while still permitting patent law to adapt to and accommodate new technology. In this respect, the proposals arguably preserve the wisdom of the older tradition without making a fetish of that tradition for its own sake.

B. Physical Transformation Doctrine

Reforming the physical transformation rule might be somewhat easier than reforming either the technological arts or mental steps rules. Judge Barrett's suggestion in *Lundgren* actually points the way to a plausible reconciliation of the autonomy principle with the principle that computer-related art should not be arbitrarily excluded from the scope of patentable subject matter, even if it transforms nothing more than electric signals representing one form of data into signals representing another form of data. Recall that, under Judge Barrett's proposal, a process is patentable as long as it (1) is useful and (2) transforms matter or energy external to the human actor.¹⁹² This definition would recognize much computer-related art as patent eligible, but it would exclude what appear to be the most troubling patents from the standpoint of human liberty interests. Absent some compelling need to come close to invading these interests, which has yet to be demonstrated, a Burkean-inspired perspective on patent law might counsel against expanding patent protection to such non-traditional subject

should the state even theoretically be able to penalize its citizens for the content of their thoughts?

192. *Ex parte Lundgren*, 76 U.S.P.Q.2D 1385, 1399 (B.P.A.I. 2005) (Barrett, J., concurring in part and dissenting in part).

matter, even if it remains agnostic or even supportive on the topic of the patentability of much computer-related art.

V. CONCLUSION

An optimist might say that the rise of the “useful, concrete, and tangible result” criterion, coupled with the concomitant abolition of the technological arts, mental steps, and physical transformation doctrines, is all part of the logical, orderly progression of patent law from some dim, archaic past. No longer will patentable subject matter be bound to arbitrary limitations. Any and all discoveries other than laws of nature, abstract ideas, and naturally occurring physical phenomena can and should be patented. In fact, let everything be patented, and the market will take care of the rest. Anything less threatens to stem the rising tide of innovation and progress.

But this rosy scenario should give us pause. Patents are an integral part of the U.S. economy, but there is no evidence that extending patent protection into every corner of human activity would bring positive returns. Further, there is potentially much to lose. What will likely disappear in the transition to an “anything goes” system are some of the less quantifiable, but real, benefits of a patent system that is more humble in its aspirations. These include potential losses to freedom of speech, personal autonomy, and other liberty interests that are compromised when virtually any human activity, including involuntary mental processes, can intrude upon someone else’s patent rights. Some of the traditional doctrines of patent law may have embodied latent liberty-preserving wisdom that we discard at our peril.

Edmund Burke concluded his *Reflections on the Revolution in France* by describing himself as someone who, “when the equipoise of the vessel in which he sails may be endangered by overloading it upon one side, is desirous of carrying the small weight of his reasons to that which may preserve its equipoise.”¹⁹³ Contemporary patent law can be an enormous force for good, but it too is arguably in danger of losing its equipoise. I have argued herein that, in pursuit of a rational, orderly system under which virtually anything constitutes patentable subject matter, patent law has cast overboard traditional limiting doctrines that silently assisted in the preservation of liberty and other human interests. Respect for the wisdom of the past may not appear as satisfying as the imposition upon messy reality of some rational, orderly, all-encompassing plan—whether symbolized by words such as “Liberté, Égalité, Fraternité,” or “Useful, Concrete, and

193. BURKE, *supra* note 3, at 210.

Tangible”—but restraint and moderation may be wiser in the longer run. Naive as it may sound to our jaded modern ears, perhaps we would be better off accepting some of those so-called “self-evident” truths¹⁹⁴ as self-evident after all. *Vive l’ancien régime*.

194. *See supra* note 192 and accompanying text.

A BRAVE NEW WORLD OF DESIGNER BABIES?

By *Sonia M. Suter*[†]

TABLE OF CONTENTS

I. INTRODUCTION	898
II. THE RISE AND FALL OF THE EUGENICS MOVEMENT	901
A. THE ORIGINS OF EUGENICS	902
B. GOVERNMENT INVOLVEMENT AND EUGENICS LAWS	906
C. CONSTITUTIONAL CHALLENGE TO EUGENICS: <i>BUCK V. BELL</i>	909
D. WORLD WAR II AND THE DECLINE OF EUGENICS.....	914
III. PROPHYLAXIS AGAINST CLASSIC EUGENICS	916
IV. TOWARD NEOEUGENICS	922
A. PRENATAL TESTING AND CURRENT GENETIC REPRODUCTIVE TECHNOLOGIES	923
B. ADVANCING TECHNOLOGIES: TOWARDS “DESIGNER BABIES”	929
C. CULTURAL NORMS AND ACCEPTANCE OF NON-THERAPEUTIC REPRODUCTIVE TECHNOLOGIES	934
D. DISTINCTIONS BETWEEN OLD AND NEW EUGENICS?	937
1. <i>Presence or Absence of State Coercion</i>	937
2. <i>Improvements in Science</i>	939
3. <i>Ethnic and Racial Bias</i>	940
4. <i>Societal Versus Individual Benefit</i>	946
V. WHAT’S WRONG WITH (NEO)EUGENICS?.....	948
A. A RELATIONAL ACCOUNT OF AUTONOMY	949
B. EVALUATING EUGENICS THROUGH THE LENS OF RELATIONAL AUTONOMY	954
VI. CONCLUSION	968

© 2007 Sonia M. Suter

[†] Associate Professor, The George Washington University Law School. B.A., Michigan State University, 1985; M.S. Human Genetics, University of Michigan, 1987; J.D., University of Michigan, 1994.

I am grateful to Naomi Cahn, Julie Steiff, Ronald Suter, and Bob Tuttle for their invaluable comments and insights. Many thanks also to Gabrielle Kohlmeier, my research assistant, and Kasia Solon, my library liaison, both of whom were incredibly efficient, thorough, and resourceful. Finally, I want to thank Dean Fred Lawrence and the George Washington University Law School for research and faculty support.

I. INTRODUCTION

With recent advances in genetics, the possibilities for reproductive uses are escalating. Prenatal testing and screening have become a routine part of pregnancy for most women in the United States, leaving the once-narrow confines of genetics clinics for the broader world of general obstetrics. Couples undergoing in vitro fertilization may now have their embryos tested for genetic defects through preimplantation genetic diagnosis. Gene therapy is slowly offering the possibility of treating genetic and other diseases and may one day allow us to enhance or eliminate desirable and undesirable traits, respectively. Cloning, though not yet technologically feasible in humans, no longer seems merely the stuff of science fiction. As genetics has gained more prominence in the public discourse, inevitable concerns have been raised about the implications of reproductive advancements. The worries are often both forward and backward looking. Many worry about technologies we have never seen before: using gene therapy to enhance individuals, cloning those we find desirable, and creating chimeras of animals and humans. Others express concerns about returning to the attitudes and mistakes of our past. Indeed, many have condemned widely accepted (as well as some still theoretical) practices in reproductive genetics as a form of eugenics.

This Article explores the latter concerns—namely, that we are currently using, or will soon use, reproductive technologies in eugenic ways. I refer to these modern practices as “neoeugenics” to suggest that they share some key features with classic eugenics—e.g., the goal of increasing “good birth”—and that they differ because they occur primarily at the individual, rather than state, level. I make this distinction because the history of classic eugenics here and in other countries is reprehensible: people have been prohibited from certain unions, sterilized, and, in Nazi Germany, exterminated. “Eugenics,” once a term suggesting scientific promise, public health improvements, and progress, now connotes injustice, abrogation of basic liberties, and poor science. To label a practice as eugenic is to deem it morally problematic at best and abusive and violating at worst. Modern geneticists, deeply cognizant of the troubled history of eugenics, have worked hard to distance their practices from those of the first half of the twentieth century.

Many articles describe certain reproductive technologies as eugenic or as a form of new eugenics to suggest they are of moral concern.¹ Far too

1. See, e.g., Robert H. Bork, *The Challenges of Biology for Law*, 4 TEX. REV. L. & POL. 1, 3 (1999) (“If the possibility of cloning does not make the concept of offspring obsolete, the specter of eugenics once again looms.”); Marsha Garrison, *Law Making for*

often, commentators fail to elaborate on the widely shared assumption that eugenics is “bad.” While many aspects of classic eugenics were indisputably horrific, this alone does not support the implication that eugenics is per se problematic. Without developing an understanding of what we mean by this term, the discourse regarding the propriety of current and future genetic technologies will be necessarily thin.

My goal is to give fuller substance to the term and to elaborate on the various aspects of eugenics so that we can more carefully evaluate current and future uses of reproductive technologies. Since many criticize these technologies as eugenic, I compare eugenics with neoeugenics to identify more precisely the features of neoeugenics reminiscent of and different from eugenics. What is it about today’s technologies that raises fears about eugenics, and which aspects of these technologies deviate in important ways from eugenics? Recognizing these differences and similarities can help us isolate the areas of possible concern regarding neoeugenics. But, this is only the first step.

My next goal is to wrestle with the prevailing presumption that anything reminiscent of eugenics is per se problematic. Neoeugenics (and even eugenics), I shall argue, is not per se problematic. That is, many of the underlying goals are legitimate. This is not to say that neoeugenics is not problematic in practice; in fact, I shall point out various ways in which we should be deeply troubled by neoeugenics. The analysis, however, is highly contextual, depending both on social factors and individual circumstances. We may ultimately conclude that the context in which neoeugenics is now and will be practiced raises too many concerns. If that is so, the real issue is the social context that makes neoeugenics problematic. If practiced in the right context, neoeugenics need not be problematic. A contextual evaluation, however, suggests that social factors and individual circumstances, intent, and motivation often argue against neoeugenics.

In order to compare neoeugenics with eugenics, Part II addresses the first question: “What exactly is eugenics?” On the hundredth anniversary

Baby Making: An Interpretive Approach to the Determination of Legal Parentage, 113 HARV. L. REV. 835, 919 (2000) (“Use of donated preembryos also presents policy issues For example, a couple might use preembryo donation to engage in eugenic manipulation by choosing sperm and egg donors with traits they deem particularly desirable.”); S. Rebecca Holmes-Farley & Michael A. Grodin, *Law, Medicine and Socially Responsible Research*, 24 AM. J.L. & MED. 153, 157 (1998) (“In addition, the feasibility of gene therapy and the prospect of human cloning raise anew the specter of eugenics”); Michael J. Malinowski & Maureen A. O’Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163, 243-44 (1996) (“Ironically . . . the most readily available technologies—genetic diagnostic and screening capability—raise many of the most ominous ethical questions . . . , [including] eugenics.”).

of the first sterilization law in this country, I begin with a brief history, highlighting how the movement was understood, who supported it and why, and what policies were implemented to achieve its goals. Part II also discusses various features of the eugenics programs, including the interference with reproductive autonomy, the underlying racism and discriminatory views, and the poor scientific basis for the practices. Of course, there are many features of eugenics that, at least with respect to intent, could be praised today: the mission to reduce disease in the population, the efforts to protect the public fisc, and the goal of reducing suffering. What makes “eugenics” such a complex term is that its practitioners were well-intentioned and it meant different things to different people.

Part III emphasizes the distinction between the eugenics era and modern reproductive genetics. I begin by noting the demise of some key features of the eugenics movement and then describe aspects of the twenty-first century that protect against many dangers of the eugenics era. In particular, I show that developments within genetics, norms in genetic counseling, the development of the bioethics movement, and legal protections of reproductive rights distinguish the social milieu of current reproductive technologies from classic eugenics in important ways. Nevertheless, in Part IV, I argue that certain attitudes of the eugenics era remain today, including a resurgence of interest in heredity, race-based categorizations in genetics, a privileging of science, and a focus not only on individual beneficence but also on social welfare. I argue further that an individualized form of eugenics—neoeugenics—is emerging. Neoeugenics strives towards “good birth” at the individual, rather than state level. Current pressures drive many toward selection against genetic disease, and evolving technologies may only enhance the pressures toward voluntary “improvement” of the human species at the individual level. Part IV is merely descriptive, however, offering no normative assessment of these developments.

Part V examines whether prophylactic measures actually eliminate all the concerns associated with eugenics in the modern practice of reproductive genetics. If we evaluate neoeugenics through the lens of individual autonomy and reproductive rights as commonly understood, neoeugenics looks substantially different and much improved from classic American eugenics. Because this conception of autonomy tends to emphasize libertarian ideals, the restrictions on reproduction are the primary problem, and the absence of state coercion over reproduction constitutes an important distinction between neoeugenics and eugenics. I suggest, however, that we evaluate neoeugenics through the lens of relational autonomy. This perspective considers not only whether choices are made free of state and

medical coercion, but whether choices are made in ways that enrich the individual vis-à-vis his or her relationships with others—family, friends, and community. This perspective reveals that the problems with eugenics go beyond state coercion and include underlying prejudices, harms to the disadvantaged, social inequities, and commodification. When we evaluate neo-eugenics through the lens of relational autonomy, we see that many of these concerns still exist. Yet, we also see that many are not unique to eugenics and neo-eugenics but instead reflect broader concerns about existing discriminatory attitudes, inequities, or parental pressures that neo-eugenics might exacerbate. In other words, the root of the problem is the social context in which eugenics and neo-eugenics are practiced.

In this Article, my goal is first to emphasize that the concerns regarding eugenics and neo-eugenics are more similar than we might think if we restrict ourselves to a liberal conception of autonomy. Second, I want to emphasize that neither eugenics nor neo-eugenics can on its face be condemned, because evaluations and criticisms depend deeply on context and intent. As a result, an evaluation of neo-eugenics may raise concerns to which we should be attentive, but it should not require broad scale dismissal of the entire enterprise.

II. THE RISE AND FALL OF THE EUGENICS MOVEMENT

It is not surprising that “eugenics” is a dirty word,² a proxy for all that can go wrong when genetics technology is misapplied. During the reign of eugenics³ in the United States alone, over 60,000 people were involuntarily sterilized⁴ under the authority of legislation in over thirty states.⁵ Inspired by the success of the American eugenics program, Germany enacted a comprehensive sterilization law in 1933, which is estimated to

2. Owen D. Jones, Reproductive Autonomy and Evolutionary Biology: A Regulatory Framework for Trait-Selection Technologies, 19 AM. J.L. & MED. 187, 212 (1993); Daniel Wikler, Can We Learn From Eugenics?, 25 J. MED. ETHICS 183, 183 (1999) (“[T]he term ‘eugenic’ is now used primarily as an epithet.”).

3. It is hard to pin down the precise span of the eugenics era. Most agree that it began around the 1870s, but there is no clear delineation as to when it ended. *See, e.g.*, ALAN PETERSEN & ROBIN BUNTON, THE NEW GENETICS AND THE PUBLIC’S HEALTH 41 (2002) (“Eugenics was espoused and practiced from approximately 1870 to 1950.”); ELOF AXEL CARLSON, UNFIT: A HISTORY OF A BAD IDEA 401 (2001) (“What can be called the American eugenics movement . . . had its origins about the 1870s . . . [and] lasted through the 1930s and then went into eclipse.”).

4. Phillip Reilly, The Surgical Solution: A History of Involuntary Sterilization in the United States 2 (1991).

5. *See infra* text accompanying notes 108-109.

have led to the sterilization of 3,500,000 persons.⁶ Nazi policy went a gruesome step further, resulting in the extermination of various “undesirables, including Jews and Gypsies.”⁷

A. The Origins of Eugenics

To understand the eugenics era, it is essential to understand what eugenics meant to scientists, policy makers, and the public. In 1883, Francis Galton,⁸ a scientist trained in medicine and mathematics,⁹ coined the term “eugenics,” which means “good birth” or “well-born.”¹⁰ Galton’s investigation of the “origins of ‘natural ability’” revealed a disproportionate incidence of blood relatives among eminent men in various disciplines.¹¹ This discovery led him to conclude that traits like character and talent were hereditary just like physical features. With his interest in heredity, Galton pondered whether the selective breeding of plants and animals could be applied to humans. “Could not the race of men be similarly improved? . . . Could not the undesirables be got rid of and the desirables multiplied?”¹²

The scientific community embraced Galton’s ideas in the early 1900s, in large part because they coincided with other important thoughts and developments in science. Darwin’s theory of natural selection had been accepted¹³ and for many was consistent with the notion that “biology was destiny.”¹⁴ Darwin himself became a believer in eugenics.¹⁵ But most im-

6. Phillip R. Reilly, *Eugenics, Ethics, Sterilization Laws*, in 1 ENCYCLOPEDIA OF ETHICAL, LEGAL AND POLICY ISSUES IN BIOTECHNOLOGY 205, 210 (Thomas H. Murray & Maxwell J. Mehlman eds., 2000); see *infra* text accompanying note 102.

7. Lori B. Andrews et al., *Genetics: Ethics, Law and Policy* 60 (2d ed. 2006) [hereinafter *Genetics*].

8. Reilly, *supra* note 6, at 205; Wikler, *supra* note 2, at 184.

9. DANIEL J. KEVLES, *IN THE NAME OF EUGENICS* 7 (1985); Reilly, *supra* note 6, at 205; Wikler, *supra* note 2, at 184.

10. FRANCIS GALTON, *INQUIRIES INTO HUMAN FACULTY AND ITS DEVELOPMENT* 24 (1883); Paul A. Lombardo, *Carrie Buck’s Pedigree*, 138 J. LAB. CLIN. MED. 278, 278 (2001) [hereinafter Lombardo, *Pedigree*]. The term fuses the Greek words for “good” and “birth.” Reilly, *supra* note 6, at 204.

11. KEVLES, *supra* note 9, at 3.

12. *Id.* (citation omitted). Ultimately, Galton described eugenics as the “science of improving stock—not only by judicious mating, but whatever tends to give the more suitable races or strains of blood a better chance of prevailing over the less suitable than they otherwise would have.” Wikler, *supra* note 2, at 184 (citing GALTON, *supra* note 10).

13. Wikler, *supra* note 2, at 184. Indeed, Galton claimed that the publication of the *Origin of Species* in 1859 had sparked his thinking in this area. KEVLES, *supra* note 9, at 8.

14. KEVLES, *supra* note 9, at 20. “Many eugenicists regarded disease as nature’s way of weeding out the unfit.” Martin S. Pernick, *Eugenics and Public Health in American History*, 87 AM. J. PUB. HEALTH 1767, 1767 (1997). One speaker at the first major

portant, Mendel's laws of inheritance, which had attracted little attention when published in 1866, were rediscovered in 1900.¹⁶ The emerging field of genetics was soon inextricably linked to the eugenics movement.¹⁷

Galton's theories of heritability led to research programs across the world.¹⁸ In the United States, Charles Davenport, who would become the leader of American eugenics,¹⁹ received funds to study evolution²⁰ and develop a eugenics research facility. In 1910, he created the infamous Eugenics Records Office at Cold Spring Harbor on Long Island,²¹ which collected extensive family pedigrees to test theories of inheritance.²² Davenport "provided eugenics with a cloak of scientific legitimacy that it wore for more than three decades."²³

Many eugenicists too readily relied on Mendelian theory to explain complex traits.²⁴ Davenport claimed, for example, that "'nomadism,' 'shiftness,' and 'thalassophilia'—the love of the sea"—were based on single Mendelian characters.²⁵ Eugenicists paid little attention to the role of

American conference on eugenics described death as "the normal process of elimination in the social organism, and . . . in prolonging the lives of defectives we are tampering with the functioning of the social kidneys." *Id.*

15. KEVLES, *supra* note 9, at 20 (noting that Darwin remarked Galton had made "a convert of an opponent in one sense, for I have always maintained that excepting fools, men did not differ much in intellect, only in zeal and hard work. . . . [W]e now know, through the admirable labours of Mr. Galton, that genius . . . tends to be inherited.").

16. Reilly, *supra* note 6, at 205; KEVLES, *supra* note 9, at 43.

17. Every member of the first editorial board of the journal *Genetics*, for example, supported the eugenics movement. In addition, textbooks in genetics and biology began to include sections on eugenics. Jon Beckwith, *Thinking of Biology: A Historical View of Social Responsibility in Genetics*, 43 *BIOSCIENCE* 327, 327-28 (1993); Wikler, *supra* note 2, at 184.

18. Wikler, *supra* note 2, at 184.

19. Glenn McGee & David Magnus, *Eugenics, Ethics*, in 1 *ENCYCLOPEDIA OF ETHICAL, LEGAL AND POLICY ISSUES IN BIOTECHNOLOGY* 199, 204 (Thomas H. Murray & Maxwell J. Mehlman eds., 2000).

20. RUTH HUBBARD & ELIJAH WALD, *EXPLODING THE GENE MYTH* 18 (1993); KEVLES, *supra* note 9, at 45; Reilly, *supra* note 6, at 205.

21. Reilly, *supra* note 6, at 205.

22. KEVLES, *supra* note 9, at 45; Reilly, *supra* note 6, at 43. This work led to Davenport's 1911 publication of *HEREDITY IN RELATION TO EUGENICS*, which was based on information about hundreds of families, often extending back three generations. KEVLES, *supra* note 9, at 46.

23. Reilly, *supra* note 6, at 205.

24. For example, Davenport and Galton were strong proponents of Mendel's theories. Both were quick to conclude that a particular trait was heritable solely on the basis that it appeared with high frequency in a family pedigree. KEVLES, *supra* note 9, at 43.

25. *Id.* at 48-49.

environment in the many complex traits they studied²⁶ and relied on unproven assumptions about race.²⁷ They conflated national and racial identity and believed that race determined behavior. Davenport, for example, described the Poles as “independent and self-reliant though clannish” and the Italians as prone to “crimes of personal violence.”²⁸ Like Galton, Davenport identified the white Protestant middle class as good stock.²⁹

This combination of racist notions and sweeping claims about the heredity of complex and amorphous traits led many to answer Galton’s initial question in the affirmative: The “race of men” could be improved; “undesirables” could “be got rid of and the desirables multiplied.”³⁰ This background reveals some key elements of the evolving eugenics movement in the early part of the twentieth century. First, it was in large part a comprehensive research program. Second, it was grounded in an overly simplistic, and often mistaken, understanding of heredity.³¹ Third, and perhaps most fundamental, its underlying goal was improvement of the human race by influencing heredity through patterns of breeding. As Galton once described, eugenics could “providently, quickly, and kindly” do “what Nature does blindly, slowly, and ruthlessly.”³²

26. Davenport acknowledged that individuals were the products of “conditions *and* blood,” but he viewed the “protoplasm” as crucial to “human fate.” KEVLES, *supra* note 9, at 46. He wrote:

Pauperism is a result of complex causes. On one side it is mainly environmental in origin as, for instance, in the case when a sudden accident. . . leaves a widow or family of children without means of livelihood, or a prolonged disease of the wage earner exhausts savings. But it is easy to see that in these cases heredity also plays a part; for the effective worker will be able to save enough money to care for his family in case of accident; and the man of strong stock will not suffer from prolonged disease. Barring a few highly exceptional conditions poverty means relative inefficiency and this in turn usually means mental inferiority.

CHARLES BENEDICT DAVENPORT, HEREDITY IN RELATION TO EUGENICS 80 (1913), *cited in* HUBBARD & WALD, *supra* note 20, at 14.

27. KEVLES, *supra* note 9, at 46-47.

28. *Id.* at 46-47.

29. *Id.* at 47.

30. *Id.* at 4; *see supra* text accompanying note 12.

31. *Cf.* ANGELA FRANKS, MARGARET SANGER’S EUGENIC LEGACY: THE CONTROL OF FEMALE FERTILITY 100 (2005) (describing one scientist who urged eugenics to broaden its narrow focus to allow for the role of environmental influences on human traits). *See generally* CARLSON, *supra* note 3, at 337-45 (detailing the complexities of gene expression that went unrecognized throughout the eugenics era).

32. KEVLES, *supra* note 9, at 12.

The underlying goals and scientific assumptions, however, reveal nothing about how these goals could be achieved. One strand of eugenics—positive eugenics—encouraged the “fit” to choose mates and procreate in accord with eugenic ideals.³³ The father of eugenics, Galton, promoted this strand. In his utopian world, informed people would make the “right” procreative decisions.³⁴ But it was not positive eugenics that “stirred the passions of the crowd.”³⁵ Rather, it was negative eugenics—the attempts to discourage the “unfit” from procreating³⁶—that led to particularly troubling policies in many countries, including the United States.

