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TABLE OF CONTENTS

THE ESSENTIAL FACILITIES DOCTRINE IN THE DEREGULATED TELECOMMUNICATIONS INDUSTRY

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ABSTRACT

The Telecommunications Act of 1996 required the formerly monopolistic telephone local exchange companies to open their networks up for competitors' use. This shift from anticompetitive federal regulation to mandated competition shook up an industry and necessitates another look at the basic antitrust jurisprudence undergirding the pro-competitive rationale. As this article points out, sections 251 and 252 of the Act, while purporting to encourage competition, actually may hamper entry into the local services market and provide a disincentive for current market participants to innovate. These deleterious effects can be overcome, the authors postulate, by returning to antitrust principles enumerated in the essential facilities doctrine.

TABLE OF CONTENTS

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I. INTRODUCTION

After six decades of regulation, the judicial break-up of the Bell System, and no fewer than four legislative endeavors to regulate telecommunications, the advent of the Telecommunications Act of 1996 (1996 Act)[1] attempts to create the collapse of an anticompetitive telecommunications industry "like the walls of Jericho."[2] A transition away from an antiquated regulatory paradigm, however, is "never complete and immediate."[3] Rather, the transition toward a truly competitive telecommunications environment necessitates the return to basic antitrust jurisprudence.[4] Specifically, invocation of the essential facilities doctrine within section 251[5] and section 252[6] of the 1996 Act provides the doctrinal tool necessary to unravel the Gordian knot of federal telecommunications regulation.[7]

Part I of this article reviews the telecommunications regulatory history preceding the 1996 Act. Part II examines the 1996 Act and its purposes. Part III explains the interconnection, unbundling, and resale provisions of the 1996 Act. Part IV evaluates the emergence of the essential facilities doctrine and provides its historical underpinnings and doctrinal justifications. Finally, part V posits a vital role for the essential facilities doctrine

1. Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (1996).

2. J. Gregory Sidak, *Telecommunications in Jericho*, 81 CAL. L. REV. 1209, 1209 (1993) (book review).

3. Robert Pitofsky, Address at the Glasser LegalWorks Seminar on Competitive Policy in Communications Industries, Washington, D.C., *Competition Policy in Communications Industries: New Antitrust Approaches* (Mar. 10, 1997).

4. *See id.*

5. *See infra* notes 81-93 and accompanying text.

6. *See infra* notes 94-102 and accompanying text.

7. *See generally* Elizabeth A. Nowicki, *Competition in the Local Telecommunications Market: Legislate or Litigate?*, 9 HARV. J.L. & TECH. 353 (1996).

within a deregulated telecommunications industry to achieve facilities-based competition and an ordered transition toward competition.

II. TELECOMMUNICATIONS REGULATORY BACKGROUND

Telecommunications, as an industry, has transformed from "technical balkanization" to a "reality of technological convergence."[8] This technological convergence, however, has not engendered a consonant response in the regulatory field. Of consequence, only four significant governmental responses have occurred in the past 63 years,[9] the last of which is the 1996 Act.[10] These responses furnish the relevant telecommunications regulatory and legal backdrop for this discussion.[11]

The Federal Communications Act of 1934 (1934 Act)[12] provided the original and only national telecommunications policy for more than sixty years. Congress enacted the 1934 Act to address the monopoly of the Bell System[13] over telephony in the United States.[14] Functionally, the most important attributes of the 1934 Act were the creation of a dualistic regulatory scheme and the establishment of the Federal Communications Commission (FCC).[15] Pursuant to the 1934 Act, the FCC inherited the regulatory authority over interstate wire and radio communications, a dominion

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8. Thomas G. Krattenmaker, *The Telecommunications Act of 1996*, 29 CONN. L. REV. 123, 127 (1996) ("The perception of technological balkanization has yielded to the reality of technological convergence. Since the 1934 Act, we have witnessed satellites, microwave, television, computers (with their transistors and microprocessors), fiber optics, and the World Wide Web. These have shattered our previous illusion of tightly compartmentalized technologies.").

9. These include the passage of the Federal Communications Act of 1934, the 1956 Consent Decree, the 1982 Modified Final Judgment, and the Telecommunications Act of 1996.

10. The Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (1996).

11. *See* Krattenmaker, *supra* note 8, at 127 (noting that the governmental response to the technological convergence has been one of forcing the new technologies into the regulatory framework of the old technologies thereby creating a "Procrustean bed").

12. 47 U.S.C. §§ 151-613 (1994).

13. AT&T, the Bell Operating Companies, and Western Electric were colloquially known as the Bell System.

14. *See* James E. Meadows, *Telecommunications Law in the Age of Convergence*, 444 PLI/PAT 201, 203 (1996).

15. *See id.*; *see also* Robert B. Friedrich, *Regulatory and Antitrust Implications of Emerging Competition in Local Access Telecommunications: How Congress and the FCC Can Encourage Competition and Technological Progress in Telecommunications*, 80 CORNELL L. REV. 646, 655 (1995) (stating that "[t]he most important feature of the Communications Act [was] its establishment of the FCC").

formerly held by the Interstate Commerce Commission.[16] The states retained regulatory control over intrastate wire and radio communications.[17]

The AT&T antitrust litigation provided the next two pertinent regulatory and legal developments. Until 1984, the Bell System represented both the largest company[18] and the largest monopoly in the world.[19] The Bell System controlled "nearly every sector of the telecommunications industry within the United States," of which the most influential included long-distance service, local communications networks, and telecommunications equipment manufacturing and leasing.[20] The Department of Justice (DOJ) initially addressed the anticompetitive aspects of the Bell System in 1949, which resulted in the 1956 Consent Decree.[21] In 1974, the DOJ attacked AT&T's Bell System again, resulting in the 1982 Modified Final Judgment (MFJ).[22] Although both actions sought structural adjustments, it was not until the 1982 MFJ that radical changes transpired.[23]

The 1949 DOJ suit against the Bell System sought to end the anticompetitive equipment manufacturing and leasing activity of Western Electric.[24] The DOJ alleged "that the defendants had monopolized and conspired to restrain trade in the manufacture, distribution, sale, and installation of telephones, telephone apparatus, equipment, materials, and sup-

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16. *See* 47 U.S.C. § 151 (1994).

17. *See id.* § 152. This section provides in part:

> Except as provided in sections 223 through 227 of this title, inclusive, and section 332 of this title, and subject to the provisions of section 301 of this title and subchapter V-A of this chapter, nothing in this chapter shall be construed to apply or to give the Commission jurisdiction with respect to (1) charges, classifications, practices, services, facilities, or regulations for or in connection with intrastate communication service by wire or radio of any carrier ....

Id.

18. *See* Friedrich, *supra* note 15, at 655 & n.50 (stating that "[i]n 1980, the Bell System's operating revenues exceeded $50 billion—almost 2% of the gross national product of the United States"); SONNY KLEINFIELD, THE BIGGEST COMPANY ON EARTH 3-12 (1981).

19. *See* Friedrich, *supra* note 15, at 655.

20. *See id.* The Long Lines Division provided the long-distance services while the Bell Operating Companies (BOCs) exclusively maintained the local communications networks. AT&T's Western Electric division maintained almost exclusive control over the telecommunications equipment manufacturing and leasing. *See id.*

21. *See* United States v. American Telephone & Telegraph Co., 552 F. Supp. 131, 135 (D.D.C. 1982) (*AT&T*).

22. *See id.* at 225.

23. *See id.* at 136, 160-95.

24. *See id.* at 135.

plies, in violation of Sections 1, 2, and 3 of the Sherman Act."[25] Thwarting divestiture, AT&T utilized its political influence over the DOJ by arguing that a divestiture of Western Electric from the Bell System would "effectively disintegrate the coordinated organization which [was] fundamental to the successful carrying forward of critical defense projects" contrary to the "vital interests of the nation."[26] In 1956, to serve the interests of the public, the United States District Court for the District of New Jersey approved the Consent Decree absent any structural changes within the Bell System.[27] AT&T, however, did agree to focus exclusively on the telecommunications industry and, of course, remain regulated by the FCC and the 50 state public utility commissions (PUCs). Remedially, the 1956 Consent Decree was considered "virtually useless in restraining AT&T's exercise of its anticompetitive capabilities."[28]

The DOJ's next offensive stratagem against the Bell System began on November 20, 1974,[29] when the DOJ filed suit against AT&T, Western Electric, and Bell Telephone Laboratories alleging that AT&T had violated section 2 of the Sherman Act by monopolizing a range of telecommunications services and equipment markets.[30] Again, the DOJ brought suit seeking remedial divestiture of the Bell Operating Companies (BOCs) and the dissolution of Western Electric.[31] The MFJ resulted from Judge Harold Greene's review of the Consent Decree proposed by the parties.[32]

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25. *See id.* at 135-36; *see also* 15 U.S.C. §§ 1-2 (1994).

26. STAFF OF ANTITRUST SUBCOMM. OF HOUSE COMM. OF JUDICIARY, 86TH CONG., REPORT ON THE CONSENT DECREE PROGRAM OF THE DEP'T OF JUSTICE, 56 (Comm. Print 1959); *see also* Friedrich, *supra* note 15, at 656.

27. *See AT&T*, 552 F. Supp. at 138.

28. Friedrich, *supra* note 15, at 656. The Consent Decree remedy consisted of:

> (i) precluding AT&T from engaging in any business other than the provision of common carrier communications services (i.e., both local and long-distance), (ii) precluding Western Electric from manufacturing equipment other than that used by the Bell System, and (iii) requiring the defendants to license their patents to all applicants upon the payment of appropriate royalties.

Meadows, *supra* note 14, at 206.

29. *See* Friedrich, *supra* note 15, at 656.

30. *See AT&T*, 552 F. Supp. at 139. The DOJ instituted this lawsuit because "the 1956 consent decree was not adequate to prevent activities that unreasonably restrained competition in telecommunications equipment markets, and did not protect against antitrust violations in the intercity telecommunications field." *Id.* at 139 n.18; *see also* Competitive Impact Statement, 47 Fed. Reg. 7170 (1982).

31. *See AT&T*, 552 F. Supp. at 139.

32. *See id.* at 225.

The MFJ mandated divestiture of the BOCs, inclusion of line-of-business restrictions on the BOCs, and equal exchange access.[33]

A. Divestiture of the Bell Operating Companies

The first remedy mandated by the MFJ was the total divestiture of the 22 BOCs.[34] Due to this forced divestiture, seven surviving independent Local Exchange Carriers (LECs)[35] emerged as the controllers of the local telephony service domain.[36] Each of the seven LECs maintained a monopoly over several local networks, also known as "exchange areas" or "local access and transport areas" (LATAs).[37] Each exchange area was designed to be "large enough to comprehend contiguous areas having common social and economic characteristics but not so large as to defeat the intent of the decree to separate the provision of intercity services from the provision of local exchange service."[38] In essence, the LECs would "provide[] telephone service from one point in an exchange area to other points in the same exchange area (called 'exchange telecommunications'), and to originate and terminate calls from one exchange area to another exchange area (called 'exchange access')."[39] Any interexchange of a call from one exchange area to another remained the province of AT&T and other interexchange carriers like Sprint and MCI.[40]

The rationale underlying the divestiture of the BOCs was that AT&T would be unable to exercise monopoly control over the long-distance market without control of access to the local operating networks.[41] Prior to the divestiture, AT&T restrained competitors' endeavors to provide competitive long-distance service by requiring customers of competing carriers to dial significantly more numbers to acquire network access than users of

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33. *See id. at* 160-95.

34. *See id.*

35. These included Ameritech Corporation, Bell Atlantic Corporation, BellSouth Corporation, NYNEX Corporation, Pacific Telesis Group, SBC Communications, Inc., and U.S. West, Inc. These seven BOCs commonly became known as the Baby Bells.

36. *See* United States v. American Telephone & Telegraph Co., 569 F. Supp. 990 (D.D.C. 1983) (LATA Opinion) (noting that the seven remaining BOCs provide local service to the 164 local access and transport areas (LATAs) created by the reorganization). A Local Operating Company could encompass several LATAs, but the LECs were only authorized to transmit telecommunications information between points within a single LATA. *See id.*

37. *See id.*

38. Competitive Impact Statement, 47 Fed. Reg. 7176 (1982).

39. Meadows, *supra* note 14, at 208.

40. *Id.*

41. *See* United States v. American Telephone & Telegraph Co., 552 F. Supp. 131, 160-70 (D.D.C. 1982).

AT&T long-distance.[42] AT&T also refused to provide a number of specialized local services to competing long-distance service purchasers.[43] Last, evidence during the suit demonstrated that AT&T subsidized its long-distance rates with monopoly profits from its local access operations.[44]

Central to all of these practices was the fact that the BOCs were "functioning as bottlenecks."[45] The BOCs possessed facilities deemed essential to competition for the competing interexchange carriers. These facilities were the local network. Local networks dictated all access to long-distance communications, and thus, all "user premises telephone equipment had to be connected to the local network."[46] The MFJ countered AT&T's monopolistic anticompetitive practices with divestiture[47] because the local networks were "textbook examples of natural monopolies."[48]

B. Line-of-Business Restrictions on the Local Operating Companies

The MFJ also included restrictions on the newly created independent LECs to avert the recurrence of monopolistic control by the Bell System.[49] Of importance to this discussion were the restrictions on the LECs' ability to enter interexchange markets.[50] These particular restrictions were thought necessary because, even with heavy regulation from the district court and the FCC, each of the seven independent LECs maintained monopolistic control over their corresponding local access networks.[51] As with the Bell System before divestiture, any company with monopoly

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42. *See id.* at 161-63; *see also* BRIDGER M. MITCHELL & INGO VOGELSANG, TELECOMMUNICATIONS PRICING: THEORY AND PRACTICE 166-67 (1991).

43. *AT&T*, 552 F. Supp. at 161 n.124 (detailing discriminatory practices such as denying customers of competing carriers foreign exchange service and common control switching arrangements).

44. *See id.* at 223.

45. Friedrich, *supra* note 15, at 659.

46. *Id.*

47. *See id.*

48. *Id.* at 659 & n.81 ("The local access sector of the telecommunications industry traditionally has been considered a natural monopoly because of the high capital costs of entry and sharply declining long-run average costs.").

49. *See AT&T*, 552 F. Supp. at 186-94.

50. *See id.* The interexchange market is also commonly known as the long-distance market. "Long-distance service is defined within the industry as service between 'local access and transport areas,' or 'LATAs.'" Meadows, *supra* note 14, at 215.

51. *See* Friedrich, *supra* note 15, at 660 (citing United States v. Western Elec. Co., 969 F.2d 1231, 1238 (D.C. Cir. 1992)).

control over the local access networks could discriminate against competing interexchange carriers with respect to interconnection facilities essential for service.[52] This discrimination could occur by means of complete denial, or if they allowed access, inferior quality of access and transmission.[53] Further, the LECs would have the impetus and the capacity to cross-subsidize their prices with profits from the local exchange markets.[54]

Although the restrictions applied to all seven of the independent LECs, a provision in the MFJ allowed courts to waive the competition restriction under certain circumstances.[55] Originally, a petitioning LEC only had to demonstrate that "no substantial possibility" existed that the LEC "could use its monopoly power to impede[] competition in the market" it sought to enter.[56] Subsequent case law, however, expanded the requirements to include the public interest considerations so prevalent throughout the MFJ.[57] Examples of these considerations include protection of equal access for interexchange carriers and the maintenance of quality telephony services.[58]

C. Equal Exchange Access

Part VIII of the MFJ focused on the removal of barriers to interconnection.[59] A central concern was the inherent bias in favor of AT&T that existed in the telephone network.[60] To alleviate this bias, the MFJ required that by September 1, 1986, the LECs would have to provide access services to competing interexchange carriers that were "equal in type, quality and price" to the services provided to AT&T and its affiliates.[61]

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52. *See* Meadows, *supra* note 14, at 215.

53. *See AT&T*, 552 F. Supp. at 188-90.

54. *See id.*

55. *See id.* at 231.

56. *Id.*

57. *See* United States v. Western Elec. Co., 592 F. Supp. 846, 858 (D.D.C. 1984) (noting that the court must "take into account ... the decree's fundamental principles and purposes" when ruling on a petition to waive the line-of-business restrictions).

58. *See id.* at 860-62.

59. *See AT&T*, 552 F. Supp. at 197-200.

60. *See id.* For example, before divestiture, a caller would only have to dial ten or eleven digits to place a long distance call with AT&T as opposed to 22 or 23 with a competing carrier. *See* Meadows, *supra* note 14, at 217.

61. *AT&T*, 552 F. Supp. at 196. The MFJ approved an exception to Equal Exchange Access involving the number of digits a customer had to dial. Total equality in the number of digits between AT&T and other carriers was simply not feasible because it would have required a change in the numbering system for all of the telephones in the United States. The court, therefore, approved reduction in digits to fourteen for competitors. *See id.* at 197-200; *see also* Meadows, *supra* note 14, at 218.

III. THE IMPETUS FOR AND PURPOSE OF THE 1996 TELECOMMUNICATIONS ACT

Since the MFJ, the advent of new technologies has continually altered the telecommunications landscape. Though by no means complete, many monopolies in the local telecommunications markets have been eroded.[62] Cellular communication providers, cable providers, and "bypass" access carriers[63] serve as the catalysts for change.[64] Although questions exist whether these alternatives can provide direct competition, "satellites, cellular service, land microwave networks, and expanded fiber optics have been viewed as technologies capable of allowing direct competition in transmission of local calls."[65] Moreover, "[n]ew developments in switching facilities" and "coaxial cables" may also furnish potential competition. These changes provided the impetus for the 1996 Act.[66]

The purpose of the 1996 Act is to "promote competition and reduce regulation in order to secure lower prices and higher quality services for American telecommunications consumers and encourage the rapid deployment of new telecommunications technologies."[67] The 1996 Act's delineated goals were to establish a "national policy framework" calculated to deploy private sector advanced telecommunications services to all customers in the United States by opening up competition.[68] In addition, the 1996 Act sought to: (1) promote and encourage affordable advanced telecommunications; (2) spur economic growth; and (3) preserve and advance universal service.[69] Congress also issued a series of findings pertaining to

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62. *See* Daniel F. Spulber, *Deregulating Telecommunications*, 12 YALE J. ON REG. 25, 34-44 (1995).

63. *See* Nowicki, *supra* note 7, at 357 n.19.

64. *See id.* at 357-58.

65. *Id.* at 358.

66. *See infra* notes 69-79.

67. The Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (1996).

68. Section 4 states that "[t]his Act is intended to establish a national policy framework designed to accelerate rapidly the private sector deployment of advanced telecommunications and information technologies and services to all Americans by opening all telecommunications markets to competition ...." S. 652, 104th Cong., 1st Sess. § 4 (1995).

69. Section 4 included the following goals:

> (1) To promote and encourage advanced telecommunications networks, capable of enabling users to originate and receive affordable, high-quality voice, data, image, graphic, and video telecommunications services.
>
> (2) To improve international competitiveness markedly.
>
> (3) To spur economic growth, create jobs, and increase productivity.

the stated goals.[70] Among these findings were that: (1) competition should supplant regulation as the impetus for technological advancement;[71] (2) the monopolistic nature[72] of local telephony market hindered competition[73] and necessitated a cooperative effort on the part of both the state and federal systems[74] to develop a regulatory regime[75] that facilitated a transition[76]

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(4) To deliver a better quality of life through the preservation and advancement of universal service to allow the more efficient delivery of educational, health care, and other social services.

Id.

70. Section 5 set forth the list of findings. *See id.* § 5.

71. These findings include:

(1) Competition, not regulation, is the best way to spur innovation and the development of new services. A competitive market place is the most efficient way to lower prices and increase value for consumers ...

(9) Achieving full and fair competition requires strict parity of marketplace opportunities and responsibilities on the part of incumbent telecommunications service providers as well as new entrants into the telecommunications marketplace, provided that any responsibilities placed on providers should be the minimum required to advance a clearly defined public policy goal.

Id.

72. "Local telephone service is predominantly a monopoly service .... Some States have begun to open local telephone markets to competition. A national policy framework is needed to accelerate the process." *Id.*

73. The section includes "[b]ecause of their monopoly status, local telephone companies and the Bell operating companies have been prevented from competing in certain markets. It is time to eliminate these restrictions. Nonetheless, transition rules designed to open monopoly markets to competition must be in place before certain restrictions are lifted." *Id.*

74. These include:

(11) Ensuring that all Americans, regardless of where they may work, live, or visit, ultimately have comparable access to the full benefits of competitive communications markets requires Federal and State authorities to work together affirmatively to minimize and remove unnecessary institutional and regulatory barriers to new entry and competition ...

(10) Congress should not cede its constitutional responsibility regarding interstate and foreign commerce in communications to the Judiciary through the establishment of procedures which will encourage or necessitate judicial interpretation or intervention into the communications marketplace.

Id.

75. This regime includes:

(6) Congress should establish clear statutory guidelines, standards, and time frames to facilitate more effective communications competition and, by so doing, will reduce business and customer uncertainty, lessen regulatory processes, court appeals, and litigation, and thus encourage

from regulation to a competitive marketplace; (3) a competitive marketplace engenders technological development;[77] and (4) the protections of antitrust law within a competitive marketplace ensure economic growth and universal access.[78] The importance of these findings is set forth in part V in conjunction with a discussion of the deficiencies of the 1996 Act and the overlay of antitrust law to its current interconnection mandate.[79]

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the business community to focus more on competing in the domestic and international communications marketplace.

(7) Where competitive markets are demonstrably inadequate to safeguard important public policy goals, such as the continued universal availability of telecommunications services at reasonable and affordable prices, particularly in rural America, Congress should establish workable regulatory procedures to advance those goals ....

Id.

76. This includes:

(4) Transition rules must be truly transitional, not protectionism for certain industry segments or artificial impediments to increased competition in all markets. Where possible, transition rules should create investment incentives through increased competition. Regulatory safeguards should be adopted only where competitive conditions would not prevent anticompetitive behavior.

Id.

77. These include:

(5) More competitive American telecommunications markets will promote United States technological advances, domestic job and investment opportunities, national competitiveness, sustained economic development, and improved quality of American life more effectively than regulation ....

(12) Effectively competitive communications markets will ensure customers the widest possible choice of services and equipment, tailored to individual desires and needs, and at prices they are willing to pay.

(13) Investment in and deployment of existing and future advanced, multipurpose technologies will best be fostered by minimizing government limitations on the commercial use of those technologies.

Id.

78. This includes "[c]ompetitive communications markets, safeguarded by effective Federal and State antitrust enforcement, and strong economic growth in the United States which such markets will foster are the most effective means of assuring that all segments of the American public command access to advanced telecommunications technologies." *Id.*

79. *See infra* part VI.

IV. THE CURRENT MANDATE

Section 251(a) of the 1996 Act[80] imposes a general duty upon all telecommunications carriers[81] to "interconnect directly or indirectly with the facilities and equipment of other telecommunications carriers."[82] The 1996 Act also requires LECs to provide: (1) resale of telecommunication services;[83] (2) nondiscriminatory access to "telephone numbers, operator services, directory assistance, ... directory listing[s;]"[84] and (3) access to "poles, ducts, conduits, and rights-of-way" to competing telecommunications service providers.[85] Section 251(c) imposes coterminous requirements on incumbent local exchange carriers (ILEC).[86] ILECs[87] must pro-

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80. The Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (1996).

81. The section states, "(49) Telecommunications Carrier – ... A telecommunications carrier shall be treated as a common carrier under this Act only to the extent that it is providing telecommunications services ...." 47 U.S.C. § 251 (1994).

82. *Id.* Specifically, "(a) GENERAL DUTY OF TELECOMMUNICATIONS CARRIERS - Each telecommunications carrier has the duty—(1) to interconnect directly or indirectly with the facilities and equipment of other telecommunications carriers; ...." *Id.*

83. *See id.* § 251(b) (providing that "[e]ach local exchange carrier has the following duties: (1) Resale - The duty not to prohibit, and not to impose unreasonable or discriminatory conditions or limitations on, the resale of its telecommunications services").

84. *See id.* § 251(b)(3). Section 251(b)(3) states:

> Dialing Parity - The duty to provide dialing parity to competing providers of telephone exchange service and telephone toll service, and the duty to permit all such providers to have nondiscriminatory access to telephone numbers, operator services, directory assistance, and directory listing, with no unreasonable dialing delays.

Id.

85. *See id.* § 251(b)(4) (providing carriers with a duty to "afford access to the poles, ducts, conduits, and rights-of-way of such carrier to competing providers of telecommunications services on rates, terms, and conditions that are consistent with section 224).

86. ADDITIONAL OBLIGATIONS OF INCUMBENT LOCAL EXCHANGE CARRIERS - In addition to the duties contained in subsection (b), each incumbent local exchange carrier has the following duties:

> DUTY TO NEGOTIATE - The duty to negotiate in good faith in accordance with section 252 the particular terms and conditions of agreements to fulfill the duties described in paragraphs (1) through (5) of subsection (b) and this subsection. The requesting telecommunications carrier also has the duty to negotiate in good faith the terms and conditions of such agreements.

Id. § 251(c).

87. *See id.* § 251(c)(h)(1) (defining an ILEC as "the local exchange carrier that — (A) on the date of enactment of the Telecommunications Act of 1996, provided telephone exchange service in such area").

vide interconnection to facilities and equipment at the request of any challenging local exchange carrier (CLEC)[88] and unbundled access to "network elements."[89] In order to render interconnection and unbundled access economically feasible, ILECs must permit physical collocation of their competitors' equipment.[90] Additionally, in order to effectuate price

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88. Section 251(c)(2) states:

> INTERCONNECTION - The duty to provide, for the facilities and equipment of any requesting telecommunications carrier, interconnection with the local exchange carrier's network —
> (A) for the transmission and routing of telephone exchange service and exchange access;
> (B) at any technically feasible point within the carrier's network;
> (C) that is at least equal in quality to that provided by the local exchange carrier to itself or to any subsidiary, affiliate, or any other party to which the carrier provides interconnection; ....

Id. § 251(c)(2).

89. Section 251(c)(3) provides:

> Unbundled Access - The duty to provide, to any requesting telecommunications carrier for the provision of a telecommunications service, nondiscriminatory access to network elements on an unbundled basis at any technically feasible point on rates, terms, and conditions that are just, reasonable, and nondiscriminatory. An incumbent local exchange carrier shall provide such unbundled network elements in a manner that allows requesting carriers to combine such elements in order to provide such telecommunications service. A "network element" includes not only the physical equipment used to provide telecommunications service, but also significant functions, systems, and information used in the transmission of, telecommunications service. These would include local loops and sub-loops, switching, and signaling functions ....

Id. § 251(c)(3).

90. Section 251(c)(6):

> Collocation - The duty to provide, on rates, terms, and conditions that are just, reasonable, and nondiscriminatory, for physical collocation of equipment necessary for interconnection or access to unbundled network elements at the premises of the local exchange carrier, except that the carrier may provide for virtual collocation if the local exchange carrier demonstrates to the State commission that physical collocation is not practical for technical reasons or because of space limitations. In other words, incumbent LECs must allow other telecommunication carriers to place their equipment at the site of the incumbent's own switching center. Again, rates charged for using these premises must be reasonable and nondiscriminatory.

Id. § 251(c)(6).

competition, the 1996 Act requires ILECs to resell their telecommunications services to CLECs at wholesale prices.[91]

Section 251's interconnectivity, unbundling, and resale mandates are premised upon the supposition that permitting competitors to interconnect with an incumbent's network, expedites both price-based competition and facility based competition: ultimately enabling the generation of an acquired customer base from which new entrants may construct rival facilities. The 1996 Act's interconnectivity, unbundling, and resale mandates remain effective until "explicitly superseded by regulations prescribed by the Commission."[92] Notwithstanding an express legislative override, the only limitation on the Act's interconnectivity and unbundling mandates is a simultaneous requirement that the rates, terms, and conditions of interconnectivity and unbundled access be just, reasonable, and nondiscriminatory.[93]

A host of harmonious standards exists for determining the reasonableness of rates, terms, and conditions of interconnectivity.[94] The result is a

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91. (4) Resale - The duty — (A) to offer for resale at wholesale rates any telecommunications service that the carrier provides at retail to subscribers who are not telecommunications carriers; and (B) not to prohibit, and not to impose unreasonable or discriminatory conditions or limitations on, the resale of such telecommunications service, except that a State commission may, consistent with regulations prescribed by the Commission under this section, prohibit a reseller that obtains at wholesale rates a telecommunications service that is available at retail only to a category of subscribers from offering such service to a different category of subscribers.

Id. § 251(c)(4).

92. This includes:

(g) Continued Enforcement of Exchange Access and Interconnection Requirements - On and after the date of enactment of the Telecommunications Act of 1996, each local exchange carrier, to the extent that it provides wireline services, shall provide exchange access, information access, and exchange services for such access to interexchange carriers and information service providers in acordance with the same equal access and nondiscriminatory interconnection restrictions and obligations (including receipt of compensation) that apply to such carrier on the date immediately preceding the date of enactment of the Telecommunications Act of 1996 under any court order, consent decree, or regulation, order, or policy of the Commission, until such restrictions and obligations are explicitly superseded by regulations prescribed by the Commission after such date of enactment.

Id. § 251(g).

93. *See id.* § 251(c)(2)(d).

94. Section 252(d) establishes relatively few standards for determining whether rates for interconnection, unbundling, and resale are reasonable:

quagmire of disjunctive standards. In response to the anticipated conflict between ILECs and CLECs, the 1996 Act imposes a system of dispute resolution by which either party may request mediation by a state commission during the negotiation process.[95]

Failure to reach a negotiated settlement for interconnectivity within 135 days[96] leads to mandatory binding arbitration to settle any remaining unresolved issues.[97] The 1996 Act designates the State as the arbitrator of the dispute[98] and mandates the resolution of all contested issues no later than nine months after the dispute becomes the subject of arbitration.[99]

(d) Pricing Standards - (1) Interconnection and Network Element Charges - Determinations by a State commission of the just and reasonable rate for the interconnection of facilities and equipment for purposes of subsection (c)(2) of section 251, and the just and reasonable rate for network elements for purposes of subsection (c)(3) of such section — (A) shall be — (i) based on the cost (determined without reference to a rate-of-return or other rate-based proceeding) of providing the interconnection or network element (whichever is applicable), and (ii) nondiscriminatory, and (B) may include a reasonable profit. (3) Wholesale Prices for Telecommunications Services - For the purposes of section 251(c)(4), a State commission shall determine wholesale rates on the basis of retail rates charged to subscribers for the telecommunications service requested, excluding the portion thereof attributable to any marketing, billing, collection, and other costs that will be avoided by the local exchange carrier.

Id. § 252(d).

95. *See id.* § 252(a)(2) ("Any party negotiating an agreement under this section may, at any point in the negotiation, ask a State commission to participate in the negotiation and to mediate any differences arising in the course of the negotiation.").

96. *See id.* § 252(e)(2).

97. Section 252(b)(1):

(b) AGREEMENTS ARRIVED AT THROUGH COMPULSORY ARBITRATION -

(1) ARBITRATION - During the period from the 135th to the 160th day (inclusive) after the date on which an incumbent local exchange carrier receives a request for negotiation under this section, the carrier or any other party to the negotiation may petition a State commission to arbitrate any open issues.

Id. § 252(b)(1).

98. *See id.*

99. Section 252(b)(4)(c):

(c) The State commission shall resolve each issue set forth in the petition and the response, if any, by imposing appropriate conditions as required to implement subsection (c) upon the parties to the agreement, and shall conclude the resolution of any unresolved issues not later than 9 months after the date on which the local exchange carrier received the request under this section.

The state commission must review all negotiated and arbitrated agreements.[100] Rejection of an agreement is warranted if the agreement fails to comply with the interconnection requirements of section 251 or the pricing standards of section 252(d).[101] Despite these ostensible requirements, the 1996 Act purports to entitle an aggrieved party to appeal a state commission's determination to a federal district court.[102]

V. THE ESSENTIAL FACILITIES DOCTRINE WITHIN THE DEREGULATED TELECOMMUNICATIONS MARKET

Section 251 clearly imparts a duty to deal on the part of telecommunication providers, LECs, and ILECs with respect to facilities and equipment useful for providing telephony services.[103] Antitrust law confers a corresponding duty to deal in the form of the essential facilities doctrine.[104] The essential facilities doctrine imparts liability on a monopolist who denies competitor access to a resource essential[105] for competition in a relevant antitrust market.[106] This confined duty to confer access to an essential resource provides a viable mechanism to supplant section 251's general

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Id. § 252(b)(4)(c).

100. *See id.* § 252(e) ("Approval by State Commission - (1) Approval Required - Any interconnection agreement adopted by negotiation or arbitration shall be submitted for approval to the State commission.").

101. This includes:

> Grounds for Rejection - The State commission may only reject—(A) an agreement (or any portion thereof) adopted by negotiation under subsection (a) if it finds that—(i) the agreement (or portion thereof) discriminates against a telecommunications carrier not a party to the agreement; or (ii) the implementation of such agreement or portion is not consistent with the public interest, convenience, and necessity; 252(B) an agreement (or any portion thereof) adopted by arbitration under subsection (b) if it finds that the agreement does not meet the requirements of section 251, including the regulations prescribed by the Commission pursuant to section 251, or the standards set forth in subsection (d) of this section.

Id. § 252(e)(2).

102. *See id.* § 252(e)(6).

103. Notice there is no requirement that the duty to deal be based on equipment "necessary" for the provision of telephony service.

104. *See* A.D. NEALE, THE ANTITRUST LAWS OF THE UNITED STATES OF AMERICA: A STUDY OF COMPETITION ENFORCED BY LAW 67 (2d ed. 1970) ("The Sherman Act requires that where facilities cannot practicably be duplicated by would-be competitors, those in possession of them must allow them to be shared on fair terms. It is illegal restraint of trade to foreclose the scarce facility.").

105. See discussion *infra* notes 253-66 and accompanying text.

106. *See id.*

duty to share equipment necessary for the provision of local telephony services.

In addition to offering an ordered deregulation of the local exchange market, the essential facilities doctrine provides an alternative avenue for challenging a monopolist's conduct. To understand fully the role of the essential facilities doctrine in the deregulation of the local exchange market, however, it is necessary to examine antitrust's doctrinal justifications, the essential facility doctrine's role within antitrust jurisprudence, and the doctrine's historic underpinnings.

A. Antitrust's Doctrinal Justifications and the Essential Facilities Doctrine

Congress enacted the antitrust laws to promote economic efficiency[107] via the protection of the competitive process.[108] Courts and commentators have recognized that distortion occurs in the competitive process when a monopolist refuses access to an essential facility.[109] The instances in which a monopolist has a duty to provide access to an essential facility is "one of the most 'unsettled and vexatious' issues in antitrust law."[110] Antitrust law rarely mandates access to a monopolist's facility for several reasons: (1) liberal access encourages firms to abstain from significant in-

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107. *See* Northern Pac. Ry. v. United States, 356 U.S. 1, 4 (1958) (identifying economic efficiency as one of the principal goals of antitrust law); United States v. Gypsum Co., 438 U.S. 422, 441 n.16 (1978) (characterizing efficiency as procompetitive conduct); Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 605-11 (1985) (accepting that monopoly conduct challenged as being exclusionary, anticompetitive, or predatory may be justified on the basis of an efficiency explanation); ROBERT H. BORK, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF 91 (1978) (noting that the sole goal of antitrust is "to improve allocative efficiency without impairing productive efficiency so greatly as to produce either no gain or a net loss in consumer welfare"). *But see* Robert H. Lande, *Wealth Transfers as the Original and Primary Concern of Antitrust: The Efficiency Interpretation Challenged*, 34 HASTINGS L.J. 65, 72-74, 77-80 (1982).

108. *See* Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 224 (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962)).

109. "The foremost question facing antitrust is when you get a firm that achieves monopoly and is also an essential facility, what should we do?" Katrina M. Dewey, *A New Mission, Media Mergers Raise Issues About Goals of U.S. Antitrust Policy*, S.F. DAILY J., Sept. 25, 1995, at 5; *see also* Allen Kezsbom & Alan V. Goldman, *No Shortcut To Antitrust Analysis: The Twisted Journey of The "Essential Facilities" Doctrine*, 1996 COLUM. BUS. L. REV. 1, 7 (1996); William B. Tye, *Competitive Access: A Comparative Industry Approach to the Essential Facility Doctrine*, 8 ENERGY L.J. 337, 346 (1987).

110. Aspen Highlands Skiing Corp. v. Aspen Skiing Co., 738 F.2d 1509, 1519 (10th Cir.), *aff'd*, 472 U.S. 585 (1985) (quoting Byars v. Bluff City News Co., 609 F.2d 843, 846 (6th Cir. 1980)).

vestment initiatives in an attempt to free ride on the investment of their competitors; (2) access inhibits firms from undertaking risky and costly investment in the absence of countervailing first-mover advantages; and (3) mandated access does not have pro-competitive effects unless the terms and conditions of access are reasonable. Absent reasonable access requirements, a monopolist can either permit access on terms that are so onerous that, as a practical matter, access is unavailable[111] or charge monopoly rents for access, in which case price competition becomes impossible.[112]

Despite these implications, antitrust policy supports a limited duty to deal only when an actual probability exists for enhancing competition.[113] The essential facilities doctrine facilitates competition in two circumstances: (1) a monopolistic consortium of competitors jointly controls an essential facility enabling the consortium to restrain trade;[114] and (2) a single monopolist controls an essential facility and via this control unilaterally forecloses competition in a relevant antitrust market.[115] Antitrust liability attaches only when a particular resource is central to a competitor's viability in the marketplace.[116] Liability primarily occurs when a monopolist obtains a substantial cost advantage by possessing an essential

111. *See generally* Pitofsky, *supra* note 3.

112. *See* PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 736.2b, at 667 (Supp. 1996).

113. Before liability attaches, courts must discern whether a refusal to deal has a truly deleterious effect upon competition. A monopolist has no duty to deal unless doing so actually enhances competition. Absent enhanced competition, a monopolist's refusal to deal does not trigger invocation of the essential facilities doctrine. *See, e.g.*, Rural Tel. Serv. Co., Inc. v. Feist Publications, Inc., 957 F.2d 765 (10th Cir. 1992); *see also* Gas Utilities Co. of Alabama, Inc. v. Southern Natural Gas Co., 1993-2 Trade Cas. (CCH) ¶ 70,316, ¶ 70,650, ¶ 70,651 (11th Cir. 1993) (invalidating the plaintiff's claim that a refusal to deal violated section 2 because it could not show that it was prepared to enter the market but for the refusal to deal, and therefore could not demonstrate that it had been foreclosed from the market). *But see* Oahu Gas Serv. v. Pacific Resources, Inc., 838 F.2d 360, 368 (9th Cir. 1988). In *Oahu Gas*, the Ninth Circuit stated that an affirmative duty to deal arises when there is no justification for refusing to aid a competitor. *Id.* This passage suggests that the Ninth Circuit would impose an affirmative duty to deal without first finding a negative effect on competition.

114. *See* Thomas A. Piraino, Jr., *The Antitrust Analysis Of Network Joint Ventures*, 47 HASTINGS L.J. 5, 12 (1995).

115. *See, e.g.*, Kenneth L. Glazer & Abbott B. Lipsky, Jr., *Unilateral Refusals to Deal Under Section 2 of the Sherman Act*, 63 ANTITRUST L.J. 749, 756-59 (1995).

116. *See* Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 605 (1985); MCI Communications v. American Telephone & Telegraph Co., 708 F.2d 1081, 1133 (7th Cir. 1982), *cert. denied*, 464 U.S. 891 (1983).

resource[117] that competitors cannot practicably duplicate;[118] the monopolist possesses a natural monopoly; and the monopolist has no valid business justification for denying access to the essential resource.[119]

B. The Doctrine's Historical Underpinnings: Supreme Court Recognition Of The Essential Facilities Doctrine

In support of the essential facilities doctrine, two clusters of Supreme Court precedents have emerged: concerted horizontal combination cases in violation of section 1 of the Sherman Act[120] and unilateral monopoly misuse cases in violation of section 2.[121] Concerted action among unrelated enterprises occurs infrequently, is readily detectable, and is easily remedied.[122] Unilateral activity, however, is pervasive, evades detection, and frequently requires remedial measures that consign the courts' duties to those of a regulatory agency.

1. The Essential Facilities Doctrine as Applied to Horizontal Combination Cases: Concerted Action In Violation of Section 1

The seminal case establishing the essential facilities doctrine pursuant to section 1 of the Sherman Act is *United States v. Terminal Railroad Ass'n of St. Louis*.[123] The Terminal Railroad Association (Association)

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117. *See, e.g.,* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.1a (describing an essential facility as providing a substantial cost advantage).

118. Inability to duplicate the essential facility has been broadly construed as being fulfilled if it is not economically feasible or practical to duplicate the facility. *See* Delaware & Hudson Ry. Co. v. Consolidated Rail Corp., 902 F.2d 174, 179 (2d Cir. 1990). However, mere inconvenience or some economic loss does not suffice. *See* Twin Lab. v. Weider Health & Fitness, 900 F.2d 566, 570 (2d Cir. 1990).

119. *See infra* notes 250-69 and accompanying text.

120. Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, ..." 15 U.S.C. § 1 (1994). Section 1 has been expansively utilized to control such practices as price fixing, tying arrangements, and refusals to deal. *See generally* WILLIAM C. HOLMES, 1987 ANTITRUST LAW HANDBOOK 35-137 (1987).

121. Section 2 condemns "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations." 15 U.S.C. § 2 (1994).

122. *See* David J. Gerber, *Rethinking the Monopolist's Duty to Deal: A Legal and Economic Critique of the Doctrine of "Essential Facilities,"* 74 VA. L. REV. 1069, 1095-98 (1988).

123. 224 U.S. 383 (1912).

was a unitary corporation consisting of fourteen competing railroads.[124] The Association acquired numerous independent terminal companies and operated them as a united system.[125] The Association sought to control all practicable means of railroad access through St. Louis by acquiring ownership of all trackage, access bridges, and terminal facilities necessary for effective interchange in the St. Louis terminal.[126] At the time, St. Louis was the terminus for numerous trunk-line railroads and a critical terminal for a substantial amount of rail transportation.[127]

The Association permitted all railroads to use its facilities, whether or not they were Association members.[128] While no showing existed that the Association had excluded nonparticipating carriers, there was nothing preventing the Association from doing so.[129] Consonant with the simplest economic theory of vertical integration, the Association charged nonmembers the same price for terminal access that they charged themselves.[130] This price, however, constituted monopoly rents[131] that disadvantaged nonparticipating carriers.[132]

The Supreme Court recognized that in ordinary circumstances, a number of independent entities could combine for the purpose of controlling or acquiring terminals for their common but exclusive use.[133] If access or exclusion terms were excessively onerous, competitors had the ability to exercise the right and power to construct plausible substitutes.[134] Two factors were determinative of the inability to construct plausible substitutes in this case. First, the Association was a natural monopoly.[135] The geographical constraints made the construction of a viable rail alternative

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124. *Id.* at 391.

125. *Id.*

126. *Id.* at 393-95.

127. *Id.* at 403 (noting that "St. Louis is one of the largest railroad centers in the world").

128. *Id.* at 400.

129. *Id.* at 410-11.

130. *Id.* at 400 (noting "[t]hat other companies are permitted to use the facilities of the terminal company upon paying the same charges paid by the proprietary companies").

131. *Id.* at 410-11.

132. *Id.* at 406.

133. *Id.* at 405.

134. *Id.*

135. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.1b, at 646 (stating that the monopoly was "apparently 'natural'"). A "natural monopoly" is a market structure where one firm can satisfy the demand in a market at a lower cost than could two or more firms. *See* MARSHALL HOWARD, ANTITRUST AND TRADE REGULATION 7 (1983); F.M. SCHERER & DAVID ROSS, INDUSTRIAL MARKET STRUCTURE & ECONOMIC PERFORMANCE 111 (3d ed. 1990).

infeasible.[136] The minimum efficient scale also easily accommodated all existing railway traffic.[137] Secondly, control over the trackage and access bridges created a bottleneck. Limiting access to the St. Louis interchange threatened to substantially curtail travel along an extensive rail network on either side of the interchange.[138]

Given the essential nature of the St. Louis interchange[139] and resultant inability to construct a viable substitute,[140] the Court viewed the Association's unified ownership[141] as "an obstacle, a hindrance, and a restriction upon interstate commerce."[142] Rather than ordering dissolution of the Association, the Court entered a decree requiring the consortium to allow nonparticipating competitor railroads access to the facilities essential for the St. Louis interchange.[143] The Court ordered access for the ten remaining railroads "upon such just and reasonable terms as shall place such [railroads] upon a plane of equality in respect of benefits and burdens [incurred by Association members]."[144] Forcing the Association to admit competitors to their collaboration enabled the Court to avoid becoming a regulatory agency charged with ordering the rationing of the Association's assets.[145]

The Court's focus upon the essential nature of the trackage, access bridges, and terminals accessing the St. Louis terminal lends support for the existence of the essential facilities doctrine.[146] Even the most conten-

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136. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.1b, at 646 ("The Terminal Company's St. Louis monopoly was apparently 'natural' in the double sense that its minimum efficient scale could accommodate all the traffic and that topographical features of the terrain made construction of an alternative impossible or prohibitively expensive"); *see also Terminal R.R. Ass'n*, 224 U.S. at 396, 404 (noting the importance of "[t]he physical or topographical conditions peculiar to the locality").

137. *Terminal R.R. Ass'n*, 224 U.S. at 396-98.

138. *Id.*

139. *See supra* notes 17-23 and accompanying text.

140. *Terminal R.R. Ass'n*, 224 U.S. at 396-98.

141. *Id.* at 399-401.

142. *Id.* at 405.

143. *Id.* at 410-11.

144. *Id.*

145. *Id.* at 412-13.

146. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.1b, at 645; *see also* Kezsbom & Goldman, *supra* note 109, at 4 (stating that the doctrine was derived from the *Terminal Railroad* decision); Robert H. Lande & Sturgis M. Sobin, *Reverse Engineering of Computer Software And U.S. Antitrust Law* 9 HARV. J.L. & TECH. 237, 262 (1996) (noting the essential facilities doctrine originated in part in the *Terminal Railroad* decision).

tious critics[147] acknowledge that the *Terminal Railroad* decision imparts a limited responsibility upon competitors who jointly acquire a natural monopoly to allow reasonable access for rivals.[148]

The rationale undergirding *Terminal Railroad* was eventually extended in *Associated Press v. United States*.[149] Approximately 1,200 newspapers joined together creating the Associated Press News Organization (AP). The AP provided a vehicle for the gathering, transmission, and exchange of news reports created by domestic and foreign newspaper members.[150] The collaboration realized significant economies of scale resulting in the saturation of the news gathering market.[151] Although the AP generally extended membership to all news-generating newspapers,[152] the AP bylaws established oppressive entry requirements for applicant papers in competition with existing local incumbents.[153] Each existing member could "block membership by competing newspapers and thereby remain

147. Commentators have criticized the doctrine as having nothing to do with the purposes of antitrust law. *See, e.g.*, Phillip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST L.J. 841 (1990); HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE § 7.7 (1994); Scott D. Makar, *The Essential Facilities Doctrine and the Health Care Industry*, 21 FLA. ST. U. L. REV. 913 (1994). As one court stated:

> Had the terminal facilities been owned by a firm unaffiliated with any railroad, the firm could have charged whatever prices it wanted, including prices that discriminated against some of the users (monopolists frequently price discriminate), because the antitrust laws do not regulate the prices of natural monopolists. A natural monopolist that acquired and maintained its monopoly without excluding competitors by improper means is not guilty of 'monopolizing' in violation of the Sherman Act, and can therefore charge any price that it wants, for the antitrust laws are not a price-control statute or a public-utility or common-carrier rate-regulation statute.

Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic, 65 F.3d 1406, 1412 (7th Cir. 1995) (internal citations omitted).

148. *See generally* HOVENKAMP, *supra* note 147.

149. 326 U.S. 1 (1945).

150. *Id.* at 4.

151. The record demonstrated that "morning newspapers, which control 96% of the total circulation in the United States, have AP news service." *Id.* at 18. In fact, the record evidenced that "[e]ighty-one per cent of the morning newspapers of the United States ... [were] members, and 59% of the evening newspapers; the aggregate of circulation of these newspapers ... [was] 96% of the total circulation of morning newspapers in the United States, and 77% of that of the evening newspapers." United States v. Associated Press, 52 F. Supp. 362, 366 (S.D.N.Y. 1943), *aff'd*, 326 U.S. 1 (1945).

152. *Associated Press*, 326 U.S. at 9.

153. *Id.* at 10-11.

the exclusive outlet for AP news in its locality."[154] Blocked entrants were able to access a limited number of alternative news gathering organizations.[155]

Despite the existence of limited competition among newsgathering enterprises,[156] the Supreme Court, in a plurality opinion, determined that the concerted effort of AP members to exclude local competitors violated section 1 of the Sherman Act.[157] Justice Frankfurter's concurring opinion offers the only clear support for the essential facilities doctrine.[158] Equating the AP with a public utility,[159] Justice Frankfurter opined that AP was clothed in public interest and must, therefore, deal with its rivals.[160] Although the remaining Justices expressly disclaimed Frankfurter's public utility rationale for the opinion,[161] it provides a useful perspective for invoking the essential facilities doctrine.

Despite confusion over the proper rationale underlying the decision,[162] the case seems to stand for the proposition that in limited situations, collaborators must allow access to rivals on nearly equal terms.[163] These limited circumstances exist when competitors collaboratively conceive a profitable facility, the facility is essential to the competitive viability of rivals and to a competitive market, and admission of rivals is consonant with the legitimate goals of the collaboration.[164]

2. *Monopoly Misuse Cases in Violation of Section 2*

The *Otter Tail Power Co. v. United States*[165] decision formed the foundation of the essential facilities doctrine within the single firm con-

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154. PHILLIP AREEDA & LOUIS KAPLOW, ANTITRUST ANALYSIS: PROBLEMS, TEXT, CASES 380-81 (4th ed. 1988).

155. The district court noted that "[t]here are a great many other news gathering associations of one sort or another in the United States; but of these, only two are comparable in size and efficiency with AP—United Press ... and International News Service." *Associated Press*, 52 F. Supp. at 366.

156. *See id.*

157. *Associated Press*, 326 U.S. at 24-25.

158. *Id.* at 26-29 (Frankfurter, J., concurring).

159. "A free press is indispensable to the workings of our democratic society." *Id.* at 28 (Frankfurter, J., concurring).

160. *Id.* at 28-29 (Frankfurter, J., concurring).

161. *Id.* at 46-47.

162. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.1c, at 647-48.

163. *See id.*; Areeda, *supra* note 147, at 844.

164. *See id.*

165. 410 U.S. 366, *reh'g denied*, 411 U.S. 910 (1973).

text.[166] Otter Tail Power Co. (Otter Tail) was a regulated public power utility[167] that maintained an upstream monopoly in electric transmission lines[168] while simultaneously selling power at the retail level.[169] Otter Tail refused to sell wholesale power to municipal systems[170] and to transfer electric power from one utility to another over the facilities of an intermediate utility.[171] Additionally, Otter Tail instituted litigation aimed at forestalling or delaying the establishment of alternative systems, and invoked contract provisions aimed at denying municipal systems access to alternative suppliers requiring the use of Otter Tail's transmission lines.[172] The effect of Otter Tail's refusal to deal was the elimination of competition in the downstream market.[173]

The Court determined that Otter Tail violated section 2 of the Sherman Act by intentionally exploiting its wholesale energy monopoly power to gain a competitive advantage at the retail level.[174] The Court affirmed the decree enjoining Otter Tail to either sell its own power or wheel power supplied by other wholesalers to the downstream retail market.[175]

The *Otter Tail* decision has generated a torrent of conflicting commentary over the duties owed to competitors by the owner of an essential facility. Some commentators suggest that *Otter Tail* does not establish a general duty to deal.[176] The unique circumstances surrounding the case serve as the premise of this argument. [177] Otter Tail possessed a natural monopoly subject to governmental regulation. The regulatory agency had the authority and capacity to regulate prices and terms of transmission. The existence of agency oversight supplanted the need for the Court to

166. *Id.* at 368 (delineating that the suit was brought against a single electric utility company).

167. *Id.* at 373.

168. *Id.* at 368, 370 & n.2.

169. *Id.* at 368.

170. *Id.* at 371.

171. *Id.*

172. *Id.* at 371, 372.

173. *Id.* at 372.

174. *Id.* at 377-82. The decree also provided "that the District Court, concluding that Otter Tail violated the antitrust laws, should be impervious to Otter Tail's assertion that compulsory interconnection or wheeling will erode its integrated system and threaten its capacity to serve adequately the public." *Id.* at 382.

175. *Id.* at 381.

176. *See* Areeda, *supra* note 147, at 848.