One method of achieving both positive and negative eugenic goals was through the popularization of eugenics ideas. Eugenics captured the public imagination; according to the Index of Periodical Literature, it was the second most popular topic in the print media in 1910.³⁷ Journalists widely described the now-infamous pedigrees of “white trash” families like the Jukes and the Kallikaks as evidence of the dangers of reproduction among the unfit.³⁸ In the 1920s, the American Eugenics Society further popularized eugenics with exhibits and “Fitter Family” competitions held “in the ‘human stock’ sections” at state fairs.³⁹ The state fairs were used to emphasize not only the positive benefits of heritable traits, like health and sound mind,⁴⁰ but also the social costs of poor inheritance⁴¹ and the “menace of the moron.”⁴² One exhibit posed the question: “How long are we Americans to be so careful for the pedigree of our pigs and chickens and cattle—and then leave the *ancestry of our children* to chance or to ‘blind’ sentiment?”⁴³

33. Robert J. Cynkar, *Buck v. Bell: “Felt Necessities” v. Fundamental Values?*, 81 COLUM. L. REV. 1418, 1428 (1981).

34. ALLEN BUCHANAN ET AL., *FROM CHANCE TO CHOICE: GENETICS AND JUSTICE* 42 (2000) (“Galton . . . wanted to secure voluntary acquiescence with eugenic guidelines by making eugenics a civil religion . . .”).

35. Cynkar, *supra* note 33, at 1428.

36. *Id.*

37. Reilly, *supra* note 6, at 205; Robert G. Resta, *The Twisted Helix: An Essay on Genetic Counselors, Eugenics, and Social Responsibility*, 1 J. GENETIC COUNSELING 227, 231 (1992) (“By the start of World War I, popular publications contained more articles on eugenics than on slums, tenements, and living standards combined.”).

38. Reilly, *supra* note 6, at 205; Wikler, *supra* note 2, at 184.

39. KEVLES, *supra* note 9, at 61-62; Wikler, *supra* note 2, at 184.

40. KEVLES, *supra* note 9, at 62.

41. McGee & Magnus, *supra* note 19, at 200.

42. KEVLES, *supra* note 9, at 78-79; DIANE B. PAUL, *CONTROLLING HUMAN HEREDITY: 1865 TO THE PRESENT*, ch. 4 (1995) [hereinafter PAUL, *HEREDITY*]; McGee & Magnus, *supra* note 19, at 200.

43. KEVLES, *supra* note 9, at 62-63.

B. Government Involvement and Eugenics Laws

What had begun as a movement among scientists and intellectuals around the turn of the century⁴⁴ soon inspired political action to protect the public against the threat of poor genes. Both America and England were highly influential forces in the eugenics movement, but England demonstrated that the movement could be powerful even without restricting liberties in the way that the United States did. England's Parliament enacted only one eugenic statute—the Mental Deficiency Act—which gave a central authority the power to detain and segregate some “feebleminded” individuals,⁴⁵ thereby indirectly interfering with their reproduction. Despite being “the source of much—indeed most—eugenic science and propaganda in the first forty years of the twentieth century,” England never passed laws restricting marriage among the “feebleminded” nor compelled their sterilization.⁴⁶

In the United States, in contrast, legislatures were prolific in enacting eugenics legislation.⁴⁷ By 1914, thirty American states had legal restrictions on marriage of the “feebleminded.”⁴⁸ Anti-miscegenation laws both

44. McGee & Magnus, *supra* note 19, at 200.

45. KEVLES, *supra* note 9, at 98-99. Control and segregation of the mentally deficient was seen as an effective solution to the hereditary threats this group posed to the larger public. As Winston Churchill, then Home Secretary in the Asquith government, explained, although the “feebleminded in Britain deserved ‘all that could be done for them by a Christian and scientific civilization now that they were in the world,’ they should, if possible, be ‘segregated under proper conditions [so] that their curse died with them and was not transmitted to future generations.’” *Id.* at 98. This legislation, however, did not go as far as many eugenicists would have hoped; it did not result in the complete segregation of the “feebleminded and other degenerate types,” allowing many such individuals to avoid institutionalization. *Id.* Moreover, the test of deficiency was “not heredity but social incapacity.” *Id.* at 99.

46. Matt Ridley, *Genome: The Autobiography of a Species in 23 Chapters* 291 (1999).

47. Kevles attributes the different levels of legislative activity in England and the United States to jurisdictional differences: “[I]n Britain such matters fell to a national body, Parliament, whereas in America they were the province of the state legislatures, whose level of deliberation even today leaves a good deal to be desired.” KEVLES, *supra* note 9, at 100-01. More significant, perhaps, was the view in the early twentieth century America that public policy was best served “with the aid of scientific experts,” of whom there were many in the area of eugenics eager to assist the government in social reform. *Id.* at 101.

48. KEVLES, *supra* note 9, at 99. The majority of such statutes voided marriages involving the idiots or insane, and the rest imposed restrictions on marriage among groups like the feebleminded or those with venereal disease. The justification for such laws was usually based on the inability of the mentally deficient to enter into contracts, but sometimes it was overtly eugenic. *Id.*

furthered and were justified by eugenics goals.⁴⁹ But it is the anti-immigration and involuntary sterilization legislation that most clearly marks the eugenics movement in the United States. With the support of other interest groups that lobbied for immigration restrictions at the end of the nineteenth century, eugenicists pushed to reduce the influx of the “genetically inferior.”⁵⁰ As the movement grew, its principles became central to the passage of the Immigration Restriction Act of 1924, which set quotas limiting the immigration of “biologically inferior” ethnic groups into the United States and favored the entrance of Northern Europeans.⁵¹ Harry Laughlin, director of the Eugenics Record Office, served as eugenics expert to the House Committee on Immigration and Naturalization, where he and others presented testimony that certain races and ethnic groups, particularly those from southern and eastern Europe, were biologically inferior.⁵² In the midst of post-World War I xenophobia, concerns about job loss, and racism, Congress eagerly adopted eugenics theories and passed the Immigration Act by an overwhelming majority. President Calvin Coolidge quickly signed the bill into law.⁵³

Eugenicists believed that keeping “unfit” immigrants out of the United States, however, was insufficient to protect the “deteriorating germ-plasm.”⁵⁴ In fact, they believed that negative eugenics required active government involvement to prevent degenerates within the United States from reproducing. The first sterilization law, enacted in Indiana in 1907, ad-

49. *Id.* at 100.

50. A general immigration statute from 1882, which had prevented “idiots, lunatics, convicts, and persons likely to become public charges” from entering the United States, was expanded in 1903 to restrict the immigration of known criminals, epileptics, those with infections or disease, polygamists, beggars, and anarchists. Cynkar, *supra* note 33, at 1432.

51. 22 Stat. 214 (1882) (excluding idiots, lunatics, convicts, and persons likely to become public charges).

52. Among the claims was the assertion that “80-90% of Italian, Russian, Hungarian, and Jewish immigrants were feeble-minded.” Resta, *supra* note 37, at 232.

53. KEVLES, *supra* note 9, at 96-97; McGee & Magnus, *supra* note 19, at 200; Reilly, *supra* note 6, at 205; Resta, *supra* note 37, at 231 (describing how Laughlin argued in favor of this legislation by suggesting that it was not only in the interests of American society but also in the interests of the restricted immigrants). As Vice-President, Calvin Coolidge had declared that “America must be kept American. Biological laws show . . . that Nordics deteriorate when mixed with other races. KEVLES, *supra* note 9, at 97.

54. EDWIN BLACK, WAR AGAINST THE WEAK: EUGENICS AND AMERICA’S CAMPAIGN TO CREATE A MASTER RACE 58 (2003) (describing groups that were “identified as ‘socially unfit’ and targeted for ‘elimination,’” whose extended families were considered “equally unfit because they supposedly carried the defective germ-plasm that might crop up in a future generation”).

dressed those concerns.⁵⁵ Within six years, 14 states had enacted involuntary sterilization programs.⁵⁶ Their statutes authorized compulsory sterilization of habitual criminals and often of the insane, mentally ill, or idiots.⁵⁷ Sterilization, it was thought, would limit the inheritance of “feeble-mindedness” and reduce sexual licentiousness,⁵⁸ which eugenicists believed was linked to “feeble-mindedness.”⁵⁹

In spite of the many sterilization laws and estimates of a “feeble-minded menace” of three to four hundred thousand people,⁶⁰ by 1928, fewer than 9,000 people had been sterilized in the United States.⁶¹ Sterilization laws were more symbolic than effective. They were also the subject of legal battles at various levels of government. In some states, legislatures opposed the laws; in others, executives refused to enforce them; in still others, governors vetoed them;⁶² and finally, in some, courts overturned the statutes as unconstitutional under the Fourteenth or Eighth Amendments.⁶³ As the constitutional challenges proved effective and the influx of immigrants dropped, the eugenics movement temporarily lost steam, and

55. KEVLES, *supra* note 9, at 100; Reilly, *supra* note 6, at 206. The first sterilization bill was introduced in 1897 to the Michigan legislature, but it did not come to a floor vote. *Id.* Pennsylvania’s legislature went a step further in 1905 when it passed a bill authorizing involuntary legislation, but that bill was vetoed by the governor. *Id.*

56. Reilly, *supra* note 6, at 207. By 1917, involuntary sterilization laws existed in fifteen states and in all regions except the South. KEVLES, *supra* note 9, at 100.

57. KEVLES, *supra* note 9, at 100. Iowa’s statute was the most far reaching, requiring sterilization of individuals with such behaviors and conditions as “drug addiction, sexual offenses, and epilepsy.” *Id.*

58. *Id.* at 107-08. Of course, these views seemed to equate sterilization with castration. In fact, sterilization did not reduce sexual drive in men or women. *Id.* at 108; Reilly, *supra* note 6, at 206.

59. This link was hopelessly circular: “Immoral behavior was taken ipso facto as evidence of feeble-mindedness, which in turn was claimed to produce immoral behavior.” KEVLES, *supra* note 9, at 107.

60. *Id.* at 106-07.

61. *Id.* at 106.

62. *Id.* at 109. When vetoing the Pennsylvania sterilization bill, Governor Pennypacker remarked: “It is plain that the safest and most effective method of preventing procreation would be to cut off the heads of the inmates.” *Id.*

63. KEVLES, *supra* note 9, at 109; Reilly, *supra* note 6, at 207. By World War I, courts had found sterilization statutes unconstitutional in seven states. KEVLES, *supra* note 9, at 110. In New York, the constitutional challenge of its sterilization law revealed some disagreements among the eugenics experts regarding the best strategy to reduce retardation. Davenport testified that he favored segregation over sterilization, and another prominent eugenicist argued that sterilization should be voluntary. Reilly, *supra* note 6, at 207.

very little involuntary sterilization legislation was enacted around and during World War I.⁶⁴

The hiatus was short-lived, however. The 1920s saw a stronger and more powerful eugenics movement. Prominent eugenicists were members of prestigious intellectual institutions, wealthy donors founded more eugenics organizations, and local eugenics organizations proliferated.⁶⁵ Most important, however, were Harry Laughlin's efforts to revitalize sterilization laws. He not only published the highly influential *Eugenical Sterilization in the United States*,⁶⁶ which demonstrated the societal benefits of the eugenics strategy, but he also drafted a model sterilization law to overcome the constitutional objections that had stymied previous sterilization laws. Finally, legislatures revisited the question of eugenic sterilization and enacted new laws, even in states where governors had vetoed prior attempts.⁶⁷ Seventeen states had sterilization laws by 1926 and, in a few states, directors of state institutions allowed involuntary sterilizations for eugenics purposes even without statutory authority.⁶⁸

C. Constitutional Challenge to Eugenics: *Buck v. Bell*

The constitutionality of eugenics sterilization was still at issue, however, even after the Michigan Supreme Court upheld a sterilization law against constitutional challenges in 1925.⁶⁹ Determined proponents of eugenics sterilization initiated a lawsuit in Virginia, *Buck v. Bell*, to test the constitutionality of Virginia's sterilization law, which had been carefully drafted to avoid many of the legal pitfalls of prior legislation.⁷⁰ The litiga-

64. KEVLES, *supra* note 9, at 110; Reilly, *supra* note 6, at 207.

65. Reilly, *supra* note 6, at 207.

66. The work became a "prized reference text among sterilization activists." Lombardo, *Pedigree*, *supra* note 10, at 279. Indeed, it was so highly respected in Nazi Germany that the University of Heidelberg awarded Laughlin an honorary degree in 1934. Reilly, *supra* note 6, at 207.

67. Reilly, *supra* note 6, at 206-07.

68. *Id.* at 208.

69. *Smith v. Wayne*, 231 Mich. 409, 415-16 (1925) (finding that the statute was "justified by the findings of biological science" and was a "proper and reasonable exercise of the police power of the state"); Reilly, *supra* note 6, at 207-08.

70. Dr. Priddy, the superintendent of the Virginia Colony for Epileptics and Feeble-minded, relied on Laughlin's 1914 Model Sterilization Act in proposing the legislation that was enacted in Virginia. Lombardo, *Pedigree*, *supra* note 10, at 279. This legislation was one of several statutes that Dr. Priddy initiated in his efforts to rid society of the "blight of mankind" caused by the growing number of "feeble-minded." Among the early statutes was one that allowed the superintendent of the Colony to provide "moral, medical and surgical treatment as [he] may deem proper," which he used to justify the sterilization of more than two dozen women. One patient brought an action for damages associated with her involuntary sterilization. Although Dr. Priddy received a jury verdict in

tion and reasoning of the courts in this infamous case vividly illustrate how deeply eugenic ideals had penetrated American culture.

Carrie Buck was chosen for the first sterilization under the new Virginia law because she was considered a classic example of a sexually immoral and mentally deficient individual accounted for by “hereditary qualities.”⁷¹ Her putative life of “immorality, prostitution, and untruthfulness” and illegitimate pregnancy led her foster parents to institutionalize her at the Virginia Colony for Epileptics and Feeble-minded.⁷² Not only was she deemed “‘socially inadequate’ and ‘the probable potential parent of socially inadequate offspring,’”⁷³ but an IQ test also placed her at the intellectual level of a nine-year-old. In addition, her mother, who was also institutionalized, was considered equally morally deficient⁷⁴ as was Carrie’s illegitimate daughter of less than a year, who “showed backwardness.”⁷⁵

When Carrie’s guardian challenged the petition to sterilize Carrie, numerous eugenics experts and others testified in support of the heritability of Carrie Buck’s “feeble-mindedness.”⁷⁶ Laughlin testified in writing that Carrie’s “family history . . . demonstrates the hereditary nature of the feeble-mindedness and moral delinquency described in Carrie Buck.”⁷⁷ With

his favor, after claiming the defense of therapeutic prerogative, the case highlighted “the importance of complying with every technical requirement of law,” and likely inspired him to pursue legislation that specifically granted the power to perform involuntary sterilizations for eugenic purposes. Paul A. Lombardo, *Three Generations, No Imbeciles: New Light on Buck v. Bell*, 60 N.Y.U. L. REV. 30, 36-45 (1985) [hereinafter Lombardo, *Three Generations*].

71. Lombardo, *Pedigree*, *supra* note 10, at 280.

72. *Id.*

73. *Id.* (quoting Virginia Colony officials).

74. Carrie’s mother had several illegitimate children, each with a different father; had a history of syphilis; and was thought to be a prostitute. *Id.* at 279-80.

75. KEVLES, *supra* note 9, at 110; Reilly, *supra* note 6, at 208; Cynkar, *supra* note 33, at 1418; Lombardo, *Pedigree*, *supra* note 10, at 278-80. Carrie’s child, Vivian, was given a mental test at just six months and diagnosed by a sociologist and field worker from the Eugenics Record Office as “below the average.” *Id.* Not surprisingly, psychologists criticized these field workers’ amateur diagnoses of mental abilities as being based on improper testing simply to support their eugenic theories. *Id.* At one point, “the secretary of the local Red Cross pointed out to Dr. Priddy that Carrie’s daughter had never undergone a psychiatric examination and that there was no evidence” she was in fact “feeble-minded.” Cynkar, *supra* note 33, at 1438.

76. One teacher spoke of Carrie’s flirtatious behavior; a nurse described Carrie’s infant daughter as having “a look about [her] that is not quite normal”; and other witnesses described Carrie and other members of her family as “peculiar.” Lombardo, *Pedigree*, *supra* note 10, at 280.

77. Cynkar, *supra* note 33, at 1439. In fact, the pedigree was drawn from rather vague and scanty descriptions of Carrie and her family members. Moreover, Laughlin never

so much evidence supporting that Carrie would be a “potential source of [an] incalculable number” of “feeble-minded” descendants, the Circuit Court upheld the sterilization order, and the Virginia Supreme Court affirmed.⁷⁸ The case ultimately reached the United States Supreme Court. Readily accepting the lower court’s findings that Carrie Buck was “the probable potential parent of socially inadequate offspring,”⁷⁹ Justice Holmes infamously declared that “three generations of imbeciles are enough.”⁸⁰ In a remarkably short five-paragraph opinion, he held that the sterilization statute did not violate Carrie Buck’s rights of due process and equal protection under the Fourteenth Amendment and upheld the lower court rulings.⁸¹

Justice Holmes concluded that the procedural rights of patients under the statute “are most carefully considered.”⁸² As to the substantive due

actually examined Carrie. *Id.* Nevertheless, the illegitimacy in Carrie’s family was damning given that many eugenicists found a high correlation between illegitimacy and “feble-mindedness.” Lombardo, *Pedigree*, *supra* note 10, at 280.

78. Cynkar, *supra* note 33, at 1439-40.

79. *Buck v. Bell*, 274 U.S. 200, 207 (1927).

80. *Id.*

81. Carrie Buck’s attorney, I.P. Whitehead, raised a substantive due process claim, arguing that the statute violated her “constitutional right of ‘bodily integrity’” and that it deprived her of life without due process of law—which the Fourteenth Amendment protected by prohibiting “deprivation not only of life, but of whatever God has given to everyone with life.” His equal protection argument rested on the fact that only the “feeble-minded” individuals who were institutionalized were subject to involuntary sterilization, and that the state had no good justification for singling out this group, particularly since their segregation in institutions already achieved the objectives of preventing their procreation. Cynkar, *supra* note 33, at 1447.

82. Justice Holmes noted that the statute required (1) a petition to the “special board of directors of his hospital or colony, stating the facts and the grounds for [sterilization], verified by affidavit,” (2) that the inmate, and his guardian be served notice “of the petition and of the time and place of the hearing in the institution, . . . and if there is no guardian the superintendent is to apply to the Circuit Court of the County to appoint one,” (3) “that the inmate may attend the hearings if desired by him or his guardian,” (4) that the evidence for the sterilization “be reduced to writing,” (5) that any party may appeal to the Circuit Court of the County “after the board has made its order for or against the operation,” and (6) that any party may apply to “the Supreme Court of Appeals, which, if it grants the appeal, is to hear the case upon the record of the trial in the Circuit Court and may enter such order as it thinks the Circuit Court should have entered.” *Buck*, 274 U.S. at 206. He failed to note the procedural protections that are missing, such as the inmate’s “right to an attorney and the right to subpoena and cross-examine witnesses, including experts who would be paid by the state to testify on behalf of the inmate.” LORI B. ANDREWS ET AL., *TEACHER’S MANUAL TO ACCOMPANY GENETICS: ETHICS, LAW, AND POLICY* 8 (2d ed. 2006). And of course, as Paul Lombardo has shown, the procedural protections in place did little to protect those like Carrie Buck, when there was “no true advo-

process claim, he declared that compulsory sterilization was no worse than drafting good men for war or compulsory vaccination to protect the public.⁸³ Better, he concluded, to “prevent those who are manifestly unfit from continuing their kind” than to wait “to execute degenerate offspring for crime, or to let them starve for their imbecility.”⁸⁴ Finally, he summarily dispensed with the equal protection claim,⁸⁵ concluding that the statute actually promoted equality by enabling “those who otherwise must be kept confined to be returned to the world.”⁸⁶ In short, Holmes was thoroughly persuaded by eugenic claims that “sterilization was the most humane way to deal with the feebleminded.”⁸⁷

Buck v. Bell marks the pinnacle of legal legitimacy of compulsory sterilization and also represents much of what was wrong with eugenics, including the underlying racism and class biases,⁸⁸ reinforcement of social inequities,⁸⁹ and threats against democracy.⁹⁰ Although the movement enjoyed widespread support from various camps until the Second World War, there were notable critics⁹¹ who voiced these concerns and others. A few religious leaders, especially those of the Catholic Church, objected

cate for the victim and no unbiased decision-maker.” *Id.* (referring to Lombardo, *Three Generations*, *supra* note 70, at 50-55).

83. *Buck*, 274 U.S. at 207.

84. *Id.*

85. He did so almost snidely, remarking that such claims are the “usual last resort of constitutional arguments to point out shortcomings of this sort.” *Id.* at 208.

86. *Id.*

87. Cynkar, *supra* note 33, at 1450. Justice Holmes explicitly accepted the lower court’s finding that sterilization was not detrimental to Carrie Buck’s health and would actually promote her and society’s welfare. *Buck*, 274 U.S. at 207.

88. KEVLES, *supra* note 9, at 121; PAUL, *supra* note 42, at 11; Garland E. Allen, *Is a New Eugenics Afoot?*, 294 SCI. 59, 61 (2001) (noting that one critic, for example, “claimed that eugenics was racism disguised as science”); Jennifer Geetter, *Coding for Change: The Power of the Human Genome to Transform the American Health Insurance System*, 28 AM. J.L. & MED. 1, 20 (2002).

89. MARK H. HALLER, EUGENICS 89 (1984) (stating that one of the main critics on these grounds “feared the belief in innate class differences, since such a belief often excused inequalities between the classes and thwarted efforts to extend protection and opportunities to individuals in the poorer classes”); KEVLES, *supra* note 9, at 121 (“In the impassioned view of many dissidents, to rank the merits of the national germ plasm of the future ahead of the human needs of the socially disadvantaged in the present seemed morally outrageous.”).

90. KEVLES, *supra* note 9, at 120 (“Various critics pointed to the mainline eugenic movement’s distrust of democracy, to its claims that men were not created equal even in political right, to its threat to establish some sort of caste system of government.”).

91. PAUL, HEREDITY *supra* note 42, at 11-12 (noting, however, that some of the “harsh critics of the eugenics movement often shared some of its assumptions”).

that eugenics threatened human dignity by commodifying and restricting reproduction.⁹²

The most common criticism was eugenics' reliance on erroneous and oversimplified scientific notions and careless, often false, characterizations of individuals based on class, education, and status.⁹³ Carrie Buck, for example, the "ideal" candidate for eugenic sterilization, was in fact neither an imbecile nor immoral, as Paul Lombardo has shown. Her attorney could easily have countered the state's evidence of her "feeble-mindedness," had he chosen to be a true advocate for her.⁹⁴ Carrie's school re-

92. See HARRY BRUNIUS, *BETTER FOR ALL THE WORLD: THE SECRET HISTORY OF FORCED STERILIZATION AND AMERICA'S QUEST FOR RACIAL PURITY* 230 (2006) ("[Catholics] insisted on the essential *spiritual* dignity of every human individual. [T]he physical attributes of mankind . . . were still subject to an immutable 'natural law' governed by the laws of God . . . Marriage and bringing forth children were considered sacred rights or even duties . . ."); KEVLES, *supra* note 9, at 119 ("The Church stressed the role of love and religious ethics, rather than parental perfection of physique and intelligence, in producing offspring with eugenic qualities."); CHRISTINE ROSEN, *PREACHING EUGENICS: RELIGIOUS LEADERS AND THE AMERICAN EUGENICS MOVEMENT* 140 (2004) ("Catholic interpretation of natural law . . . stresses the dignity of the individual.").

93. See KEVLES, *supra* note 9, at 121-22 (noting that "for most scientists, much of what passed as eugenic research was slipshod in method, evidence, and reasoning" and a form of biological reductionism); NANCY ORDOVER, *AMERICAN EUGENICS: RACE, QUEER ANATOMY AND THE SCIENCE OF NATIONALISM* 230 n.103 (2003) (describing one who defected from the American Eugenics Society because of Laughlin's dismally "skewed statistics"); Allen, *supra* note 88, at 64 (noting the criticisms regarding poor data collection and "the failure of eugenicists to define traits like feeble-mindedness or criminality"); Geetter, *supra* note 88, at 19-21 (2002) (noting critics' concerns that eugenics privileged heredity over environment, and their belief that "society largely made people bad, rather than heredity"). Nevertheless, "[n]early all geneticists of the 1920s and 1930s—including those traditionally characterized as opponents of eugenics—took for granted that the "feeble-minded" should be prevented from breeding." DIANE B. PAUL, *Did Eugenics Rest on an Elementary Mistake?*, in *THE POLITICS OF HEREDITY* 127 (1998) [hereinafter PAUL, POLITICS]. It was not until the late 1920s or 1930s that the scientific criticisms really began to mount. ANGELIQUE RICHARDSON, *LOVE AND EUGENICS IN THE LATE NINETEENTH CENTURY: RATIONAL REPRODUCTION AND THE NEW WOMAN* 222-23 (2003); Allen, *supra* note 88, at 59.