177. The Court held that the Federal Power Commission's authority to compel "procompetitive" conduct did not provide antitrust immunity. *Otter Tail*, 410 U.S. at 374.

assume the role of energy transmission regulator.[178] Some commentators conclude that in these limited circumstances, a duty to deal exists.[179]

Aspen Skiing Co. v. Aspen Highlands Skiing Corp.[180] represents the second unilateral refusal to deal case considered by the Supreme Court.[181] Aspen Skiing Company (Ski Co.) and Aspen Highlands Skiing Corp. (Highlands) competed in the Aspen Ski basin skiing facilities market.[182] Ski Co. owned three of the four skiing mountains in Aspen[183] and thereby obtained control of 80 percent of the Aspen area ski ticket sales.[184] For many years, Ski Co. cooperated with Highlands, the owner of the fourth mountain,[185] to jointly provide a four-mountain, multi-area, six-day, ski pass.[186] Ski passes are typically sold on a daily basis, but the four mountain pass enabled skiers to access any of the four mountains throughout a six-day ski week.[187] Ski Co. and Highlands sold the six-day pass at nearly 14 percent below the equivalent six-day daily rate.[188] Initially, Ski Co. and Highlands divided revenues received from the multi-area pass based upon the actual usage of their respective facilities.[189] The Highlands facility

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178. Areeda, *supra* note 147, at 848 (noting that the existing regulatory agency enabled the court to "airily require Otter Tail to deal but never burden itself with the administrative details").

179. *See generally* AREEDA & HOVENKAMP, *supra* note 112.

180. 472 U.S. 585 (1985).

181. *Aspen* was more conspicuous for what it did not decide than for what it did. Many thought that the case would resolve the debate over the so-called "bottleneck" or "essential facilities" doctrine; arguably it did not .... Instead, *Aspen* appeared to open a Pandora's box in which a Section 2 plaintiff could claim that any refusal to deal by a monopolist that is not justified with concrete evidence supporting a valid business purpose can form the basis of Section 2 liability.

Patrick J. Ahern, *Refusals To Deal After Aspen*, 63 ANTITRUST L.J. 153, 157 (1994).

182. *Id.* at 587-90.

183. *Id.*

184. *Id.* at 590 & n.8.

185. *Id.* at 589-90.

186. *Id.* at 589.

187. *Id.* The Court did not worry that joint marketing by the only two firms in the Aspen market could easily facilitate price fixing among them. In fact, the Colorado Attorney General had previously filed a complaint against the two companies under Section 1, and had obtained a consent decree under which the parties were permitted to participate in joint making provided "they set their own ticket prices unilaterally before negotiating ... terms." *Id.* at 591 n.9.

188. *Id.* at 589.

189. *Id.* at 589-90.

typically received 16 to 18 percent of total revenues from the multi-area pass.[190]

Ski Co. threatened to discontinue the multi-day pass unless Highlands was willing to reduce its percentage of the revenue to 13.2 percent without regard to actual usage.[191] Despite the abandonment of this particular effort to reduce Highlands' share, Ski Co. became increasingly dissatisfied.[192] Ski Co. continued its efforts to reduce Highlands' revenue share from the four-mountain pass. Ultimately, Ski Co. refused to continue its participation in the four-area ski pass.[193]

After discontinuing the four-area pass, Ski Co. instituted its own three-area pass allowing access exclusively to its three skiing facilities.[194] Highlands made several attempts to accommodate Ski Co.'s new position including marketing its own multi-area pass that contained coupons exchangeable for Ski Co.'s day pass, at day pass prices.[195] Despite the backing of a local bank, Ski Co. refused to accept Highlands' coupons.[196] Highlands responded by offering to purchase passes directly from Ski Co.[197] Ski Co. refused to sell any skiing passes to Highlands despite continual requests from Highlands.[198] The result of Ski Co.'s actions was a significant decline in Highlands' revenue share of the skiing market.[199] Ski Co.'s lower prices also had the practical effect of capturing consumers unwilling to purchase a more expensive Highlands' pass.[200] Once Ski Co. was determined to be a monopolist in possession of a unique facility, its actions constituted a de facto exclusive dealing arrangement.[201]

Ski Co. justified its actions on the grounds that (1) Highlands was an inferior skiing facility; (2) the method of determining actual usage was unsatisfactory; and (3) accepting Highlands' coupons created an undue administrative burden. Ski Co. offered these explanations despite no evidence of a greater administrative burden, Highlands' willingness to pro-

190. *Id.* at 590-91.
191. *Id.* at 591.
192. *Id.* at 591-92.
193. *Id.* at 592-93.
194. *Id.* at 593.
195. *Id.* at 593-94.
196. *Id.* at 594.
197. *Id.* at 593.
198. *Id.*
199. *Id.* at 594-95.
200. *Id.* at 594 n.15.
201. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.1g, at 657-658.

vide qualified accountants to survey usage rates, and Ski Co.'s continued dealings with inferior ski facilities in other markets.[202]

The Tenth Circuit determined that the multi-day, multi-area, ski pass was an essential facility;[203] and that Ski Co.'s actions evidenced intent to create or maintain a monopoly.[204] Without addressing the essential facilities claim,[205] the Supreme Court affirmed the decision.[206] The Court declared that a monopolist does not have an unqualified duty to deal with competitors, but refusals to deal may have "evidentiary significance."[207] The Court seemed to suggest that the refusal to deal might evidence an anticompetitive intent for the purposes of determining impermissible exclusionary conduct. Ski Co.'s radical departure from its cooperative effort with Highlands,[208] coupled with a lack of valid business justifications,[209] formed the basis of the Court's conclusion that Ski Co. willfully acquired, maintained, and used its monopoly power in the destination ski resort market for anticompetitive and exclusionary purposes and this violated section 2 of the Sherman Act.[210] Affirming the lower court's decision, the Court upheld a jury instruction requiring jurists to find the defendant liable if "the defendant acted 'with exclusionary or anticompetitive purpose or effect.'"[211] Despite the possibility that nearly any act by a monopolist

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202. *Aspen Skiing*, 472 U.S. at 608-10.

203. Aspen Highlands Skiing Corp. v. Aspen Skiing Co., 738 F.2d 1509, 1520-21 (10th Cir. 1984), *aff'd*, 472 U.S. 585 (1985) (relying on United States v. Terminal Railroad Ass'n. of St. Louis, 224 U.S. 383 (1912)).

204. *Aspen Highlands*, 738 F.2d at 1522.

205. *Aspen Skiing*, 472 U.S. at 611 n.44.

206. *Id.* at 611.

207. As the Court explained, the refusal to cooperate may have evidentiary significance or give rise to liability under certain circumstances: "The absence of an unqualified duty to cooperate does not mean that every time a firm declines to participate in a particular cooperative venture, that decision may not have evidentiary significance, or that it may not give rise to liability in certain circumstances." *Id.* at 601.

208. The Court concluded that, by abandoning the All-Aspen ticket, Ski Co., a monopolist, had intentionally changed a pattern of distribution in the competitive market and therefore its conduct raised the inference that it had acted anticompetitively—on some basis other than efficiency. *Id.* at 603-04.

209. *Id.* at 608. Refusal to accept Highlands Ski Pass Coupons resulted in a decline of short-run profits thereby evidencing that Ski Co. was interested in more than reducing competition by harming smaller competitors. *Id.* at 610.

210. *Id.* at 611.

211. *Id.* at 595-96.

could render a monopolist liable pursuant to this jury instruction,[212] several factors limit the instruction's application.[213]

First, the Court's formulation emanates from the particular factual background of the case. The Court never implied that monopolists have a general duty to cooperate with rivals.[214] Secondly, the decision does not mandate the particular terms on which Ski Co. must deal with Highlands. Nothing in the opinion prevents Ski Co. from charging monopoly prices for its goods and services either to its customers or to Highlands. Finally, the decision allows a monopolist to deny access to particular goods, services, and facilities if a legitimate business reason exists.[215] The Court seemed to suggest that a legitimate business justification negates a monopolist's anticompetitive purpose.

3. *Lower Courts' Distillation of Supreme Court Doctrine: The* MCI *Test*

Attempts to distill Supreme Court precedent in a consistent and predictable way has confounded lower courts and generated a torrent of conflicting commentary.[216] Given the Court's insistence on an ad hoc ap-

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212. *Id.* at 597.

213. *See generally* Note, *The Efficiency Defense: Section Two Limits on Monopolist Conduct After* Aspen, 86 COLUM. L. REV. 1712 (1986); Note, *Duty to Cooperate Under Section 2 of the Sherman Act:* Aspen Skiing's *Slippery Slope*, 72 CORNELL L. REV. 1047 (1987).

214. *Aspen Skiing*, 472 U.S. at 600 (stating that "even a firm with monopoly power has no general duty to engage in a joint marketing program with a competitor"). In this respect, the Court reiterated what has been the law since *United States v. Colgate & Co.*, 250 U.S. 300 (1919), that a monopolist has a general right to refuse to deal with anyone, including its competitors, "[i]n the absence of any purpose to create or maintain a monopoly." *Colgate*, 250 U.S. at 307; *see also* Becker v. Egypt News Co., 713 F.2d 363, 366 (8th Cir. 1983); Oreck Corp. v. Whirlpool Corp., 579 F.2d 126, 133 (2d Cir. 1978) (en banc) ("It has always been the prerogative of a manufacturer to decide with whom it will deal.").

215. *Aspen Skiing*, 472 U.S. at 597. This was reinforced by the Supreme Court in *Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451 (1992). The post-*Aspen* cases raise several distinct issues: (1) When does a monopolist have a duty to deal absent a legitimate business justification?; (2) If an alleged monopolist must offer a business justification for its refusal to deal with a competitor, who bears the burden of proof and what is the scope of that burden?; (3) Which business justifications have been accepted or rejected since *Aspen*? The answers to these questions show that, even after nearly a decade, the legacy of *Aspen* has not been fully defined.

216. The essential facilities doctrine has been the subject of a good deal of academic and other criticism because of its potential to frustrate rather than promote competitive behavior and economic efficiency. *See, e.g.*, Kenneth L. Glazer & Abbott B. Lipsky, Jr., *Unilateral Refusals to Deal Under Section 2 of the Sherman Act*, 63 ANTITRUST L.J. 749, 756-59 (1995); William Blumenthal, *Three Vexing Issues Under the Essential Facilities*

proach to the essential facilities doctrine, the key issue is its proper scope. Courts should employ a theoretical framework that limits the doctrine's applicability to situations that enhance competition. This is the only viable reconciliation of Supreme Court precedent, antitrust law's conventional underpinnings, and congressional intent as embodied in the Telecommunications Act of 1996.[217]

In *MCI Communications Corp. v. American Telephone & Telegraph Co.*[218] *(MCI)*, the Seventh Circuit devised a useful test delineating the applicable standards for invoking the essential facilities doctrine.[219] MCI filed its original complaint on March 6, 1974, alleging four counts, including "monopolization, attempt to monopolize ... conspiracy to monopolize ... and conspiracy in restraint of trade ...."[220] A major contention by MCI was the extent to which AT&T allowed MCI to interconnect with "local circuits."[221] According to MCI, it was imperative that MCI make contact with the AT&T operating companies' local networks to provide "full end-to-end transmission."[222] MCI attested that AT&T unlawfully proscribed interconnections for particular switches and local lines.[223] MCI further alleged that AT&T unlawfully refused multipoint interconnections.[224] These behaviors, according to MCI, "constituted an abuse of AT&T's monopoly power over facilities essential to MCI's success."[225]

Doctrine: ATM Networks as Illustration, 58 ANTITRUST L.J. 855 (1990); David Reiffen & Andrew N. Kleit, Terminal Railroad *Revisited: Foreclosure of an Essential Facility or Simply Horizontal Monopoly?*, 33 J.L. & ECON. 419 (1990).

217. *See infra* notes 300-41 and accompanying text.

218. 708 F.2d 1081 (7th Cir. 1983).

219. *Id.* at 1132-33.

220. *Id.* at 1092.

221. *Id.* at 1131 ("The interconnection issue arose in part because MCI had facilities in place to serve only a limited number of cities and in part because MCI was unable to provide the local circuits necessary to connect its long-distance service to the telephone customer.").

222. *Id.* (noting that "[t]he dispute thus focuse[d] on the local interconnections between MCI towers and its customers' premises and on 'multipoint' interconnections ... between MCI towers and certain AT&T long-distance circuits").

223. *Id.* at 1132. These included "interconnection for FX and CCSA services, both of which use switching machines, and for essentially local lines that led beyond a limited, defined geographical area." *Id.*

224. *Id.*

225. *Id.* Although AT&T supplied some interconnections when required by a 1973 district court injunction, it promptly terminated those connections when the injunction was vacated on appeal because the same issues were pending before the FCC. MCI alleged that these terminations were aimed at maintaining AT&T's monopoly by injuring MCI's reputation as a reliable firm and were improper because an FCC decision on the very matter of interconnections was imminent.

The court set forth a four-part test to discern the merits of MCI's essentiality claim. This test has come to dominate the essential facilities landscape.[226] Pursuant to *MCI*, courts must examine the following factors: "(1) control of the essential facility by a monopolist; (2) a competitor's inability practically or reasonably to duplicate the essential facility; (3) the denial of the use of the facility to a competitor; and (4) the feasibility of providing the facility."[227] The second element of the test is effectively part of the definition of what constitutes an essential facility. If a competitor can reasonably or practically duplicate[228] the facility, the facility is not essential.[229] The fourth element implicates the question of whether a legitimate business justification exists for the refusal to provide access to the facility.[230] An analysis of each aspect of this test illuminates the proper role of the essential facilities doctrine.

4. Control of an Essential Facility by a Monopolist

The essentiality of a facility is the initial condition required by the doctrine before a duty to deal attaches. A facility is essential only when two conditions are satisfied: (1) an alternative viable facility is impossible or unduly expensive to construct;[231] and (2) the facility is central to the

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226. *See* Frank A. Edgar, Jr., *The Essential Facilities Doctrine And Public Utilities: Another Layer Of Regulation?*, 29 IDAHO L. REV. 283, 303 (1992/93) (noting that "[m]ost courts apply a variation of the test for liability set out by the Seventh Circuit Court of Appeals *in MCI Communications Corp. v. American Telephone & Telegraph Company*").

227. *MCI*, 708 F.2d at 1132-33 (citations omitted).

228. *Id.* at 1132 (noting that "a competitor's inability practically or reasonably to duplicate the essential facility" is the second element of the doctrine); Hecht v. Pro-Football, Inc., 570 F.2d 982, 992 (D.C. Cir. 1977) ("To be 'essential' a facility need not be indispensable; it is sufficient if duplication of the facility would be economically infeasible and if denial of its use inflicts a severe handicap on potential market entrants.").

229. *See infra* notes 253-66 and accompanying text; *see also* Willman v. Heartland Hosp. E., 836 F. Supp. 1522 (W.D. Mo. 1993), *aff'd*, 34 F.3d 605 (8th Cir. 1994) (stating that the hospital was not an essential facility with respect to surgery when the general surgical market was competitive); Thompson v. Metropolitan Multi-List, 1990-2 Trade Cas. 69,173 (N.D. Ga.) (holding multi-listing service for real estate not an essential facility where a competing service existed), *aff'd in part*, 934 F.2d 1566 (11th Cir. 1991).

230. *See infra* notes 285-99 and accompanying text.

231. *See* Consolidated Gas Co. v. City Gas Co., 665 F. Supp. 1493 (S.D. Fla. 1987), *aff'd*, 880 F.2d 297 (11th Cir.), *vacated*, 889 F.2d 264 (11th Cir. 1989), *reh'g granted*, 912 F.2d 1262 (11th Cir. 1990), *rev'd per curiam on non-antitrust grounds*, 499 U.S. 915 (1991) (finding that a natural gas pipeline was essential and duplication was possible, though expensive and unnecessary, because the defendant's pipeline could easily carry gas for the plaintiff as well as the defendant.).

competitor's viability in the relevant antitrust market.[232] A number of factors operate to satisfy the first condition: geographical and topographical conditions prevent construction of alternatives; a legal license precludes duplication;[233] a natural monopoly exists;[234] the unique physical characteristics of the resource are not duplicable; a bottleneck exists;[235] the governmental regulatory environment prohibits the construction; the existing resource satisfies the minimum efficiencies of scale; public subsidies are necessary for construction and are lacking;[236] a minimum market condition exists;[237] natural fortuity disallows the construction of an alternative;[238] lags in technology render the alternative infeasible or unduly expensive; or any other factor that provides a substantial cost disincentive for the creation of a viable alternative.[239]

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232. *See Willman*, 836 F. Supp. at 1522; *Thompson*, 1990-2 Trade Cas. ¶ 69,173 (holding multi-listing service for real estate not an essential facility where a competing service existed).

233. For example, a telecommunications provider may hold a patent upon a particular switching device, or be required to obtain a license, or have obtained either copyright or trademark protection for a database used in connecting customers across lines.

234. *See generally* Lawrence Sullivan, *Elusive Goals Under the Telecommunications Act*, 25 SW. U. L. REV. 487, 494-507 (1996); Joseph Farrell, *Creating Local Competition*, 49 FED. COMM. L.J. 201, 201 (1996) (noting that "[t]he bottleneck segment of the telecommunications network is traditionally viewed as a 'natural monopoly'").

235. A bottleneck occurs when a competitive market exists on either side of a particular monopoly. Consider, for example, a situation in which the geographical and topographical conditions render only one plausible mode to transmit telecommunications across a particular area and on either side of this area exists multiple suppliers and buyers. For examples of bottlenecks within the telecommunications industry, *see* Nowicki, *supra* note 7, at 373 n.56 (concluding that "[f]or local exchange purposes, a bottleneck exists in the access service market which supplies the connection between incoming telecommunications from outside areas and the local loop receivers"); Farrell, *supra* note 234, at 201.

236. The telecommunications industry provides many examples of how governmental subsidies affect entry by new suppliers in regulated markets. *See* David L. Kaserman & John W. Mayo, *The Economics of Regulation: Theory and Policy in the Postdivestiture Telecommunications Industry*, *in* PUB. POL'Y TOWARD CORP. 141, 148 (Arnold A. Heggestad ed., 1988) (noting that unregulated entities chose to enter unsubsidized portions of the telecommunications industry).

237. A minimum market typically means there are few buyers and sellers participating in the market. For example, a sparsely populated area could only support a single telecommunications provider.

238. Natural fortuity would exist if only one facility is able to produce a resource needed for the production of advanced communication technologies.

239. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶736.2b, at 671.

Although a substantial reproductive cost may render a facility essential,[240] the key factor is that the reproductive cost be enormous.[241] The requisite high costs are most frequently typified by the existence of public subsidization. The substantiality of the requisite cost advantage, however, involves difficult questions of degree. A competitor can invariably replicate a facility at some price, constrained only by technological and legal impediments. The existence of technological impediments, legal prohibitions, or the necessity of public subsidization, coupled with a natural monopolistic market condition, are all factors in determining if a facility is essential.[242]

Satisfaction of the second condition proves equally onerous because successful invocation of the doctrine imposes two distinct requirements: (1) a competitor must demonstrate that the facility is central[243] to competitive viability, and (2) in a relevant antitrust market.[244] Examination of

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240. *See, e.g., id.* ¶ 736.1a, at 670 (describing an essential facility as providing a "significant cost advantage").

241. Presumptively, a monopolist depends upon substantial cost advantages to maintain its monopoly. However, using substantial cost advantage as a criteria for the invocation of the essential facilities doctrine is "too broad to be useful." *See, e.g., id.*

242. *See id.*

243. Courts and commentators have employed various modifiers to determine the degree of centrality required for invocation of the essential facility doctrine. *See, e.g., id.* ¶ 736.2d, at 675-76 (stating that the facility must be vital to competition). Still other courts have seemed to interlineate monopoly leveraging theory into the essential facilities doctrine. *See, e.g., In re* Air Passenger Computer Reservations Systems Antitrust Litig., 694 F. Supp. 1443, 1455 (C.D. Cal. 1988), *aff'd*, 948 F.2d 536 (9th Cir. 1991) (concluding that "when applying the essential facilities doctrine in the context of section 2 of the Sherman Act, a facility should be deemed essential to the downstream market only where control of the facility by a competitor poses a danger of monopolization of the down stream market"). This is true because:

> The essential facilities doctrine is designed to deal with the danger that a monopolist in control of a scarce resource will "extend its power vertically from one level of production to an other." ... [A] facility becomes essential if, in restricting competitors' access to that facility, a monopolist gains a competitive advantage in another level of the market — that is, a market downstream or upstream from the market containing the facility itself.

Consolidated Gas Co. v. City Gas Co., 912 F.2d 1262, 1292 (11th Cir. 1990) (Tjoflaj, C.J., dissenting), *vacated*, 499 U.S. 915 (1991), *dismissed with prejudice on remand pursuant to settlement*, 931 F.2d 710 (11th Cir. 1991).

244. *See* Southern Pacific Comm. Co. v. American Telephone & Telegraph Co., 740 F.2d 980 (D.C. Cir. 1984) (holding that local distribution facilities are essential facilities and by using its control over access to these essential facilities, AT&T had the ability to extend its natural monopoly power in the market for local public switched telephone service to the competitive market for intercity private line service). Twin Lab., Inc. v.

these requirements in inverse order necessitates the owner of the essential facility first to be a monopolist in the relevant antitrust market.[245] An analysis of the relevant antitrust market requires an examination of the market allegedly controlled by the owner of an essential facility and the market for the unique facility itself.[246] To illustrate the distinction, sup-

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Weider, 900 F.2d 566, 569 (2d Cir. 1990) (determining that a valid essential facilities claim requires that the defendant possessed monopoly power in relevant antitrust market); Oahu Gas Serv., Inc. v. Pacific Resources, Inc., 838 F.2d 360, 369 n.4 (9th Cir. 1988) (rejecting, in dictum, applicability of the essential facilities theory because defendant had no monopoly power over supplies of propane to the relevant geographic market); Consul Ltd. v. Transco Energy Co., 805 F.2d 490, 494 n.11 (4th Cir. 1986) (rejecting the plaintiff's argument that "essential facility," "leveraging," and "market foreclosure" cases are not concerned with market definition). Some courts have mistakenly replaced the analysis of whether the defendant has power in the "relevant market" with a determination of whether the plaintiff is able to duplicate the defendant's facility. *See* MCI Communications Corp. v. American Telephone & Telegraph Co., 708 F.2d 1081, 1132 (7th Cir. 1983) (noting that "a competitor's inability practically or reasonably to duplicate the essential facility" is the second element of the doctrine); Hecht v. Pro-Football, Inc., 570 F.2d 982, 992 (D.C. Cir. 1977); Gamco, Inc. v. Providence Fruit & Produce Bldg., Inc., 194 F.2d 484, 487 (1st Cir. 1952) (suggesting that because "a monopolized resource seldom lacks substitutes," the existence of "alternatives will not excuse monopolization," so that a produce warehouse was the "most economical" facility where "[t]o impose upon plaintiff the additional expenses of developing another site, attracting buyers, and transshipping his fruits and produce by truck is clearly to extract a monopolist's advantage").

245. *See* International Audiotext Network v. American Telephone & Telegraph Co., 893 F. Supp. 1207 (S.D.N.Y. 1994), *aff'd*, 62 F.3d 69 (2d Cir. 1995) (AT&T's international calling services were not an essential facility to which the plaintiff billing service provider was denied access because numerous other firms provided similar calling services.).

246. The first step in a court's analysis must be to define the relevant market or markets involved in the case. *See* Soap Opera Now, Inc. v. Network Publishing Corp., 737 F. Supp. 1338, 1343 (S.D.N.Y. 1990) (supporting the proposition that an essential facilities claim exists only when ownership of the facility enables a firm to monopolize a relevant market); Olympia Equip. Leasing v. Western Union Tel. Co., 797 F.2d 370, 375 (7th Cir. 1986) (concluding the "relevant market" is the market "to which access had allegedly been foreclosed by the challenged conduct, not the market for similar business opportunities"). Other courts have mistakenly ignored the relevant market analysis. *See, e.g.*, Woods Exploration & Producing Co. v. Aluminum Co., 438 F.2d 1286, 1306 (5th Cir. 1971). As explained in *Woods Exploration*:

> When one must "look" for a monopoly, determining a relevant market in which to look and in which to evaluate competitive effects is obviously an essential first step. But when, with an illegal practice such as is present here in mind, one can look at an area and see the existence of monopoly power, not by inference from market share, but by determining actual ability to exclude competition and control prices, there appears no real need to go further.

pose an ILEC in the telecommunications industry owns all of the copper telephone lines that comprise the local exchange grid. Although the ILEC is a monopolist of copper telephone lines, the essential facilities doctrine is not premised upon a copper telephone line monopoly. Rather, application of the doctrine requires the examination of competition in the relevant market controlled by the facility, anticompetitive radiations among local telephony service providers. If cellular, fiber-optic, cable, and satellite technologies effectively compete with the copper telephone lines, the ownership of copper telephone lines would not be central to the provision of telephone service within the relevant market.[247] Possession of a copper telephone line monopoly would also not be central to competitive viability if: (1) the copper telephone lines are available from another source;[248] (2) copper telephone lines are easily duplicable by a competitor;[249] or (3) other technology provides an equivalent substitute.[250] Allowing access to copper telephone lines within the confines of these divisions enables a competitor to simply substitute itself for the incumbent local exchange pro-

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Id. But cf. City of Chanute v. Williams Natural Gas Co., 678 F. Supp. 1517, 1532 (D. Kan. 1989), *aff'd*, 955 F.2d 641 (10th Cir. 1992) (expressly rejecting the plaintiffs' contention that *Woods Exploration* stands for the proposition that traditional market definition is not required under an essential facility claim, although observing that "under the 'essential facilities' doctrine, analysis of the relevant market may not take on the same implications as it does in other cases").

247. If they are essential, the owner is not using his ownership to obtain a monopoly. Therefore, antitrust liability would not attach.

248. *See* Data Gen. Corp. v. Grumman Sys. Support Corp., 761 F. Supp. 185 (D. Mass. 1991), *aff'd*, 36 F.3d 1147 (1st Cir. 1994) (holding that the defendant's diagnostic program for analyzing its computers was not an essential facility as to independent computer repairers where (1) such repairers were capable of producing their own diagnostic programs, and (2) the program was made available to purchasers of the defendant's computers); Rural Tel. Serv. Co., Inc. v. Feist Publications, Inc., 737 F. Supp. 610 (D. Kan. 1990) (holding that Rural Telephone Services Company's refusal to license its white pages listings to the publisher of a competing directory was not the denial of an essential facility; the information contained in the listings could have been obtained economically from other sources); Illinois *ex rel.* Hartigan v. Panhandle E. Pipe Line Co., 730 F. Supp 826 (C.D. Ill. 1990), *aff'd*, 935 F.2d 1469 (7th Cir. 1991) (finding no violation under the essential facilities doctrine where others could have entered the market through alternative pipelines).

249. *See Grumman*, 761 F. Supp. at 185.