94. Carrie's attorney was "an ineffective and unenthusiastic defender of his client's interests." Elliott A. Brown, *Case Histories, Interest Group Litigation, and Mr. Justice Holmes: Some Unexplored Questions on Psycho-Political Behavior*, 24 *EMORY L.J.* 1037, 1049-50 (1975). He challenged the State's attempt to use surgical sterilization, but conceded that "the State has the right to segregate the feeble-minded and thereby deprive them of the 'power to procreate.'" Cynkar, *supra* note 33, at 1448. He failed to challenge the alleged social utility of limiting the procreation of the "feeble-minded," the power of the state to pursue eugenic goals, and the underlying "'scientific' theories." *Id.* Moreover, he failed to bring forward any witnesses to challenge the assertions regarding Carrie Buck, which ultimately proved false. Lombardo, *Three Generations*, *supra* note 70, at 51.

cords indicated that she was a normal child promoted to sixth grade in five years, and a teacher commented that she was “very good—deportment and lessons.”⁹⁵ Later in life, she was an avid reader who “regularly displayed intelligence and kindness that belied the ‘feble-mindedness’ and ‘immorality’ that was used as an excuse to sterilize her.”⁹⁶ Moreover, her illegitimate pregnancy, which resulted in her institutionalization and “evidenced” her moral impropriety and “feble-mindedness,” was probably the result of rape by her foster mother’s nephew.⁹⁷

Although *Buck v. Bell* was based on shoddy science, shoddy advocacy, and a shoddy investigation into the true state of Carrie Buck’s life and health, it was a milestone for eugenics policymaking, laying to rest any constitutional concerns surrounding sterilization statutes. By 1931, four years after *Buck* was decided, 28 states had eugenic sterilization laws, which they then implemented vigorously. For over a decade, the nation sterilized roughly 2,500 to 3,000 individuals a year.⁹⁸ America had reached the pinnacle of its eugenics efforts.

D. World War II and the Decline of Eugenics

Inspired by the dominance of American eugenicists in their legislative and research efforts, other countries soon followed suit.⁹⁹ Germany’s program of “Racial Hygiene” and sterilization ultimately dwarfed the eugenic efforts of the United States and others.¹⁰⁰ In 1933, Germany enacted a comprehensive eugenic sterilization act, which created a system of Hereditary Health Courts with authority to sterilize the unfit. The act originally targeted those with a “great probability” of passing on “feble-mindedness,” mental illness, and various disabilities and diseases.¹⁰¹ Eventually, the law included non-Germans and many others on the “weakest of pre-

In fact, Lombardo has suggested that the behavior of Carrie’s attorney “suggests a deliberate decision not to defend Carrie.” *Id.*

95. Lombardo, *Three Generations*, *supra* note 70, at 52.

96. *Id.* at 61.

97. *Id.* at 52-54, 60-61.

98. One year the total reached nearly 4,000; and as late as 1940, a reported 2,800 sterilizations took place. Reilly, *supra* note 6, at 208.

99. BLACK, *supra* note 54, at 258, 262-77 (2003). Many European countries—including Germany, Norway, Sweden, and Finland—enacted sterilization laws. Reilly, *supra* note 6, at 210.

100. Germany, like many other countries, did not start immediately with sterilization but first employed other eugenics efforts, such as legislating against sexual relations between Aryans and Jews; creating marriage advice clinics; and instituting the positive-eugenics Lebensborn programs, which encouraged ideal Aryans to procreate by providing extra public benefits. Reilly, *supra* note 6, at 210; Wikler, *supra* note 2, at 185-86.

101. Reilly, *supra* note 6, at 210.

tenses,” including being half-Jewish. It is estimated that the Nazi programs sterilized 3.5 million individuals.¹⁰² In 1939, the Third Reich went far beyond sterilization, implementing euthanasia to eliminate the mentally diseased, the disabled, and the Jews. Roughly 70,000 patients were selected for euthanasia, including tens of thousands of “Aryans,” most of whom were young children.¹⁰³ Ultimately, the Germans would expand their eugenics program into the Holocaust, which took the lives of roughly 11 million individuals.¹⁰⁴

The World War II era reflects both the extremes of eugenics and the beginning of its end. When Germany lost the war, its eugenics efforts necessarily stopped. Around that time, eugenics also fell out of fashion in the United States. Most believe that its demise was primarily due to “universal revulsion” of the Nazi version of eugenics.¹⁰⁵ Some argue instead that it

102. Within a year of the law’s enactment, the courts approved two-thirds of the 84,500 petitions for sterilization. By the next year, the number sterilized nearly tripled. *Id.*

103. KEVLES, *supra* note 9, at 118; Wikler, *supra* note 2, at 185. It is humbling to note that in England and the United States, the eugenics community seriously debated and considered euthanasia. Although ultimately unsuccessful, some lawmakers proposed legislation giving physicians the authority to euthanize mentally retarded and permanently diseased individuals. Euthanasia was considered by Laughlin and others at the Eugenics Section of the American Breeders Association as the eighth of nine eugenic options. As one eugenicist wrote, “[h]eredity is the fundamental cause of human wretchedness. The surest, the simplest, the kindest, and most humane means for preventing reproduction among those whom we deem unworthy of this high privilege [reproduction], is a gentle, painless death.” Cynkar, *supra* note 33, at 1429. Davenport himself argued in defense of a physician who publicized his euthanasia of infants with birth defects, writing, “If the progress of surgery is to be used to the detriment of the race . . . [i]t may conceivably destroy the race. Shortsighted they who would unduly restrict the operation of what is one of Nature’s greatest racial blessings—death.” BLACK, *supra* note 54, at 247-56 (quoting W. DUNCAN MCKIM, HEREDITY AND HUMAN PROGRESS 120 (1900)). Propaganda in favor of eugenic euthanasia resulted in a successful film called THE BLACK STORK, in which a woman who is counseled against having children for eugenic reasons gives birth to a defective child who is allowed to die and ends up in the welcoming arms of Jesus Christ. *Id.* at 257-58; see also MARIN S. PERNICK, THE BLACK STORK: EUGENICS AND THE DEATH OF “DEFECTIVE” BABIES IN AMERICAN MEDICINE AND MOTION PICTURES SINCE 1915 (1996).

104. MICHAEL BERENBAUM, *The Uniqueness and Universality of the Holocaust, in A MOSAIC OF VICTIMS: NON-JEWS PERSECUTED AND MURDERED BY THE NAZIS* 20 (Michael Berenbaum ed., 1990) (describing the Holocaust as “the systematic murder of eleven million people, six million of whom were Jews . . . and five million of whom were non-Jews”).

105. KEVLES, *supra* note 9, at 251 (“[The] Holocaust had all but buried the eugenic ideal. After the Second World War, ‘eugenics’ became a word to be hedged with caveats in Britain and virtually a dirty word in the United States, where it had long been identified with racism.”); Beckwith, *supra* note 17, at 329. In 1954, the *Annals of Eugenics* was

was due to a shortage of nurses and surgeons available to perform the sterilizations.¹⁰⁶ In addition, the maturation of genetics revealed that eugenic explanations of complex traits were “at best quaint and at worst dangerous.”¹⁰⁷ Nonetheless, eugenics programs did not completely die for several decades—eugenic sterilizations continued until the 1970s and perhaps early 1980s.¹⁰⁸ Even now, only a handful of states have repealed their eugenics sterilization laws, although the programs are inactive in those states that still retain such legislation. In Europe, countries no longer provide legal authority for involuntary sterilizations and some countries actively prohibit them.¹⁰⁹ Today, in the United States and Europe, at least, most would argue that classic eugenics has come to an end.¹¹⁰

III. PROPHYLAXIS AGAINST CLASSIC EUGENICS

While most argue that the classic eugenics movement met its demise in the mid-1930s and ‘40s or later,¹¹¹ some suggest that eugenics never died, but merely transformed itself.¹¹² If some form of eugenics exists or is

renamed the *Annals of Human Genetics*, reflecting the attempts among geneticists to distance the science of genetics from eugenics. KEVLES, *supra* note 9, at 251-52.

106. Reilly, *supra* note 6, at 210.

107. *Id.* at 211.

108. In the 1950s, Georgia, North Carolina, and Virginia performed one-half to three-quarters of the nation’s involuntary sterilizations. In 1958 alone, these three states performed nearly 600 such surgeries. In the early 1970s, North Carolina performed more than twenty sterilizations under its eugenics statute. Reilly, *supra* note 6, at 211 (“Although one cannot point to a moment in which state-sanctioned eugenical sterilization in the United States ended, a satisfactory date is 1983 when a class-action lawsuit brought by women in Virginia who had been sterilized without their consent while in state facilities was settled.”).

109. *Id.* at 212.

110. Existing programs and legislation in some Asian countries could be described as eugenic. For example, China’s Maternal and Infant Health Care Law enacted in 1994 requires medical counseling for the marriage of people with relatives who have such conditions as mental retardation, epilepsy, and mental illness. In addition, some of the language suggests that sterilization or long-term contraception is required for individuals to marry if they are at risk of having children with those conditions. Reilly, *supra* note 6, at 213; see *China’s ‘Eugenics’ Law Still Disturbing Despite Relabelling*, NATURE, Aug. 20, 1998, at 707; Dennis Normile, *Geneticists Debate Eugenics and China’s Infant Health Law*, 281 SCI. 1118 (1998); Jack Kim, *North Korea Tied to Baby Deaths*, WASH. TIMES, Mar. 23, 2006, at 14 (describing the lack of people with physical disabilities in North Korea because “they are killed almost as soon as they are born”).

111. Lene Koch, *The Meaning of Eugenics: Reflections on the Government of Genetic Knowledge in the Past and the Present*, 17 SCI. IN CONTEXT 315, 317 (2004).

112. See, e.g., WENDY KLINE, *BUILDING A BETTER RACE: GENDER, SEXUALITY AND EUGENICS FROM THE TURN OF THE CENTURY TO THE BABY BOOM* (2001) (arguing that

possible today, one thing is clear—it is not precisely the same kind of eugenics as that of the twentieth century. Many of the features that marked “classic” eugenics are now absent in the United States. “Fitter family” competitions no longer exist; individuals are no longer diagnosed as “feebleminded” or segregated and institutionalized on that basis; the Immigration Restriction Act of 1924 and anti-miscegenation laws were repealed;¹¹³ the Eugenics Records Office, home of many of the eugenic theories and policy work, officially closed in 1939;¹¹⁴ and, most importantly, statewide programs of involuntary sterilization and “euthanasia” of the unfit no longer exist. Indeed, in some states, governors have formally apologized to the victims of eugenics.¹¹⁵ Moreover, developments within the field of genetics and genetic counseling, bioethical norms, and modern legal protections of reproductive rights act as a prophylaxis against some of the most troubling features of classical eugenics. These developments would have likely protected the Carrie Bucks of the past from the law’s indifference to their reproductive rights, the medical profession’s indifference to their ability to make informed and personal medical decisions, and the scientific community’s indifference to their true intellectual and medical status.

As human genetics evolved into a legitimate discipline, geneticists began to distance themselves from the wildly over-simplistic, racially biased, and sweeping claims that marked the eugenics movement.¹¹⁶ Advancements in genetics ultimately debunked the “science” of classic eugenics by revealing the complexities of inheritance and the multifactorial components of traits and even disease.¹¹⁷ The science of the eugenics era was

eugenicists shifted their tactics from a focus on heredity to a focus on the home environment of children and, with this shift in focus, embarked on a form of “positive” eugenics where the fit were encouraged to procreate, contributing to the baby boom of the 1950s).

113. Jones, *supra* note 2, at 215 n.140 (Immigration Act of 1924, ch. 190, 43 Stat. 153 (repealed 1952)); Resta, *supra* note 37, at 231 (describing repeal of anti-miscegenation laws in the 1960s).

114. Resta, *supra* note 37, at 233.

115. See Michael G. Silver, *Eugenics and Compulsory Sterilization Laws: Providing Redress for the Victims of a Shameful Era in United States History*, 72 GEO. WASH. L. REV. 862, 886-88 (describing the apologies of governors in Virginia, North Carolina, Oregon, South Carolina, and California).

116. *But see* KEVLES, *supra* note 9, at 259-68 (describing lingering attitudes in favor of positive eugenics among some scientists); Resta, *supra* note 37, at 232-33 (noting that the geneticists rejected eugenics “slowly and not as completely as some authors have suggested”).

117. Evidence suggests that some of the pedigrees of dysgenic families, intended to prove the eugenic theories about the inheritance of unfit traits, were manipulated consciously and unconsciously. Resta, *supra* note 37, at 230.

shoddy and careless, and many of its strongest proponents were non-scientists with only a slim grasp of genetics. As Troy Duster writes, “[t]hose on the fringe of genetics and biology commonly preached the gospel of eugenics, magically converting spurious correlations into causation, and subsequently into social policy.”¹¹⁸ Even the scientists were careless and inaccurate in collecting and interpreting data and in reaching conclusions, often reducing complicated patterns of inheritance into simple Mendelian patterns.¹¹⁹

Carrie Buck’s case is a prime example. Treating her merely as a pawn in his social agenda, Laughlin tried to “construct a ‘precise’ psychological and genealogical analysis of Carrie Buck that would stand up in a court of law” without bothering to examine her or to collect careful data about her or her family.¹²⁰ While diagnoses are still not always perfect, it would be rare to find physicians making such reckless diagnoses today. In part, this is because modern genetic claims, though surely to be revised as we learn more in the future, are based on more accurate clinical evaluations and molecular analysis. In short, genetics is not only more advanced today—it is more careful and rigorous than the “science” of eugenics.¹²¹

As genetics grew more sophisticated, the focus turned away from social reform to biochemical understandings and prevention of genetic disease.¹²² Whereas eugenics was in many ways separate from medicine,¹²³

118. Troy Duster, *Backdoor to Eugenics* xii (2003).

119. *See supra* text accompanying notes 24-29.

120. Cynkar, *supra* note 33, at 1439; *see supra* note 75.

121. DUSTER, *supra* note 118, at xii. Duster writes:

[T]he old eugenics movement was not based upon any demonstrable successful intervention by medicine or science into human genetic affairs. The current technology is both eminently successful in its predictive power, and potent in extending its impact to such concerns as the prenatal detection of human birth defects, and the application of growth hormones from gene-splicing techniques with recombinant DNA. . . . [T]he new genetics technology is more immediate in its promise: the mitigation of problems (birth defects, mental illness, nutritional deficiency) not the creation or sustenance of discredited claims of racial superiority or purity.

Id.

122. KEVLES, *supra* note 9, at 251-53; Seymour Kessler, *The Psychological Paradigm Shift in Genetic Counseling*, 27 *SOC. BIO.* 167, 168 (1980).

123. The pioneer genetic counselors tended to be non-medical geneticists or non-practicing physicians, who brought about legislation to require sterilization of some mentally handicapped people. They focused on societal, rather than individual, concerns. Kessler, *supra* note 122, at 168; *see also* Dorothy Wertz, *Eugenics and Genetics*, *GENE-LETTER*, Feb. 1999, available at <http://www.genesage.com/professionals/geneletter/archives/eugenicsdefinitions.html>. Wertz writes:

the new human genetics found a legitimate home within medicine by the middle of the twentieth century.¹²⁴ The science of heredity was no longer primarily a tool for social and legislative reform, indifferent to the plight of individuals like Carrie Buck; it was now a tool within medicine used for individuals' benefit. As human genetics entered the medical community, a new field of "genetic counseling" emerged.¹²⁵ In its infancy, genetic counseling was described as "genetic hygiene"¹²⁶ or even "eugenic,"¹²⁷ but its "new, improved" eugenics philosophy emphasized "individual idealism regarding future generations," with some genetic counselors withdrawing their support from the eugenics movement altogether.¹²⁸ Others did "not oppose eugenics, per se," but opposed the particular methods of "traditional eugenicists."¹²⁹ To distance themselves from the "more pretentious eugenic suggestions,"¹³⁰ many of these early genetic counselors strongly objected to compulsory sterilization and urged voluntary compliance from affected individuals. In addition, they tried to provide "informed, sympathetic counseling" for people with genetic risks who faced reproductive decisions.¹³¹

For some time, genetic counselors were often explicitly directive, which is to say they were prescriptive about patients' medical options.¹³² In the new medical setting, many features of the doctor-patient relationship temporarily became a part of genetic counseling. The genetic coun-

The leaders of eugenic thought in the 19th and 20th centuries were a mixed lot, including socialists and conservatives, philosophers (John Stuart Mill and Bertrand Russell), feminists, birth control crusaders (Margaret Sanger), psychologists, behavioral scientists, politicians, and even playwright George Bernard Shaw. Few were physicians or geneticists, who were mostly concerned with their patients or their research, rather than with improving society.

Id. See also ANNE KERR & TOM SHAKESPEARE, *GENETIC POLITICS: FROM EUGENICS TO GENOME* 11 (2002) (describing "a general disinterest in eugenics amongst the medical profession"); KEVLES, *supra* note 9, at 332 n.36 ("Predominantly laymen, eugenic activists were usually so much more concerned with propaganda than with knowledge that even pro-eugenic scientists found the situation an embarrassment.").

124. KEVLES, *supra* note 9, at 253.

125. Ian H. Porter, *Evolution of Genetic Counseling in America*, in *GENETIC COUNSELING* 26 (Herbert A. Lubs & Felix de la Cruz eds., 1977); Sheldon C. Reed, *A Short History of Genetic Counseling*, 21 *SOC. BIO.* 332, 334-35 (1974).

126. KEVLES, *supra* note 9, at 253.

127. Koch, *supra* note 111, at 317.

128. Kessler, *supra* note 122, at 168.

129. Resta, *supra* note 37, at 233.

130. Porter, *supra* note 125, at 24.

131. *Id.* at 23-24.

132. Koch, *supra* note 111, at 317.

selor was seen as educator and advisor, and the counselees were expected to comply with the counselor's recommendations.¹³³ With the growing sense of "individual idealism," however, genetic counselors adopted a non-directive style¹³⁴ in which the counselor (usually a physician) did not have ultimate control over the client.¹³⁵ Non-directiveness markedly contrasts with the norms of eugenicists, who were directive, controlling, and completely indifferent to the choices of young women like Carrie Buck.¹³⁶ Under non-directiveness, the medical professional is expected to remain neutral as to an individual's ultimate decisions, because genetic counselors strongly believe such decisions are for the patient and no one else to make.

The commitment to non-directiveness grew as more non-physician genetic counselors entered the profession. Genetic counselors realized that preventive goals were no longer realistic. Moreover, they recognized that genetic information could evoke strong emotional responses and have potential long-term effects on the individual and family.¹³⁷ Social and cultural changes were perhaps equally important. Our culture was becoming increasingly uncomfortable making moral judgments about others, adopting a "language of therapy" to respond to issues that once would have been included in moral discourse.¹³⁸ Thus, the psychological-paradigm for genetic counselors mirrored cultural changes, emphasizing the need to help patients reach decisions in a non-judgmental, supportive manner—again, in sharp contrast to eugenics.

133. Kessler, *supra* note 122, at 168.

134. *Id.*

135. One key difference between the counselor-counselee and the typical physician-patient relationship was that the counselee was usually not a "patient." That is, she did not require treatment or therapy but rather education about her reproductive options. *Id.* at 169. Conflicting perspectives regarding the professional's role created a tension that somewhat remains even today as to how directive genetic counselors should be. The tension is greatest among geneticists who were trained under the more traditional medical model. A commentator explains: "One traditional principle of genetic counseling is the neutrality of the counselor in decisions about reproduction. This is unusual in medical practice, and is a difficult attitude for many physicians to adopt . . ." Porter, *supra* note 125, at 24-25.

136. These attitudes lasted until at least the late 1930s. CARLSON, *supra* note 3, at 202-15 (describing the debate among physicians regarding compulsory sterilization, which focused on societal effects with no discussion of patient choice except to describe cases where the patient him or herself urgently wanted the procedure).

137. Kessler, *supra* note 122, at 169-70.

138. I thank Professor Carl Schneider of the University of Michigan Law School for these insights.

The bioethics movement has been an additional antidote to eugenics. The movement, which emerged in the early 1970s,¹³⁹ reflects an “unqualified” commitment to individual rights and autonomy.¹⁴⁰ In both theoretical and practical ways, it has altered the relationship between doctor and patient, emphasizing the central role of the patient in medical decision making and rejecting the stark paternalism of the eugenics era. Indeed, this deep commitment to patient autonomy has been a driving force behind the principle of non-directiveness among genetic counselors and the efforts not to force or direct reproductive decision making.¹⁴¹

A related development in the law and bioethics, which perhaps offers the greatest protections against some of the eugenic measures of the twentieth century, is the recognition of individual interests in procreative autonomy. *Roe v. Wade*¹⁴² and *Planned Parenthood of Southeastern Pennsylvania v. Casey*,¹⁴³ while failing to overturn the holding of *Buck v. Bell*,¹⁴⁴ reflect a very different attitude toward reproductive interests. Jus-

139. DAVID J. ROTHMAN, STRANGERS AT THE BEDSIDE 193 (1991). Within only a few years, the movement had gained “a vitality and a standing that were in every way remarkable.” *Id.* at 241.

140. So great is this focus, that some have criticized the movement for overvaluing individualism at the expense of other social values. *Id.* at 243.

141. The growing number of genetic associates is an additional force behind the norm of non-directiveness. This group of professionals tends to consist mostly of well-educated, bright women, who are committed to patient autonomy and individual rights and who are not trained within the traditional medical model. In fact, many find that model offensive and degrading to the client. They therefore work hard to resist the paternalism and directiveness of traditional medicine. Genetic associates have played a significant role in reinforcing non-directiveness for additional reasons. Because their profession is relatively new, genetic counselors have had to make a place for themselves in the hierarchical medical world. In some situations, genetic associates have felt physicians curtail their opportunity to practice the counseling for which they have been trained. CHARLES L. BOSK, ALL GOD’S MISTAKES: GENETIC COUNSELING IN A PEDIATRIC HOSPITAL 24 (1992) (describing a genetic associate’s frustration with her limited opportunities to provide genetic counseling). This conflict allies many genetic associates with patients in a struggle to overcome the physician’s attachment to control over medical decision making. Consequently, it may have heightened genetic counselors’ dedication to non-directiveness.

142. 410 U.S. 113 (1973).

143. 505 U.S. 833 (1992).

144. In fact, *Roe* cites *Buck* as authority for the notion that reproductive rights are not unlimited, as follows:

[I]t is not clear to us that the claim asserted by some amici that one has an unlimited right to do with one’s body as one pleases bears a close relationship to the right of privacy previously articulated in the Court’s decisions. The Court has refused to recognize an unlimited right of this

tice Holmes, in *Buck v. Bell*, claimed to be concerned with due process protections with respect to procreation, but he was ultimately only concerned with procedural due process.¹⁴⁵ In contrast, *Roe* and *Casey* rely on theories of substantive due process that align procreative decision making with other decisions “central to personal dignity and autonomy, [and] central to the liberty protected by the Fourteenth Amendment,”¹⁴⁶ such as decisions relating to child rearing and marriage. These rights have been internalized within a substantial portion of our culture and strongly reinforce non-directive norms and the notion that reproductive decisions are the individual’s to make without interference from medical or other authority.¹⁴⁷

IV. TOWARD NEOEUGENICS

With these developments in science, bioethics, and the law, it would seem that we are safely removed from the norms and attitudes of the eugenics movement. Yet, some claim that prenatal genetic testing and future genetic technologies are a “backdoor to eugenics,” achieving the same goals of “good birth” (albeit at the individual, rather than state, level).¹⁴⁸ In Sections IV.A and IV.B below, I argue that contemporary attitudes, combined with current and evolving technologies, drive us towards Galton’s utopia: a new form of eugenics, or “neoeugenics”—a voluntary “improvement” of the human species at the individual level. Galton never supported compulsory sterilization; he believed that an educated and enlightened public would make the “right”—i.e., eugenic—reproductive decisions.¹⁴⁹ As we shall see, the underlying goal of eugenics—improving

kind in the past. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (vaccination); *Buck*, 274 U.S. 200 (1927) (sterilization).

Roe, 410 U.S. at 153-54.

145. See *supra* text accompanying notes 79-87 (describing how Justice Holmes gave substantive due process short shrift).

146. *Casey*, 505 U.S. at 851.

147. Most genetic counselors are advocates of their counselees’ “right to choose and decide about [their] reproductive destin[ies].” Kessler, *supra* note 122, at 169.

148. DUSTER, *supra* note 118, at 114-15; see also Angus Clarke, *Is Non-Directive Genetic Counselling Possible?*, 338 LANCET 998, 1000 (1991) (contending that “an offer of prenatal diagnosis implies a recommendation to accept that offer, which in turn entails a tacit recommendation to terminate a pregnancy if it is found to show any abnormality”); Resta, *supra* note 37, at 240.

149. See *supra* text accompanying notes 32-34. Just under 40 years ago, Robert Sinshemer, a molecular biologist at the California Institute of Technology, “argued that freedom of choice would vindicate the new genetics, and set it apart from the discredited eugenics of old.” Michael J. Sandel, *The Case Against Perfection*, ATLANTIC MONTHLY, Apr. 2004, at 62. The “new eugenics would be voluntary rather than coerced, and also

reproduction—can exist with or without state mandate. In Section IV.C, I then compare old and new eugenics and argue that the differences between some attitudes of the eugenics era and our contemporary culture are not as dramatic as people often describe.

My claims in Part IV are largely descriptive. Given that legal, medical, and cultural developments have greatly enhanced autonomy with respect to reproductive decisions, our concerns regarding eugenics are arguably over. In Part V, I contend that these protective norms are grounded in a Kantian, libertarian conception of autonomy, which serves as a powerful weapon against government and medical tyranny. Nevertheless, these developments may be inadequate to deal with other problematic aspects of eugenics and neoeugenics. Thus, Part V also offers a contextual and relational conception of autonomy through which to evaluate whether we have really eradicated all of the concerns surrounding eugenics. It concludes that motivations, intentions, and responses to eugenic efforts are central to evaluating the moral propriety of eugenics. The mere fact that something appears eugenic-like cannot alone be grounds for condemnation. Instead, certain cultural and individual norms and attitudes are what make some reproductive practices problematic.

A. Prenatal Testing and Current Genetic Reproductive Technologies

Since the mid-1970s, families have been able to use prenatal testing to select against various genetic and chromosomal diseases and other birth defects. Numerous pressures have made diagnostic tests like amniocentesis and chorionic villus testing, as well as ever-improving prenatal screening tests,¹⁵⁰ a routine part of pregnancy.¹⁵¹ Although decisions to undergo prenatal testing are voluntary, “they still take place within a normative context favoring prophylaxis . . .”¹⁵² Perhaps the greatest social pressure is

more humane. Rather than segregating and eliminating the unfit, it would improve them.” *Id.* at 50.

150. See, e.g., Rob Stein, *Down Syndrome Now Detectable in 1st Trimester*, WASH. POST, Nov. 10, 2005, at A1 (describing the results of a study of more than 38,000 women who underwent a new, first-trimester, prenatal screening test for Down syndrome, which allows “women to decide sooner whether to undergo the riskier follow-up testing needed to confirm the diagnosis”).

151. See Sonia M. Suter, *The Routinization of Prenatal Testing*, 28 AM. J.L. & MED. 233, 235 (2002) [hereinafter Suter, *Routinization*]. The American College of Obstetricians and Gynecologists recently issued new practice guidelines advising that “[a]ll pregnant women, regardless of their age, should be offered screening for Down syndrome in their first trimester.” Thomas H. Maugh II, *Down Syndrome Screening Advised for All Pregnancies*, L.A. TIMES, Dec. 31, 2006, at A19.

152. Koch, *supra* note 111, at 324.

the view that one should undergo prenatal testing and screening because it is in the best interests of one's future child.¹⁵³ This view is prevalent because testing is presented as "treatment" or "doing what's best," when of course such treatment merely "prevents disease" by preventing the existence of someone with the disease.¹⁵⁴ Thus, some undergo testing because of a mistaken belief that it offers the possibility of true treatment.¹⁵⁵ Others think that good parenting requires one to prevent future suffering in a child with a genetic condition by terminating the pregnancy.¹⁵⁶ Some pa-

153. Whether the goal is to remove a genetic defect or enhance a male child's ultimate height from 5'3" to 6'3", the parents are usually motivated by what will be in the best interests of the child. Robert Wachbroit, *What is Wrong with Eugenics?*, in *ETHICAL ISSUES IN SCIENTIFIC RESEARCH: AN ANTHOLOGY* 331 (Edward Erwin et al. eds., 1994) ("[A]ny property that is a plausible candidate for eugenics is one that prospective parents reasonably believe confers an advantage to the child. Any advocacy of eugenics will start with that thought.").

154. Suter, *Routinization*, *supra* note 151, at 247-48 (discussing that patients and popular pregnancy books often cast prenatal testing as "doing what's best" for the fetus or future child rather than as an effort to "select the best child"); Elizabeth Weil, *A Wrongful Birth*, *N.Y. TIMES MAG.*, Mar. 12, 2006, at 51 ("[Prenatal testing] is not a medical procedure to promote the health of the fetus. It is a procedure to give prospective parents information to decide whether or not to eliminate a possible future life." (quoting Professor Adrienne Asch)).

155. Suter, *Routinization*, *supra* note 151, at 247. That article notes:

Some pregnancy books present information about amniocentesis in a manner that suggests it protects the fetus. *Your Pregnancy Week by Week* discusses amniocentesis in a section of the chapter entitled "How Your Actions Affect Your Baby's Development." This same section heading is used in other chapters to discuss the harmful effects of smoking and alcohol consumption. In describing amniocentesis under such a heading, the book suggests that prenatal testing "constitutes maternal good behavior." *What to Expect When You're Expecting* places a boxed insert entitled "Reducing the Risk in Any Pregnancy," which includes advice on such things as smoking, alcohol and weight gain, in the middle of its discussion of amniocentesis.

Id. (citing HELENA MICHIE & NAOMI R. CAHN, *CONFINEMENTS: FERTILITY AND INFERTILITY IN CONTEMPORARY CULTURE* 84 (1997) (describing this approach as creating the "completely unsupported inference . . . that genetic disorders can be prevented by behavioral changes.")).

156. See Michael J. Malinowski, *Coming Into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening*, 45 *HASTINGS L.J.* 1435, 1472-74 (1994) (describing a couple's decision to terminate a pregnancy because they "could [not] watch a child suffer through life"); Suter, *Routinization*, *supra* note 151, at 247-48. Perhaps equally important is the parents' desire to prevent the suffering they themselves might experience in watching a child endure a serious disability.

tients and physicians believe parents have an obligation to prevent the birth of children with even minor birth defects.¹⁵⁷

In addition, the economic, psychological, and social difficulties of caring for a child with multiple or serious birth defects or diseases may lead families to pursue prenatal testing to select against unhealthy children.¹⁵⁸ For some, a largely unspoken motivation is discomfort with disabilities and imperfections.¹⁵⁹ In addition, social norms that view the “gathering of

157. See ANDREA KALFOGLOU ET AL., WASHINGTON, DC: GENETICS AND PUBLIC POLICY CENTER, REPRODUCTIVE GENETIC TESTING: WHAT AMERICA THINKS 14 (2004) (discussing public opinion surveys, which found that 51.5% of respondents agreed or strongly agreed that “parents ought to do everything technologically possible to prevent their child from suffering including using reproductive genetic technologies”). As an example:

When a television anchorwoman with ectrodactyly—a mild genetic condition that fused the bones of her hands—chose to continue a pregnancy with a fetus that inherited the condition, many accused her of being immoral or irresponsible. Even healthcare professionals sometimes blame women for the birth of a child with a genetic condition, particularly if the woman refused testing.

Suter, *Routinization*, *supra* note 151, at 248 (citing Lori B. Andrews, *Prenatal Screening and the Culture of Motherhood*, 47 HASTINGS L.J. 967, 981-82 (1996) [hereinafter Andrews, *Prenatal Screening*]).

158. *But see* Weil, *supra* note 154, at 52-53 (describing studies that “have shown that the raising of children with impairments is on the whole a lot less difficult and a lot less different from raising so-called normal kids than we imagine it will be”); *id.* at 53 (“Families with severely impaired children do not differ significantly in stresses and burdens from families with normal children A child prodigy can have just as much impact on a family as a child with cystic fibrosis or Down.” (quoting Professor David Wasserman)). However, in response to Weil’s article, several readers wrote to express their disagreement with the idea that the stress of raising severely disabled children is comparable to that of raising normal children, asserting that families with severely disabled children do face greater difficulties and burdens. One letter read:

Parents of children with severe disabilities must provide round-the-clock supervision and care. Then there’s the enormous cost of specialized medical equipment and supplies, and the heartache of constant medical crises and setbacks. Parents of severely impaired children also worry about who will care for their children after they’re gone, and few have malpractice-settlement trust funds to rely on.

Julia E.S. Spencer, Letter to the Editor, *A Wrongful Birth?*, N.Y. TIMES MAG., Mar. 26, 2006, at 8. “Regardless of how many studies have been conducted, only the parents of a special-needs child can truly understand the difficulties and heartbreak of being in such a situation.” *Id.*

159. Allen, *supra* note 88, at 61; Malinowski, *supra* note 156, at 1453; Suter, *Routinization*, *supra* note 151, at 249-50.

information as a sign of responsible behavior and good decision making” also push many towards prenatal testing.¹⁶⁰

Not surprisingly, the medical profession, which is strongly motivated by the “moral imperative to know,”¹⁶¹ also enthusiastically supports prenatal testing and screening. Genetic counselors believe families can benefit from this technology: those with normal results can be reassured and those with abnormal results can make decisions about whether or not to continue the pregnancy in light of their own values.¹⁶² Most health-care professionals think that being informed and prepared is always better for families that have children with disabilities.¹⁶³ Others favor prenatal testing because of their “bias toward termination” when abnormalities are found¹⁶⁴ and their belief that such terminations benefit the families and society.¹⁶⁵

160. KALFOGLOU ET AL., *supra* note 157, at 13-14 (describing survey results showing that the most important benefit people found for genetic testing was “the ability to plan and prepare for the challenges of having a special need child,” with study participants asserting that “[t]he information is . . . just a powerful thing to have”); Suter, *Routinization*, *supra* note 151, at 246.

161. Gwen Anderson, *Nondirectiveness in Prenatal Genetics: Patients Read Between the Lines*, 6 NURSING ETHICS 126, 129-30 (1999) (“In genetics, clinicians and researchers believe that knowledge and genetic science are moral goods.”).

162. Suter, *Routinization*, *supra* note 151, at 245 (describing the view that couples can use the information to prepare for the arrival of a child with a disability even if they ultimately choose not to terminate the pregnancy).

163. Cf. DOROTHY C. WERTZ, JOHN C. FLETCHER & KÅRE BERG, WHO HUMAN GENETICS PROGRAMME, REVIEW OF ETHICAL ISSUES IN MEDICAL GENETICS 62 (2003) (setting forth policy recommendations by health care professionals, including that “[p]renatal diagnosis can be used to prepare for the birth of a child with a disability instead of making a decision about abortion”).

164. Weil, *supra* note 154, at 53 (describing the ways in which medical professionals systemically and subtly express this bias, from their manner of and systems for delivering bad news to the way they describe the prognosis and options to families).

165. Numerous studies have collected data on the societal and cost benefits of screening and mandatory offer of screening. See, e.g., Nancy Anne Press & Carole H. Browner, *Collective Silences, Collective Fictions: How Prenatal Diagnostic Testing Became Part of Routine Prenatal Care*, in WOMEN AND PRENATAL TESTING: FACING THE CHALLENGES OF GENETIC TECHNOLOGY 202 (Karen H. Rothenberg & Elizabeth J. Thomson eds., 1994) (citations omitted) (noting that “the Department of Health and Human Services recently made it a goal . . . to ‘increase to at least 90 percent [from 65%] the proportion of women . . . who are offered screening and counseling on prenatal detection of fetal abnormalities.”); Tryfon Beazoglou et al., *Economic Evaluation of Prenatal Screening for Down Syndrome in the U.S.A.*, 12 PRENATAL DIAGNOSIS 1241,1245 (1998) (estimating that “a universal triple test could prevent the birth of 1136 babies with Down syndrome . . . , while allowing 2057 live births with Down syndrome. The total financial savings per year are \$140 million”); Jo-Ann Johnson et al., *Prenatal Genetic Screening for Down Syndrome and Open Neural Tube Defects Using Maternal Serum Marker Screening*, 21 J. SOC’Y OBSTETRICIANS & GYNAECOLOGISTS CAN. 887, 889 (1999) (noting that the added

Just as eugenicists often spoke in the same breath about the social and individual benefits of eugenics, physicians often justify genetic testing in the same manner.

The professional attitudes in favor of prenatal testing are often communicated to patients, directly or indirectly, which can lead to powerful pressure to undergo such testing. Generally, genetic counselors try to hide any biases they might have in favor of or against prenatal testing, given their commitment to non-directiveness.¹⁶⁶ Medical geneticists, however, are more directive and non-geneticist physicians even more so.¹⁶⁷ In addition, legal pressures create incentives for health-care providers to push or encourage prenatal testing. For example, if a patient has undergone prenatal testing or screening, the provider is better shielded from wrongful birth claims.¹⁶⁸ Indeed, one study has shown that in response to a legal mandate requiring that a prenatal screening test be *offered*, medical professionals provided limited, directive counseling, suggesting they were “more interested in *persuading* . . . than *informing* patients.”¹⁶⁹ As prenatal testing becomes more routine and moves out of genetics clinics into obstetricians’ offices, more directive and less frequent counseling may lead more patients to experience discussions with physicians as recommendations or

costs of prenatal screening are “likely to be offset by . . . a higher detection rate of [Down Syndrome] and [spina bifida], a lower false-positive rate and, . . . a decrease in the overall number of amniocenteses performed.”)

166. ROBIN BUNTON, *NEW GENETICS AND NEW PUBLIC HEALTH* 139 (2001) (noting that “adherence to a nonprescriptive (often referred to as ‘nondirective’) approach is perhaps the most defining feature of genetic counseling” and “stems from a firm belief that genetic counseling should—insofar as is possible—be devoid of any eugenic motivation” (citing ANN PLATT WALKER, *A GUIDE TO GENETIC COUNSELING* 8 (1998))).

167. See generally Deborah F. Pencarinha, *Ethical Issues in Genetic Counseling: A Comparison of M.S. Counselor and Medical Geneticist Perspectives*, 1 *J. GEN. COUNSELING* 19 (1992); Suter, *Routinization*, *supra* note 151, at 245. For example, approximately 30% of genetics professionals in the United States would provide negative slanted counseling for some serious genetic conditions. DOROTHY C. WERTZ & JOHN C. FLETCHER, *GENETICS AND ETHICS IN GLOBAL PERSPECTIVE* 373 (2004) (49 percent of genetics professionals in the United States would give negatively slanted counseling for anencephaly, and 37 percent would give negatively slanted information for Trisomy 13); Dorothy C. Wertz, *Eugenics Is Alive and Well: A Survey of Genetic Professionals Around the World*, 11 *SCI. CONTEXT* 499 (1998) (28 percent of genetics professionals in the United States and 42 percent of U.S. primary care physicians would give negatively slanted counseling for open spina bifida).

168. Suter, *Routinization*, *supra* note 151, at 251; Weil, *supra* note 154, at 52.

169. Press & Browner, *supra* note 165, at 201. The study showed that in California, where the offer of such screening was mandated, the acceptance rates for the screening test were 85% as compared with the national average of 65%. *Id.* at 216 n.10.

requirements that they *should* have genetic testing,¹⁷⁰ and sometimes that they should terminate if an abnormality is detected.¹⁷¹

Although not everyone undergoes prenatal testing, the use of this technology to select against disease has become part of the culture of pregnancy, accepted by most and expected by many.¹⁷² Nevertheless, current technologies are not cost free (physically, emotionally, or economically). The two most common forms of diagnostic testing, amniocentesis and chorionic villus sampling (CVS), are invasive procedures that pose a small but real risk of pregnancy complications, including miscarriage.¹⁷³ The risk associated with amniocentesis is lower than with CVS, but the former has the downside of being performed in the second trimester, whereas CVS can be done in the first trimester. Thus, if an abnormality is found via amniocentesis and the patient wants to terminate, the procedure will be more physically and emotionally difficult than it would have been if done during the first trimester.¹⁷⁴ In addition, amniocentesis and CVS are not inexpensive, although insurance generally provides coverage if the tests are medically indicated.¹⁷⁵ Finally, the options available if abnormalities

170. Suter, *Routinization*, *supra* note 151, at 242-46.

171. Andrews, *Prenatal Screening*, *supra* note 157, at 990 n.117 (1996) (noting that even when defects are not severe, many physicians pressure women to terminate affected pregnancies).

172. Suter, *Routinization*, *supra* note 151, at 242-46.

173. Richard L. Berkowitz et al., *Challenging the Strategy of Maternal Age-Based Prenatal Genetic Counseling*, 295 JAMA 1446, 1446 (2006). In a low risk population with a background pregnancy loss of around 2%, a second trimester amniocentesis will increase this risk by another 1%. This difference did not reach statistical significance, but the increase in spontaneous miscarriages following second trimester amniocentesis compared with controls (no amniocentesis) did (2.1% versus 1.3%). Compared with second trimester amniocentesis, transcervical CVS carries a significantly higher risk of pregnancy loss (14.5% versus 11%) and spontaneous miscarriage (12.9% versus 9.4%). Zarko Alfircvic et al., *Amniocentesis and Chorionic Villus Sampling for Prenatal Diagnosis*, Vol. COCHRANE DATABASE SYSTEMATIC REVIEWS (2003) (CD003252).

174. For several reasons, terminations in the second trimester are generally more emotionally taxing. Women usually have felt fetal movement, enhancing the bonding with the fetus. In addition, most people will be aware of the woman's pregnancy by that stage, making the decision to terminate more complicated because the end of the pregnancy will be more public. And, of course, the termination procedure is more physically demanding later in the pregnancy. Suter, *Routinization*, *supra* note 151, at 258 n.155.

175. The full cost of invasive testing for chromosomal disorders is approximately \$1300. Ryan Harris et al., *Cost Utility of Prenatal Diagnosis and the Risk-Based Threshold*, 363 LANCET 497 (2004); *see also* Miriam Kuppermann et al., *Procedure-Related Miscarriages and Down Syndrome-Affected Births: Implications for Prenatal Testing Based on Women's Preferences*, 96 OBSTETRICS & GYNECOLOGY 511 (2000). Kuppermann writes:

are found are still woefully inadequate. Treatment or amelioration of genetic conditions is rarely if ever possible. While many ultimately choose termination, others have no such option for religious, moral, or personal reasons. Thus, although many people do use prenatal testing or screening to decide whether or not to continue pregnancies, the costs associated with these tests limit how many ultimately use them to select against disease.

B. Advancing Technologies: Towards “Designer Babies”

As assisted reproductive technologies develop, they will overcome many of the barriers that currently prevent some people from choosing to select against disease. They may even move many towards selection of “fitter” or “improved” children, a form of positive neoeugenics. Several new technologies will aid this progression of neoeugenics.

One technique, which is still in the experimental stage, is to analyze fetal cells that have been isolated from maternal blood. This form of prenatal testing eliminates the risks of complications associated with amniocentesis and CVS and may therefore make prenatal testing more desirable to some.¹⁷⁶ It does not, however, overcome the difficult reality that most prenatally diagnosed diseases cannot be treated, but only prevented through pregnancy termination.

Another option available to couples who want to select against disease, but do not want to terminate a pregnancy, is preimplantation genetic diagnosis (PGD) of embryos created through in vitro fertilization (IVF). This technique involves prenatal diagnosis of fertilized embryos, which can be implanted in the woman’s uterus.¹⁷⁷ Unfortunately, PGD shares many of

For several decades, prenatal diagnoses of chromosomal disorders, including amniocentesis and later chorionic villus sampling (CVS), have been reserved for women aged 35 years or older at delivery. With the emergence of expanded maternal serum and ultrasonography screening programs, that age- and risk-based cutoff has become entrenched further. Insurance coverage for invasive testing has become more available to younger women, but only to the extent that they have been found via serum or ultrasonographic screening to be at least as high a risk as an unscreened 35 year old.

Id.

176. Lori B. Andrews, *Future Perfect: Confronting Decisions About Genetics* 59 (2001).

177. Jeffrey R. Botkin, *Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis*, 26 *J.L. Med. & Ethics* 17, 17 (1998); see also Susannah Baruch et al., *Preimplantation Genetic Diagnosis: A Discussion of Challenges, Concerns, and Preliminary Policy Options Related to the Genetic Testing of Human Embryos 3-4*, available at <http://www.dnapolicy.org/images/reportpdfs/PGDDiscussionChallengesConcerns.pdf> (presenting an overview of preimplantation genetic diagnosis).

the problems associated with IVF. First, it is fairly expensive and not always covered by insurance.¹⁷⁸ Second, because the success rate of impregnation is lower than most would like, harvesting eggs from the woman—a procedure not without burdens—may have to be done multiple times.¹⁷⁹ As a result, some are skeptical as to how high the demand for this technology will be in the near future.¹⁸⁰ Researchers are developing techniques to reduce cost and eliminate some of the physical hardships currently associated with IVF and PGD.¹⁸¹ Although PGD overcomes some of the emotional complications associated with prenatal testing and termi-

178. BARUCH ET AL., *supra* note 177, at 22 (“PGD is expensive. It requires IVF, which costs on average \$10,000-\$12,000. The addition of PGD can add \$2,500-\$4,000, bringing the total cost to approximately \$12,500-\$16,000. Insurers may not cover PGD at all, or may pay only for the genetic testing, leaving prospective parents to pay for the IVF.”); *id.* at 6 (“If there is to be widespread insurance reimbursement of PGD, those who underwrite coverage—mainly employers and insurance companies—must view it as cost effective. Otherwise, the cost of PGD will be paid out-of-pocket by patients.”); Botkin, *supra* note 177, at 18 (noting that “insurance carriers or government funding agencies” are unlikely to cover these costs “given the nonessential nature of this intervention, the cheaper alternatives, and the controversial nature of prenatal diagnosis in general”).

179. Botkin, *supra* note 177, at 17-18.

180. *Id.* at 18 (noting that older women are unlikely to choose this procedure when the “efficiency of IVF declines significantly with age” and there are much cheaper and more reliable methods, and questioning generally whether “many couples will believe that the added benefits of PGD technology will justify its costs and other burdens”); *see also* Andrea L. Kalfoglou, *PGD Patients’ and Providers’ Attitudes to the Use and Regulation of Preimplantation Genetic Diagnosis*, 11 REPRODUCTIVE BIOMEDICINE ONLINE 486, 487 (2005). Kalfoglou writes:

Disadvantages [of IVF] included failure to conceive using IVF, risks for the mother and resulting child, the physical burdens and side effects of IVF cost, and the ‘dilemma of what to do with spare embryos.’ Two studies found that ‘unreliability of the genetic test results’ or ‘unsuccessful genetic analysis’ were also a concern for potential consumers. While [some studies] found that low success rates, cost, and risk of misdiagnosis were identified as disadvantages by PGD users, [other studies] found these were not major concerns.

Id. (citations omitted). *But see* BARUCH ET AL., *supra* note 177, at 5 (“For the moment, one would expect very few people who otherwise have no problems achieving a healthy pregnancy to utilize PGD. Nonetheless, that could change as IVF techniques improve and the number of genetic tests that can be employed successfully in PGD increases.”).

181. *See* THE ETHICS OF INHERITABLE GENETIC MODIFICATION: A DIVIDING LINE (John E. J. Rasko et al. eds., 2006) (“PIGD is not a simple procedure; it involves hormonal stimulation to retrieve multiple eggs . . .”). Researchers are working on new techniques to facilitate the process. *See Hospital Is First to Adopt Cheaper IVF*, TIMES (London), Jan. 9, 2007, at 4 (reporting on a UK hospital which has received permission to adopt in vitro maturation, a “safer method of [IVF] that it claims could save couples up to £1,700”).

nation, those who believe that life begins at conception may still be troubled by the prospect of embryo destruction if the embryo is found to carry disease genes.¹⁸²

A third technological advance that will push us further toward neoeugenics is the ever-increasing identification of genes and our understanding of how they work.¹⁸³ In time, we are likely to learn about genes associated with (if not determinative of) various traits and behaviors. Not only will we have knowledge about the genetics of more diseases and traits, but our capacity to genetically analyze biological samples (whether from amniotic fluid, maternal serum, or IVF embryos) will exponentially increase. The technological imperative to learn as much as possible about our future children with respect to disease, and possibly traits, may similarly increase.¹⁸⁴ In the not too distant future, DNA chips and next-generation technologies will allow for the analysis of thousands of genetic variants, in contrast to the more limited analysis of a handful of disease genes today.¹⁸⁵ These technologies will inevitably reduce the cost and increase the efficiency of testing, making prenatal diagnosis even more desirable and broader in its scope.