250. *See* Picker Int'l. v. Leavitt, 865 F. Supp. 951, 965 (D. Mass. 1994) (holding that a replacement part for a sophisticated machine was not an essential facility where the part had adequate substitutes); Flip Side Prod. v. Jam Prods., 843 F.2d 1024 (7th Cir. 1988) (declaring that a rock concert arena was not an essential facility where several alternatives were available); McKenzie v. Mercy Hosp., 854 F.2d 365 (10th Cir. 1988) (declining to find a hospital emergency room and obstetrical care unit essential facilities for a plaintiff who performed the same services in his own private office.).

vider. This substitution creates few (if any) pro-competitive effects and has the potential of chilling desirable behavior.[251]

Determining the required level of monopolistic control that ownership of an essential facility must have before antitrust liability attaches has spawned numerous judicial decisions. Some courts treat the threat of downstream monopolization as the *sine qua non* of a valid essential facilities claim.[252] Other courts require that the control of the facility actually be accompanied by the power to eliminate competition in the relevant downstream market.

5. The denial of the use of the facility to a competitor

Under the essential facility doctrine, a valid antitrust claim is contingent upon the denial of access to the essential facility.[253] Obviously, a competitor permitted to access an essential facility has little room to contest the actions of a monopolist. The denial need not be a total denial; rather, it is sufficient that the "terms of [access] be unreasonable in price, profit margin, time obligation, or other substantive criteria."[254] Additionally, denying access does not automatically implicate antitrust liability.[255]

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251. *See* analysis *infra* part VI.

252. *See In re* Air Passenger Computer Reservations Sys. Antitrust Litig., 694 F. Supp. 1443, 1455 (C.D. Cal. 1988), *aff'd*, 948 F.2d 536 (9th Cir. 1991). ("[W]hen applying the essential facilities doctrine in the context of section 2 of the Sherman Act, a facility should be deemed essential to the downstream market only where control of the facility by a competitor poses a danger of monopolization of the downstream market."); *see also* Consolidated Gas Co. v. City Gas Co., 912 F.2d 1262, 1292 (11th Cir. 1990) (Tjoflaj, C.J., dissenting), *vacated*, 499 U.S. 915 (1991), *dismissed with prejudice on remand pursuant to settlement*, 931 F.2d 710 (11th Cir. 1991). As explained in *Consolidated Gas*:

> [T]he essential facilities doctrine is designed to deal with the danger that a monopolist in control of a scarce resource will "extend its power vertically from one level of production to an other."... [A] facility becomes essential if, in restricting competitors' access to that facility, a monopolist gains a competitive advantage in another level of the market—that is, a market downstream or upstream from the market containing the facility itself.

Id.

253. *See* David A. Balto, *Access Demands To Payment Systems Joint Ventures*, 18 HARV. J.L. & PUB. POL'Y 623, 640 (1995) (noting that the essential facilities doctrine "requires a monopolist to share its facility or business relationship where the denial of access would permit the monopolist to extend its monopoly into an adjacent market").

254. Nowicki, *supra* note 7, at 366.

255. Numerous cases have expressly precluded liability under the essential facilities doctrine where the denial of access did not create a risk of monopolization in the "downstream" market. *See, e.g.*, Interface Group, Inc. v. Massachusetts Port Auth., 816 F.2d 9, 12 (1st Cir. 1987) (holding the doctrine inapplicable to Port Authority's refusal to allow a

Antitrust liability is premised on the enhancement of competition.[256] Denying access to a competitor or potential competitor may do little to effectuate competition.[257] Output and price-competition are unaffected so long as the monopolist is permitted to charge monopoly rents for use of the facility.[258] A different result occurs when the monopolist operates in a regulatory environment. When a regulated monopolist denies access to a competitor and this denial aids in the evasion of rate regulation or undermines the regulatory competition enhancement scheme, an antitrust claim exists.[259]

In situations involving firms that do not compete in the market dominated by the essential facility owner, a duty to deal does not attach, as a monopolist has little incentive to restrain competition in an upstream or downstream market in which the monopolist does not compete.[260] A monopolist refusing to deal with a non-competitor may have a negative impact upon firms in competition in a downstream market. For example, dealing with firm A while simultaneously refusing to deal with firm B, firm A's competitor, may enable firm A to charge lower prices, thereby distorting competition in a downstream market. Courts recognizing this

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charter airline to use particular terminal because "the doctrine aims to prevent a firm with monopoly power from extending that power 'from one stage of production to another, and from one market into another'...; [thus] it is difficult to see how denying a facility to one who, like [the plaintiff], is not an actual or potential competitor (of the facility owner) could enhance or reinforce [that owner's] market power"); Official Airline Guides, Inc. v. Federal Trade Commission, 630 F.2d 920, 927-28 (2d Cir. 1980) (finding the doctrine inapplicable where a monopolist has "no purpose to restrain competition or to enhance or expand his monopoly, and does not act coercively").

256. *See generally* Pitofsky, *supra* note 3.

257. For example, a network-controlling firm may deny access to a second firm for reasons unrelated to competition. *See* Drinkwine v. Federated Publications, 780 F.2d 735, 740 (9th Cir. 1985) (noting that a newspaper's refusal to carry a rival's advertising insert was based on the rival's failure to pay bills); HyPoint Tech., Inc. v. Hewlett Packard Co., 949 F.2d 874 (6th Cir. 1991) (finding that although the defendant's withdrawal of a favorable service option hurt the plaintiff's business, it effectively increased competition because it lowered the standard of service, making it easier for competitors to enter the business).

258. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.2b, at 671.

259. *See id.*

260. *See* Mid-South Grizzlies v. National Football League, 720 F.2d 772 (3rd Cir. 1983) (acknowledging that the essential facilities' goal of competition enhancement would not be fostered by allowing a non-competitor access to an essential facility); *Interface Group,* 816 F.2d at 11 (noting that "it is difficult to see how denying use of a facility to one who ... is not an actual or potential competitor could enhance or reinforce the monopolist's market power"); Garshman v. Universal Resource Holding, 824 F.2d 223 (3rd Cir. 1987) (refusing to apply the essential facilities doctrine when the plaintiff was not in competition with the essential facility owner).

phenomenon have entertained an essential facilities claim in situations where a monopolist has refused access to a non-competitor.[261] This precedent, however, ignores the fact that refusal to deal with non-competitors neither produces competitive dominance in a vertically related market[262] nor bolsters the monopolist's power in the monopolized market.[263] The absence of these effects necessarily confines the essential facilities doctrine to refusals of a competitor or a potential competitor to deal with the owner of the essential facility.[264]

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261. *See* LaPeyre v. Federal Trade Commission, 366 F.2d 117, 120 (5th Cir. 1966); Official Airline Guides, Inc. v. Federal Trade Commission, 630 F.2d 920 (2d Cir. 1980). Although not stating this explicitly, the decision in *Byars v. Bluff City News Co.*, 609 F.2d 843, 860 (6th Cir. 1979), in which the essential facility charge was brought by a customer-competitor, implicitly supports extending the doctrine to non-competitors. The FTC had not found it necessary that the denial be to a competitor in order to grant relief. *But see* Grand Caillou Packing Co., 65 F.T.C. 799, 868-69 (1964), *aff'd in part, rev'd in part sub nom. LaPeyre*, 366 F.2d at 117 (separate opinion of Commissioner Elman) (suggesting that a finding of harm to competitor was not necessary for a violation of section 5 of the Federal Trade Commission Act). The Fifth Circuit upheld the portion of the FTC decision concerning the denial to a non-competitor. *See LaPeyre*, 366 F.2d at 121-22; *see also* Getaway Travel, Inc. v. Philadelphia, No. 88-3126, 1989 U.S. Dist. LEXIS 2673, at *3 (E.D. Pa. Mar. 16, 1989) (holding that the doctrine was inapplicable to the denial of airline terminal counter space to a travel agency because such space was not essential to the conduct of agency business and the agency was "not a competitor of any defendant which has monopoly control over the Philadelphia airport.").

262. *See Official Airline Guides,* 630 F.2d at 920 (acknowledging that arbitrary refusals to deal among different customers in a market in which a monopolist does not directly participate does not impair competition in a downstream market).

263. *See id.* (opining that a monopolist is legally free to refuse to deal with non-competitors, so long as the monopolist does not have a purpose to restrain competition or enhance or expand monopoly power). The *Official Airline Guides* court concluded that refusing to deal with a non-competitor neither evinced an anti-discriminatory purpose nor enhanced monopoly power. In reaching this conclusion, however, the court agreed that competition in another market might improve if access to an essential facility was ordered. Additionally, hindered access often hurts the monopolist. *See* Weiss v. York Hospital, 745 F.2d 786 (3d Cir. 1984) (denying an essential facilities claim on the grounds that the monopolist denied access to a non-competitior and no incentive existed to monopolize a downstream market because providing access would maximize the monopolist's revenue). Thus, denials of access are often undergirded by a legitimate business justification or constitute a bad business decision for which antitrust policy is ill-equipped to remedy. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.2, at 685.

264. *See* TV Communications Network v. ESPN, 767 F. Supp. 1062 (D. Colo. 1991), *aff'd*, 964 F.2d 1022 (10th Cir. 1992) (holding that the essential facilities doctrine did not apply to a cable television programmer's refusal to deal with a cable operator because the two were not competitors, but stood in a vertical relationship); Garshman v. Universal Resources Holding, Inc., 824 F.2d 223, 230 (3rd Cir. 1987); Interface Group, Inc. v. Massachusetts Port Auth., 816 F.2d 9, 12 (1st Cir. 1987). Courts usually permit unilateral refusals by a defendant who does not compete with the plaintiff in another market.

6. *The feasibility of providing the facility*

The scope of the doctrine is further limited by the existence of a legitimate business justification for denial of access.[265] Several ensuing subordinate questions arise. First, what constitutes a legitimate business purpose and what criteria are to be used to evaluate whether a business purpose is legitimate?[266] Second, does the fact-finder have unfettered discretion to determine the legitimacy of the business justification?[267] Third, does the monopolist have deference in devising a legitimate business justification? Fourth, does the monopolist's state of mind factor into the legitimacy afforded the business justification? And finally, does a legiti-

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See, e.g., *Official Airline Guides*, 630 F.2d at 920 (single publisher of an airline flight schedule guide not liable for refusal to include plaintiff airlines); Homefinders of Am., Inc. v. Providence Journal Co., 621 F.2d 441 (1st Cir. 1980) (monopolist newspaper need not sell space to a rental service bureau); Mannington Mills, Inc. v. Congoleum Indus., 610 F.2d 1059, 1069 (3d Cir. 1979) ("We seriously doubt that an arbitrary or discriminatory unilateral refusal to deal by a lawful monopolist is actionable under § 2 of the Sherman Act."); Fulton v. Hecht, 580 F.2d 1243, 1247-48 (5th Cir. 1978) (single-firm owner of race track); Fishman v. Wirtz, 807 F.2d 520 (7th Cir. 1986). Similarly, while not couching the issue in essential facilities terms, the Second Circuit found that the Official Airline Guide was not required to provide access to a customer who was not a competitor. *See Official Airline Guide*, 630 F.2d at 927-28.

265. *See* Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 608-10 (1985) (placing an affirmative duty to deal on a monopolist that controls an essential facility, absent a legitimate business justification). A duty to deal will not be imposed where a monopolist offers a legitimate business justification to excuse its refusal. *See, e.g.*, Town of Massena v. Niagara Mohawk Power Corp., 1980-82 Trade Cas. (CCH) ¶ 63,526 (N.D.N.Y. Sept. 8, 1980) (permitting a power company to refuse to 'wheel' power to a municipally owned retail electric distribution system because the town's subtransmission plan was unsound from an engineering standpoint). Courts have recognized valid business justifications in a wide range of circumstances. *See, e.g.*, Almeda Mall, Inc. v. Houston Lighting & Power Co., 615 F.2d 343 (5th Cir. 1980) (refusal to sell electricity to mall owners for resale to business tenants); *Homefinders of Am.*, 621 F.2d at 441 (refusal to print admittedly deceptive advertisement); *Aspen Skiing*, 472 U.S. at 605, 608 (determining that liability under an attempted monopolization analysis was predicated on the defendant's "failure to offer any efficiency justification" or other "valid business reasons" for its refusal to continue joint ski lift ticket marketing program with competitor); *In re* Air Passenger Computer Reservations Sys. Antitrust Litig., 694 F. Supp. 1443, 1456 (C.D. Cal. 1988), *aff'd*, 948 F.2d 536 (9th Cir. 1991); Laurel Sand & Gravel, Inc. v. CSX Transp., Inc., 704 F. Supp. 1309, 1325 (4th Cir. 1989), *aff'd*, 924 F.2d 539, 545 (1991) (finding that it was "not feasible" for CSX to provide trackage rights without altering the very basic nature of its permissible business).

266. *See* AREEDA & HOVENKAMP, *supra* note 112, at 660.

267. *See* Areeda, *supra* note 147, at 849.

mate business justification accompanied by an anticompetitive intent warrant a finding of illegitimacy?[268]

The answers to these questions continue to confound courts and commentators. In general, "a business justification is valid if it relates directly or indirectly to the enhancement of consumer welfare."[269] A proper distillation of a legitimate business justification defense, however, must recognize such a defense at both a micro and a macro level.[270] The micro level consists of the particular facts of each case.[271] For example, if a firm can demonstrate that providing access would violate an existing regulatory scheme, a legitimate business justification exists.[272] Telephone interconnection cases provide good examples. AT&T was a natural monopoly protected from rivalry by public restrictions on entry.[273] Prior to divestiture, AT&T provided local and long-distance service.[274] Rival producers of long-distance service needed to connect their long-distance lines with callers through the local telephone exchanges.[275] AT&T allegedly misused its local monopolies to protect its long-distance power by denying or obstructing those interconnections.[276] The Seventh Circuit held that notwithstanding any duty to interconnect, AT&T may deny interconnection if it had a "reasonable basis in regulatory policy to conclude, and in good faith concluded that denial of interconnection is required by concrete, articulable concerns for public interest ...."[277] AT&T failed to articulate any such legitimate reason.[278]

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268. *See* Oahu Gas Serv. v. Pacific Resources, 838 F.2d 360 (9th Cir. 1988) (refusing to hold a defendant liable where the defendant had both economically legitimate motives for refusing to deal with competitors and a desire to restrict the supply of goods). "A legitimate purpose renders any accompanying purpose irrelevant." AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.2, at 688.

269. Data General Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147, 1183 (1st Cir. 1994).

270. *See* Areeda, *supra* note 147, at 850-51.

271. *See id.*

272. *See* City of Malden v. Union Elec. Co., 887 F.2d 157 (8th Cir. 1989) (noting that the owner of an essential facility, an electric transmission line, could refuse to deal if dealing was impractical under a regulatory tariff); Illinois *ex rel.* Hartigan v. Panhandle E. Pipe Line Co., 730 F. Supp 826 (C.D. Ill. 1990), *aff'd*, 935 F.2d 1469 (7th Cir. 1991) (finding no illegal denial of an essential facility where the owner was constrained by a regulatory regime in providing access to others).

273. *See* MCI Communications v. American Telephone & Telegraph Co., 708 F.2d 1081, 1133 (7th Cir. 1982), *cert. denied*, 464 U.S. 891 (1983).

274. *See id.* at 1093.

275. *See id.* at 1093 n.9.

276. *See id.* at 1094.

277. *See id.* at 1137.

278. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.2c, at 674.

The proper methodology for determining the legitimacy of the monopolist's business justification at the micro level begins with the plaintiff's burden to persuade the fact-finder that the defendant's refusal is unreasonable.[279] The burden of production then shifts to the defendant to provide evidence establishing a legitimate business justification.[280] An important caveat exists: Claims of economic self-interest rarely serve as a legitimate justification for denying access.[281] A firm is never obliged to sacrifice legitimate business objectives.[282] Upon evidencing a legitimate business justification, the plaintiff is charged with demonstrating that the defendant's justification is merely pretextual.[283]

The essential facilities doctrine also recognizes a legitimate business justification at the macro level.[284] Macro legitimate business justifications do not pertain to any particular firm, but constitute "propositions of general policy."[285] For example, the justification for refusing access to a patented invention does not implicate the practicality of providing access. Such a denial is predicated on social policy grounds that access would both deprive a lawful monopolist of its legitimate rewards and chill desirable innovative activities.[286] Determining whether access deprives a law-

279. *See id.* ¶ 736.2, at 688.

280. *See id.*

281. *But see* Olympia Equip. Leasing v. Western Union Tel. Co., 797 F.2d 370 (7th Cir. 1986) (holding that Western Union's desire to enhance sales of its own product constituted a legitimate business justification). The facts of *Western Union* illuminate the court's reasoning. Western Union sought to sell terminals used in providing telex service. Olympia purchased Western Union's terminals for resale. For a period of time, Olympia relied upon Western Union's sales force and vendors' list to sell terminals. Western Union determined that the liquidation of its own terminals was occurring too slowly. Western Union responded by discouraging its sales force from promoting Olympian owned terminals. Olympia had no sales force of its own. The Seventh Circuit determined that the essential facilities doctrine was inapt because firms have no duty to sell the wares of their competitors and all firms have access to advertising and marketing devices. Thus, Western Union did not engage in predatory acts worthy of antitrust proscriptions.

282. *See* Oahu Gas Serv. v. Pacific Resources, 838 F.2d 360 (9th Cir. 1988) (concluding that antitrust liability did not attach when the defendant refused to expand his plant when economic conditions did not support such an expansion); Illinois *ex rel.* Burris v. Panhandle E. Pipe Line Co., 935 F.2d 1469 (7th Cir. 1991) (noting that the essential facilities doctrine does not require a defendant to cut back its own use of its own facility in order to serve a competitor).

283. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.2, at 688.

284. *See* Areeda, *supra* note 147, at 851.

285. *Id.*

286. *See* Nowicki, *supra* note 7, at 372:

> [M]andated interconnections actually would stimulate a skewed competitive result because any service provider requesting interconnections

ful monopolist of legitimate rewards or chills desirable behavior[287] provides the requisite criteria for determining the applicability of legitimate business justifications at the macro level. Macro level policy decisions necessitate the oversight of a judge rather than a jury.[288] This requirement facilitates the development of consonant standards for similar firms in similar markets, and removes the determination of national economic policy from the unqualified hands of jurors.[289]

C. The Role of the Regulatory Regime Within the Essential Facilities Doctrine

Invocation of the essential facilities doctrine necessarily implicates the prices upon which the court orders compulsory access. Plaintiffs invariably will challenge the defendant's access price on the grounds that the price: (1) is so excessive as to constitute a denial of access, (2) impedes price competition, or (3) precludes a reasonable rate of return.[290] Courts are often ill-equipped adequately to assume the role of a price regulatory agency by entertaining such claims.[291] Courts willing to undertake a price control function still must grapple with the unyielding antitrust principal that a legal monopolist may charge monopoly rents for an essential facility.[292] Charging monopoly rents for access does little to effectuate compe-

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would probably receive them. Also, mandated interconnections would discourage innovations: market entrants would have no need to innovate because interconnections are readily available, and market incumbents would have no incentive to innovate because they would be forced to share anything they produced. Mandated interconnections would also stifle the true competitive functioning of the market.

287. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.2, at 689.

288. *See* Areeda, *supra* note 147, at 851.

289. *See id.*

290. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.2, at 692.

291. According to one commentator:

> [T]he essential facility doctrine should not be invoked unless there is a pre-existing regulatory agency capable of adequately supervising relief, and there are a number of reasons for completely eliminating the doctrine as an antitrust cause of action. Essential facility issues often are best addressed on an industry-wide basis, through legislation or administrative regulation.

Gregory Werden, *The Law and Economics of the Essential Facility Doctrine,* 32 ST. LOUIS U. L.J. 433, 479-80 (1987).

292. *See* David J. Gerber, *Rethinking The Monopolist's Duty To Deal: A Legal And Economic Critique Of The Doctrine Of 'Essential Facilities,'* 74 VA. L. REV. 1069, 1087 (1988) (noting that a monopolist can generally "charge a fee that extracts monopoly rents from the users' market"). This situation does not arise when a monopolist is precluded from extracting such fees in the case of a regulated industry. *See id.*

tition within a relevant antitrust market.[293] Additionally, the essential facilities doctrine heavily relies on legal precedent derived from various courts resulting in a lack of coherence and consistency.[294]

The regulatory environment rectifies many of the problems that elude antitrust enforcement.[295] For example, the existence of a regulatory agency both facilitates the price control function and provides an industry-specific solution. Regulatory agencies have the expertise and continuing relationship with a regulated industry so as to eliminate the presumption that a monopolist may charge monopoly rents for access.[296] It is within this regulatory context that the essential facilities doctrine has unique relevance.[297] The case for applying the doctrine is strongest when a regulated monopolist's "denial of access aids [the monopolist] in evading rate regulation or undermines the regulator's plan to encourage rivalry in either the primary or adjacent markets."[298] This situation currently confronts the telecommunications industry.

VI. THE ROLE OF THE ESSENTIAL FACILITIES DOCTRINE WITHIN THE DEREGULATED TELECOMMUNICATIONS INDUSTRY

Despite the transformation of the telecommunications industry from "technical balkanization" to a "reality of technological convergence," the local telephony market remains highly concentrated.[299] Currently, ILECs control 99.7 percent of the local exchange market.[300] The advent of section 251 was intended to provide a transitory legislative decree aimed at facilitating a competitive local exchange market via interconnectivity, un-

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293. Obviously the price competition cannot occur when a competitor is forced to charge monopoly rents simply to recover the costs of access.

294. *See generally* Pitofsky, *supra* note 3.

295. Regulators often fulfill the role of taking into account antitrust considerations in the regulatory process. This is especially true where the regulatory agency has been commanded specifically to consider the competitive aspects of its decisions. *See* Otter Tail Power Co. v. United States, 410 U.S. 366, 374 (1973).

296. *See generally* Pitofsky, *supra* note 3.

297. *See* AREEDA & HOVENKAMP, *supra* note 112, ¶ 736.2b-c, at 672-75.

298. *Id.* ¶ 736.2a, at 665. Some commentators go as far as to claim that some regulatory agencies are ill-equipped to handle some situations which, without application of the antitrust laws, would harm both consumers and competition. *See, e.g.*, Bruce M. Owen, *Determining Optimal Access to Regulated Essential Facilities*, 58 ANTITRUST L.J. 887, 893 (1990).

299. *See generally* Krattenmaker, *supra* note 8.

300. *See* Robert E. Stoffels, *Getting into the Act: Lots of Questions, Not Many Answers*, AMERICA'S NETWORK, Aug. 15, 1996, at 38.

bundling, and resale provisions.[301] Despite its purpose, congressional enactment of section 251 is incongruous with a transitional regulatory regime free from artificial impediments. The result is price competition without limitation and retarded growth in facilities-based competition.

Section 251 is premised upon the notion that competition, rather than regulation, provides the necessary incentive to spur innovation and alternative telephony services.[302] Section 251, however, establishes highly discounted resale rates, unbundling below-full-cost items, and ordered interconnectivity.[303] ILECs confronted with below cost resale and unbundling requirements have little incentive to invest in the public network when doing so automatically benefits competitors.[304] Section 251's interconnectivity, unbundling, and resale provisions also discourage incumbents and competitors from directing their efforts toward alternative technologies and delivery systems. Entrants permitted to access an incumbent's facilities are obligated to obtain market share by engaging in price warfare for delivery differentiation.[305]

Absent substantial improvements in efficiency, price competition necessarily entails revenue losses. Telecommunication providers are forced to lower prices to obtain a sizeable customer base.[306] Discursively, the development of alternative telephony infrastructure is highly capital intensive and generally requires subsidization via the price mechanism.[307] Reduced revenue coupled with capital intensive technological development threatens to create stasis for the industry where competitors simply divide a dollar market without simultaneously facilitating new demand sources via technological differentiation.[308] The resulting predicament threatens to freeze current communication modes for the next ten years.[309]

Additionally, section 251's resale, unbundling, and interconnectivity requirements remain effective until explicitly superseded by regulations

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301. *See supra* notes 69-79.

302. *See id.*

303. *See* John N. Rose, *Trouble with The Telecom Act: How Did the Lofty Goals Get So Entangled?*, AMERICA'S NETWORK, Dec. 15, 1996, at 10.

304. *See id.*

305. *See* Peter Alexander, *What Hath Telecom Reform Wrought?*, 230 TELEPHONY 48, 56 (1996).

306. *See id.*

307. *See* Laurence Huntley, *The Telecommunications Revolution: A Survivor's Guide*, 230 TELEPHONY 78, 88 (1996) ("[E]very extra call or minute is in practice a direct contribution to fixed costs and overheads. Once these are paid for, incremental traffic is virtually 100% profit.").

308. *See* Alexander, *supra* note 305, at 56.

309. *See id.*

prescribed by the FCC.[310] The absence of any clear statutory time limitation on section 251 expressly contradicts congressional findings[311] and undermines the rationale underlying the 1996 Act. Three problem areas may arise. First, Congress intended section 251 to expedite facility-based competition by first fostering price-based competition on the assumption that price-based competition enables new entrants to acquire a requisite customer base from which they may construct rival facilities.[312] Many of the new entrants, however, are multi-billion-dollar service providers such as AT&T, Sprint, and MCI. These service providers have historically invested billions of dollars in their brand images and have obtained more than 80 percent customer awareness.[313] Entrants armed with an arsenal of name-brand recognition and capital base do not seem to require the ability to piggyback off incumbents' facilities.

Second, section 251 makes no distinction among these multi-billion-dollar entrants and smaller revenue based entrants with respect to interconnectivity, unbundling, and resale. Smaller revenue based entrants face a daunting challenge in attempting to compete with large scale service providers other than incumbents possessing name-brand recognition and large capital bases.[314] The 1996 Act thus paves the way for an oligopolistic market structure in which well-financed and well-known entrants piggyback off the facilities of incumbents, driving prices down and stripping the incumbents of their most profitable customers while simultaneously overpowering smaller, revenue-based competitors. Third, an absence of temporal limitations on the 1996 Act forces incumbents to provide access, resale, and unbundling in perpetuity. Incumbents are thus forced to commit massive resources to the sustenance of the current copper wire system. As technological developments render this system obsolete, incumbents are placed at a competitive disadvantage. Entrants are encouraged to resell copper wire service in an effort to cross subsidize the development of new technology. Without proper judicial interpretation, the 1996 Act could simultaneously relegate incumbents to ditch diggers and force service repair personnel to maintain an outdated exchange system for competitor exploitation.

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310. *See supra* notes 69-79.

311. *See id.*

312. *See* 47 U.S.C. § 251(c)(2)(d) (1994).

313. *See generally* Vaneetha Demski, *Finding the Formula for Success*, 232 TELEPHONY 74 (1997).

314. *See id.* (recognizing that commentators believe "that because of the tremendous amount of money that interexchange carriers have already spent on their advertising, the LECs can never catch up").