182. PGD almost always involves excess embryos, and “embryos that have been found to carry genetic mutations linked to diseases or disabilities are less likely to be candidates for donation.” Some people view this as morally or ethically problematic but nevertheless think it may be defensible in some limited situations and that PGD should be strictly regulated and limited in order to minimize the creation and destruction of embryos. Still others believe the creation and potential destruction of embryos is categorically unacceptable and thus are opposed to PGD and IVF under all circumstances. BARUCHET AL., *supra* note 177, at 5.

183. Weil, *supra* note 154, at 50 (“[T]he number of prenatal genetic tests is increasing exponentially—it jumped from 100 to 1,000 between 1993 and 2003.”).

184. See Suter, *Routinization*, *supra* note 151, at 249 (describing the way in which identification of new disease genes leads to increased interest in this information and need for reassurance).

185. George M. Church, *Genomes for All*, SCI. AM., Jan., 2006, at 40-41, 47 (describing “next-generation technologies that make reading DNA fast, cheap and widely accessible,” and which are “coming in less than a decade”); Michael J. Malinowski, *Law, Policy, and Market Implications of Genetic Profiling in Drug Development*, 2 HOUS. J. HEALTH L. & POL’Y 31, 40-43 (2002) (“DNA chips can be used to test the samples of individuals for the presence of thousands of identified genetic variations and, alternatively, to screen hundreds of thousands of individuals with a shared phenotype characteristic to isolate and identify shared genetic expressions.”).

Fourth, gene therapy, or transfer,¹⁸⁶ may also create pressures toward neo Eugenics. In spite of their initial optimism, scientists have been disappointed at how little gene transfer has progressed since the 1990s.¹⁸⁷ In addition, the procedure is not without risks.¹⁸⁸ Despite these difficulties,

186. Larry R. Churchill et al., *Genetic Research as Therapy: Implications of "Gene Therapy" for Informed Consent*, 26 J.L. MED. ETHICS 38, 42, 45 (1998) (suggesting that federal agencies "delete the terms gene therapy . . . and any language that would imply that a gene therapy already exists from the informed consent process" because, "[a]t present, gene transfer research amplifies the . . . existing confusions between research and therapy and intensifies extant problems of informed consent"). Churchill also writes:

[The] tendency of policy-makers to see entry into gene transfer research protocols as a viable avenue of treatment further diminishes the possibility for a robust exercise of informed consent in the research context. Such thinking indicates to the potential research subject that clear therapeutic benefits can be obtained in gene transfer research, when the actual likelihood of individual benefit for the subject is often minimal or non-existent.

Id. at 42-43.

187. Despite the public's enthusiasm for and belief in the success of gene therapy, Churchill et al., *supra* note 186, at 43-44, the "FDA has not yet approved any human gene therapy product for sale." U.S. Food and Drug Administration Center for Biologics Evaluation and Research, Cellular & Gene Therapy, <http://www.fda.gov/cber/gene.htm> (last visited Feb. 6, 2007). Even the one putative success cannot be described as such without qualification:

Because the gene therapy was superimposed, for appropriate reasons of safety, on the new but standard . . . treatment [with a synthetic enzyme that the participants were missing], it has been very difficult to determine precisely how much of either the scientific or the clinical success was due to [the synthetic enzyme], the gene-corrected cells, or to some combination of the two.

Churchill et al., *supra* note 186, at 44. Another observer writes:

A central challenge . . . is perfecting methods for delivering therapeutic genes to cells. Often genes introduced into patients do not reach enough of the appropriate cells or, for reasons that are not always clear, function poorly or shut off after a time. Under those conditions, a gene that could potentially be helpful would have little chance of affecting a disease process.

Theodore Friedmann, *Overcoming the Obstacles to Gene Therapy*, SCI. AM., June 1997, at 96. Gene therapy faces a number of technical hurdles, from getting the DNA into the patient to the appropriate site, to making sure the therapeutic genes function properly and continue functioning for the time necessary to achieve the desired therapeutic effect. GENETICS, *supra* note 7, at 483-84.

188. In the most famous tragic outcome of gene-transfer research, eighteen-year-old Jesse Gelsinger died after participating in a study to determine whether gene transfer would produce the enzyme that individuals lack who have ornithine transcarbamylase deficiency, an x-linked, dominant, single-gene disorder, which prevents the metabolism of ammonia. Jesse was participating in a "Phase I" trial intended to determine the "maximum tolerated dose" of the treatment; he received the highest dose in the trial.

one can easily imagine that in the future (perhaps more remote than researchers would like to believe), we will be able to use gene transfer to treat some genetic diseases.¹⁸⁹ When and if that becomes possible, it is easy to imagine that the desire to select against and *treat* genetic disease will be great. At this point, eugenics—creating the “well-born”—would become intertwined with true disease treatment.¹⁹⁰

Gene transfer may also open the door to positive eugenics, where the focus would be on *improving* births rather than preventing undesirable births. Theoretically, the technology will be used to *enhance* certain desirable qualities—not merely to treat disease. At the extreme, the distinction between treatment and enhancement seems clear. The former aims to eradicate disease, such as to provide a gene to prevent a child from inheriting a form of immune deficiency,¹⁹¹ whereas the latter aims to improve what is “normal,” such as using gene transfer to help a child of average height

Within twelve hours, he started experiencing adverse reactions, which culminated in a clotting disorder, coma, kidney failure, and eventually death. See Sheryl G. Stolberg, *The Biotech Death of Jesse Gelsinger*, N.Y. TIMES MAG., Nov. 28, 1999, at 137. “[A]fter his death, reports surfaced of other adverse events, including several deaths, that had not been disclosed to reviewers, experimental subjects, or the public.” GENETICS, *supra* note 7, at 482. More recently, three children with “severe combined immunodeficiency disease, or SCID, a potentially fatal genetic disorder that leaves its victims susceptible to life-threatening infections,” participated in gene-transfer research and developed leukemia; sadly, one of those children died. Seventeen children had been “treated,” and “virtually all [had] shown major improvement if not a cure.” Thomas H. Maugh II, *Gene Therapy Experiments Put on Hold*, L.A. TIMES, Mar. 4, 2005, at A16. The leukemias were attributed to “insertional mutagenesis,” the creation of a mutation caused by a retrovirus—which was used to transfer the gene—inserting into a working gene, in this case an oncogene, which if mutated can cause leukemia. Matthew P. McCormack & Terence H. Rabbitts, *Activation of the T-Cell Oncogene LMO2 after Gene Therapy for X-Linked Severe Combined Immunodeficiency*, 350 N. ENG. J. MED. 913 (2004).

189. It will be problematic, if not impossible, to use gene therapy to treat certain genetic conditions. So far scientists have focused on using the technique to transfer working genes to individuals with recessive genetic conditions caused by the failure of their genes to produce necessary enzymes. Using gene transfer to help a body produce a missing enzyme is complicated enough, but far simpler than using it to overcome the health effects of dominant mutations or chromosomal abnormalities. In addition, some conditions are caused by the harmful effects of mutations (whether recessive or dominant) early in development, and therefore are not likely to be treated by somatic cell gene transfer. See Friedmann, *supra* note 187, at 101 (discussing the need to carry out gene therapy very early in life before the immune system is fully competent to prevent an inactivating immune reaction).

190. This form of neoeugenics would likely be the least morally problematic (assuming of course safety issues were overcome) because it would be “true” treatment of disease. See *infra* text accompanying note 285.

191. See Maugh II, *supra* note 187, at A16.

become taller.¹⁹² Genetic enhancement, and gene therapy, for that matter, can theoretically occur at the somatic cell level (where the genetic alteration would occur in non-reproductive cells and therefore would not be inherited by future progeny) or at the germline level (where the genetic alterations would occur in the reproductive cells so that future generations could inherit the alterations).¹⁹³ Germline level enhancement is more relevant to the focus of this Article since it is a technology that can “improve” future generations. In some ways, it represents the greatest extreme of trying to create the “well born.”

C. Cultural Norms and Acceptance of Non-Therapeutic Reproductive Technologies

In spite of the public’s unease with some of these technologies,¹⁹⁴ there is good reason to believe that, if genetic enhancement becomes technologically feasible and safe, many (though surely not all) would choose it for their children. In a culture where parents seek advantages for their children in schooling, diet, exercise, extracurricular activities, and the like, it is hard to imagine that cultural pressures would not be great to pursue the same for their children with respect to enhanced traits.¹⁹⁵ As has been

192. Of course, distinguishing between treatment and enhancement at the margins becomes problematic.

193. SUSANNAH BARUCH ET AL., HUMAN GERMLINE GENETIC MODIFICATION: ISSUES AND OPTIONS FOR POLICYMAKERS 13 (2005), available at <http://www.dnapolicy.org/images/reportpdfs/HumanGermlineGeneticMod.pdf> (“If and when it occurs, germline genetic modification would involve introducing a new genetic sequence into a person’s germline cells that could be passed to future generations.”). See generally *id.* at 13-24 (providing an overview of the ethical and safety concerns involved, as well as presenting various policy options).

194. See KALFOGLOU ET AL., *supra* note 157, at 16-17 (“All data indicate that most Americans disapprove of the use of hypothetical reproductive genetic testing to select socially desirable traits such as intelligence, strength, or hair and eye color.”).

195. It has been observed that:

[There] is enormous public interest in enhancing appearance and performance: television shows feature “extreme makeovers” and other types of cosmetic surgery; the market for dietary supplements, many of which are touted for their “enhancement” effects, is huge; and parents in record numbers are enrolling their children in tutoring and other educational enhancement programs in an effort to give them academic advantages. As the President’s Council on Bioethics observes . . . “We have every reason to expect exponential increases in biotechnologies and, therefore, in their potential uses in all aspects of human life.”

GENETICS, *supra* note 7, at 566. Although genetic enhancement “may indeed be very far down the road,” for technological reasons, “the potential demand may be so great that private companies may soon begin making a substantial commitment toward enhancement research and development.” *Id.* at 439-40; see also GREGORY STOCK, REDESIGNING

demonstrated in the competitive world of sports, once one individual uses a technique or drug that enhances performance, the pressure on other competitors to do the same is enormous.¹⁹⁶ Of course, parenting is not a competitive sport and the pressures “to win” may not be so great. But when major life opportunities depend so strongly on abilities (admission to good schools being the prime example), it is hard to imagine that many parents wouldn’t feel subtle, or perhaps not so subtle, pressures to seek such advantages for their children. In fact, public opinion polls suggest that there may be substantial demand for genetic enhancement. Forty to forty-five percent of the American public polled in 1986 and 1992 approved of gene therapy to enhance physical and intellectual traits.¹⁹⁷

All of these technologies will likely push us further toward treatment of or selection against not just serious diseases, but also more trivial diseases and even traits. If we discover that some genes are associated with lesser conditions or traits we want to improve,¹⁹⁸ and the genes are detectable through genetic testing, then a measurable biological factor will be associated with the conditions or traits. The ability to test for these conditions, or to improve them, may contribute to a technologically created

HUMANS: OUR INEVITABLE GENETIC FUTURE 5 (2002) (“The coming possibilities [of genetic enhancement] will be the inadvertent spinoff of mainstream research that virtually everyone supports [O]nce a relatively inexpensive technology becomes feasible in thousands of laboratories around the world and a sizable fraction of the population sees it as beneficial, it *will* be used.”).

196. One physician’s experiment surveyed nearly 200 athletes between 16 years old and mid-30s: “He asks each: ‘I have a magic pill that would ensure you win every single competition, but you will die in five years. Will you take it?’ More than 50 percent respond yes.” Rick Maese, *Gene Therapy’s Impact on Sports Worries Experts: It Could Be Used to Create Bigger, Stronger, Faster Super-Athletes*, ORLANDO SENTINEL, May 22, 2005, at A1.

197. Rick Weiss, *Gene Enhancements’ Thorny Ethical Traits: Rapid-Fire Discoveries Force Examination of Consequences*, WASH. POST, Oct. 12, 1997, at A1; cf. KALFOGLOU ET AL., *supra* note 157, at 11, fig.3.1 (showing nearly thirty percent approval for use of reproductive genetic testing for intelligence/strength). However:

[t]hose polls also suggested . . . that the science had gotten ahead of the public understanding about the possible consequences of a free market in genes. Few people realize, for example, that although gene therapy holds promise against inherited diseases and cancer, none of the approximately 2,000 patients treated so far has been cured by the still experimental technique. Meanwhile, the procedure—which generally uses special viruses to inject new genes into people’s cells—has the potential to cause cancer or other problems.

Weiss, *supra* at A1.

198. It is likely that, at most, we will find an association between genes and traits, i.e., increased probabilities of a trait in the presence of a gene, rather than anything genetically determinative.

need for “treatment” or reassurance. For example, prenatal testing is medically indicated for conditions associated with extremely low intelligence. If we develop the means to treat or select against less extreme versions of low intelligence, it may also become medically indicated to treat or select against lower than average intelligence.¹⁹⁹

On a societal scale, the more we use technology to select against lesser conditions and traits, the more perfectionist we may become as a culture, and the more demanding we may become with respect to what is acceptable, normal, or healthy. The distinction between disease and normalcy may evolve. If enhancement and trait selection are widely used, it is easy to imagine that what was once normal will start to seem abnormal and perhaps disease-like. If we begin to medicalize what we now consider normal traits, enhancement and trait-selection will become more “legitimate” because they will be understood as part of medical treatment, driving people toward using these technologies.

All of these factors—advancing technologies and cultural norms—may exert a coercive effect on individuals’ reproductive choices. As the American Medical Association Council on Ethical and Judicial Affairs has stated, the most likely risk today is not “overt eugenics” or “government imposed constraints on marriage and reproduction” but instead “that the aggregate result of individual choices creates societal and cultural norms

199. The ability to do so accurately is problematic, but we may find genes that contribute to intelligence, the presence or absence of which may lead to predispositions toward ranges of intelligence. Karen Wright, *How Do Cognitive Abilities Relate to General Intelligence?*, SCI. AM., May 1998, at 62, 64 (“In the past few decades, genetic studies have convinced most psychologists that heredity exerts considerable influence on intelligence. In fact, research suggests that as much as half of the variation in intelligence among individuals may be attributed to genetic factors.”). Of course, the inherent indeterminacy of intelligence is precisely what makes testing and enhancement in this area problematic. See MATT RIDLEY, *NATURE VIA NURTURE: GENES, EXPERIENCE, AND WHAT MAKES US HUMAN* 90 (2003) [hereinafter RIDLEY, *NATURE*] (“There is no accepted definition of intelligence. Is it thinking speed, reasoning ability, memory, vocabulary, mental arithmetic, mental energy or simply appetite of somebody for intellectual pursuits that marks them out as intelligent?”); see also Jon W. Gordon, *Genetic Enhancement in Humans*, 283 SCI. 2023 (1999) (“Where [more] complex traits such as intelligence are concerned, we have no idea what to do, and in fact we may never be able to use gene transfer for enhancement of such phenotypes.”); Robert Plomin & John C. DeFries, *The Genetics of Cognitive Abilities and Disabilities*, SCI. AM., May 1998, at 62, 68 (noting that enhancing intelligence would be much more difficult than preventing many diseases that impair cognitive development because “[n]ormal cognitive functioning . . . is almost certainly orchestrated by many subtly acting genes working together, rather than by single genes operating in isolation”).

which substantially influence or limit the scope of autonomous decision making in regard to the use of genetic technology.”²⁰⁰

D. Distinctions Between Old and New Eugenics?

Having examined the various current and future technologies that may constitute a form of “neoeugenics,” that is, an attempt to influence reproduction to have healthier, fitter offspring, it is worth comparing old eugenics with neoeugenics. “Neoeugenics,” as the name suggests, is not precisely the same as classic eugenics. One writer states that “[t]raditional eugenics was an effort to select parents. Modern eugenics is an effort to select children. Or better yet, to design them.”²⁰¹ Another writes:

Numerous attempts have been made by scientists and politicians alike to denounce any relationship between eugenics in the past and the “new” genetics. In these rhetorical practices, eugenics is most often identified with compulsion, bad science, and state control of reproductive matters. In contrast, the “new” genetics, as it is significantly called, has allied itself with the norms of modern bioethics and legitimates itself with reference to the principles of informed consent and individual rights.²⁰²

1. Presence or Absence of State Coercion

To many the key difference between old and new eugenics is that new eugenics is not marked by state coercion over reproduction.²⁰³ Today, se-

200. AMA Council on Ethical and Judicial Affairs, CEJA Report A – A-91: Ethical Issues in Carrier Screening of Cystic Fibrosis and Other Genetic Disorders (1991), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_aa91.pdf (“Avoidance of negative consequences, such as increased marginalization of individuals who are affected by genetic disorders or socially coercive attitudes toward certain reproductive choices, requires careful attention to possible conflicts or problems incurred by the implementation of screening.”).

201. Wachbroit, *supra* note 153, at 329.

202. Koch, *supra* note 111, at 315.

203. *Id.* at 325 (“The role of the state as the prime actor of eugenic practices . . . is often seen as a constitutive political feature of eugenics.”); *see also* Wachbroit, *supra* note 153, at 335-36. Wachbroit writes:

The old eugenics pitted an alleged state interest in the quality of the genetic composition of the community (the gene pool) against individual rights and liberties over reproduction, that is, the value of improving the gene pool versus the value of individual reproductive autonomy In contrast, the new eugenics pits the alleged interests of an individual against the value the state would find in not having certain human conditions manipulated—against a concern for the stability and harmony of the community.

lecting against undesirable births is an individual decision. In the classic eugenics era, such selection was often a decision made by the state or by physicians at prisons and institutions for the “feeble-minded.”²⁰⁴ This is one of the key features that makes classic eugenics so distasteful.²⁰⁵

Yet, many of the features that are used to distinguish neoeugenics from eugenics are not as sharply distinct as many would have us believe. Even the assertions that eugenics represented coercion, whereas neoeugenics reflects voluntarism must be tempered. To be sure, state mandates resulted in shameless compulsory sterilizations, at least in the United States, Germany, and some other countries. But the eugenics era cannot be defined solely in those terms. In England, for the most part, eugenic goals were not compulsory but were encouraged through public education. Even in the United States, much of the eugenic efforts included education, with the hopes that people would adopt these goals.²⁰⁶ Today, genetics and reproductive technologies are not coerced by the state. Instead, various programs make efforts to educate couples and women about the availability of these technologies. Indeed, as I argued in Section IV.A, although the choice is always the individual’s, pressures from providers and society may have coercive effects. In the era of compulsory sterilizations, efforts were made to persuade individuals to make particular reproductive choices. Likewise, in the midst of the voluntarism of neoeugenics, efforts are made to persuade individuals to make particular reproductive choices.²⁰⁷ Thus, although the landscapes of eugenics and neoeugenics are clearly different, the distinctions are not as extreme as commentators often suggest.

204. Of course, as we’ve seen, *see supra* text accompanying notes 45-46, and as I shall discuss, *see infra* text accompanying note 206, this was not a necessary condition for a practice to be eugenic.

205. Koch argues, at least with respect to Scandinavian countries, that the State was not a “unified actor.” It was a “fragmented and complex unit . . . [with] no single political direction connecting the various fragmented state actors. Thus, we . . . [cannot] assume that the direction towards which eugenics was heading in practice was at all congruent with the official state political goal that was decided upon by parliament.” Koch, *supra* note 111, at 325-26. Similar fragmentation existed within American eugenics programs, since decisions about whether and whom to sterilize were made by physicians within various institutions, each of whom had their own ideas and agendas about the aims of eugenics. *See Reilly, supra* note 6, at 208.

206. *See supra* text accompanying notes 37-43.

207. Koch puts it perhaps too strongly in asserting that “voluntarism cannot be considered constitutive of a modern reproductive and genetic policy as compulsion cannot be considered constitutive of eugenics.” Koch, *supra* note 111, at 322 (noting that in spite of non-directiveness, medical professionals will still sometimes go against the decisions of counselees, for example, by informing high-risk relatives of their genetic risks if the counselees fail to do so).

2. *Improvements in Science*

Another asserted distinction is that eugenics was just bad science, with an inordinate focus on heredity, whereas our understanding of the role of genetics is vastly more sophisticated today. While our knowledge of genetics is far improved, advances in genetics have revitalized some of the underlying assumptions that motivated the eugenics movement, including a faith in the power of genetics and a belief in genetic determinism. Just as the media popularized eugenics theories in the early 1900s, the “DNA Mystique” looms large in the public mind today.²⁰⁸ In the eugenics era, the pendulum had swung sharply toward the nature extreme, resulting in hereditary explanations about individual and group characteristics, with little focus on environmental influences.²⁰⁹ Although the pendulum swung almost as sharply in the other direction in the late 1950s through the 1970s—when the tendency was to dismiss theories of heritability of traits and behaviors²¹⁰—the pendulum is returning again to the nature end of the spectrum. As a result, even though geneticists generally caution against genetic determinism, the popular culture eagerly welcomes genetic explanations for complex traits.²¹¹ The media and public speak in overly simplistic and deterministic terms about the “aggression” gene, the “novelty-seeking” gene, or the “infidelity” gene, to name a few.²¹² They often misinterpret genetics research as showing that genes are all or primarily determinative. As we learn more about genetics, there is a growing tendency

208. DOROTHY NELKIN & M. SUSAN LINDEE, *THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON* (1995); *see also*, Sonia M. Suter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79 WASH. U. L.Q. 669, 674-700 (2001) [hereinafter Suter, *Allure*] (describing the allure and mystique of genetics).

209. *See supra* text accompanying notes 24-26.

210. DUSTER, *supra* note 118, at 15 (“[T]he *zeitgeist* of the 1960s was such that few would take the *public* stage (or publish in scholarly journals) and argue the ‘genetics’ of intelligence, crime, or athletic or job performance.”); *see also* PAUL, *POLITICS*, *supra* note 93, at 85 (1998) (Some were “bewildered by the refusal to admit that genes contributed to individual differences in human abilities and aptitudes. But in the politically charged atmosphere of the 1970s, to concede such difference was to risk . . . being seen as aligned . . . with the social views of Arthur Jensen and Richard Herrnstein.”).

211. For example, the cover of *Time Magazine* once suggested that infidelity may be in our genes. Robert Wright, *Infidelity—It May Be in Our Genes. Our Cheating Hearts*, TIME MAG., Aug. 15, 1994, at 44.

212. Studies attempting to locate these genes “have been roundly criticized on methodological grounds. Behavioral genetics is generally highly controversial politically and scientifically.” Suter, *Allure*, *supra* note 208, at 675 n.9.

to believe it's "all in our genes."²¹³ However, genes are not all-determining; "[h]eritability and determinism are very different things."²¹⁴

Even some contemporary scientists have made comments that reinforce the public's belief in genetic determinism. Most famously, Daniel Koshland, Editor-in-Chief of *Science*, wrote in an editorial that the Human Genome Project could provide solutions to many of our social problems, including homelessness and crime. He reasoned that research from the Human Genome Project could eliminate such conditions as manic depression, schizophrenia, and Alzheimer's, which he described as among the root causes of homelessness.²¹⁵ In taking "social problems and re-cast[ing] them as essentially medical problems," and in defining medical problems as if primarily genetic, Koshland does not sound so dissimilar from the eugenicists of yesteryear.²¹⁶

3. *Ethnic and Racial Bias*

Another area where classic eugenics views may reemerge concerns the relationship between inheritance and ethnic or racial groups.²¹⁷ Eugenicists were grossly biased and racist in their crude descriptions of ethnic groups, making sweeping and incorrect claims about supposed genetic traits. Future Nobel laureate Hermann J. Muller wrote that by 1935, "eugenics had become 'hopelessly perverted' into a pseudoscientific façade for 'advocates of race and class prejudice, defenders of vested interests of church and state, Fascists, Hitlerites, and reactionaries, generally.'"²¹⁸ To-

213. *Id.* at 674-75 (describing the public's view that genes are all (or nearly all) determining).

214. RIDLEY, *supra* note 46, at 86.

215. Daniel E. Koshland, *Sequences and Consequences of the Human Genome*, 246 SCI. 189 (1989). He also argued for solutions "that involve prevention, not care taking," and that the "great new technology" should be used to "aid the poor, infirm, and underprivileged." *Id.*; see also Daniel E. Koshland, *The Rational Approach to the Irrational*, 250 SCI. 189 (1990) ("Advancing research can cure some fraction of these illnesses. It may also provide predictive diagnoses to distinguish those who are severely ill from those who merely represent harmless aberrations from the norms of society.").

216. Resta, *supra* note 37, at 234 (describing other examples of research that oversimplified complex traits like race, "religiosity," and "traditionalism").

217. Race and ethnicity, of course, are not precisely the same, although in the eugenics era, distinctions were not made between the two. Even today, the two terms are often used interchangeably. Screening tests, for example, are offered on the basis of race or ethnic origin, because both serve as crude proxies for relatedness to certain groups that are prone to certain genetic conditions. See *infra* notes 222-225 and accompanying text.

218. KEVLES, *supra* note 9, at 164. We should not forget that during the latter part of the eugenics era, scientists rejected many of the eugenic premises. *Id.*; see also PAUL, HEREDITY, *supra* note 42, at 115 (describing T.H. Morgan, a key figure in the development of modern genetics). Morgan argued in 1925 that "almost nothing was known about

day, geneticists often argue that the Human Genome Project has done much to disprove claims of genetic racial distinctions. It has shown that the genetic variation among groups is far less than the variation of individuals within groups.²¹⁹ Each of us is an individual, but we share the vast majority (99.9%) of our inherited material with other human beings.²²⁰

Yet, even as geneticists point out the difficulty in defining race in genetic terms,²²¹ discoveries in molecular biology have shown that certain ethnic groups are more susceptible to certain genetic mutations than others.²²² Mutations—while sometimes the cause of genetic diseases if two

the causes of mental differences among individuals, much less among nations or races,” and further “deplored the frequent confusion of nature and nurture, suggesting that much of the behavior associated with feeble-mindedness was probably due to ‘demoralizing social conditions’ rather than to heredity.” *Id.*; see also ROSEN, *supra* note 92, at 11 (2004) (The “scientifically trained proponents of eugenics often expressed alarm over the eugenic claims made by non-scientists. From the scientists’ perspective, amateurs popularized eugenics at the expense of the very science that fueled it. [However,] . . . the eugenics movement benefited from the participation of amateur enthusiasts.”). The voices of these more circumspect scientists, however, were overcome by the swell of enthusiasm for “eugenic” science.

219. Luigi Luca Cavalli-Sforza, Remarks Upon Being Awarded the Balzan Prize for The Science of Human Origins (1999) (noting that “we find that any population, however small, has enormous genetic variation; on average, one finds 85% of the total human variation is within populations, and only 15% between”), *cited in* GENETICS, *supra* note 7, at 4.

220. GENETICS, *supra* note 7, at 6.

221. “[A]lthough everyone, from geneticists to laypersons, tends to use ‘race’ as if it were a scientific category, with rare exceptions, no one offers a quantifiable definition of what a race is in genetic terms.” Richard S. Cooper et al., *Race and Genomics*, 348 *NEW ENG. J. MED.* 1166, 1168 (2003); see also Sharona Hoffman, *Is There a Place for “Race” as a Legal Concept?*, 36 *ARIZ. ST. L.J.* 1093, 1116 (2004) (“In recent years a vigorous debate has developed in the fields of medicine and genetics concerning the validity of ‘racial’ categories. Some have asserted that ‘race’ is ‘biologically meaningless,’ while others have strongly supported the continued use of ‘race’ for scientific purposes.”); David Rotman, *Genes, Medicine, and the New Race Debate*, *TECH. REV.*, June 2003, at 41, 50 (“It is possible to detect very small genetic differences between different populations if you look closely enough . . . ‘but that doesn’t support the idea of race.’”).

222. Diseases like cystic fibrosis, a “dangerous disease of the lungs and intestines,” RIDLEY, *supra* note 46, at 142; sickle cell anemia, “a condition that impairs a person’s red blood cells from carrying oxygen,” causing “mild or severe pain in organs, joints or muscles, and in extreme cases even death,” Jonathan Kahn, *How a Drug Becomes “Ethnic”*: *Law, Commerce, and the Production of Racial Categories in Medicine*, 4 *YALE J. HEALTH POL’Y L. & ETHICS* 1, 38 (2004); and Tay Sachs, “a progressive neurological disorder that usually strikes in infancy and results in . . . death by the age of two to three years after” a previously normal child develops “dementia, blindness, paralysis, and death,” Sonia M. Suter, *Whose Genes Are These Anyway?: Familial Conflicts Over Access to Genetic Information*, 91 *MICH. L. REV.* 1854, 1861 n.47 (1993) [hereinafter Suter,

copies are inherited (one from each parent)—may provide selective advantages against environmental insults if one copy is inherited (making one a carrier).²²³ If groups from a particular region intermarried, then evolutionary pressures would have led to an increase in the number of carriers of the advantageous mutation.²²⁴ Since evolution is a slow process, these effects last long after the groups have moved or the environmental insults have changed. Consequently, racial categories central to genetic diagnosis are “entrenched in genetic research, and pervade scientific and medical journals.”²²⁵ Unfortunately, the focus on racial classification may “indirectly . . . legitimate and reinvigorate the old nature-nurture debate over the issues of race, ethnicity, gender, and mental capacity.”²²⁶ Although the

Whose Genes], are all more prevalent in certain ethnic groups because the incidence of carriers in these groups is higher than average. Carriers are not affected by the disease, but have a 1/4 chance of having a child with the condition if their partner is also a carrier. Suter, *Routinization*, *supra* note 151, at 235 n.13. “For example, 1/25 of Caucasians (particularly those of Northern European descent) carries the gene for cystic fibrosis, 1/12 of African Americans carries the gene for sickle-cell anemia and 1/30 of Jews of Ashkenazi descent carries the Tay Sachs gene. Asian, Mediterranean, and Middle Eastern populations are at varying increased risks of carrying the gene for thalassemia,” *id.*, another form of anemia, RIDLEY, *supra* note 46, at 141.

223. For example, carriers of the gene for sickle cell anemia and thalassemia “are largely resistant to malaria.” RIDLEY, *supra* note 46, at 141-42. In addition, studies suggest that carriers of cystic fibrosis are “almost immune to the debilitating dysentery and fever caused by typhoid.” *Id.* at 142. “Some have theorized that Tay-Sachs carriers were more resistant to tuberculosis, which ran rampant among many Ashkenazi Jews in urban settings.” Suter, *Whose Genes*, *supra* note 222, at 1861 n.47.

224. Suter, *Whose Genes*, *supra* note 222, at 1861 n.47. An additional explanation for the disproportionate presence of a mutation in an ethnic group is the founder effect. That is to say, “the common ancestry has allowed a single mutation to pass ‘silently’ through a multitude of generations because recessive genes remain unexpressed unless paired with another similar recessive gene.” *Id.*

225. David J. Rothman & Sheila M. Rothman, *Race Without Racism?*, NEW REPUBLIC ONLINE, Nov. 14, 2005, <http://www.tnr.com/docprint.mhtml?i=20051114&s=rothman111405> (“Francis Collins, head of the Human Genome Project . . . , is one of many who justify applications of racial categories on pragmatic grounds: they are a convenient tool for exploring the genetic origins of disease[, such as] the link that has been forged between Ashkenazi Jews and breast cancer.”).

226. DUSTER, *supra* note 118, at 3. Compare RICHARD J. HERRNSTEIN & CHARLES MURRAY, *THE BELL CURVE* (1994) (arguing that intelligence is genetically determined and the major cause of socioeconomic success, and that therefore socioeconomic success, crime rates, and academic success between classes and races are genetic and not environmental in origin, and further that social welfare, affirmative action, and similar ideas are doomed to failure), and J. PHILIPPE RUSHTON, *RACE, EVOLUTION & BEHAVIOR* (1994) (arguing that race is a valid scientific category and that racial differences are due to genetic, not environmental factors), and SEYMOUR W. ITZKOFF, *THE DECLINE OF INTELLIGENCE IN AMERICA* (1994) (arguing that intelligence is falling because lower classes are

geneticists of today do not draw the careless, racist conclusions about ethnicity and behavior of the eugenicists, the work of genetics has made it difficult to remove inheritance from the discussion of race or ethnicity.

Unfortunately such findings have led those inclined to understand race in biological terms to ask, “If genetic disorders are differentially distributed by race and ethnicity, why aren’t other human traits and characteristics?”²²⁷ One doesn’t have to look too far to find groups that rely on some of these data to make claims that sound frighteningly like those from the era of classic eugenics. Numerous websites espouse the virtues of eugenics and its underlying goals of racial and genetic cleansing.²²⁸ Many la-

procreating more than others), with Alan H. Goodman, *The Race Pit*, ANTHROPOLOGY NEWSL., May 1998, at 50 (“Falling into the race pit starts with thinking that race is a biological and scientific concept . . . [which prevents the understanding of] human variation. Medical proclamations made without a biological basis result in a great deal of unseen harm . . . [and sometimes] feed political abuse.”), and James J. Heckman, *Lessons from the Bell Curve*, 103 J. POL. ECON. 1091-2020 (1995) (discussing five critical flaws regarding the use of the data presented by Herrnstein and Murray).

227. DUSTER, *supra* note 118, at 3.

228. See, e.g., NeoEugenics’ Web Site, <http://neoeugenics.home.comcast.net/> (last visited Aug. 18, 2006); Welcome to Simon O’s Conscious Evolution, <http://www.evolution.com/> (last visited Feb. 6, 2007); Future Generations, <http://www.eugenics.net/> (last visited Feb. 24, 2007); Eugenics—A Planned Evolution for Life, <http://www.onelife.com/ethics/eugenics.html> (last visited Aug. 18, 2006); Millennium: A Better Future, <http://www.childrenofmillennium.org/eugenics.htm> (last visited Aug. 18, 2006); Future Human Evolution: Eugenics in the Twenty-First Century, <http://www.whatwemaybe.org/> (last visited Feb. 24, 2007); Richard Lynn, <http://www.rlynn.co.uk/> (last visited Feb. 24, 2007); Yahoo! Tech Groups, e-l: Eugenics List, <http://tech.groups.yahoo.com/group/e-l/> (last visited Feb. 24, 2007) (describing a “Eugenics List . . . formed to shed light on the concept of eugenics, the world’s most misunderstood subject,” to disabuse the world of the notion that it is “the ultimate form of cruelty”); Editor’s Note: Scandalizing the Science of Eugenics, <http://theoccidentalquarterly.com/vol4no1/toq-editnote4-1.html> (last visited Feb. 24, 2007); Noontide Press, Race and Culture, <http://www.noontidepress.com/catalog/index.php?cPath=22&sort=2a> (last visited Feb. 24, 2007) (selling white supremacist literature and media, including JAMES HART, EUGENICS MANIFESTO); Center for Genetics and Society, Advocacy by Supporters of Traditional Eugenics and Neo-Eugenics, <http://www.genetics-and-society.org/analysis/promoencouraging/tradeugenics.html> (last visited Mar. 26, 2007) (including links to various websites “Encouraging Public Acceptance of the New Eugenics”). Not all focus on racial differences. See, e.g., Center for Genetics and Society, Advocacy by Supporters of Traditional Eugenics and Neo-Eugenics, <http://www.genetics-and-society.org/analysis/pro-moencouraging/tradeugenics.html> (last modified Nov. 16, 2004) (“Traditional eugenicists tend to focus on the perennial topics of racial and group differences in intelligence and behavior, [whereas] Neo-eugenicists incorporate some of the futurist visions promoted by the transhumanists.”). The Center for Genetics and Society website also provides links to various transhumanist societies.

ment the degeneration of the genome. For example, one website proclaims that:

Those handicapped in body, mind or criminal inclination, those who are not able to care for themselves within normal society and require public assistance, must be taken care of in the most humane and economical way possible - through institutions. To allow these groups to have more children is stupid, not from a genetics standpoint, but from the standpoint of the welfare of the child and its burden on the producing portion of the society. . . . The human genome was certainly not designed for modern living, and is now degenerating under an evolution which we have crippled.²²⁹

The solution, they argue, is to “change the innate nature of humans” and to “encourage the breeding of people with a higher intellect, people better able to understand what motivates them and who can eventually revolt against the subjugation by the state or the controlling elite.”²³⁰ Unfortunately, some of these notions of ethnic and genetic inferiority are not limited to fringe websites, but appear in popular publications such as *The Bell Curve*.²³¹

229. Eugenics—A Planned Evolution for Life, <http://www.onelife.com/ethics/eugenics.html> (last visited Aug. 18, 2006); see also Millennium: A Better Future, <http://www.childrenofmillennium.org/eugenics.htm> (last visited Aug. 18, 2006) (“Humanity is losing its edge. Fertility rates among the gifted are low. By contrast, the unintelligent thrive. The outcome of this is obvious: Intelligence is declining. And before too long, civilization itself will fall.”); Future Human Evolution: Eugenics in the Twenty-First Century, <http://www.whatwemaybe.org/> (last visited Feb. 24, 2007) (“Formerly, natural selection took place largely as a result of differential mortality, but now . . . selection is determined largely by differential fertility. Aside from genetic illnesses, this new selection is also characterized by a negative correlation between fertility and intelligence—the core of eugenic concern for over a century.”).

230. NeoEugenics’ Web Site, <http://neoeugenics.home.comcast.net/> (last visited Aug. 18, 2006); Yahoo! Tech Groups, e-l: Eugenics List, <http://tech.groups.yahoo.com/group/e-l/> (last visited Feb. 24, 2007) (arguing that “[e]ugenics has the potential to alleviate suffering on a vast scale”); Center for Genetics and Society, Advocacy by Supporters of Traditional Eugenics and Neo-Eugenics, <http://www.genetics-and-society.org/analysis/promoencouraging/tradeugenics.html> (last visited Mar. 26, 2007) (“[H]uman genetic modification comes easily to eugenicists, who see it as an efficient, rapid and powerful means of encouraging the spread of desirable traits and decreasing the incidence of undesirable traits.”); Future Generations, <http://www.eugenics.net/> (last visited Feb. 24, 2007) (promoting “humanitarian eugenics,” which “strives to leave a genuine legacy of love to future generations: good health, high intelligence, and noble character,” and advocates “measures to improve the innate quality of humankind which are entirely voluntary”).

231. HERRNSTEIN & MURRAY, *supra* note 226, at 269-369 (1994).

Even if our attitudes generally are not as widely racist as those of the eugenics movement, there is reason to worry about potential harm to ethnic groups in the name of genetics. Motivated by good intentions and public health concerns, as were many eugenicists, some state legislatures in the 1970s mandated that African Americans be screened for sickle cell anemia, an inherited disease most common within this group.²³² In spite of good intentions, the legislation was problematic in several respects:

Several criticisms were leveled at these statutes (and even those that made genetic testing voluntary) including: the fact that testing was limited to only African-Americans, when other ethnic groups, such as those of Mediterranean origin, can also carry the gene; the “scientific inaccuracy” of much of the legislation, which led to confusion and stigmatization of unaffected carriers of the disease gene (those who had one, as opposed to two, copies of the disease gene); and the lack of protective safeguards to ensure confidentiality of results, genetic counseling, and education.²³³

More recently, some Jewish groups have expressed concern that their population has been studied more than most other groups. Like the Finns, it is a highly homogenous group, making it ideal for genetic research.²³⁴ But this fact, coupled with the isolation of so many genes associated with Ashkenazi Jews,²³⁵ has led some within the Jewish community to criticize the “creepy irony of using Jews as guinea pigs for their genes,” both for symbolic reasons and because of the risks of discrimination to their community.²³⁶

As we compare the modern era with the eugenic era, it is easy to pat ourselves on the back and dismiss classic eugenics as unscientific and amateurish. But we should not forget that “eugenic ideas could not be

232. Howard Markel, *The Stigma of Disease: Implications of Genetic Screening*, 93 *AM. J. MED.* 209, 212 (1992).

233. Suter, *Allure*, *supra* note 208, at 676 n.21.

234. Masha Gessen, *Jewish Guinea Pigs: What If a Gene Patent Is Bad for the Jews?*, *SLATE*, July 26, 2005, <http://www.slate.com/id/2123397/>. In addition, “Ashkenazi Jews . . . offer the advantage of geographical diversity: They are found everywhere and even seem to have a certain propensity for settling near major research centers.” *Id.*

235. Rothman & Rothman, *supra* note 225. (“Only a few years ago, the term [Ashkenazi Jew] was relatively obscure to anyone outside the group; now it is common in breast cancer literature. ‘AJ’ is a well-known medical acronym in publications and medical charts . . .”).

236. Gessen, *supra* note 234. Of course, these views are not unanimous within the Jewish culture. Some American rabbis have “enthusiastically embraced the research and introduced genetic screening programs in their communities.” *Id.*

called unscientific by the standards of the day.”²³⁷ As our understanding of science advances, the standards by which we evaluate science will similarly evolve. Although the science of eugenics does not live up to modern standards, “the same could be said of most of the science produced in the past—and probably could be said of much of today’s science if scrutinized fifty years from now.”²³⁸ We should, therefore, be careful not to privilege our contemporary standards of science; such privileging of science contributed to the problems with eugenics.

4. *Societal Versus Individual Benefit*

Another distinction made between eugenics and neoeugenics is that the former was justified by general societal welfare, whereas reproductive choices today are justified in terms of beneficence toward the future child or family. In fact, in both periods, the motives were mixed. The classic rationale for eugenic sterilization included benefits to the sterilized individual. Indeed, such claims were crucial to garnering widespread support for a practice that many find abominable today. It is tempting, though not fair, to describe eugenics as “bad science practiced by bad people.” Most eugenicists viewed their mission as a form of charity and assistance.²³⁹ As Dr. John H. Bell, the superintendent at the colony where Carrie Buck was institutionalized, described in 1929:

[T]he parole of mental defectives without sterilization is, on account of their propensity for the production of defective children, fraught with considerable danger both to the *individual* and the State. . . . [I]t is vastly *more humane* to relieve these individuals of a function which they cannot properly use and allow them to return to their homes or society, than to keep them confined in an institution for the greater part of their young lives. . . .²⁴⁰

237. Koch, *supra* note 111, at 323.

238. *Id.* at 323-24.

239. *Id.* at 329 (“Ironically most eugenicists of the 1930s and 1940s considered eugenics a progressive, rational, and scientifically based humanitarian project as compared to the [past practice of] incarcerat[ing] and punish[ing] the asocial elements of society rather than re-socializ[ing], steriliz[ing], and subsequently releas[ing] them.”); Resta, *supra* note 37, at 233.

240. John Bell, *Eugenical Sterilization* 3-4 (May 13, 1929) (unpublished paper presented at a meeting of the American Psychiatric Association, Atlanta, Georgia) (emphasis added) (“[I]t is also sound economic policy in that it converts a definite liability into a reasonable asset.”), *quoted in* Cynkar, *supra* note 33, at 1430; *see also* Cynkar, *supra* note 33, at 1450 (noting that Strode “maintained that sterilization was the most humane way to deal with the feebleminded”).

Similarly, Dr. Priddy, who argued that the Virginia sterilization laws should be held constitutional in *Buck v. Bell*, claimed, somewhat self-servingly, that his patients “clamor[ed] for” eugenic sterilization.²⁴¹ Others spoke of the despair one would feel on behalf of their child, if they were to give birth to a “feebleminded” individual,²⁴² suggesting that eugenical sterilization benefitted the unborn as much as the sterilized “feebleminded.” Modern prenatal testing is also often motivated by similar concerns for the well-being of the unborn child. To prevent suffering, many believe, good parents should avoid giving birth to a child with genetic defects.²⁴³

Just as classic eugenics was not motivated solely by social well-being, current and future reproductive technologies are advocated not solely to allow individuals to make decisions compatible with their values and goals. The technologies are also promoted and encouraged as socially responsible. The success of prenatal screening programs is often measured in terms of the savings to society by reducing the incidence of children born with certain genetic conditions. For example, analysis for the federal government in 1974 estimated that voluntary prenatal testing at a cost of \$5 billion over 20 years would save \$18 billion by reducing the incidence of Down syndrome.²⁴⁴ In other words, our judgments today about appro-

241. Cynkar, *supra* note 33, at 1439.

242. “For our own sakes—for our children’s sakes—’ plead the mothers, ‘help us!’ . . . The women who thus cry out are pleading not only for themselves and their children but for society itself.” MARGARET SANGER, *Cries and Despair*, in *WOMAN AND THE NEW RACE* 72, 78-82 (1920) (introducing a chapter entitled “Cries and Despair, which excerpts some of the many letters received from “unfortunate” women, including one from “a woman praying for help to avoid adding to the number of mentally helpless,” one from an insane woman seeking to protect herself and society from perpetuating that insanity by giving birth, and another from a woman who “prayed and prayed that [her children] would die when they were born” because she knew she had no right to bring such children into the world.).

243. See *supra* text accompanying notes 153-157; see also Karen H. Rothenberg & R. Alta Charo, *The Good Mother: The Limits of Reproductive Responsibility and Genetic Choice*, in *WOMEN & PRENATAL TESTING: FACING THE CHALLENGES OF GENETIC TECHNOLOGY* 116 (Karen Rothenberg & Elizabeth Thomson eds., 1994) (“There is strong public sentiment against bringing children into the world knowing they will suffer debilitating and painful illness.”); Jeffrey R. Botkin, *Symposium: Prenatal Diagnosis and the Selection of Children*, 30 FLA. ST. U. L. REV., 265, 272 (2003) (noting that one geneticist and attorney would sanction wrongful birth suits against parents for “knowingly bringing a child to birth with a genetic condition” since they have added to familial burdens, incurred a cost to society, and, “caused needless suffering in their child.”).

244. BUCHANAN ET AL., *supra* note 34, at 55 (“[A]ssuming a reduction of 50 percent [, voluntary prenatal testing could] save the United States more than \$18 billion, and other screening programs had the potential to save another \$75 to \$100 billion.” (citing KEVLES, *supra* note 9)).

priate reproductive decisions are not wholly divorced from social welfare concerns.²⁴⁵ We may focus far more on reproductive autonomy than in the last century; but, just as eugenicists saw sterilization or segregation programs as valuable because of cost savings to society, many advocate voluntary prenatal testing and termination for the same reasons.²⁴⁶

V. WHAT'S WRONG WITH (NEO)EUGENICS?

As we've seen, neoeugenics is not identical to eugenics. Indeed, it does not share some of the most troubling features of the American eugenics movement: it is not a state-imposed restriction on reproduction, indeed, it is voluntary; it is not implemented in the context of insidious and widespread racism, with the goal of eliminating or reducing the prevalence of ethnic groups; and it is not based on oversimplified notions of the inheritance of complex traits and behaviors. As a result, neoeugenics appears less threatening than eugenics. If those three elements were the only ones that constituted eugenics or that made eugenics troubling, then perhaps few concerns would exist regarding genetic and reproductive technologies. But, as Part IV suggested, some of the attitudes and concerns of eugenics remain today—a focus on the heritability of traits, a tendency toward genetic determinism, a privileging of science, a focus on societal benefits of genetic technologies, and most important, societal pressure to increase the chances of having “well-born” children or to decrease the incidence of “less fit” children. “At its root, eugenics simply concerns *perceptions* of improvement.”²⁴⁷ Our notions of what constitutes an improvement may not be precisely the same today, but the fundamental goal of improving our unborn children remains.

This goal of improvement, perhaps more than any other, is what many mean when they describe modern reproductive genetics as neoeugenic. Such a description is usually laden with condemnation, an epithet of sorts.²⁴⁸ To determine whether the label should appropriately be treated as

245. Koch, *supra* note 111, at 322 (“The preventive practices of clinical genetics have sometimes been interpreted as neo-eugenic attempts to improve the genetic health of the population.”).

246. *Id.* at 326 (“Cost benefit considerations, which are often seen as an ethically problematic eugenic motive, are not obsolete either.”); *see also* note 165 (describing the societal benefits associated with prenatal screening).

247. Jones, *supra* note 2, at 215 (emphasis added); *see also* Wachbroit, *supra* note 153, at 329 (“Eugenics . . . was an effort to improve the human race by applying the wisdom of animal breeders.”).

248. Jones, *supra* note 2, at 213 (“[M]any use the term ‘eugenics’ pejoratively (and almost reflexively), attaching to it a payload of disturbing connotations . . .”).

an epithet, we should examine whether the concerns attached to classic eugenics remain today. If we evaluate eugenics through a Kantian notion of autonomy, then neoeugenics seems less problematic given that our laws and cultural norms have largely overcome the shackles of governmental and medical restrictions on reproductive and medical decision making. Section V.A, however, offers a more contextual, relationship-based conception of autonomy through which to evaluate neoeugenics.²⁴⁹ Using this lens, Section V.B shows the contextual importance of evaluating eugenics. It suggests that the concerns regarding eugenics are broader than state and medical tyranny, and that some of those problems still exist with neoeugenics. Nevertheless, some of the concerns are speculative and not unique to eugenics or neoeugenics. In short, I argue that the propriety of neoeugenics, or eugenics for that matter, depends on motivation, context, and results; it cannot easily be categorized as always or never problematic.