Ironically, the 1996 Act provides no evidence of congressional intent to divest incumbents of their local networks, even if some natural monopolies survive.[315] Indeed, the 1996 Act verifies congressional intent that ILECs be vigorous competitors.[316] Mandating interconnection, however, enables a competitor to abstain from economically and technologically duplicating the incumbent's facilities. The 1996 Act permits a competitor simply to request interconnection without further justification or explanation.[317] Competitors thus have little incentive to construct alternative rival facilities or engage in highly capital intensive technological development.[318] LECs are faced with a Hobbesean choice of either incurring substantial development costs while risking the potential of allowing competitor access, or choosing not to take the development initiative, instead relying upon competitors to develop the new facility. Either choice has deleterious consequences upon competition by discouraging the development of new facilities among competitors.

The solution lies in the antitrust principles embodied within the essential facilities doctrine. Congress explicitly recognized the role of antitrust enforcement in the deregulation of the telecommunications industry but failed to interlineate antitrust principles properly within the confines of section 251.[319] Instead, Congress generated a highly complex regulatory environment. The Interconnection Order alone comprises more than 700 pages of regulations and guidelines.[320] The highly regulatory environment is entirely inconsistent with congressional findings that the "deployment of

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315. *See* Stoffels, *supra* note 301, at 38.

316. *See id.*

317. *See* Nowicki, *supra* note 7, at 369-70.

318. A legislative mandate requiring one to "share" innovations when this innovation has led to a position of market domination seems contrary to public policy. The judiciary in *United States v. Aluminum Co. of America,* 148 F.2d 416, 430 (2d Cir.1945), expressed the same concern, stating that "[t]he successful competitor, having been urged to compete, must not be turned upon when he wins." Even the spokesman for the Department of Justice, Antitrust Division, conceded that valid protest can exist when a facility's owner is denied a legitimate return on his investment. *See* Michael Boudin, *Antitrust Doctrine and the Sway of Metaphor,* 75 GEO. L.J. 395, 402 n.52 (1986). The argument against mandating interconnections is best summarized by the simple observation that this is a policy consideration; "[r]equired sharing discourages building facilities ... even though they benefit consumers." Areeda, *supra* note 147, at 851. A legislative mandate of interconnection would fuel these concerns, while a restraint via the antitrust laws would not.

319. *See supra* notes 69-79. Governmental regulation and antitrust laws may be viewed as flip sides of the same coin; "regulation is an alternative to antitrust" laws, as both focus on a competitive goal. STEPHEN BREYER, REGULATION AND ITS REFORM 158 (1982).

320. *See* Rose, *supra* note 303, at 10.

existing and future advanced, multipurpose technologies will best be fostered by minimizing government limitations on the commercial use of those technologies."[321]

Fortunately, the existing provisions of section 251, coupled with modification of section 252 pricing terms, enable a regulatory reduction and the infusion of the essential facilities doctrine. Section 251 requires that access, resale, and unbundling be just, reasonable, and nondiscriminatory. In determining just, reasonable, and nondiscriminatory interconnectivity, resale, and unbundling terms the following criteria should be considered. First, the duration of ordered resale must reflect the relative size of each entrant. Well-established interexchange market carriers should receive less deference than fledgling exchange providers when determining the continuance of the resale provisions as applied. Second, below-cost resale must be limited in duration to the time necessary to give each carrier an adequate opportunity to establish a necessary customer base. Carriers such as MCI and AT&T obviously need less time to establish the requisite customer base than lesser-known entrants. This limitation would preclude carriers with substantial name recognition and an established customer base from overly relying on an incumbent's facilities. Third, regulators must determine access and unbundling terms by drawing upon the essential facilities doctrine. The essentiality of a facility becomes the first relevant inquiry.[322] The particular facility must be central to competition in the local telecommunications market and not practicably duplicable.[323]

Within the local exchange networks, operational features such as switching elements, transport elements, signaling systems, and databases seem to satisfy these requirements.[324] The essentiality of ILEC's local exchange networks arise inter alia from legal licenses; the existence of a

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321. S. 652, 104th Cong., 1st Sess. § 5 (1995).

322. *See* discussion *supra* part V.

323. *See id.*

324. *See* Counsel on Competition, *Competition Policy: Unclocking the National Information Infrastructure* (visited Apr. 29, 1997) <http://icg.stwing.upenn.edu/cis590/reading.054.txt>. *Cf.* Spulber, *supra* note 62, at 57:

> [T]he local loop is not an essential facility because there exist many alternatives to the existing local exchange network provided by the regulated local exchange carriers. The multiple technologies currently available for telecommunications transmission, including coaxial cable, fiber optics, and wireless technologies such as cellular and microwave, are sufficient to establish the feasibility of constructing alternative transmission facilities to supplement, compete with, or even replace portions of the local exchange network provided by the RBOCs.

bottlenecks; a historically rigid regulatory environment; the satisfaction of minimum efficiencies of scale by the existing local exchange loop; the necessity of public subsidies for the development of relevant exchange loop elements and telephony services; the presence of a minimum market within rural areas; the high cost associated with the development of technologically viable alternatives; and the ability of ILECs to cross-subsidize future endeavors by their ownership of the local exchange loop.[325] Despite the fact that technological development promises to erode the essentiality of the facilities and generate facilities-based competition,[326] ILECS currently supply the wires, which provide the path for the vast majority of voice and data services reaching consumers.[327] Replication of the essential elements built over 120 years and valued at $270 billion would cost trillions of dollars.[328] Thus, ILECs have effectively obtained a vital bottleneck on the local exchange market.[329]

The essential facilities doctrine recognizes that the effect the copper telephone line monopoly has is limited over time.[330] As cellular, fiber-optic, cable, and satellite technologies become more prevalent, ownership of a copper telephone delivery system no longer remains central to the

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325. *See* Lawrence A. Sullivan, *Elusive Goals Under The Telecommunications Act: Preserving Long-Distance Competition Upon Baby Bell Entry And Attaining Local Exchange Competition: We'll Not Preserve the One Unless We Attain The Other*, 25 SW. U. L. REV. 487, 496 (1996) (noting that the "RBOCs have long been and still remain LX monopolists protected by the vast sunk costs of their systems and the technological and economic constraints on duplicating them as well as by regulation and exploitative conduct").

326. *See* Spulber, *supra* note 62, at 38-39:

> Improvements in computers and related switching technology allow different firms to build and operate multiple networks that can then be interconnected. The costs of interconnection have fallen substantially as the costs of switching technology have decreased. Open network architecture further reduces the benefits of a centrally switched network. In addition, new developments in switching have allowed customer premises equipment, such as the private branch exchange (PBX) and local area networks, to be substituted for transmission and switching by the telecommunications utility. These significant developments promise to render the concept of a natural monopoly telecommunications network obsolete.

327. Will Rodger, *Telecommunications Reform Doesn't Ring True*, INTER@CTIVE WEEK, Feb. 10, 1997, at 64.

328. *See id.*

329. *See id.*

330. *See* discussion *supra* part V.

provision of telephone service within the relevant exchange market.[331] If the potential market entrant is able to duplicate the copper lines monopoly with a new telecommunications technology, the essential facilities doctrine does not apply.[332] Thus, the essential facilities doctrine recognizes the dynamic nature of the telecommunications industry and serves as a catalyst for advanced multi-purpose technologies.[333] Potential market entrants unwilling to forgo the expanding telecommunications market will either develop alternate facilities or merge with other telecommunications providers to engender facilities-based competition with the incumbent provider.[334]

The second inquiry pertains to the denial of the essential facility to a competitor.[335] Because the 1996 Act mandates interconnectivity and unbundling, this question seems moot. The terms of access, however, remain relevant. Access terms pertaining to a facility deemed essential should remain consistent with section 252. The essential facilities doctrine forecloses an entrant's ability to free ride on nonessential facilities owned by the ILECs.

The final inquiry pertaining to the essential facilities doctrine is the feasibility of providing access to the facility.[336] The 1996 Act partially addresses this issue. Section 251 permits regulators to deny access plans that are contrary to the public interest.[337] This broad policy statement rec-

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331. *See* Spulber, *supra* note 62, at 34-35. The traditional justifications for regulating industries, such as the presence of natural monopoly technologies, may no longer apply in the presence of technological change and competitive entry. *See id.* at 29, 34. Multiple telecommunications technologies in addition to the traditional copper wire—including coaxial cable, fiber-optic cable, satellite, microwave, cellular, and other radio technologies—signify that it may no longer be possible to define a natural monopoly technology for local telephony. *See id.* at 34.

332. *See* Nowicki, *supra* note 7, at 369-70.

333. *See id.* at 368 (arguing that the essential facilities doctrine "litigation would bring the technological discussion to the forefront").

334. *See id.* at 370. It seems as though telecommunication providers have chosen the latter route. *See* Rodger, *supra* note 327, at 64 (noting that one year after the 1996 Act, media and telephone companies merged like never before. U.S. West purchased Continental Cablevision Corp. for $10.8 billion, Walt Disney Co. purchased Capital Cities/ABC Inc. for $19 billion, Bell Atlantic Corp. and Nynex Corp. agreed to merge for $22.7 billion, SBC Communications Inc. purchased Pacific Telesis Group for $16.7 billion, Time Warner Inc. purchased Turner Broadcasting for $7.8 billion, British Telecommunications PLC purchased MCI Communications Corp. for $20 billion, WorldCom Inc. purchased MFS Communications Co. for $12 billion, and Westinghouse Electric Corp. purchased Infinity Broadcasting Corp. for $3.9 billion).

335. *See* discussion *supra* part V.

336. *See id.*

337. *See* 47 U.S.C. § 251 (1994).

ognizes a legitimate business justification for denying access at the macro level. The ability to deny access plans should also extend to micro legitimate business justifications when an incumbent can establish that access is not technically or economically practicable. The nature of the existing local loop limits the applicability of a micro level business justification.

Disputes will invariably arise over the essentiality of a particular facility or the existence of a legitimate business justification. Infusing the essential facilities doctrine into the 1996 Act's interconnectivity, unbundling, and resale provisions, however, provides a superior mechanism to continuing adherence to the rigid anticompetitive terms of section 251[338] for achieving ordered deregulation of the telecommunications industry. Simply allowing access to copper telephone delivery systems without invocation of the essential facilities doctrine enables a competitor to substitute itself for the incumbent local exchange provider. This substitution has limited pro-competitive effects and has the potential of chilling desirable behavior. Nothing in the legislative history of the 1996 Act suggests that Congress intended such a skewed competitive result.

VII. CONCLUSION

Recognition of the essential facilities doctrine provides invaluable transition rules and criteria in the ordered deregulation of the telecommunications industry. Infusing essential facilities principles within section 251 of the 1996 Act creates investment incentives and ensures a competitive marketplace by mandating interconnectivity, resale, and unbundling at competitive rates only when a monopolist denies access to a facility essential to competition in the local telecommunications market that cannot be practicably duplicated by a competitor.[339] The essential facilities doc-

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338. *See* Nowicki, *supra* note 7, at 371-72 (arguing that the rigidity of the interconnection order is unnerving).

> The Congressional mandate on interconnections in § 101 of the Act makes the denial of access virtually unlawful per se for local exchange carriers. The obligation of interconnection seems directly opposed to the theory that "denial of access is never per se unlawful." ... While Sherman Act § 2 claims allow flexibility, mandated interconnection allows none. Even at the most basic level, in achieving the goal of competition, mandating interconnections is wrong. Regulating by mandating interconnections "replicates the results of competition." The antitrust laws, however, "seek to create or maintain the conditions of a competitive marketplace." Congress intended a competitive marketplace, not a marketplace that replicates competition.

Id. (internal citations omitted).

339. *See* discussion *supra* part V.

trine thus provides an incentive for facilities-based competition necessary to achieve the congressional goal that "all Americans, regardless of where they may work, live, or visit, ultimately have comparable access to the full benefits of competitive communications markets."[340]

340. S. 652, 104th Cong., 1st Sess. § 5 (1995).

THE EVOLVING APPLICATION OF THE WRITTEN DESCRIPTION REQUIREMENT TO BIOTECHNOLOGICAL INVENTIONS

By Janice M. Mueller†

ABSTRACT

A United States patent must provide a "written description" of the invention claimed therein. In its earliest implementation, a patent's written description fulfilled a notice function of putting the public in possession of the boundaries of the patentee's property right. Under modern practice, that notice function is instead performed by the claims of the patent. In 1967, the Court of Customs and Patent Appeals (CCPA) breathed new life into the written description requirement of section 112 of the Patent Act, by applying it for a different purpose, that of ensuring "support" for claims first presented or substantively amended after a patent application has been filed. The court viewed written description compliance as a means of ensuring that the patent applicant had actually invented the later-claimed subject matter as of the earlier filing date of the application. The CCPA and its successor, the Court of Appeals for the Federal Circuit, repeatedly recognized that the manner in which the written description was provided was not critical, so long as those of ordinary skill would understand the newly-claimed subject matter to be fairly within the patentee's original contribution.

Written description jurisprudence significantly diverged from these principles with the Federal Circuit's 1997 decision in *Regents of the University of California v. Eli Lilly*. In *Lilly*, the court applied the written description requirement to claims originally filed in a pioneering University of California patent application directed to the recombinant production of insulin, and held that the written description requirement is not satisfied for claims to DNA absent an express disclosure of nucleotide sequence. The *Lilly* decision may profoundly limit the scope of protection available for new gene inventions; viewed in tandem with recent decisions interpreting the enablement requirement of § 112 of the Patent Act, it represents the latest advance in an ominous trend towards imposition of uniquely heightened patentability requirements for biotechnological inventions. *Lilly* aptly illustrates the increased widening of the gulf

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between the norms of the business and scientific communities and the U.S. patent system, as users of the latter come to understand that the patent system no longer reflects the realities of scientific contribution.

TABLE OF CONTENTS

I. INTRODUCTION

The specification of a United States patent must provide:

> a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same ....[1]

Though codified in the Patent Act of 1952, it was not until 1967 that the United States Court of Customs and Patent Appeals (CCPA) in *In re Ruschig*[2] first characterized this statutory language as requiring a "written description" of an invention, separate from and in addition to an "ena-

1. 35 U.S.C. § 112 (1994).
2. 379 F.2d 990 (C.C.P.A. 1967).

bling" disclosure of how to make and use that invention.[3] Since *Ruschig*, understanding and applying the written description requirement as a statutory criterion of separate purpose and function from the enablement requirement have proven difficult. Recent developments in the application of the written description requirement to biotechnological inventions illustrate the difficulties of maintaining a clear demarcation between the written description and enablement requirements.

At the forefront of the United States Court of Appeals for the Federal Circuit's evolving written description jurisprudence stands its recent and controversial invalidation of patents covering the pioneering recombinant DNA technology at issue in *Regents of the University of California v. Eli Lilly and Co.*[4] (*Lilly*). The *Lilly* decision establishes uniquely rigorous rules for the description of biotechnological subject matter that significantly contort written description doctrine away from its historic origins and policy grounding. The *Lilly* court's elevation of written description to an effective "super enablement" standard of uncertain scope and applicability will likely chill development in this critically important technological field and frustrate the United States patent system's policy goal of encouraging prompt disclosure of new inventions.

Part I of this article provides an overview of the United States patent law evolution of the written description requirement, which initially fulfilled a notice function that today has been supplanted by patent claims. The description requirement was given new life in the modern era by the CCPA, which adapted it to the fundamentally different purpose of ensuring support for later-filed or later-amended claims. Part II examines the Federal Circuit's application of the written description requirement in *Lilly*. Part III contends that the *Lilly* court improperly diverged from established description doctrine in two significant aspects: first, by utilizing the description requirement to invalidate original application claims; and second, by requiring that a written description of a claim to DNA[5] must set

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3. *Id.* at 995 (characterizing issue on appeal as "not whether [one skilled in the art] would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented").

4. 119 F.3d 1559 (Fed. Cir. 1997); *see also A Bitter Battle over Insulin Gene*, 277 SCIENCE 1028, 1028 (1997) (describing suit as a "vicious fight [that] centers on a landmark discovery by [University of California at San Francisco] biologists at the dawn of the biotechnology era: the first successful cloning of the rat insulin gene") [hereinafter *Bitter Battle*].

5. Deoxyribonucleic acid (DNA) consists of two complementary strands of nucleotides, which include the four basic compounds adenine (A), guanine (G), cytosine (C), and thymine (T), oriented so that bases from one strand non-covalently bond to the

forth the specific nucleotide sequence of that DNA. Part IV considers the potential negative impact on the biotechnology industry of *Lilly* and other recent Federal Circuit decisions that have introduced a heightened set of patentability rules specifically targeted at this technology.

II. THE PURPOSE AND DEVELOPMENT OF THE WRITTEN DESCRIPTION REQUIREMENT

A. The Historic "Notice" Function of the Written Description Requirement

The purpose and function of the written description requirement have changed over time as United States patent law has evolved from a central claiming system to the peripheral claiming system now in use. [6] All United States patent statutes have required a "description" of the applicant's invention. The Patent Act of 1790 required the grantee of a patent to deliver to the Secretary of State:

> a specification in writing, containing a description ... of the thing or things by him ... invented or discovered ... which specification shall be so particular, ... as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art ... to make, construct or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term ....[7]

The early Supreme Court case of *Evans v. Eaton*[8] interpreted this statutory language as containing two separate requirements, written description and enablement, with separate and distinct roles. At stake in *Evans* was the validity of a patent on a "hopperboy," a mechanical device

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bases of the opposite strand. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1207 n.4 (Fed. Cir. 1991).

6. Central claiming of an invention refers to the drafting of a narrow claim to a particular embodiment with broad judicial interpretation of that claim as covering all equivalents. Peripheral claiming or definition of an invention involves reciting the periphery or boundaries thereof and finding only those devices infringing that fall within the periphery. *See* Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1565 (Fed. Cir. 1995) (Nies, J., dissenting).

7. Patent Act of 1790, § 2, 1 Stat. 109, 110 (repealed 1793). For a detailed discussion of the statutory development of the written description requirement from the Patent Act of 1790 through the Patent Act of 1952, see *In re Barker*, 559 F.2d 588, 592-93 (C.C.P.A. 1977).

8. 20 U.S. (7 Wheat.) 356 (1822).

used to stir and cool flour prior to its packaging.[9] The written description of Evans' patent specification failed to make clear that what the patentee Evans had invented was not an entire hopperboy (already in the public domain), but rather an improvement involving the provision of adjustable arms that accommodated varying levels of flour.[10] Interpreting the requirement of the Patent Act of 1793 that the specification must describe the invention "'in such full, clear and distinct [sic] terms, as to distinguish the same from all other things before known,'"[11] the Court invalidated Evans' patent for "mixing up the new and old"[12] and failing "to describe what his own improvement is, and to limit his patent to such improvement."[13] Although Evans' specification was enabling,[14] it failed to comport with the other objective of a patent specification:

> to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.[15]

When *Evans* was decided in 1822, modern peripheral claiming practice had not yet evolved in the United States.[16] Absent claims as we know

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9. *Id.* at 358-59.

10. *Id.* at 364-66.

11. *Id.* at 434 (quoting Patent Act of 1793, § 3, 1 Stat. 318, 321 (repealed 1836)). The "description" language of section 3 of the Patent Act of 1793, interpreted by the *Evans* Court, substantially tracked the Patent Act of 1790:

> [E]very inventor, before he can receive a patent ... shall deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art ... to make, compound, and use the same.

Patent Act of 1793, § 3, 1 Stat. 318, 321 (repealed 1836).

12. *Evans*, 20 U.S. (7 Wheat.) at 434.

13. *Id.* at 435.

14. *Id.* at 433-34 (stating with respect to the enablement requirement that "[i]t is not pretended that the plaintiff's patent is not in this respect sufficiently exact and minute in the description").

15. *Id.* at 434.

16. *See* Markman v. Westview Instruments, Inc. 517 U.S. 370, 375 (1996) (explaining that "[c]laim practice did not achieve statutory recognition until the passage of the Act of 1836 and inclusion of a claim did not become a statutory requirement until 1870 ... '[T]he idea that the claim is just as important if not more important than the description and drawings did not develop until the Act of 1870 or thereabouts.'") (citations omitted)).

them today, the written description provided notice to the public of the scope of exclusive rights asserted by an inventor. Through the written description, the public was to be "put in possession" of the boundaries of a patentee's asserted monopoly.[17]

Today, this role is played by claims, single-sentence statements that must "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention."[18] Thus, the written description requirement as extant in *Evans* can be viewed as the historic predecessor of modern claiming requirements. The written description requirement in its current form, however, no longer focuses on putting the public "in possession" of the claimed invention in the sense of fulfilling a notice requirement. Rather, written description now asks whether the inventor was "in possession" of the claimed invention as of a particular date.

B. The Modern "Support" Function of the Written Description Requirement

After the development of claims, first expressly required in the Patent Act of 1870,[19] the "written description" requirement took on a different role. No longer necessary to provide notice to the public of the asserted scope of the patentee's right to exclude, the "written description" language of section 112 of the Patent Act became a historical anachronism without a role in the statutory scheme.[20]

The written description requirement had its modern "rebirth" in 1967, with the CCPA's decision in *In re Ruschig*.[21] For the first time, the CCPA identified, within the language in section 112 of the Patent Act, a legal requirement for a written description that played a role different from that of enablement.[22] The *Ruschig* court applied the written description require-

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17. *See Evans*, 20 U.S. (7 Wheat.) at 434 (stating that one object of a patent specification is "to put the public in possession" of the claimed invention).

18. 35 U.S.C. § 112, ¶ 2 (1994).

19. *See Markman*, 517 U.S. at 379 (explaining that "inclusion of a claim did not become a statutory requirement until 1870 ...").

20. *Cf. In re* Barker, 559 F.2d 588, 594 (C.C.P.A. 1977) (Rich, J., concurring) (noting "evolutionary history of the language of § 112 whose "words are of ancient lineage and, in spite of the fact they are inappropriate to some situations, they were preserved, in writing the Patent Act of 1952, because they were familiar and had many times been construed").

21. 379 F.2d 990 (C.C.P.A. 1967).

22. *See* Harris A. Pitlick, *Looking Beyond Blazemarks on Trees—It's Time to Revisit the Description Requirement in the Wake of* Warner-Jenkinson, 79 J. PAT. & TRADEMARK OFF. SOC'Y 625, 628 & n.12 (1997) (characterizing *Ruschig* as "first identif[ying] in 1967 the written description requirement").

ment to a claim presented after the application was filed.[23] In so doing, the court sought to ascertain if the application would disclose to one skilled in the art that the later-claimed invention was something that the applicant had "actually invented" as of the earlier application filing date.[24] Thus, in *Ruschig*, the CCPA effectively transitioned the written description requirement from a superfluous, claim-like notice role into a convenient statutory descriptor for the general concept of "support" for claims not filed in an original application.

Though not expressly stated, the policy of concern to the *Ruschig* court appeared to be one of preventing the inventor from claiming, after-the-fact, more than she had a right to; the inventor would be limited to claiming that which she had identified as within the scope of her invention at the time of filing her original application. As phrased in the CCPA's 1973 *In re Smith*[25] decision, compliance with the written description requirement "insures that subject matter presented in the form of a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application."[26] More recently, the Federal Circuit in *Vas-Cath, Inc. v. Mahurkar*[27] framed this policy concern as "guard[ing] against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation."[28]

Today, the written description, rather than notifying the public at the time of patent issuance of the asserted scope of the patentee's property right, serves as a manifestation of what was within the scope of the patentee's inventive contribution as of his filing date. Thus, the written description requirement takes a "snapshot" view of the inventor's contribution based on the disclosure in her specification as originally filed, and asks whether that "snapshot" reasonably conveys to persons of ordinary skill that any subsequently-claimed subject matter was truly and fairly part of that contribution.

The need for fixing the scope of the invention on a date certain is critical to the patent system. The Patent and Trademark Office (PTO) takes

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23. *Ruschig*, 379 F.2d at 991 (noting that the claim at issue was added for purposes of invoking interference on September 25, 1957 in an application filed on July 31, 1956).

24. *Id.* at 995.

25. 481 F.2d 910 (C.C.P.A. 1973)

26. *Id.* at 914.

27. 935 F.2d 1555 (Fed. Cir. 1991).

28. *Id.* at 1561 (quoting Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551 (3d Cir. 1981)).

the filing date of a United States patent application as the presumptive or prima facie date of invention of the subject matter disclosed therein.[29] Determination of whether the invention is novel and nonobvious entails comparison of the claims (presumed to be entitled to the original filing date of the application) with the state of technology before the invention date.[30] Absent written description scrutiny, a later-presented claim not truly entitled to the earlier filing date of the application would be improperly examined against a smaller universe of prior art than is legally available. Intervening technical developments that occurred between the application's filing date and the subsequent claim presentation date would not be included in the prior art applied against the claim. If the written description requirement were not imposed, the applicant submitting a claim not entitled to the earlier filing date of the application would enjoy a windfall vis a vis the prior art.

Compliance with the written description requirement, like compliance with the enablement requirement, has been analyzed from the same perspective—that of the hypothetical person of ordinary skill in the art to which the claimed subject matter pertains.[31] The shared perspective of the two requirements is more subtle, however. Examination for enablement inquires whether those of ordinary skill would have been able to make and use the claimed invention without undue experimentation, based on the teachings of the application. This standard is a completely objective one; the "intent" or subjective view of the inventor is not relevant in determining whether the level of enabling disclosure is reasonably commensurate

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29. *See* Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 449 (Fed. Cir. 1986) (stating that prior art against which claims are analyzed for nonobviousness "must have existed as of the date of invention, presumed to be the filing date of the application until an earlier date is proved").

30. *See* 35 U.S.C. § 102(a) (1997) (stating that an invention is not patentable if "known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant ..."); *id.* § 102(e) (stating that an invention is not patentable if "described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent ..."); *id.* § 102(g) (stating that an invention is not patentable if "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it"); *id.* § 103(a)(1)(A) (stating that an invention is not patentable though novel "if the differences 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 to which said subject matter pertains").

31. *See In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1973) ("Compliance with the first paragraph of § 112 is adjudged from the perspective of the person skilled in the relevant art.").

with the scope of the claims. Written description compliance, however, is neither completely objective nor subjective. It entails a "mixed" determination, from the perspective of the person of ordinary skill, of what the inventor actually "possessed" as her invention on a particular date.[32] The inventor's "possession" of the invention must be reasonably manifested or conveyed by her patent specification, which includes the written description, any drawings, and originally-filed claims.[33] The patent specification must some how show persons of ordinary skill that, at the time the application was filed, the later-claimed subject matter was something the applicant had invented.

C. The Written Description Requirement Can Be Satisfied In Any Manner Sufficient to Convey Possession by the Inventor

Written description jurisprudence since *Ruschig* makes clear that the manner in which a claimed invention is described in the specification is not critical, so long as that description is capable of conveying to readers whether the inventor had actually invented the claimed subject matter as of the application filing date. As phrased in *Ruschig*, the inquiry is whether "the specification convey[s] clearly to those skilled in the art, to whom it is addressed, *in any way*, the information that the applicants have invented that specific compound."[34] Similarly, the CCPA in *In re Smith*[35] described the "essential goal" of the description requirement as "convey[ing] clearly to those skilled in the art the information that the applicant has invented the specific subject matter later claimed."[36] When the original specification accomplishes this goal, the written description re-

32. The written description requirement thus shares a mixed "subjective/objective" perspective with the best mode inquiry of section 112 of the Patent Act. Analysis of best mode compliance includes two elements: (1) whether, at the time the inventor filed his patent application, he knew of a mode of practicing his claimed invention that he considered to be better than any other; and (2) if the inventor in fact contemplated such a preferred mode, whether the disclosure is adequate to enable one skilled in the art to practice the best mode. *See* Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 927-28 (Fed. Cir. 1990).