A. A Relational Account of Autonomy

It seems difficult to criticize, on its face, the underlying goal of eugenics—improving birth—especially when expressed through individual decision making, without state interference. As I shall argue below, however, the practice as applied may be troubling in many instances. Because neoeugenics involves fundamental decisions about parenting, including whether to retain the capacity to become a parent or whether actually to become a parent, some aspects of it arguably fall within a fundamental liberty or privacy interest. The Supreme Court has explicitly treated parenting decisions concerning education, religion,²⁵⁰ and procreation²⁵¹ as constitutionally protected interests, describing them as “involving the most intimate and personal choices a person may make in a lifetime, choices

249. My goal here is to introduce the concept of relational autonomy to draw parallels between classic eugenics and neoeugenics. I realize, however, that much more could be said about this theory than is possible in this Article and I plan to develop a fuller account of the theory in future works.

250. *Wisconsin v. Yoder*, 406 U.S. 205, 232 (1972) (“[The] primary role of the parents in the upbringing of their children is now established beyond debate.”); *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944) (reciting precedent that recognizes the “private realm of family life which the state cannot enter”); *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 534-35 (1925) (recognizing parental liberty with respect to child rearing and education); *Meyer v. Nebraska*, 262 U.S. 390, 399-401 (1923) (same).

251. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 870 (1992) (recognizing a constitutionally protected interest in abortion); *Roe v. Wade*, 410 U.S. 113, 164-65 (1973) (same); *Eisenstadt v. Baird*, 405 U.S. 438, 453-54, 463-66 (1972) (extending recognition of privacy interests in making decisions with respect to contraception to unmarried individuals); *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965) (recognizing constitutional interests in making decisions with respect to contraception).

central to personal dignity and autonomy”²⁵² Whether they include all manner of neoeugenic reproductive decisions remains to be seen. Only one court has addressed this issue, and only in part, deciding that reproductive interests include the ability to use reproductive technologies to bring about pregnancy and submit to prenatal testing.²⁵³ One of the biggest proponents of reproductive technologies is John Robertson, who describes “procreative liberty” as “freedom in activities and choices related to procreation.”²⁵⁴ He has argued that “if bearing, begetting, or parenting children is protected as part of personal privacy or liberty, those experiences should be protected whether they are achieved coitally or noncoitally,”²⁵⁵ and thus these liberties include in vitro fertilization and other techniques to treat infertility,²⁵⁶ decisions whether or not to engage in “selection of offspring characteristics,”²⁵⁷ and some decisions to engage in reproductive cloning.²⁵⁸ Of course, even if parental autonomy encompasses much of neoeugenics technology, it does not legitimate every such use of this technology. Some uses may be so harmful that the state could lawfully limit such rights, which of course are not absolute. The presumption, however, is in favor of allowing choice because it sets a “high standard for determining when harmful consequences justify overriding reproductive choice.”²⁵⁹

Much of historical eugenics was harmful because physicians and the state grievously impinged on the procreative autonomy of thousands by

252. *Casey*, 505 U.S. at 851.

253. *Lifchez v. Hartigan*, 735 F. Supp. 1361, 1377 (N.D. Ill. 1990) (recognizing that “within the cluster of constitutionally protected choices . . . must be . . . the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy . . . [and] the right to submit to [prenatal testing,] which can then lead to a decision to abort”).

254. John A. Robertson, *Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. CAL. L. REV. 942, 955 (1986).

255. John A. Robertson, *Children of Choice: Freedom and the New Reproductive Technologies* 39 (1994).

256. *Id.* at 100.

257. *Id.* at 153 (suggesting that these techniques fall within these liberty interests if they are “determinative of decisions to procreate”). Robertson argues that mandatory carrier or prenatal screening does not interfere with procreative liberty interests because one is free to ignore the results, though he argues that such state actions would interfere with privacy interests and interests in bodily integrity. *Id.*

258. John A. Robertson, *Why Human Reproductive Cloning Should Not in All Cases Be Prohibited*, 4 N.Y.U. J. LEGIS. & PUB. POL’Y 35, 39 (2000) (arguing that reproductive cloning to treat infertility or address the risk of serious genetic disorders falls “within our standard conceptions of family or procreative liberty,” though remaining agnostic about “the question of whether one has the right not only to reproduce, but also to totally select the genome of his or her offspring”).

259. ROBERTSON, *supra* note 255, at 153.

taking away the right to make decisions about a matter so “central to [their] personal dignity and autonomy.”²⁶⁰ Some might claim that prohibiting certain uses of genetic technology—trait selection, for example—is an infringement of reproductive choices and thus harkens back to the eugenics era. This argument would suggest that the crucial distinction between neo-eugenics and eugenics is whether people can freely exercise their procreative autonomy. It suggests that as long as people can make procreative choices unimpeded by state restrictions (except perhaps where the state interest is compelling or does not impose an undue burden),²⁶¹ we avoid the concerns of eugenics.

The problem with this argument is that the concerns regarding eugenics, as we shall see in Section V.B below, are more complex; they do not simply include limits on reproductive freedoms.²⁶² Moreover, this argument suggests a thin conception of autonomy and decisional privacy interests, which tends to minimize consideration of other social concerns²⁶³ that also apply to some aspects of eugenics and neo-eugenics. Our culture seems to have adopted an “atomistic conception of self-definition, in which the individual shapes herself without reference to others.”²⁶⁴ Indeed, Justices Souter, Kennedy, and O’Connor reflected such views in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, when they wrote: “[A]t the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.”²⁶⁵ This conception of personhood sees the self “in terms of mere isolated actions”²⁶⁶ or as “independent from the interests and attachments we may have at any moment, never identified by our aims but always capable of standing back to survey

260. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992).

261. *See Gonzales v. Carhart*, 2007 U.S. LEXIS 4338 (2007) (finding that a statute that prohibits partial birth abortion is as not on its face an undue burden and is therefore constitutional).

262. *See infra* Section V.B.

263. This is not to say that social interests are irrelevant under this version of autonomy. But it does mean that the presumption is in favor of not interfering with the autonomy interest because the libertarian conception of autonomy sets a high standard for determining when harmful consequences can justify overriding the individual’s presumptive right. *See supra* text accompanying note 259.

264. Sonia M. Suter, *Disentangling Privacy from Property*, 72 GEO. WASH. L. REV. 737, 772 (2004) [hereinafter Suter, *Disentangling Privacy*].

265. 505 U.S. at 851 (plurality opinion).

266. CHARLES TAYLOR, *SOURCES OF THE SELF: THE MAKING OF MODERN IDENTITY* 206 (1989) (citing ALASDAIR MACINTYRE, *AFTER VIRTUE: A STUDY IN MORAL THEORY* 217 (1981)); Suter, *Disentangling Privacy*, *supra* note 264, at 770.

and assess and possibly to revise them.”²⁶⁷ Two philosophers describe and criticize this individualist account:

[Charles] Taylor describes a common view of the self as making life plans and seeking relationships only insofar as they are “fulfilling” and “largely based on ignoring our embedding in webs of interlocution.” . . . [Alasdair] MacIntyre describes “modern individualism” as holding that “I am what I myself choose to be. I can always, if I wish to, put in question what are taken to be the merely contingent social features of my existence.”²⁶⁸

The development of modern bioethics, in response to abuses of human research subjects and medical paternalism, has largely promoted and privileged a notion of autonomy modeled after a Kantian or “deontological self,”²⁶⁹ the “moral frailty” of which Michael Sandel rightly criticizes. He describes such an “unencumbered” and “independent” self as “essentially dispossessed” and “too thin to be capable of desert in the ordinary sense. . . . To imagine a person incapable of constitutive attachments . . . is not to conceive an ideally free and rational agent, but to imagine a person wholly without character, without moral depth.”²⁷⁰ This notion of procreative autonomy focuses “on our individual goals [which] dissolves community and divides us from each other.”²⁷¹ From this perspective, neoeugenic choices rarely seem problematic as long as they are motivated by the individual’s procreative goals and self-definition (and they do not interfere with a compelling state interest). This is so even if the procreative choices were not necessarily in the best interest of the child or society.²⁷²

267. Michael H. Sandel, *Liberalism and the Limits of Justice* 175, 178 (1987).

268. Suter, *Disentangling Privacy*, *supra* note 264, at 773 n.173.

269. Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* 348-55 (5th ed. 2001) (providing an overview of Kantianism); Barry R. Furrow et al., *Bioethics: Health Care Law and Ethics* 19 (5th ed. 2004) (noting the widespread acceptance of Kantian individualism in bioethics because “many people have come to regard the Kantian emphasis on individual rights as a necessary corrective to the crude tendency of utilitarianism to sacrifice the individual for the greater good” and “the emphasis on moral sovereignty of the individual strongly appeals to the individualistic ethos of our culture”); *see also* Barbara Secker, *The Appearance of Kant’s Deontology in Contemporary Kantianism: Concepts of Patient Autonomy*, 24 *J. Med. & Phil.* 43, 43-44 (1999) (“[A] Kantian concept of autonomy and the principle of respect for autonomy find their inspiration in Kant’s deontology, which is one of the major theoretical frameworks underlying bioethical argumentation.”).

270. SANDEL, *supra* note 267, at 178-79.

271. TAYLOR, *supra* note 266, at 500-01.

272. This approach protects individualism to a strong degree. It is not purely individualistic, because individual autonomy rights are not absolute. But the presumption is strongly in favor of individual choice. Of course, this analysis says nothing about com-

But this Kantian account is not the only conception of autonomy. Evaluating the concerns of eugenics requires us to consider what we mean by self-definition and personhood—terms which underlie our conception of reproductive autonomy and decisional privacy. In another piece conceptualizing privacy interests, I argued for a notion of personhood that is “bound up and expressed in relation to others”²⁷³ and does not focus on individual goals that are disaggregated from community and personal history. Our autonomy and privacy interests in making self-defining decisions, such as those linked to procreation, are empty and thin unless we define ourselves and our “moral identity in and through its membership in communities such as those of the family, the neighborhood, the city and the tribe.”²⁷⁴ Certain strands of feminism have similarly argued for a more relationship-based conception of procreative autonomy, criticizing a libertarian conception “for its tendency to treat individuals atomistically, emphasizing rights rather than relationships and responsibilities for others as well as for oneself.”²⁷⁵

peting moral arguments that might suggest that, even if this conception of procreative autonomy justifies the choice, other moral arguments do not.

273. Suter, *Disentangling Privacy*, *supra* note 264, at 763. *See generally id.* at 737; Robert W. Tuttle, *Reviving Privacy?*, 67 GEO. WASH. L. REV. 1183, 1189-91 (1999) (arguing that “the absolute value of self-fulfillment ends in self-defeat”).

274. MACINTYRE, *supra* note 266, at 205. MacIntyre writes:

[T]he story of my life is always embedded in the story of those communities from which I derive my identity. I am born with a past; and to try to cut myself off from the past, in the individualist mode, is to deform my present relationships What I am, therefore, is in key part what I inherit, a specific past that is present to some degree in my present.

Id.; *see also id.* at 200 (“We live out our lives, both individually and in our relationships with each other, in light of certain conceptions of a possible shared future.”); *id.* at 201 (“We enter human society . . . with one or more imputed characters—roles into which we have been drafted—and we have to learn what they are in order to . . . understand how others respond to us and how our responses to them are apt to be construed.”).

275. Mary B. Mahowald, *Genetic Technologies and Their Implications for Women*, 3 U. CHI. L. SCH. ROUNDTABLE 439, 458 (1996) (“What is essential to that critique is that it starts with a concept of human beings not as isolated individuals but as individuals whose meaning and reality are definable and sustainable only in the context of their relationships.”); *see also* CAROL GILLIGAN, *IN A DIFFERENT VOICE: PSYCHOLOGICAL THEORY AND WOMEN’S DEVELOPMENT* (1993); NEL NODDINGS, *CARING: A FEMININE APPROACH TO ETHICS AND MORAL EDUCATION* 43, 79-81 (1984) (describing care models of moral reasoning). They also suggest that because atomistic notions of liberty and autonomy tend to focus on rationality and privilege mind over body, they indirectly devalue women, who are tied so much to the physical when their bodies are so central to “gestation, birth, and early nurturance of children.” Mahowald, *supra*, at 456.

As Section V.B below will show, this conception of personhood and autonomy yields more complex conclusions as to the legitimacy of certain neoeugenic choices. Whereas the atomistic conception of autonomy justifies decisions as long as they are an exercise of individual decision making, the relationship-based conception of autonomy would evaluate neoeugenic or eugenic choices in terms of the self in relation to our families and community.²⁷⁶ Under this conception, choices would not be “central to dignity and autonomy” merely because they promoted atomistic self-definition. They must also be choices central to the development and expression of the relational self. Of course, as we shall see, the calculus can be complex: the motivations and responses may be multiple and sometimes conflicting, perhaps not fully clear to the individual making the choice, or subject to change once the child is born.

B. Evaluating Eugenics Through the Lens of Relational Autonomy

As discussed above, contemporary developments in law, medicine, and ethics, which have privileged the principle of autonomy, have done much to eradicate some of the grave injustices associated with the eugenics movement. However, the lens of relational autonomy focuses on intent and motivation and reveals problems with neoeugenics that are more subtle and contextual than state interference with reproductive and medical decision making. By asking us to think about procreative autonomy in terms of a self connected with family, friends, community, nation, and even world, this analysis asks us to consider the effects of our neoeugenic choices on all of the worlds of which we are a part. It forces us to confront underlying prejudices that may motivate our choices and to consider the larger societal impact of making such choices. We must also think about the nature of our community and how our choices will affect the less fortunate with respect to both discrimination and inequities. Further, we should consider what our goals are in influencing reproduction and what effect they may have on our future children, existing children, marriage, family, and community.

One of the key criticisms of eugenics under this analysis is the underlying prejudice and stereotyping regarding race, ethnicity, class, “tem-

276. Libertarian autonomy generally justifies a decision as long as it reflects unencumbered individual choice. In contrast, relational autonomy asks not merely whether a choice is unencumbered but whether the choice considers the self in its full relational capacity. Again, as suggested in note 272, *supra*, autonomy interests under either theory are not absolute and may be overridden by certain compelling state interests.

perament,” and cultural attitudes.²⁷⁷ Unfortunately, similar concerns exist today with respect to neoeugenics, which may ultimately contribute to and be shaped by prejudice and stereotypes of different groups. An extensive literature describes the way in which these technologies are harmful to the disabled community or any community possessing a trait that is selected against. By promoting technologies to avoid the birth of children with genetic conditions or unwanted traits, we define the “unfit” (though perhaps we don’t use precisely that expression) in terms of that disability or trait. This fact alone may devalue the lives of those with the trait.²⁷⁸ Majority views regarding disabilities often reflect the able-bodieds’ misperceptions and stereotypes about the experiences of the disabled, in large part, because of lack of experience with the disabled community.²⁷⁹ If reproductive technologies are used widely enough to reduce the incidence of children born with disabilities,²⁸⁰ then our social awareness of and sensitivity

277. See *supra* text accompanying notes 28-29, 88-90, 93, 116, 218.

278. See, e.g., Wachbroit, *supra* note 153, at 334 (stating that what is “prima facie wrong” with using sex selection to select males “is that it insults the dignity of women; it demeans the value of being female”).

279. [T]he disability movement, and many others, would contest [the medical community’s] labeling of all human genetic variation as “disease”. . . . In general, the disability movement rejects the “medical model” focus on impairment as the defining characteristic of life as a disabled person, [arguing] it is social barriers which create disability, and that the difficulties of living as a disabled person are due to discrimination and prejudice, rather than impairment.

Tom Shakespeare, *Eugenics, Genetics and Disability Equality*, 13 *DISABILITY & SOC’Y* 665, 669 (1998); see also Jerry Alan Winter, *The Development of the Disability Rights Movement as a Social Problem Solver*, 23 *DISABILITY STUD. Q.* 33, 43 (2003) (noting that the social model views “disabled persons . . . as the collective victims of an uncaring or unknowing society rather than as individual victims of circumstances [such as impairment]” and that “while not denying ‘the significance of impairment in people’s lives’ . . . the social model holds that ‘people with . . . impairments are disabled by society’s blatant failure to accommodate to their needs.’” (citation omitted)).

280. For example, “[p]renatal diagnosis and genetic counseling have drastically reduced the incidence of births of Tay-Sachs children; in 1980, only 13 cases were reported in the North American Jewish population.” Nancy K. Rhoden, *Treatment Dilemmas for Imperiled Newborns: Why Quality of Life Counts*, 58 *S. CAL. L. REV.* 1283, 1292 n.70 (1985); see also Dorothy C. Wertz & John C. Fletcher, *A Critique of Some Feminist Challenges to Prenatal Diagnosis*, 2 *J. WOMEN’S HEALTH* 173 (1993) (“The sharp reduction in incidence of certain birth defects, such as Tay-Sachs in the United States and spina bifida or thalassemia in the United Kingdom, suggests that families are making what amount to ‘eugenic’ decisions in regard to these disorders, which most people regard as serious.”). But see Weil, *supra* note 154, at 51 (“There’s enough evil and caprice to always assure there will be disabilities.” (quoting Professor Laurie Zoloth)); Wertz & Fletcher, *supra* (“For less serious disorders, . . . it is less likely that individual decisions will have a eugenic effect in a pluralistic society Even if every pregnancy underwent

to the disabled community may further diminish. Misunderstandings about quality of life for the disabled will only increase if fewer disabled people inhabit the world.

Similarly, if certain traits—e.g., short stature, gender, certain body-types, etc.—can be selected against and are widely disfavored, individual choices, in the aggregate, may lead to fewer people with those traits. The resulting lack of diversity may be problematic in several ways. First, it may contribute to a lack of tolerance for diversity and enhance existing prejudices against individuals with the particular trait. As fewer individuals exist with particular traits, we may increasingly think about those individuals in terms of their traits or disabilities, rather than for who they are.²⁸¹ As such traits or disabilities become rarer, our increasing lack of experience with them may increase our ignorance about the effect of those traits on the individuals and perhaps create some discomfort regarding those traits. The ultimate fear is that such attitudes would reinforce the very prejudices that initially drove people to select against these traits,²⁸² just as ignorance and prejudice regarding undesirable traits escalated during the eugenics era.²⁸³

Relational autonomy raises special concerns with respect to prenatal testing for diseases for which no treatment is available, i.e., selecting against genetic disease by selecting against the diseased individual. To some, the choice seems like a decision about who should exist and who should not. It tends “to reduce fetuses to a single trait, their impairment,”²⁸⁴ which may threaten the disabled community or the community that possesses the trait selected against. To phrase this criticism slightly differently, the eugenics of yesteryear and the neoeugenics of today seek “‘better’ (or ‘fortunate’) people rather than people who are made ‘better’

. . . prenatal diagnosis . . . and every woman agreed to abortion . . . , society would still have children with [genetic] birth defects . . .”).

281. See Bob Sapey, *From Stigma to the Social Exclusion of Disabled People*, in *STIGMA AND SOCIAL EXCLUSION IN HEALTHCARE* 270 (Tom Mason et al. eds., 2001) (describing how deafness is viewed as “a minor problem, rather than a major misfortune” in a community where deafness is common and individuals with disabilities were valued by relatives for “characteristics other than their impairments, although to outsiders they continued to elicit negative responses”).

282. The effects of certain traits becoming rare can, of course, be complicated. For example, if sex selection were to lead to a shortage of females, their scarcity might make them more desirable, if nothing else, for purposes of procreation. But they might then become commodified, and hence devalued, if they were desired primarily for their capacity to bear children.

283. See *supra* text accompanying notes 28-29, 88-90, 93, 116, 218.

284. Weil, *supra* note 154, at 51.

(or 'fortunate')."²⁸⁵ Until we can treat diagnosable genetic conditions, prenatal testing cures or improves no one; instead, individuals are "benefited" by being prevented from existing.

Of course many decisions we make as a society or individually influence who will come into existence and who will not. Decisions such as whom to marry, when or whether to procreate, as well as decisions about health policy and social services, for example, all influence who will be born and who will not.²⁸⁶ But in these examples, the effect is not always intended; with classic eugenics or neoeugenics, the goal *is* to influence who will exist and who will not. Yet, the intentionality alone is not sufficient to condemn eugenics. We do not view all intentionality with respect to reproduction as problematic. For example, we do not condemn the choice of a mate on the grounds of the kind of parent he or she would be.²⁸⁷ It is certain *kinds* of reproductive choices that are troubling, not the mere fact of making a reproductive choice.

When the intent to influence reproduction is grounded in prejudice or defining the fetus solely in terms of the undesirable trait or disease, then it becomes problematic under a relational-autonomy analysis. It promotes a fragmented conception of individuals with those traits or diseases and limits us from seeing them in their wholeness as humans. When the state determines which lives are unacceptable (whether based on devaluation of certain traits or to prevent suffering) or desirable (whether based on valuing certain traits or wanting to enhance opportunities),²⁸⁸ it raises acute concerns about society's devaluing (or privileging) certain groups. If individuals make such decisions, the concerns are somewhat lessened. Individuals will differ in their determinations about which lives are worth bringing into existence.²⁸⁹ Moreover, neoeugenics avoids the problem of one entity—the empowered—imposing reproductive values and choices on another—the disempowered.²⁹⁰ Nevertheless, while we are in this pre-

285. Wikler, *supra* note 2, at 187 (noting that this "complaint faults eugenics for posing as a doctrine of benevolence").

286. DEREK PARFIT, *REASONS AND PERSONS* (1984); Wikler, *supra* note 2, at 188.

287. Wikler, *supra* note 2, at 188.

288. See Jones, *supra* note 2, at 215.

289. See Weil, *supra* note 154, at 51 ("There's enough evil and caprice to always assure there will be disabilities." (quoting Professor Laurie Zoloth)); Wertz & Fletcher, *supra* ("For less serious disorders, . . . it is less likely that individual decisions will have a eugenic effect in a pluralistic society Even if every pregnancy underwent . . . prenatal diagnosis . . . and every woman agreed to abortion . . . , society would still have children with [genetic] birth defects . . .").

290. Of course, one might argue that in one sense the problem is not altogether avoided since the embryo is clearly disempowered. But at least neoeugenics avoids the

therapeutic stage where “treatment” means termination, neoeugenics creates an uneasy tension between individual reproductive interests and concerns about harms to particular groups since social norms push individuals toward similar attitudes and decisions.²⁹¹

To the extent that neoeugenics can enhance the tendency to identify individuals solely in terms of their disabilities or undesirable traits, it becomes problematic under norms of relational autonomy. This is another way of undermining the relationship between an individual and some of the vulnerable members of the community of which she is a part, which further “dissolves community and divides us from each other.”²⁹² No easy resolution can alleviate this tension, though thoughtful consideration of the meaning of “disability” within our community and among individuals facing these reproductive choices is a necessary first step. Indeed, these very tensions should be part of the moral deliberation faced by individuals, couples, and families as they confront the difficult choices about which children they do or do not want to bring into the world. The goal of relational autonomy here is to promote consideration of the full effects of reproductive choices on ourselves, those with whom we have relationships, and the larger community of which we are a part.

As relational autonomy shows, these contextual concerns lie not with reproductive technologies or eugenics per se, but with cultural attitudes and prejudice. In fact, to the extent that “stereotypes or prejudices are a problem, they are a problem for environmental interventions as well.”²⁹³ Of course, we should be concerned about actions and trends that exacerbate harmful attitudes, just as we should worry about how prejudice drives other choices made by individuals or society. But “evil use does not make eugenics evil in nature.”²⁹⁴ Classic eugenics was so wrong in large part

problem of one person imposing values on another, if one accepts the view that an embryo, while full of potential, is not a person.

291. See Koch, *supra* note 111, at 316 (noting that some express concerns that “cultural pressures and informal forms of coercion, such as social expectations or economic considerations, shape individual choices toward a common norm”); Suter, *Routinization*, *supra* note 151; *supra* Part IV.

292. SANDEL, *supra* note 267, at 178. Such a choice would be an example of the kind of individualism that impoverishes our conception of the self. See MACINTYRE, *supra* note 266, at 220-21 (criticizing such individualism for failing to recognize that “I inherit from the past of my family, my city, my tribe, my nation, a variety of debts, inheritances, rightful expectations and obligations. These constitute the given of my life This is what gives my life its own moral particularity”); TAYLOR, *supra* note 266, at 506-08 (describing the danger of giving primacy to self-definition at the expense of other moral demands, which results in, among other things, a disintegration of community affiliations).

293. BUCHANAN ET AL., *supra* note 34.

294. Jones, *supra* note 2, at 215.

because it was deeply grounded in strong, pernicious prejudices and stereotypes. As we move into the era of neoeugenics, we will face the difficult question as to whether individuals will be able to make reproductive choices that are grounded in thoughtful consideration of the implications to the self, family, and community, instead of choices grounded in uneducated prejudice and stereotyping. We may well conclude that “evil uses”—in this case prejudicially motivated choices—are unavoidable or too difficult to prevent, and therefore present a reason to limit neoeugenics. Such a conclusion, however, is not a rejection of neoeugenics per se, but a statement about our inabilities to pursue its goals fairly and justly.