33. *See* 35 U.S.C. § 112, ¶ 1 ("The specification shall contain a written description of the invention, and of the manner and process of making and using it ...."); *id.* § 112, ¶ 2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."). Drawings must also be furnished "where necessary for the understanding of the subject matter sought to be patented." *Id.* § 113.

34. *In re* Ruschig, 379 F.2d 990, 996 (C.C.P.A. 1967) (emphasis in original).

35. 481 F.2d 910 (C.C.P.A. 1973).

36. *Id.* at 914 (citing *Ruschig*, 379 F.2d at 996).

quirement is satisfied, "regardless of how" the specification accomplishes it.[37]

Prior to the Federal Circuit's decision in *Lilly*, adequate written description of chemical and biotechnological compounds had not been restricted to disclosures of physical structure. Rather, such compounds could be described in terms of their function, properties, method of making, or any other manner sufficient in the context of the claimed invention to convey possession by the inventor as of the application filing date.

For example, the chemical compound at issue in *Ruschig* was claimed after the filing of the appellant's application for purposes of provoking an interference.[38] Whether the written description requirement had been satisfied was not determined by the failure of the original application to specifically name or mention the chemical compound[39] that was first claimed over a year later.[40] However, because the disclosure encompassed "myriads of possibilities" from which persons of ordinary skill might, through selection of appropriate chemical reagents, arrive at the claimed compound, it did not adequately convey that the claimed compound was something appellants had actually invented as of the application filing date.[41] The question whether such persons would have been enabled to make the claimed compound was irrelevant to the written description inquiry.[42]

An invention in the chemical arts may be described in terms of a physical property which, though not expressly disclosed, is inherent to the invention. For example, the patent in suit in *Kennecott Corp. v. Kyocera International, Inc.*[43] claimed high-alpha silicon carbide ceramic bodies

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37. *Smith*, 481 F.2d at 914.

38. *Ruschig*, 379 F.2d at 991.

39. Claim 13 of Ruschig's application recited, "13. N-(p-chlorbenzenesulfonyl)-N-propylurea." *Id.*

40. *Id.* at 994 (agreeing with appellants and the Board that "naming is not essential ...").

41. The *Ruschig* court analogized the specification's lack of guidance in identifying the compound of claim 13 to the lack of "blaze marks" on a forest trail:

> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared—or have not yet been made, which is more like the case here—to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

Ruschig, 379 F.2d at 994-95.

42. *Id.* at 995.

43. 835 F.2d 1419, 1420 (Fed. Cir. 1987).

having a "predominantly equiaxed microstructure." The accused infringer contended that the patent was invalid because the parent application, entitlement to the filing date of which was necessary to overcome an on sale bar,[44] disclosed the ceramic bodies without revealing their later-claimed "equiaxed microstructure" property.[45] The Federal Circuit disagreed, holding that the "equiaxed microstructure" language of the continuation-in-part (CIP) application claims was supported by the inherent presence of that property in the ceramic bodies originally disclosed in the parent application. The court noted that the method disclosed in the parent application for making the ceramic bodies "invariably" produced a product having the claimed "equiaxed microstructure."[46] The fact that the "equiaxed microstructure" property was not described in words until the later CIP application did not deprive the claims reciting that property of the benefit of the earlier parent application's filing date.[47]

Written description cases in the mechanical and software arts also eschew limitations on the manner in which an adequate written description can be provided. For example, the medical device patent in suit in *Vas-Cath v. Mahurkar*[48] claimed a catheter having double lumens (tubes) of diameters within a specified range of ratios.[49] The Federal Circuit had to decide whether the drawings of Mahurkar's earlier-filed design patent application could provide adequate written description support for the diameter range limitations later claimed in Mahurkar's utility patent. Even though the design patent drawings showed only one particular ratio of diameters falling within the recited range, the Federal Circuit concluded that the drawings provided an adequate written description: "[U]nder proper circumstances, drawings alone may provide a 'written description' of an invention as required by § 112."[50] The fact that the drawings did not (and could not) show every possible embodiment of the claimed catheter within the recited diameter range was not dispositive, in view of expert testimony

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44. *Id.* at 1419.

45. *Id.* at 1420 (noting that parent application did not mention "equiaxed microstructure" property, nor state the requirements for forming such microstructure).

46. *Id.*

47. *Id.* at 1423 (holding that "[t]he disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of an earlier filing date. Nor does the inclusion of a description of that property in later-filed claims change this reasonable result.").

48. 935 F.2d 1555 (Fed. Cir. 1991).

49. *Id.* at 1558. The claimed catheter required a return lumen diameter "substantially less than 1.0 but substantially greater than 0.5 times" the diameter of the combined lumens. *Id.* at 1566.

50. *Id.* at 1565.

that persons of skill in the art viewing the drawings would be aware that only certain diameter relationships would produce a physiologically acceptable change in pressure at the transition between catheters.[51]

An inventor may convey what he has invented by describing its function rather than its structure, so long as the functional description adequately conveys that the inventor was legally in possession of the invention as of the asserted filing date. For example, the Federal Circuit gave wide latitude to the nature of a written description adequate to support a claim in the software arts in *In re Hayes Microcomputer Products.*[52] The claims asserted by Hayes recited a "timing means" in a mechanism for controlling the mode of operation of a computer modem. The accused infringer charged that Hayes improperly maintained the firmware code[53] corresponding to the "timing means" as a trade secret, rather than providing that code in the parent patent specification relied on to supply written description support.[54]

The Federal Circuit disagreed, concluding that Hayes' description of the "function" of the firmware was sufficient under the circumstances to comply with the description requirement of section 112 of the Patent Act. Although suggesting that the requisite degree of disclosure "varies according to the art to which the invention pertains,"[55] the *Hayes* court was unwilling to adopt the defendant's broad contention that "to satisfy section 112, a statement as to the specific function of a microprocessor is inadequate, that the actual program must be disclosed."[56] The evidence of record indicated that those skilled in the art would recognize how to implement the timing means without seeing the actual Hayes code;[57] thus, the functional description and flowchart Hayes provided constituted sufficient support for the claimed "timing means."

In the 1973 decision, *In re Smythe*, the CCPA identified the policy rationale for broadly permitting satisfaction of the written description requirement by disclosure of function or properties, or in any other manner

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51. *Id.* at 1566 (pointing to an affidavit of the plaintiff's physician witness as explaining "why one of skill in the art of catheter design and manufacture, studying the drawings of the '081 application in early 1982, would have understood from them that the return lumen must have a diameter within the range recited by independent claims 1 and 7 of the '329 patent").

52. 982 F.2d 1527 (Fed. Cir. 1992).

53. Firmware code is permanently stored in read-only memory (ROM).

54. *Id.* at 1533.

55. *Id.* at 1533-34.

56. *Id.* at 1534.

57. *Id.*

that adequately conveys the inventor's possession.[58] Simply stated, more restrictive readings of the written description requirement would place an unacceptably undue burden on users of the patent system.[59] The invention in *Smythe* was a system for automatic quantitative analysis of samples of body fluids.[60] The written description and originally-filed claims taught that the individual fluid samples were separated within the apparatus by a segmentizing medium of "air or other gas which is inert to the liquid" sample transmitted.[61] When the applicant subsequently presented claims by preliminary amendment that more broadly recited the segmentizing medium as "an inert fluid," the PTO entered a rejection under section 112 of the Patent Act on the ground that "inert fluid" would encompass a liquid, for which the application provided no express written description support.[62] The CCPA reversed, rejecting the PTO's "broad proposition" that the written description requirement can never be satisfied where the description in the written description portion of the specification is narrower than that recited in the claims.[63] Smythe's specification clearly taught the functions and properties required of segmentizing fluids useful in his invention, and the use of liquids fulfilling those criteria would "naturally occur" to one skilled in the art reading the application.[64] To hold otherwise, the court concluded, would:

> place[] upon patent applicants, the Patent Office, and the public the undue burden of listing, in the case of applicants, reading and examining, in the case of the Patent Office, and printing and storing, in the case of the public, descriptions of the very many structural or functional equivalents of disclosed elements or steps which are already stored in the minds of those skilled in the arts, ready for instant recall upon reading the descriptions of specific elements or steps.[65]

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58. 480 F.2d 1376 (C.C.P.A. 1973).

59. *Id.* at 1384.

60. *Id.* at 1377-78 (describing the invention and reproducing representative claims 34 and 47).

61. *Id.* at 1377.

62. *Id.* at 1378.

63. *Id.* at 1382.

64. *Id.* at 1383. The court also relied on the fact that prior art patents showed the use of liquids as segmentizing media. *Id.* (describing disclosure of Kessler patent); *id.* at 1384 (characterizing Kessler patent as "additional evidence of the knowledge of one skilled in the automatic sample analysis art [that] supports appellants' position that to such persons appellants' description conveys the idea of using inert fluids broadly").

65. *Id.* at 1384.

Written description compliance, therefore, should not be so onerous as to prohibit an applicant from claiming "undisclosed, but obviously art-recognized equivalent[s]" of expressly disclosed aspects of the invention.[66] Such "equivalents" are within the inventor's possession.

III. APPLICATION OF THE WRITTEN DESCRIPTION REQUIREMENT IN *REGENTS OF THE UNIVERSITY OF CALIFORNIA V. ELI LILLY AND CO*

Written description jurisprudence diverged from the principles discussed above when the Federal Circuit in July 1997 issued its decision in *Lilly*. The following overview of the facts and holdings in *Lilly* will provide a grounding for the critiques presented in part IV.

The Regents of the University of California (UC) sued Eli Lilly and Company (Lilly) in 1990 for infringement of two UC patents directed to the use of recombinant DNA technology to produce human insulin.[67] The patents were based on UC's cloning of the rat insulin gene, a breakthrough development that has been viewed as "open[ing] the way to modern insulin production."[68] Initially filed in the Northern District of California, the suit was eventually transferred to and tried in the Southern District of Indiana.[69]

Although Lilly raised several other defenses, this article focuses on Lilly's written description challenge to the validity of UC's '525 patent.[70]

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66. *Id.* The *Smythe* court provided the following oft-cited example to illustrate its point: If the original written description of a patent application directed to the "scales of justice" disclosed only a one-pound "lead weight" as a counterbalance to determine the weight of a pound of flesh, the applicant should not be prevented by the written description requirement from later more broadly claiming the counterbalance as a "metal weight" or even generically as a one-pound "weight." Although a "metal weight" or a one-pound "weight" are both broader than the expressly disclosed one-pound "lead weight," they are "obviously art-recognized equivalent[s]." The broader claims should be permitted because the applicant's disclosure of the "use and function" of the "lead weight" as a counterbalance would immediately convey to others that the applicant had invented a scale with a one-pound counterbalance weight, "regardless of its composition." *Id.* at 1384.

67. *See* Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1562 (Fed. Cir. 1997).

68. *Bitter Battle*, *supra* note 4, at 1029 (remarks of William Rutter, former University of California, San Francisco scientist and current chair of Chiron Corporation, Emeryville, California). UC's successful isolation of the rat insulin gene represented "the first time the entire genetic sequence for an insulin gene had been spelled out ...." *Id.*

69. *Lilly*, 119 F.3d at 1562-63.

70. *See* Regents of the University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d (BNA) 1225, 1227 (S.D. Ind. 1995). Lilly did not assert written description non-

Generic claims 1, 2, 4, 6, and 7 of the '525 patent recited complementary DNA (cDNA)[71] encoding *vertebrate* or *mammalian* insulin, while claim 5 specifically recited cDNA encoding *human* insulin.[72] The '525 patent issued in 1987[73] from an application filed in 1977.[74] As of the 1977 filing of the '525 patent, UC had determined and isolated the preproinsulin (PPI) and proinsulin (PI) cDNA sequences found in rats, but not in humans.[75] Although UC included in the '525 patent a constructive or "prophetic" example describing a method that could be used to obtain the human insulin-encoding cDNA recited in claim 5, as well as the amino acid sequences of human insulin A and B chains,[76] UC did not actually isolate and sequence the human cDNA until nearly two years after the 1977 filing date.[77]

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compliance with respect to the second UC patent in suit, U.S. Patent No. 4,431,740. *See id.* at 1241 (discussing Lilly's anticipation and enablement challenges to the '740 patent).

71. "Complementary" DNA (cDNA) is a complementary copy or "clone" of messenger RNA (mRNA), made in the laboratory by reverse transcription of mRNA. A cDNA contains only the protein-encoding regions of DNA. *See In re* Deuel, 51 F.3d 1552, 1554 (Fed. Cir. 1995).

72. The claims of UC's '525 patent provided:

> 1. A recombinant plasmid replicable in procaryotic host containing within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA [cDNA] of a vertebrate, which mRNA encodes insulin.
>
> 2. A recombinant procaryotic microorganism modified to contain a nucleotide sequence having the structure of the reverse transcript of an mRNA of a vertebrate, which mRNA encodes insulin ....
>
> 4. A microorganism according to claim 2 wherein the vertebrate is a mammal.
>
> 5. A microorganism according to claim 2 wherein the vertebrate is a human.
>
> 6. A plasmid according to claim [1] comprising a plasmid containing at least one genetic determinant of col E1.
>
> 7. A microorganism according to claim 2 comprising a strain of Escherichia coli.

Lilly, 39 U.S.P.Q.2d at 1258 nn. 23 & 24.

73. *Id.* at 1227.

74. *Lilly*, 119 F.3d at 1562.

75. *Lilly*, 39 U.S.P.Q.2d at 1240.

76. *Lilly*, 119 F.3d at 1567. Example 6 was added to the application corresponding to the '525 patent in 1978. *See Lilly*, 39 U.S.P.Q.2d at 1240 (noting that the application "was expanded on April 19, 1978, to add example six, relating to the potential isolation of human DNA").

77. *Lilly*, 39 U.S.P.Q.2d at 1240 (stating that "it was not until nearly two years after the original application for the '525 [patent] was filed that UC inventors actually isolated and characterized human insulin cDNA"); *id.* at 1243 (stating that "UC contends that the [human proinsulin amino acid] sequence was not known until [the September 12, 1979

Accused infringer Lilly never asserted that the '525 patent specification failed to *enable* the human insulin cDNA and vertebrate and mammalian insulin cDNA claims in accordance with section 112 of the Patent Act.[78] Lilly's decision to forego a challenge to the patent on enablement grounds is not surprising because UC's isolation of the rat insulin cDNA made the human insulin cDNA "relatively easy" to "fish out" thereafter.[79] Rather, Lilly asserted that the '525 patent was invalid because its specification did not contain a *written description* of the claimed inventions in accordance with section 112.[80]

Following a 1995 bench trial,[81] the district court found for Lilly and held all the '525 claims invalid.[82] With respect to species claim 5, limited to *human* insulin-encoding cDNA, the district court concluded that "[t]he inventors could not provide a description of human insulin cDNA because they were not then [as of the 1977 filing date] in possession of that DNA."[83] Seeming to confuse the written description and enablement requirements, however, the district court held with respect to generic claims 1, 2, 4, 6, and 7 that the '525 patent adequately described only the rat cDNA and did not "*enable*[] the patent's claims to all vertebrates and mammals ...."[84]

The Federal Circuit affirmed the district court's conclusion that all the asserted '525 patent claims were invalid for failure to comply with the written description requirement.[85] The appellate court first analyzed species claim 5, which recited *human* insulin-encoding cDNA, and concluded that the '525 specification was fatally defective for failing to structurally describe the claimed cDNA. It then held that the *human* insulin-encoding cDNA of claim 5 was not adequately described, because the specification

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filing date of UC's '740 patent], at which time inventors of the '740 patent actually isolated and characterized the human source DNA that codes for proinsulin").

78. *Id.* at 1239-41 (identifying the "written description requirement" as the only issue of invalidity raised with respect to '525 patent); *see also Federal Circuit Rules it Takes More Than One cDNA Sequence to Claim a Genus,* III INTELL. PROP. LAWCAST (Dec. 29, 1997) (audio interview of UC counsel Harold J. McElhinny) (stating that Lilly never raised non-enablement as a defense to UC's '525 patent).

79. *Bitter Battle, supra* note 4, at 1029.

80. *Lilly*, 39 U.S.P.Q.2d at 1239.

81. *Id.* at 1227.

82. *Id.* at 1241 (holding that "the specification of the '525 patent adequately describes only the rat insulin cDNA; the inventors' claims to the genera of vertebrates and mammals and to the human species are invalid").

83. *Id.* at 1240.

84. *Id.* at 1241 (emphasis added).

85. Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1569 (Fed. Cir. 1997).

lacked a disclosure of that cDNA's "relevant structural or physical characteristics."[86] The court specifically pointed to the absence in the specification of "sequence information indicating which nucleotides constitute human cDNA ...."[87] Nor did UC's provision in example 6 of a process that could be used to isolate the human cDNA remedy the perceived deficiency of the disclosure: the court concluded that, "describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself."[88]

The *Lilly* court thus demanded that the written description of a DNA invention meet a heightened "precise definition" test,[89] previously formulated in the 1993 decision, *Fiers v. Revel*.[90] In *Fiers*, a three-way interference case, the Federal Circuit concluded that the specification of the party Revel did not provide a sufficient written description of the DNA invention in dispute because the specification lacked a "precise definition, such as by structure, formula, chemical name, or physical properties"[91] of the DNA.[92] As a result, Revel lost the priority battle to the party who was first to set forth "the complete and correct nucleotide sequence" of the claimed DNA.[93]

The *Lilly* court also buttressed its invalidation of human insulin claim 5 with the Federal Circuit's 1995 nonobviousness decision, *In re Deuel*.[94] The Federal Circuit held in *Deuel* that a claim to a particular DNA molecule encoding a desired protein is not rendered obvious under section 103

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86. *Id.* at 1567.

87. *Id.* (contrasting the lack of human cDNA sequence data with UC's provision of rat cDNA sequence data in example 5 of the '525 patent).

88. *Id.*

89. *Id.* at 1566 (citing the "precise definition" standard of *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

90. 984 F.2d 1164 (Fed. Cir. 1993). For a further discussion of *Fiers*, see *infra* part IV.B.1.

91. *Fiers*, 984 F.2d at 1171.

92. The *Fiers* decision in turn extended the holding of *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991), into the written description arena. The *Amgen* court held that conception of a DNA invention "has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated." *Id.* at 1206. Correspondingly, the *Fiers* court held that "[i]f a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity." *Fiers*, 984 F.2d at 1171.

93. *Fiers*, 984 F.2d at 1172.

94. 51 F.3d 1552 (Fed. Cir. 1995). For a further discussion of *Deuel*, see *infra* part IV.B.2.

of the Patent Act by a prior art disclosure of the amino acid sequence of that protein. Because many different DNA sequences can code for one protein given the degeneracy of the genetic code, the particular DNA claimed would not have been obvious to a person of ordinary skill in the art who knew only the identity of the desired protein.[95] The *Lilly* court extended this nonobviousness doctrine to the written description issue before it, opining without other authority that "a fortiori, a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112, ¶ 1."[96]

The Federal Circuit then turned to the generic vertebrate and mammalian insulin claims 1, 2, 4, 6, and 7 and concluded that they, like claim 5, were invalid as not supported by an adequate written description.[97] The extent of the written description required to support claims 1, 2, 4, 6, and 7 mirrored, on the genus level, the court's pronouncement that a *structural* description must be provided to support a claim to a species of cDNA:

> [A] cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA .... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.[98]

In the Federal Circuit's view, a "functional" definition of cDNA was insufficient because it indicated only "what the gene does, rather than what it is."[99] The court viewed such a functional definition as merely a statement of result and noted that "[m]any such genes may achieve that result."[100] Without more, UC's "generic statement[s]" such as "vertebrate insulin cDNA" and "mammalian insulin cDNA" do not constitute an ade-

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95. *Deuel*, 51 F.3d at 1558.

96. Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1567 (Fed. Cir. 1997).

97. *Id.* at 1569 (rejecting "UC's argument that the district court clearly erred in finding claims 1, 2, 4, 6 and 7 invalid for failure to provide an adequate written description").

98. *Id.* at 1568-69 (citation omitted).

99. *Id.* at 1568 (citing *Fiers v. Revel*, 984 F.2d 1164, 1169-71 (Fed. Cir. 1993)).

100. *Lilly*, 119 F.3d at 1568.

quate written description of the generic claims because they "do[] not distinguish the claimed genus from others, except by function."[101]

IV. *LILLY'S* HEIGHTENED WRITTEN DESCRIPTION STANDARD TARGETING BIOTECHNOLOGICAL INVENTIONS CONTRAVENES PRECEDENT AND POLICY

The *Lilly* decision is a significant departure from prior written description cases in at least two respects. First, the Federal Circuit applied the written description requirement to claims originally filed with the application, rather than to claims presented or amended after the application filing date. In so doing, the court divorced the written description requirement from its role first envisioned in *Ruschig* and thirty years of subsequent case law development. In a case where enablement was never raised by the defendant, the *Lilly* court's application of the written description requirement to original application claims has created a new and undefined "super-enablement" standard for biotechnological inventions.

Second, the *Lilly* court extended the teachings of *Fiers* and *Deuel* to hold that the written description requirement is not satisfied for claims to a DNA absent an express disclosure in the specification of the nucleotide sequence of that DNA. This rule sets a significantly higher standard for the protection of biotechnological inventions than for other technological subject matter. Pre-*Lilly* case law established that inventions, including biotechnological and chemical subject matter, can be described in any manner sufficient to indicate to those skilled in the art that the inventor had possession of the invention as of the application filing date. *Lilly* obscures the function and purpose of the written description requirement by unnecessarily restricting the manner in which possession of a biotechnological invention can be conveyed.

A. The Written Description Requirement Should Play No Role In the Analysis of Originally-Filed Claims Which Are Part of the Disclosure

After the CCPA's express recognition of the written description requirement in *Ruschig*, that court applied the requirement only to reject or invalidate claims filed or amended after an original application's filing date, when the benefit of the earlier filing date was sought for those claims. The court rejected Patent Office attempts to assert written description noncompliance as a basis for rejecting claims originally included in the application as filed. The *Lilly* court departed from this understand-

101. *Id.*

ing of the written description requirement when it applied the requirement to originally-filed claims, and in so doing further complicated description jurisprudence. Both precedent and policy strongly favor limiting application of the written description requirement to claims presented or substantively amended after the original filing date of an application. As illustrated by *Lilly*, to do otherwise results in an unacceptable blurring between the written description and enablement requirements.

In re Ruschig,[102] the first case to recognize the written description requirement in the modern peripheral claiming era, enforced the requirement in the context of a claim to a specific chemical compound that was added to the appellant's application more than a year after its filing in order to provoke an interference.[103] The *Ruschig* court framed the issue before it as whether the original disclosure provided adequate "support" for this later-presented claim: "Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that naming is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required."[104]

The practical import of the *Ruschig* court's holding that the specification failed to provide an adequate written description of the later-claimed species was, of course, to prevent the appellant from unfairly obtaining a time-wise advantage over the subsequent and true inventor of that species. The fact that Ruschig's broadly-described genus of compounds happened to encompass the single later-claimed compound did not justify recognition of Ruschig as the first to actually invent it. In other words, Ruschig's generic description did not adequately signal that he was in possession of the species at the time of his prima facie invention date and thus the first inventor.

Following *Ruschig*'s recognition of the written description requirement, the requirement was also applied in non-interference settings, but always where the claims on appeal had been filed or amended after the original application filing date. In *In re Smith*,[105] the CCPA catalogued the factual contexts in which written description compliance is appropriately considered:

> Satisfaction of the description requirement insures that subject matter presented in the form of a claim subsequent to the filing

102. 379 F.2d 990 (C.C.P.A. 1967).
103. *Id.* at 991.
104. *Id.* at 994.
105. 481 F.2d 910 (C.C.P.A. 1973).

> date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention [of that newly-claimed subject matter] can fairly be held to be the filing date of the application. This concept applies whether the case factually arises out of an assertion of entitlement to the filing date of a previously filed application under § 120, ... or arises in the interference context wherein the issue is support for a count in the specification of one or more of the parties, ... or arises in an ex parte case involving a single application, but where the claim at issue was filed subsequent to the filing of the application ....[106]

Compliance with the written description requirement may also be appropriately raised with respect to claims substantively amended during the course of prosecution of an original application.[107] Written description compliance issues are implicated when "the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a different invention than was the original claim ...."[108] The amendment of a claim or the presentation of a new claim are both acts occurring after the filing date of the original application, and thus the issue in either case is whether the amended or new claim is adequately supported by the disclosure of that application as filed.

Nowhere does the *Smith* court suggest that the written description requirement has any applicability to claims filed at the time of the application and not amended thereafter. Indeed, that possibility had already been foreclosed by the CCPA in *In re DiLeone*[109] and *In re Gardner*.[110]

The inappropriateness of applying written description analysis to original claims filed with the application was conclusively established in 1973 with *Gardner*.[111] Reversing a PTO Board of Appeals rejection of an original claim under the written description requirement of section 112 of the Patent Act, the *Gardner* court explained that "[c]laim 2, which apparently was an original claim, in itself constituted a description in the original disclosure equivalent in scope and identical in language to the total

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106. *Id.* at 914 (citations omitted).

107. *See, e.g., In re* Smythe, 480 F.2d 1376, 1382-85, 1385 n.5 (C.C.P.A. 1973) (addressing whether the written description and original claims adequately supported "inert fluid" limitation added by preliminary amendment).

108. *In re* Wright, 866 F.2d 422, 424 (Fed. Cir. 1989); *see also* MANUAL OF PATENT EXAMINING PROCEDURE § 2163.03(a) (Rev. 2, July 1996) (citing *Wright* for the proposition that "[a]n amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed").

109. 436 F.2d 1033 (C.C.P.A. 1971).

110. 475 F.2d 1389 (C.C.P.A. 1973).