Viewed through the lens of relational autonomy and self-hood, neoeugenics raises additional concerns in light of existing inequalities. Those with the greatest advantages in society (and often with the traits most widely favored) will often have greater resources and therefore greater access to technologies that allow them to select against certain traits or disease or to enhance certain traits. One could imagine a scenario where undesirable traits or disease become less prevalent, proportionately, among the advantaged and more prevalent, proportionately, among the more socially disadvantaged. Such an outcome would further exacerbate negative associations with such traits and exacerbate inequities, further fragmenting society and the individuals within it: “dissolving community” in pernicious ways.²⁹⁵

Here again, the concern is not unique to neoeugenics; all sorts of opportunities that confer societal advantages are not equally available. Education, health care, housing, and clean environments, for example, are not evenly distributed within our culture today any more than they were during the eugenics era. These underlying inequities, not eugenic goals, raise deep and difficult challenges regarding distributive justice. Similar concerns applied to classic eugenics, including a fear that the Social Darwinism that inspired eugenics did nothing to overcome such inequalities, but instead excused them.²⁹⁶ As a society, we will have to decide whether the fragmentation will be too great and whether we should avoid adding one more advantage to the collection of advantages that are distributed unequally. But we should recognize that, again, we are condemning the consequences of underlying inequities, not neoeugenics per se.

Relational autonomy raises additional concerns about the possible harm to the community at large if there were to be an aggregate effect of

295. Sandel, however, contends that this argument assumes that enhancements are good and therefore it is the disadvantaged who are deprived here. But, if enhancement is in fact not good, then the inequality cuts the other way. Sandel, *supra* note 149, at 50.

296. See HALLER, *supra* note 89, at 84.

many individuals selecting against certain disabilities or traits. Some have argued that a reduction in diversity may be evolutionarily problematic if we end up eliminating genes that would have, at some point in the future, provided a selective advantage against environmental insults. To some extent this concern depends on how genetically homogenous the population would become. It is unlikely that the choices among the population would be so uniform as to move us toward a population with no genetic diversity. “A standard calculation from population genetics shows that reducing the frequency of a recessive gene from 5 percent to 2.5 percent, even with a vigorous eugenics program, would take more than two hundred generations.”²⁹⁷ Moreover, medical treatments generally interfere with the “natural” process of evolution, and yet, for the most part, we welcome medical advancements. Some might argue, in fact, that such advancements reflect a kind of evolution of our intellectual capacity. Ultimately, the concern seems too speculative and not sufficiently unique to condemn neoeugenics, as opposed to other medical “treatments.”

Perhaps one of the chief concerns that relational autonomy highlights with respect to eugenics is the risk that it commodifies reproduction: that is, that we may come to see the child as a commodity, not a “gift” to be accepted as he or she is.²⁹⁸ The essence of this claim is that commodifica-

297. Wachbroit, *supra* note 153, at 335.

298. See Sandel, *supra* note 149, at 55 (claiming that genetic engineering challenges parents’ ability to “appreciate children as gifts [and] to accept them as they come, not as objects of our design or products of our will or instruments of our ambition”); BARUCH ET AL., *supra* note 177, at 6 (“Rather than the currently prevailing view of reproduction as a mysterious process that results in the miraculous gift of a child, human reproduction could come to be seen more as the province of technology and children the end result of a series of meticulous, technology-driven choices.”); THE PRESIDENT’S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY xxix (2002), available at http://www.bioethics.gov/reports/cloningreport/pcbe_cloning_report.pdf (expressing concerns that children created from technologies like cloning “might come to be considered more like products of a designed manufacturing process than ‘gifts’ whom their parents are prepared to accept as they are”); THE PRESIDENT’S COUNCIL ON BIOETHICS, BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF PERFECTION 37 (2003), available at http://www.bioethics.gov/reports/beyondtherapy/beyond_therapy_final_webcorrected.pdf (Prenatal screening may “be shifting parental and societal attitudes toward prospective children: from simple acceptance to judgment and control, from seeing a child as an unconditionally welcome gift to seeing him as a conditionally acceptable product [Such attitudes] might feed the desire for better—and *still* better—children.”); cf. *Gleitman v. Cosgrove*, 227 A.2d 689, 693 (N.J. 1967) (discussing the merits of a malpractice action for failure to inform parents about risk of birth defects and concluding that a “court cannot say what defects should prevent an embryo from being allowed life A child need not be perfect to have a worthwhile life Eugenic con-

tion *intrinsically* harms our human spirit by altering our relationship with procreation and our children because it transforms reproduction into a process akin to manufacture.²⁹⁹ If neoeugenics results in such commodification, which I shall argue it sometimes will and sometimes won't, then it threatens relational autonomy because it promotes a view of the future child not in terms of his or her potential fullness, but in terms of the trait chosen or rejected. Commodification fragments our relationship with the experience of reproduction by diminishing our connection with our future child. Instead of viewing the future child as part of the community that defines us, we view it as something separate from us and our deep relationships. The risk is that we will see the future child as "thing" rather than as another human being.

The concerns regarding commodification, however, are to some extent speculative. The mere fact that individuals are interested in "improving" the birth of their children does not in and of itself mean that reproduction and the child will be commodified, or worse, that they will be *solely* viewed as a commodity. Simply because parents try to control the outcome of reproduction, rather than to allow things to happen "naturally," does not preclude them from viewing their children as a gift. As we have seen in several other instances, the evaluation of neoeugenics in terms of relational autonomy depends on motivation and intention. If, while making reproductive choices, parents are able simultaneously to view the process of reproduction as something richer than manufacture, and their resulting children as a gift, then commodification concerns are reduced. As reproductive options develop, we should pay close attention to the changes in psychological dynamics experienced by parents in terms of their relationship with reproduction and their future children. We cannot dismiss neoeugenics on the grounds of commodification without further evidence that the risk is more than speculative. Nevertheless, we should be mindful of this possibility, and providers of reproductive technologies would do well to draw this to the attention of future parents.

Fears of commodification also raise some consequentialist concerns. If we understand reproduction as the "manufacture" of children, perhaps we

siderations are not controlling. We are not talking here about the breeding of prize cattle").

299. See LEON R. KASS, *LIFE, LIBERTY AND THE DEFENSE OF DIGNITY* 159-60 (2002) ("Human cloning would . . . represent a giant step toward the transformation of . . . procreation into manufacture . . . [which] has already begun with *in vitro* fertilization and genetic testing of embryos Procreation dehumanized into manufacture is further degraded by . . . allowing babymaking to proceed under the banner of commerce.").

will engage in their “quality control.”³⁰⁰ It is worth recognizing, however, that in many different ways, parents actively try to influence and shape a child to enhance qualities the parents value and believe will benefit the child. Parents discipline and educate their children, have them vaccinated,³⁰¹ pay enormous sums to orthodontists, send their children to sports or music camps, and even take prenatal vitamins before becoming pregnant, all with the goal of improving their children morally, socially, intellectually, and physically. These goals of improvement are commended, not condemned.

Therefore, it seems that attempts to improve our children cannot be what principally troubles individuals about eugenics, unless improvement at the genetic level is fundamentally different. Perhaps the concerns stem from deeply held notions of genetics essentialism or determinism—ideas that our genes go to the essence of who we are and that to alter them in any way is to alter ourselves fundamentally.³⁰² Such views, of course, overstate the importance of genetics and understate the importance of environment. Our essence in many ways is influenced by the combination of genes we have. But our education, family, culture, and social experiences also play a tremendous role in shaping our character.³⁰³ In addition, genes and environment interact in complex ways. Environment can influence gene expression, and genes can affect the way environment influences us.³⁰⁴ Thus, it cannot alone be the fact of altering one’s genes as opposed to altering other aspects of the individual that is problematic. “For each of us, it is particular elements of our phenotype, not every element of our ge-

300. BARBARA K. ROTHMAN, *THE TENTATIVE PREGNANCY: HOW AMNIOCENTESIS CHANGES THE EXPERIENCE OF MOTHERHOOD* 11 (1996) (“In gaining the choice to control the quality of our children, we may rapidly lose the choice not to control the quality, the choice of simply accepting them as they are.”).

301. For example:

When an infant is vaccinated, the vaccine triggers an immune reaction that permanently affects the ability of the immune system to respond to particular bacteria or viruses If it were any one of us, we would not be inclined to muse, “I wonder who I would have been had my parents not altered my immune-system gene in this way.”

BUCHANAN ET AL., *supra* note 34, at 160.

302. *Id.* at 160-61.

303. *See generally* RIDLEY, *NATURE*, *supra* note 199 (discussing how environment affects the way genes express themselves).

304. *Id.* at 149-50 (describing the way long-term stress created by external events like the loss of a loved one causes the body to produce increased amounts of the hormone cortisol, which causes certain genes to be expressed, which in turn activates other genes).

notype, that we take to be central to our conceptions of self and to our essence as an individual.”³⁰⁵

An additional concern is that parents who engage in “quality control” of their children may become less willing to accept their children as they are because these parents will be less tolerant of imperfections and deviations from the norm.³⁰⁶ This lack of tolerance may lead the parents to impose considerable pressure on the child to develop the traits or characteristics that the parents sought through neoeugenics. The child born with enhanced intelligence (presuming intelligence can be enhanced genetically) may feel compelled to perform exceptionally well in school; the child that develops from an embryo selected in favor of others with genes predisposing them to short stature may feel pressure to become an accomplished basketball player. If parents care strongly enough about certain traits to manipulate reproduction, their expectations may be overwhelming for the future child. In addition, instead of basing their relationship with the child on the person the child becomes, the relationship may center on the child’s capacity to fulfill the parental expectations that drove their reproductive choices. The fear is that the relationship would be superficial and thin because it would not embrace the fullness of the child. Again, relational autonomy raises concerns of fragmentation of relationships and also fragmentation of the self because it argues that these relationships are central to the self.

Yet again these concerns are not limited to eugenics. Parents who have not manipulated reproduction may also have overbearing expectations for their children, relating to them only in terms of traits they value, while ignoring fundamental elements of the child’s personality and life. Imagine the following scenario borrowed from the television series, *Real Housewives of Orange County*. A teenager whose father and grandfather were professional baseball players is raised with the constant message that he has the “genes” for baseball and an “obligation” to fulfill his family’s dreams of his becoming another professional player. If the father’s relationship with him centers almost exclusively on baseball, the son may adopt a similarly narrow outlook, deciding that little else matters. In addition, the father’s relationship with other children may suffer if there is no baseball connection through which to bond. The son is not valued for himself and encouraged to develop broadly. Instead he is valued for his ability to fulfill parental expectations, measured narrowly by proficiency with

305. BUCHANAN ET AL., *supra* note 34, at 161.

306. This can result in the concern described earlier of reduced tolerance for diversity or imperfection, generally. *See supra* text accompanying notes 159, 198-200.

respect to a particular skill.³⁰⁷ Unfortunately, all of us could describe similar stories based on people in literature, film, or our lives. The harm in these anecdotes is not attempting to control reproduction, but attempting to control the existing child. The harm is not valuing athletic skills, intelligence, artistic ability, or any other talents, but doing so to the exclusion of other aspects of the child and failing to value the child's fullness as a human being.³⁰⁸

Concerns about overbearing parental expectations in the context of neoeugenics seem to presume that the hopes underlying the reproductive choices will increase the possibility of being overbearing. Perhaps that is true if the parents engaging in neoeugenics take a genetics essentialist perspective. But, whether parents try to shape their children through neoeugenics or environmental influences, "the experience of childrearing will sometimes transform [one's] initial impulses, making them caring, respectful, and even self-sacrificing."³⁰⁹ Of course, "[t]he pace and extent of moral development among parents . . . is infinitely variable"³¹⁰ and some parents, as in the baseball example, do not easily overcome the more detrimental impulses, whether or not they use neoeugenics. To presume that certain hopes and expectations influencing neoeugenics will crowd-out others or will diminish the capacity to experience the fullness of the child is not only speculative, but seems to dismiss the "moral complexities of parenting."³¹¹ If parental pressure ends up being too great in this context, "we would have cause to say that [such parents] wronged their chil-

307. *The Real Housewives of Orange County*, a television series that explores the sociological milieu of a wealthy, insular community in Southern California, starkly presents the way in which highly superficial attitudes can impoverish parent-child relationships, including a situation much like the one I describe. When the teenage son is drafted for professional baseball in the 36th round, the father is disappointed because he was not selected by the 6th or 7th round. Ironically, the pressure to focus solely on baseball results in the son's poor academic performance and inability to play baseball on his high school team his senior year, which ultimately harmed his drafting potential. In addition, the daughter, who excels in school, is largely ignored by her father because she does not have the baseball connection with her father. This story is one of many in a series that exposes the thinness and superficiality of a culture that values appearance, wealth, and status over substance.

308. It is understandable that a family that values baseball might hope their child would have potential as a baseball player. It is how these hopes are expressed and the extent to which they crowd out an interest in and engagement with other aspects of the child that matters.

309. Robert Wachbroit, *Genetic Encores: The Ethics of Human Cloning*, REPORT FROM THE INSTITUTE OF PHILOSOPHY AND PUBLIC POLICY, Fall 1997, at 6, available at <http://www.publicpolicy.umd.edu/IPPP/Fall97Report/cloning.htm>.

310. *Id.*

311. *Id.*

dren only because of their subsequent, and avoidable, sins of bad parenting—not because they had chosen to create the child in the first place.”³¹² Nevertheless, we should be concerned about the growing and cumulative ways in which parents may be tempted in this direction.

While relational autonomy raises several concerns that apply to neoeugenics, it also potentially justifies one of the most frequently voiced arguments in favor of neoeugenics. The State and others should not interfere with parental decision making (except in extreme cases) because we presume that parents will act in the best interests of their children. In other words, “good parents” will use genetic reproductive technologies to make choices in the best interest of their children, either to prevent suffering or to enhance opportunities. This perspective acknowledges that parents may not always get it right, and perhaps sometimes will not act in the best interests of their children. But it is a kind of rule-utilitarian argument: it presumes that the best decision makers on behalf of the child will generally be the parents, and thus, by allowing parents to make such decisions, we set in place a procedure that is most likely to achieve the best results for children.³¹³

The force of the relational-autonomy justification, however, depends on the assumption that parents can know what the best interests are in this context.³¹⁴ Because of the current inability to treat the disease or undesirable trait, a parent’s decision to select against a particular fetus to prevent suffering, for example, raises a complex and perplexing philosophical

312. *Id.* at 2.

313. The “good parenting” claim is sometimes offered to argue for the moral desirability of neoeugenics; that is, it suggests that, at least in some instances, we would *expect* parents to engage in this process, just as parents have a duty to provide the best life for their children in other areas. See BUCHANAN ET AL., *supra* note 34, at 156; Laura Purdy, *Genetic Diseases: Can Having Children Be Immoral?*, in GENETICS NOW: ETHICAL ISSUES IN GENETIC RESEARCH (John J. Buckley, Jr. ed., 1994). More frequently, the “good parenting” claim is weaker. It argues merely that these choices are legitimate, not because they are necessarily morally desirable choices (sometimes they will be, sometimes they will not be), but because they are within the legitimate authority of parents. BUCHANAN ET AL., *supra* note 34, at 162-63.

314. Note that while liberal autonomy would also argue against interference with reproductive decision making, the rationale is different—maximizing the individual’s ability to make personal choices without impediment. Under relational autonomy, in contrast, the argument for avoiding undue interference with parental decision making is that such decisions are often made in light of relational considerations. Parents make decisions about whether to undergo reproductive testing or preimplantation genetic diagnosis, for example, not solely based on their needs and desires, but also generally in the interests of their future children. Such an approach seems entirely consistent with relational autonomy—at least in theory.

question: Is it morally preferable to prevent the child's existence or to bring the child into the world with the disease or trait?³¹⁵ Some individuals with serious disabilities have declared that they would not have children if they knew they would suffer from the same condition;³¹⁶ others have taken precisely the opposite view.³¹⁷ Many argue that conditions such as Tay Sachs³¹⁸ are so severe and cause so much suffering that non-existence is preferable to existence with the condition. On the other hand, they argue, disabilities such as deafness³¹⁹ do not impose much suffering or limit one's capacity and therefore most people would choose existence with those disabilities over non-existence. Although these arguments are motivated by proper relational autonomy concerns, they risk overstating our capacity to decide what the best interests are of those who are denied existence. Parents may genuinely believe they are acting in the best interest of

315. BUCHANAN ET AL., *supra* note 34, at 225.

Standard accounts of harm compare the condition of an individual before a putative harm has occurred with the condition of that same individual after the putative harm has occurred; the individual has been harmed only if he or she is worse off in the latter condition as a result of the adverse effect of an action or event on his or her interests. But when the only alternative to the putatively harmful condition is not to exist or not to have existed at all, there is no unharmed condition, because there is no unharmed individual with whom to make the comparison.

Id.

316. The documentary, *THE BOY WHOSE SKIN FELL OFF*, offers a heart wrenching and uplifting account of a man who lived 36 years with a genetic condition called Dys-trophic Epidermolysis Bullosa, which causes constant pain because the skin is constantly peeling off, exposing the individual to sores all over his body. Despite living heroically and as fully as possible, while also preparing for his death (emotionally and practically), he nevertheless declares that he would not have wanted to bring a child into the world with his condition. See TLC.com, About the Film: The Boy Whose Skin Fell Off, <http://tlc.discovery.com/fansites/boywhoseskinfelloff/about.html> (last visited Mar. 19, 2007).

317. See Harriet M. Johnson, *The Disability Gulag*, N.Y. TIMES MAG., Nov. 23, 2003, at 59; see also Darshak M. Sanghavi, *Wanting Babies Like Themselves, Some Parents Choose Genetic Defects*, N.Y. TIMES, Dec. 5, 2006, at F1 (describing some parents who are attempting actively to select for certain conditions such as dwarfism or deafness). Dena Davis has criticized such choices when they limit a child's right to an open future. See generally Dena S. Davis, *Genetic Dilemmas and the Child's Right to an Open Future*, 28 RUTGERS L.J. 549 (1997). Her approach is consistent with relational autonomy because it considers the impact of reproductive decisions on the child.

318. See *supra* note 222 for a description of Tay Sachs.

319. "In [a] case in which the plaintiff's only affliction is deafness, it seems quite unlikely that a jury would ever conclude that life with such a condition is worse than not being born at all." *Turpin v. Sortini*, 643 P.2d 954, 962 (Cal. 1982) (discussing a wrongful birth case concerning a child born with deafness).

the child they will not bring into existence, but it is virtually impossible to know whether they are right, especially since one would tend to project one's own views about best interests on the person denied existence. How are we to know what the best interests of such a person would be?

It may be true that, in some instances, selecting against a fetus with a particular condition will be in the best interest of the individual who will not come into existence, although the instances would probably differ according to the severity of disease or disability, the nature of the person the fetus would have or has become, and the environment in which they would have lived or do live.³²⁰ Whether parents' beliefs about the best interests of the fetus are correct (or whether mere mortals can know whether the right choice was made)³²¹ is a real problem. Although this approach is consistent with relational autonomy concerns, we should be wary about relying too much on this rationale in making reproductive choices because of the difficulties of establishing the best interests in this context.

While it may be difficult to determine the best interests of those not yet in existence, we can make better assessments of the best interests of others affected by reproductive decisions—the parents, siblings, other family members, and even community. In my prior experience as a genetic counselor, it often seemed that families spoke about making reproductive decisions to serve the best interests of the unborn child when they were really addressing the best interests of their family. Choices about whether to terminate a pregnancy or to prevent the implantation of certain embryos based on consideration of the best interests of siblings, parents, and family may nevertheless be consistent with relational autonomy concerns because these decisions consider whether the choices enrich the self as understood in relation to family and larger community. In other words, considerations about the effects on the family of having a child who will suffer physically are among the kinds of considerations that relational autonomy demands.

320. It is beyond the scope of this Article to discuss whether in some situations no life is preferable to a life with some degree of suffering or disability and, if so, what those situations would be.

321. *See* *Speck v. Finegold*, 408 A.2d 496, 508 (Pa. 1979) (“Whether it is better to have never been born at all rather than to have been born with serious mental defects is a mystery more properly left to the philosophers and theologians, a mystery . . . beyond the realm of our understanding or ability to solve.”). There may be instances where the assertion that non-existence is preferable to existence with a disease is false. There may be instances in which decisions to enhance the fetus are detrimental to the well-being of the future child. Or there may be instances in which, even if the neoeugenic choices benefit the fetus or future child, they interfere with other moral obligations that parents might have. *See* BUCHANAN ET AL., *supra* note 34, at 162.

In all of these instances discussed in this Section, our evaluation of neoeugenic choices has less to do with trying to influence reproductive outcomes or genotype, than the motivation and, even more important, the response to the results. Preferring a male child over a female child cannot be deemed problematic on its face. To evaluate such a choice one would need to know the reasons for such a choice and the reactions to the reproductive outcomes. Reproductive choices made solely to promote parental goals of status or prestige—selecting the tallest child because of values with respect to sports, or the smartest embryo because of values related to intellect—seem to impoverish, not promote the dignity of this broader conception of self. A parent's decision to select against or for a trait in a child because of concerns about personal prestige, but also because of concerns about the well-being of that future child, is a more complicated choice—a choice more in keeping with relational autonomy concerns than the prior example. Parents who choose to undergo prenatal selection because they believe they cannot otherwise fulfill their obligations to their existing children, spouses, employers, or themselves are making a choice consistent with procreative autonomy.

The dignity of the relational self depends not only on promoting and nurturing relationships with others, both intimate and less intimate, but also in nurturing the individual. Sometimes choices may benefit others at the expense of the individual; in these instances, evaluation of choices depends on whether the analysis also considers the individual in its fullness, in relation to others and individually. How one approaches these choices is central to assessing whether the choice violates norms of relational autonomy. It seems difficult, given the complexity of human relationships, hopes, and expectations, to condemn most reproductive decisions on their face without understanding their context.³²² Sometimes context will reveal the problematic aspects of the choice; other times it will show that the choice is consistent with relational autonomy.

VI. CONCLUSION

The goal of this Article is to suggest, first, that although neoeugenics is not identical to the eugenics of yesteryear, many of the same impulses and

322. “‘Anything you might say about the wrongfulness or the rightness of a birth, . . . the particularity of that choice is only, and always, experienced by a particular set of parents in a particular family with certain grandparents, certain aunts and uncles, in a certain religion on a certain block in a certain neighborhood. These are circumstances that as professionals, and certainly as bioethicists, it's nearly impossible to fully understand. And then, of course, we have the luxury of walking away.’” Weil, *supra* note 154, at 53 (quoting bioethicist, Laurie Zoloth).

drives exist today; most notably, the desire to improve the human species and our children through reproductive choices. That eugenics has been so roundly criticized, rightly so, for abuses of fundamental human rights does not mean that the underlying goal is objectionable *per se*. Eugenics was problematic because of the manner in which the underlying goal was pursued—through involuntary restrictions of reproductive autonomy, which were applied discriminatorily against the weak, disempowered, and disenfranchised—not because of the goal itself.

Neoeugenics avoids some of these deeply threatening aspects of classic eugenics. Nevertheless, when examined through the lens of relational autonomy, it remains problematic when applied in ways that reflect underlying discriminatory attitudes, exacerbate inequities, or commodify individuals or reproduction. Here again, the concern does not reject the underlying goal of neoeugenics. Instead, it objects to unfortunate injustices and attitudes in our culture that are problematic with respect to many choices we might make, including reproductive choices. Neoeugenics as a practice should trouble us if the underlying intent is not focused on the best interests of the child or family, but instead is built on discriminatory attitudes, concerns about prestige, or narrow conceptions of the full value of the future child. Legally, we may be able to justify many reproductive choices based on the libertarian conception of reproductive autonomy; such choices, however, are morally suspect unless they are grounded in a relational conception of reproductive autonomy. In future works, I hope to apply this analysis to evaluate in detail the various kinds of choices that could be made with each of the existing and emerging technologies such as prenatal testing to select against serious disease, lesser disease, or traits; preimplantation genetic diagnosis to select against disease or traits; and genetic transfer to treat disease or to enhance abilities or traits.

The eugenics of yesteryear erred in privileging concerns about the social good (which were grounded on mistaken notions about what this constituted). The current neoeugenics may err in privileging concerns about a narrow conception of individual rights. A theory of procreative autonomy that is built on a notion of the self defined in terms of one's relation to family and community achieves a healthier balance between these two extremes, and thus may be the most useful tool for evaluating the evolving technologies.