111. *Id.*

subject matter now being claimed .... Nothing more is necessary for compliance with the description requirement ...."[112] On petition for rehearing, the court rejected the PTO's argument that an original application claim should not be considered part of the "written description" unless the specification contained or was amended to contain the subject matter of the claim.[113] Whether such amendment should be made was merely an "administrative matter" for the PTO rather than a proper basis for the court's decision on description requirement compliance.[114]

The reason for exemption of originally-filed claims from written description scrutiny is clear: such claims are part of the disclosure,[115] and by presenting them with the application as filed, the applicant is signifying her possession of the claimed subject matter as of that filing date. The claims must, after all, signal "the subject matter which the applicant regards as his invention."[116] As explained in *Smith*, "[w]here the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied."[117] With an original claim, there can be no temporal discontinuity between the presumptive invention date established by filing the application and the presumptive invention date to which claims originally part of that application are entitled. The filing of a claim in the original application precludes the possibility that the applicant will wrongly obtain an advantage in examination of that claim against a too-narrow universe of prior art. Whether or not through her original disclosure the applicant has *enabled* those of skill in the art to make and use the invention as broadly as claimed is an entirely separate matter.

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112. *Id.* at 1391 (citation omitted). The CCPA confirmed the *Gardner* holding that originally filed claims constitute part of the disclosure in *In re Koller*, 613 F.2d 819, 823 (C.C.P.A. 1980) (citing *Gardner* for the proposition that "original claims constitute their own description"). The *Koller* court held that method claims reciting the term "liquid medium," presented in a continuing application, were supported in accordance with section 112 of the Patent Act by a grandparent application's claims that used the same terminology. *Id.* at 823 ("the term 'liquid medium' is found in both places [and] the two sets of claims are similar in wording").

113. *Gardner*, 480 F.2d at 879.

114. *Id.*

115. *See* 35 U.S.C. § 112, ¶ 2 (1994) (requiring that the "specification shall conclude with one or more claims ...").

116. *Id.*

117. *In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1973) (citing *In re Gardner*, 475 F.2d 1389 (C.C.P.A.), *denying reh'g*, 480 F.2d 879 (C.C.P.A. 1973), and *In re DiLeone*, 436 F.2d 1303 (C.C.P.A. 1971)); *see also In re* Wertheim, 541 F.2d 257, 264 (C.C.P.A. 1976) (citing *Gardner* as support for holding that the claim on appeal, "an originally filed claim, is its own written description in the appealed application").

The Federal Circuit decision *In re Alton*[118] demonstrates a recent failure of the court to recognize these limits on the applicability of the written description requirement. Claim 70 of Alton's application recited a particular analog (a variation from the naturally-occurring sequence) of human gamma interferon (IFN-γ). The issue on appeal was whether claim 70 was entitled to the filing date of a 1983 CIP application in which it was originally filed.[119] As disclosed in the 1983 specification, the claim 70 analog shared (in shorthand terms) a modification (1)[120] with a different IFN-γ analog disclosed in example 5, but only the example 5 analog included a modification (2).[121] The *Alton* court reversed the PTO on procedural grounds for failing to give adequate weight to an expert's declaration evidencing that one of ordinary skill would have understood example 5 as separately describing the claim 70 analog.[122] This concern for the declaration evidence completely missed the point: the analog recited in claim 70 was part of the disclosure of the 1983 application as filed. No declaration interpreting what persons of ordinary skill would understand from example 5 was necessary, because the inclusion of claim 70 in the 1983 CIP application when filed was an express disclosure that this particular analog was part of Alton's invention.

The *Lilly* and *Alton* decisions significantly expand written description analysis to include scrutiny of originally-filed claims. Other recent Federal Circuit decisions have wisely resisted the temptation to follow suit in broadening the doctrine's reach. The means-plus-function claims on appeal in *In re Dossel,*[123] originally filed in the application, were directed to a device that functioned to "reconstruct" current distribution data for vis-

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118. 76 F.3d 1168 (Fed. Cir. 1996).

119. *Id.* at 1171 (explaining that '451 application on appeal was filed in 1983 as a continuation-in-part of a parent application filed in 1982 and later abandoned); *id.* (describing Board's holding that "the specific polypeptide of claim 70 was not described in the original specification of application Serial No. 06/483,451"); *id.* at 1173 (restating examiner's final rejection that "the specification did not convey that Alton had possession of the subject matter of claim 70 as of April 15, 1983—the filing date of the '451 application").

120. "Modification (1)" refers to the deletion of the first three amino acids of the natural 146-amino acid chain of IFN-γ coupled with the placement of the amino acid methionine at the beginning of the amino acid sequence of the resulting IFN-γ. *Id.* at 1171 (comparing claim 70 with example 5).

121. "Modification (2)" refers to the substitution of an asparagine, the 81st amino acid in the IFN-γ chain, with lysine. *Id.* (comparing claim 70 with example 5).

122. The expert declaration asserted that modifications (1) and (2), both possessed by the example 5 analog, were independent of each other, and thus that the description of both modifications constituted a description of each separate modification. *Id.* at 1176.

123. 115 F.3d 942 (Fed. Cir. 1997).

ual display.[124] The PTO rejected the claims as failing to comply with the claim definiteness requirement of section 112 of the Patent Act, based on an asserted failure of the specification to "disclose[] any specific structure or hardware that may be regarded as being 'corresponding structure' under 35 U.S.C. § 112 ¶ 6."[125] Although both the applicant and the PTO Solicitor argued that the section 112 rejection was untenable absent a rejection for non-compliance with the written description requirement,[126] the Federal Circuit disagreed. Whether the written description of the application adequately disclosed structure for performance of the "reconstructing" function turned on whether the claimed invention was particularly pointed out and distinctly claimed.[127] The court held that the written description requirement was not at issue.[128] An applicant's utilization of the means-plus-function claiming format provided for in section 112's sixth paragraph "does not itself implicate the requirements of § 112, ¶ 1."[129]

The presence of a claim in an application when it is filed signals others that the inventor considers the claimed subject matter to be within her possession as of that date. The claim is thus examined against the state of the art as of the application filing date (presumptive invention date). Whether the remainder of the specification, the written description and any drawings, would *enable* persons of ordinary skill to make and use the subject matter of the originally-filed claim without undue experimentation is a separate matter. The *Lilly* court failed to draw this distinction. By claiming human insulin-encoding cDNA at the time they filed the application for the '525 patent, UC conveyed to the art that the human cDNA was something it had invented. This is all that written description requires. Whether UC through its disclosure could adequately teach those of ordinary skill how to make and use the claimed human insulin-encoding cDNA without undue experimentation is a separate question never raised by Lilly. In fashioning a newly-elevated written description requirement

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124. *Id.* at 943-44 (characterizing the invention as relating to a "device for reconstructing the spatial current distribution in a biological object, such as a patient's head or brain, within which object volume elements exhibit current distributions produced by current sources in the object," and reproducing appealed claims 8 and 9 which recited "means for reconstructing the current distributions" and "reconstruction means for determining the current distributions," respectively).

125. *Id.* at 944.

126. *Id.*

127. *Id.* at 946.

128. *Id.*

129. On the merits, the *Dossel* court held that section 112 was satisfied. The application's written description in combination with the language of claims 8 and 9 constituted a sufficient disclosure of structure corresponding to the "reconstructing means."

in the absence of any challenge to enablement, the *Lilly* court failed to maintain a workable, predictable dividing line between the two requirements.

B. Adequate Written Description of a Biotechnological Invention Should Not Be Limited to a Structural Description

The *Lilly* court held that the written description requirement was not satisfied as to original application claim 5, which recited human insulin-encoding cDNA, because the UC application did not describe the physical structure of the recited cDNA: "The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity .... No sequence information indicating which nucleotides constitute human cDNA appears in the patent ...."[130]

The court thus rejected the notion that a functional description, or a description indicating the protein (here, human insulin) to be encoded by the cDNA plus a method for obtaining the cDNA's nucleotide sequence, could be an adequate written description.

The *Lilly* court's imposition of a restricted structure-only rule for DNA claims is another significant departure from prior written description precedent. Contrary to *Lilly*, the written description of biotechnological compounds need not be so limited. The better rule would allow biotechnological compounds, like any other inventions, to be described functionally,[131] by method of preparation, or in any other manner sufficient to convey that the claimed subject matter was in the inventor's possession as of her filing date.

1. Structure is not the only way to supply a written description of biotechnological subject matter

The requirement of explicit possession of the nucleotide sequences of the cDNAs claimed in *Lilly* is contrary to one of the earliest biotechnology decisions of the CCPA, *In re Fisher*.[132] Although typically cited for its

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130. Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1567 (Fed. Cir. 1997).

131. Currently unresolved is the potential for application of *Lilly*'s narrow "description by structure" requirement to biotechnological subject matter other than genes. Claims to antibodies, for example, are typically supported by descriptions of the antibody's binding function rather than its structure. *See* Kate H. Murashige, *Genome Research and Traditional Intellectual Property Protection—A Bad Fit?*, 7 RISK: HEALTH, SAFETY AND ENV'T 231, 234 (1996) (stating that PTO practice is to grant protection for antibodies claimed "in entirely functional terms").

132. 427 F.2d 833 (C.C.P.A. 1970).

"predictable/unpredictable factors" analysis of enablement,[133] *Fisher* also addressed the written description requirement.[134] *Fisher* establishes that disclosure of the physical structure of a biological compound is not required in order to provide sufficient written description support for claims thereto. More specifically, an inventor need not be able to define the amino acid sequence of a protein in order to provide adequate written description support for a later-presented claim to that sequence, if the inventor can at least functionally describe the protein.

A *Fisher* analysis considers the inherent but unrealized characteristics of a protein invention such as its amino acid structure as being within the inventor's possession for written description purposes. The inventor constructively possesses all inherent characteristics of the protein, even at a time when he is not yet subjectively aware of them. Likewise, actual knowledge of other inherent characteristics such as the nucleotide sequence of a cDNA that codes for the protein should not be required in order to show possession for written description purposes.[135]

The inventor in *Fisher* developed injectable compositions containing adrenocorticotrophic hormones (ACTH) extracted from the pituitary glands of animals,[136] which are useful for the treatment of arthritis in human patients.[137] Fisher's parent application did not disclose the amino acid sequence of the ACTH extract. After determining that sequence, Fisher filed a CIP application. Claim 4 of Fisher's CIP application recited an ACTH extract in terms of its amino acid structure, characterized as a "polypeptide of at least 24 amino acids having the following sequence ...

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133. *Id.* at 839 (explaining that "[i]n cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement .... In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved").

134. *Id.* at 836.

135. *See* KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT § 7.2(a), at 150 (1995). Burchfiel contends that:

> [a] written description of such a biotechnology invention [as in *Fisher*] does not require that the specification recite the nucleic acid sequence of a gene invention, or the amino acid sequence of a polypeptide product .... Since a chemical compound inherently has a structure, claims may be added defining that structure, and the same disclosure may be added to the specification without introducing 'new matter' prohibited under 35 U.S.C. § 132.

Id. (citation omitted).

136. Fisher's method involved extracting ACTH from the frozen pituitary glands of hogs, sheep, cows, or other animals, including whales. *Fisher*, 427 F.2d at 834.

137. *Id.*

[24 amino acid sequence listing]."[138] Compliance with the written description requirement became an issue when, in order to overcome an intervening anticipatory reference, Fisher asserted entitlement to the 1949 filing date of his parent application.[139] The PTO rejected CIP claim 4 as insufficiently supported by the parent application under section 112 of the Patent Act.[140]

Despite the absence in the parent application of any structural description of the claimed ACTH extracts, and Fisher's admitted lack of knowledge thereof,[141] the CCPA agreed with Fisher that such knowledge was not required to satisfy the written description requirement. The court also agreed that extracts disclosed in Fisher's parent application *inherently* possessed the amino acid sequence later recited in CIP claim 4.[142] This inherent disclosure was sufficient to satisfy the written description requirement, despite the fact that the physical structure of the claimed extract was not realized by the inventor as of the filing date asserted.[143]

Thus, *Fisher* established that an inventor may possess a biotechnological invention for written description purposes via "inherent" or "constructive" possession, without subjectively realizing all of its characteristics or being in a position to precisely disclose them. Later-presented claims that explicitly recite a characteristic such as physical structure which was inherently present but unrealized as of the earlier application filing date are nevertheless entitled to that filing date.

Whether the inherency rationale of *Fisher* applies with equal force to DNA encoding particular proteins as claimed in *Lilly* obviously implicates the degeneracy of the genetic code. If multiple nucleic acids can code for the same protein, can all genes or any one gene properly be viewed as an *inherent* characteristic of that protein for written description purposes? The *Lilly* decision would appear to answer the question in the negative.

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138. *Id.* at 835 (reciting claim 4).

139. *Id.* at 836.

140. *Id.*

141. *Id.*

142. *Id.* The court explained that Fisher's parent application "discloses treatment of hog pituitary extracts," and relied on the intervening Li reference's disclosure of the amino acid sequence for porcine (hog) ACTH to conclude that "[t]he hog-extracted products disclosed in [Fisher's] parent application must therefore have had the recited sequence." *Id.*

143. The *Fisher* court ultimately affirmed the PTO's section 112 rejection on a different rationale: that the parent specification did not *enable* those skilled in the art to make ACTHs as broadly as recited in CIP claim 4, which was not limited to polypeptides containing the 39 amino acids inherently present in the hog, beef, and lamb ACTH extracts disclosed in Fisher's parent application. *Id.*

The reasoning and precedent utilized in *Lilly* simply do not justify the result, however, that an inventor of a gene is never entitled to claim it before he can specify its precise structure.

The degeneracy aspect of the genetic code may help to explain, though not to justify, *Lilly*'s fundamental departure from the rationale of *Fisher*. Failing even to cite *Fisher*, the *Lilly* decision relies heavily on *Fiers v. Revel*, a 1993 decision of the Federal Circuit in a three-way interference involving a single count to a DNA encoding human fibroblast beta-interferon.[144] In *Fiers*, the party Sugano was deemed the first to invent because he was first to disclose the complete nucleotide sequence of the DNA and its method of isolation.[145] The court held that the party Fiers failed to establish an earlier conception of the DNA, applying the rule of *Amgen, Inc. v. Chugai Pharmaceutical Co.*[146] to require that Fiers show an actual reduction to practice in order to establish a conception date.[147]

Written description compliance was specifically raised as an issue in *Fiers* when the party Revel attempted to prove entitlement under section 119 of the Patent Act to the benefit of his earlier-filed foreign application.[148] Revel's foreign application included language similar to the words of the count but did not provide the nucleotide sequence of the claimed DNA.[149] The court rejected Revel's argument that because the count recited the term "DNA" but not the sequence thereof, his supporting written description likewise did not need to disclose the sequence.[150] Revel's "correspondence" argument was unpersuasive because "none of that language particularly describes the DNA."[151] Just as conception could not be established in *Amgen* absent a "precise definition" of the DNA, nor could the written description requirement be satisfied without a similarly de-

144. The count at issue in *Fiers* recited: "A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide." Fiers v. Revel, 984 F.2d 1164, 1166 (Fed. Cir. 1993).

145. *Id.* at 1171-72.

146. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

147. *Fiers*, 984 F.2d at 1167-69 (characterizing *Amgen* as requiring reduction to practice evidenced by isolation of the gene in order to establish date of conception for gene claimed per se, rather than claimed in product-by-process format).

148. *Fiers*, 984 F.2d at 1167.

149. *Id.* at 1170.

150. *Id.*

151. *Id.* at 1171. Without citation to any authority, the *Fiers* court asserted that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170.

tailed elucidation of the DNA sequence.[152] The *Fiers* court thus equated the *Amgen* "precise definition" standard for conception with the test for written description compliance, essentially requiring for gene inventions an actual reduction to practice (including sequencing) for fulfillment of either criteria.[153]

The *Lilly* court's reliance on the reasoning of *Fiers* and *Amgen* is suspect on several grounds. First, *Lilly* disregards the role of UC's concededly enabling disclosure in proving invention, a factor missing in *Fiers* and *Amgen*. The case defining written description in the modern era, *Ruschig,* teaches that the "possession" criteria of written description compliance requires an inventor to show that he had "actually invented" the later-claimed subject matter as of his earlier application filing date.[154] Thus, it is conceptually appropriate to link written description compliance to proof of invention under the well-established standards applicable to priority determinations under section 102(g) of the Patent Act.[155]

These standards necessarily implicate enablement. Conception, the mental part of invention, is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice."[156] In some cases, an inventor may not be able to establish conception until he has also reduced the invention to practice through a successful experiment.[157] This was the case in *Am-*

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152. *Id.* at 1171 (concluding that "one cannot describe what one has not conceived").

153. *Cf. id.* at 1169 (noting that "[w]hile one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity").

154. *See In re* Ruschig, 379 F.2d 990, 995 (C.C.P.A. 1967) (analyzing written description compliance by asking whether specification disclosed later-claimed invention "as something appellants actually invented").

155. The statute provides:

> A person shall be entitled to a patent unless ...
> (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102(g) (1994).

156. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) (quoting Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987)).

157. *See Amgen*, 927 F.2d at 1206 (agreeing with district court that claimed gene encoding human EPO was not conceived until reduced to practice through isolation of the gene).

gen, where art workers were unsuccessful in using the gene cloning methods used by the alleged prior inventor as proof of earlier conception under section 102(g).[158]

Contrary to *Lilly's* seemingly bright-line rule, proof of conception through an actual reduction to practice should not be required to establish "possession" of any and all gene inventions. Actual reduction to practice to show a completed conception has never been required across the board for a particular technology. Conception is complete when only ordinary skill would be required to reduce an invention to practice and can be evidenced by a contemporaneous disclosure that enables others to make the invention.[159]

In *Lilly*, UC provided an enabling disclosure of how to isolate and sequence the human insulin-encoding cDNA of claim 5. In the absence of any evidence presented by Lilly to the contrary (much less clear and convincing evidence), UC's issued '525 patent was entitled to a presumption that its disclosure complied with the enablement requirement of section 112.[160] Unlike the situation in *Amgen,* where the gene isolation methods of the alleged first inventor were not enabling, proof of an actual reduction to practice by cloning and gene sequencing should not have been required in *Lilly*. UC's enabling disclosure of how to isolate the human insulin gene evidenced a completed conception. UC was therefore sufficiently "in possession" of the claimed human insulin encoding-cDNA for written de-

158. *See id.* at 1207 (noting that evidence in the record indicating that "several companies, as well as Amgen and GI, were unsuccessful using Fritsch's approach"). The *Amgen* court specifically based its affirmance of the trial court's holding that an adequate conception of the DNA sequence was not achieved until reduction to practice on "the uncertainties of the method and lack of information concerning the amino acid sequence of the EPO protein." *Id.; see also* Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1229 (Fed. Cir. 1994) (citing *Amgen* for the proposition that "conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice").

159. *See Burroughs*, 40 F.3d at 1228 (citing Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985)); *see also* Field v. Knowles, 183 F.2d 593, 600-01 (C.C.P.A. 1950) (holding that, to establish priority of invention, "the conception and disclosure to others required is the inventor's completed thought expressed in such clear terms as to enable those skilled in the art ... to make ... the ... compound ... which constitutes the subject matter of the invention").

160. *See* 35 U.S.C. § 282 (1994) ("[a] patent shall be presumed valid"). Moreover, the methods disclosed by UC in the '525 application were those that it later used with success to isolate the human proinsulin cDNA. *See* Regents of the University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d (BNA) 1225, 1239 (S.D. Ind. 1995).

scription purposes to be entitled to the 1977 filing date of the '525 patent.[161]

Second, the gene isolation process UC described in example 6 of the '525 patent was effective for its purpose. As discussed below,[162] pre-*Lilly* written description jurisprudence made clear that a product may be described by a disclosure of the process for producing it, if that process will necessarily lead to the claimed product. This standard, though satisfied by the facts of *Lilly*, was not met in *Fiers*. The *Fiers* court recognized that "Revel's application does not even demonstrate that the disclosed method *actually leads* to the DNA, and thus that he *had possession* of the invention."[163] Rather than resolve the written description issue on this narrower ground, however, *Fiers* extended *Amgen*'s simultaneous-conception-and-reduction-to-practice rationale to require the same "precise definition" for satisfaction of the written description requirement.

Lastly, *Fiers'* treatment of the written description requirement is distinguishable because the party Revel had no sequence data whatsoever in the application he sought to use for written description support. In *Lilly*, although the inventors could not disclose the sequence of *human* insulin-encoding cDNA in 1977 (because they had not yet isolated it), they did disclose the sequence of *rat* insulin-encoding cDNA as well as an enabling method for obtaining the human cDNA sequence. The district court in *Lilly* recognized this key difference and found that "[u]nlike the inventors in *Fiers* and *Amgen*, the inventors on the '525 patent actually had isolated and characterized a cDNA gene for insulin—*i.e.*, rat insulin."[164] These are closely related molecules and, in fact, one can be used to isolate the other. The Federal Circuit ignored the critical distinction between the case before it and the precedent invoked, however; rather than factually analyzing whether persons of ordinary skill would have recognized the human cDNA as within the scope of what UC had invented as of the '525 application filing date, the court applied a per se rule that the written descrip-

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161. *See* Stephen A. Bent & Paul M. Booth, *Genomics Race Raises Ownership Boundary Issue*, NAT'L L.J., Jan. 26, 1998, at C3, C4 n.30 (characterizing *Lilly*'s requirement for "actual" rather than "conceptual" possession of claimed subject matter as "alien" to earlier written description case law).

162. *See infra* part IV.B.2.

163. Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (emphases added).

164. *Lilly*, 39 U.S.P.Q.2d at 1240. In *Amgen*, the Federal Circuit held that "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated." Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991).

tion requirement could not be satisfied absent an exposition of the precise nucleotide sequence of the claimed human cDNA.

A factually-based inquiry would have placed *Lilly* far from *Fiers* on a spectrum of written description adequacy. Nothing in *Fiers* indicated Revel's possession of the sequence of the claimed DNA as of the filing date of Revel's foreign application; Revel's application was rejected not only for failure to provide an adequate written description but also for failure to comply with the enablement requirement of section 112.[165] In contrast, UC's express disclosure of the nucleotide sequence for rat insulin-encoding cDNA in *Lilly,* coupled with a description of a process for isolating and identifying the human cDNA sequence, goes considerably further towards raising the legitimate factual issue of the scope of what UC had actually invented as of its application filing date—whether persons of ordinary skill would have interpreted the disclosure as sufficient evidence that UC had actually invented more than just the rat insulin-encoding cDNA. As emphasized by the CCPA in *In re Wertheim,*[166] "[t]he primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure."[167]

2. *A process can provide written description support for a product*

The *Lilly* court also rejected UC's argument that it had provided an adequate written description of the human insulin-encoding cDNA of claim 5 of the '525 patent by providing a process for obtaining it.[168] In concluding that UC's provision in example 6 of a "general method of producing human insulin cDNA and a description of the human insulin A and B chain amino acid sequences that cDNA encodes"[169] did not provide a written description of the claimed human cDNA, the court relied on *In re Deuel,*[170] a leading biotech nonobviousness decision.[171] In *Deuel,* the

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165. *See Fiers,* 984 F.2d at 1170 (stating that "the Board concluded that the Israeli application was not enabling since Revel had not yet conceived the DNA of the count and 'logically, one cannot ... enable an invention that has not been conceived'"). It has been suggested that, in view of the enablement rejection of Revel's application, the Federal Circuit's written description discussion in *Fiers* is entirely dicta, not required for affirmance of the Board's decision. *See* BURCHFIEL, *supra* note 135, § 7.2(b), at 150-51.

166. *In re* Wertheim, 541 F.2d 257 (C.C.P.A. 1976).

167. *Id.* at 262.

168. Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1567 (Fed. Cir. 1997) (discussing example 6).

169. *Id.*

170. 51 F.3d 1552 (Fed. Cir. 1995).

Federal Circuit recognized that a prior art disclosure of a protein's structure does not necessarily render obvious a particular DNA molecule encoding that protein, given the redundancy of the genetic code.[172] Extending this doctrine of nonobviousness to the written description inquiry, the *Lilly* court opined that "a fortiori, a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112, ¶ 1."[173] In other words, disclosure of a desired protein and a method for generating the DNA sequence that encodes it (the nature of the prior art in *Deuel*) do not satisfy the written description requirement for a claim reciting that DNA sequence.

The *Lilly* court's automatic extension of *Deuel*'s nonobviousness rule to the very different issues raised by the written description requirement is troubling. As a factual matter, the lack of suggestion to combine and expectation of success that *Deuel* recognized as resulting from the degeneracy of the genetic code was considerably lessened in *Lilly* by UC's previous sequencing of rat insulin cDNA.[174] UC's knowledge of that sequence, coupled with the methods of example 6, was of sufficient detail that Lilly did not mount an enablement challenge. UC used the example 6 methodology to actually reduce to practice the human insulin cDNA invention within two years of filing the '525 application.[175]

As a legal matter, the nonobviousness requirement of section 103 and the written description requirement of section 112 involve substantively different inquiries. The section 103 inquiry examines whether the invention, even though novel, represents enough of a qualitative advance in the art that time-limited monopoly rights are justified, from the perspective of an ordinary worker in the art. The written description inquiry asks not whether the description would have been sufficient to render obvious the claimed invention, but whether it would reasonably have signaled to those in the art that the claimed invention was actually part of the patentee's contribution. Nonobviousness is examined entirely from the perspective

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171. *Lilly*, 119 F.3d at 1567.

172. *Deuel*, 51 F.3d at 1558 (explaining that "[a] prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein").

173. *Lilly*, 119 F.3d at 1567.

174. UC's determination of the rat cDNA sequence made its subsequent isolation of the human insulin gene "relatively easy." *See Bitter Battle*, *supra* note 4, at 1029.

175. Regents of the University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d (BNA) 1225, 1239 (S.D. Ind. 1995) ("UC adds that the isolation method taught in the '525 patent was that method it subsequently used actually to isolate the human proinsulin cDNA.").

of the hypothetical person of ordinary skill, without hindsight consideration of the claimed invention. Written description operates as a timing mechanism, to maintain the correct universe of prior art against which a later-claimed invention is fairly examined for novelty and nonobviousness. Compliance with written description asks whether it is appropriate that the claimed invention be examined against the smaller universe of prior art in existence as of the earlier application filing date, or whether fairness dictates that that universe be expanded to encompass developments occurring between the application filing date and the date when the claim is subsequently presented or amended. The written description requirement should be viewed merely as a timing device and not applied as an obviousness-like criteria that judges the merits of the advance represented by the claimed invention.

The *Lilly* court did not follow earlier authority which suggests that the process disclosure of UC's example 6 should have provided adequate written description support for the resulting product, if that process would have *necessarily or inherently* produced the claimed invention. For example, in *In re Edwards*,[176] the CCPA considered whether the written description of a parent application adequately supported the applicant's later-presented CIP claim to a water-insoluble polyol having sufficient self-catalytic activity to react with organic polyisocyanates to form rigid polyurethane foams.[177] The *Edwards* court held that the disclosure of the parent was "not intrinsically defective merely because appellants chose to describe their claimed compound by the process of making it;" the court's "primary concern" was "whether the description requirement has been complied with, not the mode selected for compliance."[178] The *Edwards* court stressed the need for fact-specific analysis of every written description case and expressly declined to adopt an across-the-board rule of description adequacy via process disclosure.[179] But with respect to the process before it, which without question would inherently produce the claimed compound, a sufficient written description of the resulting product had been supplied.[180]

Following the *Edwards* rule, the proper inquiry in *Lilly* would have been whether UC's provision in example 6 of a process for obtaining the human insulin-encoding cDNA would necessarily have led one of skill in the art to the claimed cDNA. In other words, would persons of ordinary

176. 568 F.2d 1349 (C.C.P.A. 1978).
177. *Id.* at 1350-51.
178. *Id.* at 1352.
179. *Id.*
180. *Id.*

skill, looking at the '525 specification, have understood that performance of the process disclosed in example 6 would result in the cDNA of claim 5? If so, then example 6 represents a sufficient written description of the invention. UC contended at trial that the process of example 6 was in fact the process it subsequently used to arrive at the human insulin-encoding cDNA.[181] Assuming the truth of this assertion, it strongly suggests that the "process necessarily leading to the product" test of *Edwards* would have been answered affirmatively. Rather than addressing this factual issue, the *Lilly* court short-circuited the analysis to hold that, as a matter of law, UC's description of a process could not qualify as a description of the cDNA product.

V. PUBLIC POLICY DOES NOT FAVOR UNIQUELY RIGOROUS BIOTECHNOLOGY PATENTABILITY RULES

In *Lilly*, the Federal Circuit has fashioned a newly heightened written description standard unique to biotechnological inventions, without meaningful explanation of policy concerns that would justify such a significant departure from earlier written description principles. Despite the fact that Lilly did not challenge the ability of UC's application to teach art workers how to isolate and sequence the claimed human, vertebrate, and mammalian cDNA, the Federal Circuit invalidated the claims because UC had not yet specified the nucleotide sequences of those cDNAs.[182] In practical terms, *Lilly* may profoundly limit the scope of protection available for new gene inventions. Only those genes that can be precisely described by nucleotide sequence will be viable candidates for patenting; disclosure of function alone will no longer suffice.[183]

The elevation of the written description requirement for biotechnological subject matter in *Lilly* is but the latest advance in an ominous trend. Imposition of heightened patentability requirements for biotechnological

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181. Regents of the University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d (BNA) 1225, 1239 (S.D. Ind. 1995).

182. The *Lilly* court blurred the distinction between the enablement and written description requirements when, in invalidating genus claims 1, 2, 4, 6, and 7 of the '525 patent, it required that the written description of these DNA genera be provided by "means of a recitation of a representative number of cDNAs, defined by nucleotide sequence," Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1569 (Fed. Cir. 1997), and described this requirement as "analogous to enablement of a genus under § 112, ¶ 1, by showing the enablement of a representative number of species within the genus." *Id.*

183. *See Bitter Battle*, *supra* note 4, at 1029 (reporting that some patent experts view *Lilly* as having "a broad impact, compelling gene hunters to spell out the exact sequence of all the DNA they hope to claim, rather than just the function of the genes.").

inventions is also reflected in the Federal Circuit's recent significant expansion of the enablement requirement for this subject matter. Enablement holdings, including *Amgen* and *Genentech, Inc. v. Novo Nordisk A/S*,[184] illustrate the Federal Circuit's increasing willingness to essentially limit biotechnology claim scope to the embodiments disclosed in an applicant's working examples. Applying general enablement principles, the fact that some experimentation may be required to make and use a biotechnological invention such as a gene that encodes a particular protein is not fatal to validity, so long as the degree of experimentation required is not "undue." The tenor of recent Federal Circuit biotechnology decisions seems to reflect the opposite view; namely, that almost *any* independent experimentation by the art worker would be undue.

Taken in tandem with recent developments in biotechnological enablement doctrine, the parallel "ratcheting up" of the written description requirement in *Lilly* signals the creation of a unique patent law jurisprudence for genetic engineering inventions.[185] Unique patent law treatment, for biotechnology or any other particular technology, raises concern. Public policy favors uniform standards for all technologies. The development of uniquely stringent, biotech-specific patent law principles cannot help but chill the development of new biotechnological products and processes.[186]

The argument that the rigor of the written description requirement should vary with the nature of the technology at issue has intuitive appeal. Similar arguments are well accepted in the enablement context, where more extensive "make and use" disclosure is required to enable subject matter involving "unpredictable factors," like chemical reactions and physiological activity, than that required to enable claimed technology in-

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184. 108 F.3d 1361, 1367-68 (Fed. Cir.), *cert. denied*, 118 S. Ct. 397 (1997) (on appeal from the grant of a preliminary injunction, holding non-enablement with respect to claimed method for production of human growth hormone through cleavable fusion expression, and requiring that "[w]here, as here, the claimed invention is the application of an unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching").

185. The *Lilly* court did not hesitate to distinguish earlier written description cases on the ground that they did not involve biotechnological subject matter. *See Lilly*, 119 F.3d at 1568 (distinguishing *Utter v. Hiraga*, 845 F.2d 993 (Fed. Cir. 1988), as involving "machinery of limited scope bearing no relation to the complex biochemical claims before us").

186. *See* BURCHFIEL, *supra* note 135, § 18.5, at 474 (suggesting that "the 'useful arts' of biotechnology are hindered by unique requirements, such as the suggestion that identification of physical structure may be essential for a written description of biotechnological inventions .... ").

volving "predictable factors" such as mechanical or electrical elements.[187] But the Federal Circuit must do more than fall back on the mantra of "unpredictability" or "complexity"[188] as a justification for uniformly restricting the scope of protection available for biotechnological inventions.[189] A real distinction exists between critical *application* of written description and enablement criteria to inventions in the biotechnological arts, and uniquely rigorous treatment of those inventions under *sui generis* legal standards crafted to narrowly constrain the available scope of protection.

The *Lilly* court's per se rule that a claim to a cDNA must be described in terms of its specific nucleotide sequence fails to address fact-specific questions concerning the state of the art and the level of skill among art workers, from whose perspective the written description inquiry must be answered. Though attractive in its certainty, such a bright-line rule surely reduces incentives to invest in innovation by depriving potential patentees of the opportunity to fully benefit from their research. The United States patent system, until now, has always provided more in terms of patent scope than merely those embodiments expressly disclosed by the inventor in her application.[190] The patent law wisely recognizes that limiting the protection provided by a patent to the expressly disclosed embodiments would dramatically reduce the value of the grant by enabling competitors to easily avoid infringement through minor variation.

The *Lilly* decision also frustrates the policy of encouraging prompt filing of patent applications on new inventions, which in turn is thought to result in the more rapid disclosure to the public of new technical information. After *Lilly*, inventors can be expected to delay the filing of gene in-

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187. *See In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).

188. *See Lilly*, 119 F.3d at 1568 (distinguishing *Utter*, 845 F.2d 993, as "involv[ing] machinery of limited scope bearing no relation to the complex biochemical claims before us"). The *Utter* court held that "[a] specification may, within the meaning of 35 U.S.C. § 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." *Utter*, 845 F.2d at 998.

189. *See* Sean Johnston & Leora Ben-Ami, *Unpredictability Factor Narrows Biotech Patents*, NAT'L L.J., June 16, 1997, at C2 (cataloguing "various disparate areas" of biotechnology that the Federal Circuit has considered unpredictable).

190. This previously fundamental tenet of patent law is further called into question by the Federal Circuit's decision in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998). In *Gentry*, the court concluded that a patent claiming a sectional sofa was invalid for failure to comply with the written description requirement. Because the location on a center console of the controls for the recliner portions of the sofa was "essential" to the invention, in the court's view, the patentee was not entitled to claims reciting the controls as located anywhere else. *Gentry* thus represents a significant contraction from the rule that an invention may be claimed more broadly than the specific embodiments disclosed in the specification, particularly in the mechanical arts.

ventions until they have precisely determined the corresponding DNA sequences. They will be faced with a Hobson's choice of accepting a later priority date by delaying filing until written description compliance is certain, or filing sooner and risking invalidation for failure to meet a now-uncertain standard for adequate disclosure. In terms of obtaining broad generic claims, institutional patent applicants benefiting from greater resources for rapidly sequencing additional species of cDNA once a particular gene has been cloned will be at a decided advantage over independent entities or smaller firms without comparable resources.

Users of the patent system are justified in viewing the *Lilly* decision as reflecting an increasingly-widening gulf between the norms of the business and scientific community and those of the United States patent system. Persons skilled in the art of recombinant DNA technology were very likely to have understood that by making the rat insulin cDNA, the UC inventors conceptually possessed the human insulin cDNA (if not all mammalian cDNAs). But under the *Lilly* court's heightened "physical possession" standard for written description compliance, UC was denied any significant reward for its breakthrough contribution. Rather than awarding patent protection to the first to make it possible to clone a particular gene family, the written description standard of *Lilly* requires that the patent right go to the first firm to sequence a number of the genes (or, perhaps, even the first to correctly guess their sequence). The firm with the fastest or most accurate cloning and sequencing team will reap the benefits of an invention made possible by the pioneering research of others. The credibility of the patent system suffers as users come to recognize that it no longer reflects the realities of scientific contribution.

PROTECTING GENETIC DIFFERENCE

By Michael S. Yesley†

On February 20-21, 1998, the Berkeley Technology Law Journal co-sponsored a symposium with the Berkeley Center for Law and Technology entitled Biotechnology and the Law: New Perspectives on Public Access and Proprietary Rights. *The symposium explored the impact of current patent law and policy on biotechnological research, as well as the legal and ethical questions stemming from that research. Mr. Yesley presented this paper during the Information Privacy session, which addressed the social ramifications of lax privacy rules for genetic data and considered whether there should be a property right in this data.*

ABSTRACT

This article surveys current legislation related to genetic privacy and discrimination, including Federal and State laws that prohibit, or could be used to prohibit, genetic discrimination in employment and insurance, and laws that protect genetic privacy. The relationship between protecting genetic privacy and prohibiting genetic discrimination is discussed.

In part II of the article, the author discusses impediments to the creation of effective legislation to combat genetic discrimination. These include: (1) the difficulty of defining "genetic information," given the variety of information with genetic significance; and (2) the limited usefulness of laws narrowly focused on prohibiting genetic discrimination and the possibility of perverse results from such measures.

Finally, the article addresses whether a property right in genetic data is needed to address the issue of genetic privacy. The author concludes that, unlike the case where a person's biological materials are used to develop a commercial product, intangible genetic data probably would not generate sufficient value to warrant the cost of enforcement by those affected. As the author explains, "the goal of protecting genetic information is not to preserve any value of the information, but to control its use and disclosure. For this purpose, requiring informed consent is probably sufficient, and the disincentive of potential recovery for conversion of the property is unnecessary."

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TABLE OF CONTENTS

I. INTRODUCTION

In the world of biotechnology, John Moore (an unwitting donor of cells for medical research) learned to his surprise that you can be valuable if you are different.[1] But in the rest of the universe, being different is not necessarily an advantage—particularly if one's difference is a basis for discrimination. Genetics provides a new lexicon of difference, for better and for worse. We focus here on "worse:" the possibility that genetic difference can be used as a basis for discrimination in employment and insurance.

Anti-discrimination laws protect many kinds of difference—race, sex, national origin, disability, and more.[2] Privacy rules have also been used as a means to protect difference,[3] and privacy ranks high as an end in itself. But privacy may hinder as well as promote anti-discrimination efforts because one's differences must often be revealed in order to protect them. Also, privacy will not protect a difference that is obvious.

Genetics reintroduces privacy as a potential weapon against discrimination, because unexpressed molecular differences are hidden. However, these differences can be identified by direct tests or inferred from a variety of sources, like family history and routine medical tests. Thus, the veil of

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1. Moore's cells were obtained in the course of his treatment for leukemia at UCLA Medical Center and, unbeknownst to him, used to established a cell line that was patented. *See* Moore v. Regents of the University of California, 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

2. *See, e.g.* Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (1964); American with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (1990).

3. For example, some genetic anti-discrimination laws bar insurers from requesting individuals to reveal whether they have been tested or the results of any genetic testing. *See, e.g.*, WIS. STAT. § 631.89 (1996).

molecularity can be pierced in many ways. This raises the question of how best to prevent genetic discrimination. Which approach—property, privacy, civil rights, the free market, public subsidy, or some other—will provide the greatest protection against social misuse of genetic difference?

This article addresses the question of whether the law should recognize a property right in genetic data. There are, of course, more direct ways to prevent the social consequences of losing genetic privacy. We can use privacy measures to control the development and disclosure of genetic information about individuals, or prohibit genetic discrimination, or eliminate economic incentives to discriminate. The last goal, for example, might be accomplished by providing health coverage to those with genetic disorders (or to everyone), or by discovering treatments and preventives that reduce the fateful significance of genetic difference. But until we can prevent as well as predict genetic disorders, we must use legal or economic tools to guard against potential misuse of genetic information. As this article will show, however, the laws on genetic privacy and discrimination, though well-intentioned, are ineffective, impracticable, ambiguous, inflexible, or too narrowly focused on genetics. The article concludes that creating a property interest in genetic information would not significantly increase the protection against misuse of genetic information afforded by informed consent requirements and other measures to protect privacy.

II. CURRENT LAW RELATING TO GENETIC PRIVACY AND DISCRIMINATION

Before considering the recent legislation specific to genetic information, the applicability of general privacy and anti-discrimination law should be noted. An interpretation of the Americans with Disabilities Act[4] (ADA) by the Equal Employment Opportunity Commission (EEOC) may provide limited federal protection against genetic discrimination in employment. The ADA does not specifically mention genetics but clearly covers expressed genetic disorders to the same extent as impairments without a genetic component. Whether the ADA also covers unexpressed genetic predispositions and recessive traits is, however, unclear. The EEOC, which administers the employment provisions of the ADA, has taken the position that the ADA covers a genetic predisposition that is "regarded" as an impairment by an employer,[5] but this position has not yet been upheld judicially. However, the Ninth Circuit Court of Appeals re-

4. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (1990).

5. *See* 2 EEOC COMPLIANCE MANUAL § 902 (1995).

cently found that genetic testing of prospective employees by Lawrence Berkeley Laboratory could violate both the federal and California constitutional rights of privacy if the employees did not authorize the tests and had no reason to know that the tests were part of a general physical examination.[6]

Last year, there was a flurry of state legislation regarding genetic privacy and discrimination. The number of states that prohibit genetic discrimination by health insurers more than doubled, to 23 states.[7] Also, four states prohibited genetic discrimination by employers, bringing the total in this category to 11 states.[8] In all, 13 states adopted laws last year to prohibit genetic discrimination in insurance and/or employment,[9] bringing the total to 28 states[10] that have enacted such laws since 1989. Earlier, several states had prohibited discrimination against carriers of recessive traits, like sickle cell anemia, that could affect only the carriers' offspring,[11] but the recent laws also protect individuals with genetic anomalies that could affect themselves.

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6. *See* Norman-Bloodsaw v. Lawrence Berkeley Lab., 135 F.3d 1260 (9th Cir. 1998) (reversing summary judgment against employees in part because material issues of fact existed as to whether the employees authorized or knew that a government-operated research facility employer was testing them for sensitive medical information).

7. *See* 1997 Ala. Acts 97-721; CAL. HEALTH & SAFETY CODE § 1374.7 (West 1998); CAL. INS. CODE §§ 742.405, 10123.3, 10140 (West 1998); COLO. REV. STAT. ANN. § 10-3-1104.7 (West 1998); 1997 Conn. Pub. Acts 97-95; 1997 Fla. Laws ch. 97-182; GA. CODE ANN. §§ 33-54-1 to 8 (1997); 1997 Haw. Sess. Laws 91; 1997 Ill. Pub. Act 90-25; IND. CODE ANN. § 27-8-26-7 (Michie 1997); 1997 Kan. Sess. Laws 190; 1997 La. Acts 1418; MD. CODE ANN., INS. § 223.1 (1997); MINN. STAT. § 72A.139 (1997); 1997 Nev. Stat. 412; 1997 N.C. Sess. Laws 350; N.H. REV. STAT. ANN. § 141-H:4 (1996); N.J. STAT. ANN. §§ 17:48-6.18, 17:48A-6.11, 17:48E-15.2, 17B:26-3.2, 17B-27-36.2, 26:2J-15.1 (West 1998); OHIO REV. CODE ANN. §§ 1742.42, 3901.49, 3901.50 (Banks-Baldwin 1997); OR. REV. STAT. § 746.135 (1996); 1997 Tenn. Pub. Acts 121; 1997 Tex. Gen. Laws 1215; VA. CODE ANN. § 38.2-508.4 (Michie 1997); WIS. STAT. § 631.89 (1996).

8. *See* 1997 Ariz. Sess. Laws 229; 1997 Ill. Pub. Act 90-25; IOWA CODE ANN. § 729.6 (West 1997); N.H. REV. STAT. ANN. § 141:H-3 (1996); N.J. STAT. ANN. § 10:5-12 (West 1998); 1997 N.C. Sess. Laws 350; N.Y. EXEC. LAW § 296 (McKinney 1993 & Supp. 1997); OR. REV. STAT. §§ 659.036, 659.227 (1996); R.I. GEN. LAWS § 28-6.7-1 (1997); 1997 Tex. Gen. Laws 1215; WIS. STAT. § 111.372 (1996).

9. Specifically, Alabama, Arizona, Connecticut, Florida, Hawaii, Illinois, Indiana, Kansas, Louisiana, Nevada, North Carolina, Tennessee, and Texas prohibited genetic discrimination last year.

10. In addition to the 13 states listed *supra* note 9, California, Colorado, Georgia, Iowa, Maryland, Minnesota, Montana, New Hampshire, New Jersey, New York, Ohio, Oregon, Rhode Island, Virginia, and Wisconsin have prohibited genetic discrimination.

11. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 1374.7 (1993).

Nearly all the laws on genetic discrimination incorporate measures to protect genetic privacy. Also, four states have declared that genetic information is the property of the individual to whom the information pertains.[12] In New Jersey, however, the legislature adopted genetic antidiscrimination legislation in 1996 only after a declaration that genetic information is the property of the individual was deleted at the insistence of the governor. That action was prompted by a complaint from a biotechnological industry organization that characterizing "genetic information as property could create 'conflicts over ownership rights [that] will slow research and development efforts and likely [foment] unnecessary litigation.'"[13]

Most states have also adopted portability and access laws that limit preexisting condition exclusions and bar discrimination based on genetic information or, more broadly, health status in determining eligibility to enroll in group health insurance plans.[14] Following the terms of the federal Health Insurance Portability and Accountability Act of 1996,[15] the states adopted these laws in 1997 in order to preserve their jurisdiction over insurers.[16] The portability and access laws add little protection against discrimination, genetic or otherwise, because they apply to plans that do not look at individual employees' records but determine their eligibility for health coverage solely on the basis of their employment.[17]

One way to protect genetic privacy is to increase the protection of medical privacy generally, including genetic data. Unfortunately, medical privacy is a myth today. Our medical records are not well protected in hospitals, doctors' offices, employers' records, or pharmacies. Computerization has exposed medical records to a variety of worthy and not-so-

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12. *See, e.g.*, COLO. REV. STAT. ANN. § 10-3-1104.7(1)(a) (West 1998); GA. CODE ANN. § 33-54-1(1) (1997); 1997 La. Acts 1418; OR. REV. STAT. § 659.715(1) (1996) (as amended by 1997 Or. Laws 780).

13. Philip R. Reilly, *Governer Not Expected to Sign New Jersey Genetic Privacy Act*, (visited Sept. 1, 1996) <http://www.geneletter.org/0996/governor.htm>.

14. *See, e.g.*, 1997 Ark. Acts 997.

15. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat 1936 (1996).

16. The U.S. Department of Health and Human Services is responsible for enforcing Health Insurance Portability and Accountability Act provisions in states that do not pass and enforce laws imposing similar protections. U.S. General Accounting Office, Health Insurance Standards: New Federal Law Creates Challenges for Consumers, Insurers, Regulators, GAO/HEHS-98-67 (1998) at 5 (available at <http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPaddress=wais.access.gpo.gov&filename=he98067.txt&directory=/diskb/wais/data/gao>).

17. *See generally* Health Insurance Portability and Accountability Act of 1996, *supra* note 16.

worthy enterprises. Federal protection of medical records is coming, by law and/or regulation,[18] and it will surely increase genetic privacy. The advantages of protecting genetic privacy as a subset of medical privacy include avoiding the problems of (1) defining what information is genetic and (2) justifying special protection for genetic information (we shall return to these issues). However, even enhanced medical privacy rules will not protect genetic information in non-medical contexts, such as genetic research unrelated to medical care or testing conducted by employers and insurers.

Therefore, many have argued for a special embargo on disclosure of genetic information, like the protection afforded movie rental records.[19] In fact, as noted above, about half the states have laws of various sorts to protect genetic privacy. These measures include prohibitions on requiring a genetic test or disclosure of previous test results as a condition of employment[20] or insurance,[21] prohibitions on genetic testing or disclosure of genetic information without informed consent,[22] and statutory declarations that genetic information is confidential.[23] Provisions like these can provide some assurance of genetic privacy. Not all genetic privacy measures will guard against genetic discrimination, however. Merely requiring informed consent for genetic testing will not prevent an employer or insurer from insisting on testing as a condition of employment or insurance. An applicant can refuse testing but only at the cost of not becoming employed or insured. Unless testing itself or the use of test results is prohibited, the privacy protection is of limited value.

For example, New York requires all insurers to obtain informed consent for genetic testing but does not prohibit use of the test results for underwriting.[24] Several states require life insurers to obtain informed consent for genetic testing,[25] but no state bars life insurers from discriminating

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18. The present Congress is considering several comprehensive health privacy bills. Also, the "administrative simplification" provisions of the Health Insurance Portability and Accountability Act of 1996 require the Department of Health and Human Services to adopt uniform national standards, including measures to protect confidentiality, for the electronic processing of insurance claims.

19. *See* 18 U.S.C.A. § 2710 (1996) (consumer privacy protection law providing a remedy for wrongful disclosure of video tape rental or sale records).

20. *See, e.g.*, IOWA CODE ANN. § 729.6(2)(a) (West 1997).

21. *See, e.g.*, WIS. STAT. § 631.89(2) (1996).

22. *See, e.g.*, CAL. CIV. CODE § 56.17 (West 1998); N.J. STAT. ANN. § 10:5-45 (West 1998).

23. *See, e.g.*, N.Y. CIV. RIGHTS LAW § 79-1.3 (McKinney Supp. 1997).

24. *See* N.Y. INS. LAW § 2612 (McKinney Supp. 1997).

25. *See, e.g.*, MINN. STAT. § 72A.139(5) (1997).

on the basis of genetic information about an individual, provided the differential treatment is actuarially supported.[26] Thus, life insurers may not conduct genetic testing without informed consent, but they may deny insurance to an applicant who refuses to be tested or who is tested and found to have a genetic anomaly that reduces life expectancy.

Finally, prohibiting genetic discrimination does not have to incorporate privacy laws. A few states that bar genetic discrimination do not have any provisions to guard the privacy of genetic information.[27] New York bars employers from discriminating on the basis of genetic information, but permits them to require genetic testing, as a condition of employment, for a genetic anomaly that indicates "increased risk of disease as a result of working in [the occupational] environment."[28] Employers may deny employment for refusal to be tested, but not on the basis of the test results. The decision whether to work in the risky occupational environment is left to the individual. Thus, New York permits employers to invade genetic privacy but not to discriminate on the basis of genetic information.

III. DIFFICULTIES IN CREATING EFFECTIVE GENETIC ANTI-DISCRIMINATION LEGISLATION

A. Defining Genetic Information

Legislative efforts concerning genetic privacy and discrimination are complicated by the difficulty of determining what constitutes "genetic information." Information with genetic significance includes not only the results of tests for genetic material but also many non-genetic medical tests and family medical history. The plethora of genetically significant data makes it difficult, if not impossible, to distinguish what information should be protected by genetic privacy and discrimination laws.

All statutory definitions of "genetic information," "genetic testing," or similar terms cover testing, or the results of testing, for genetic material. Beyond this basic category, the definitions vary substantially. Several states broaden the definition to include inherited characteristics "derived" from a family member.[29] This phrase is apparently intended to extend

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26. *See, e.g.*, CAL. INS. CODE § 10148(e) (West 1998); ARIZ. REV. STAT. ANN. § 20-448E (West 1997).

27. *See, e.g.*, 1997 N.C. Sess. Laws 350.

28. N.Y. EXEC. LAW § 296(19)(b) (McKinney 1993 & Supp. 1997).

29. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 1374.7(d) (West 1998); CAL. INS. CODE § 10123.3(d) (West 1998) (covering genetic discrimination in health insurance, but see the narrower definition of "genetic characteristic" in California Insurance Code section 10147(b) for purposes of barring unfair (which is defined as not actuarially sup-

protection to genetically significant aspects of family medical history. On the other hand, two states specifically exclude family medical history,[30] and several states exclude routine tests such as blood and urine analysis done in the course of a physical examination, unless the tests were conducted specifically to identify a genetic anomaly.[31] Some states specify "direct measures" of genetic alterations and exclude "indirect manifestations" of such alterations.[32] About half the definitions include tests for gene products.[33] A few states use different definitions in different contexts (for example, in the context of a prohibition on genetic discrimination in employment versus health insurance).[34]

Illustrating further the variety of possible definitions, the Maryland legislature considered a definition of "genetic test" that included gene products and inherited characteristics, but finally adopted a narrow definition limited to a "laboratory test of human chromosomes or DNA."[35] New Hampshire excludes a test "undertaken for the purpose of determining whether an individual meets reasonable functional standards for a specific

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ported) genetic discrimination in life and disability insurance); 1997 Conn. Pub. Acts 95; 1997 Haw. Sess. Laws 91; N.J. REV. STAT. § 10:5-5(oo) (1997) (covering genetic discrimination in employment, but see the narrower definition of "genetic characteristic" in New Jersey Revised Statutes sections 17:48-6.18, 17:48A-6.11, 17:48E-15.2, 17B:26-3.2, 17B-27-36.2, and 26:2J-15.1 for the purposes of barring genetic discrimination in health coverage); 1997 N.C. Sess. Laws 350; VA. CODE ANN. § 38.2-508.4(A) (Michie 1997).

30. *See* 1997 Fla. Laws ch. 182; 1997 Tenn. Pub. Acts 121.

31. *See* 1997 Fla. Laws ch. 182; GA. CODE ANN. § 33-54-2(1) (1997); 1997 Ill. Pub. Act 90-25; MINN. STAT. § 72A.139, subd. (2)(b) (1997); N.Y. CIV. RIGHTS LAW § 79-1.1(a) (McKinney Supp. 1997); 1997 Tenn. Pub. Acts 121; 1997 Tex. Gen. Laws 1215.

32. COLO. REV. STAT. ANN. § 10-3-1104.7(2)(b) (West 1998); IND. CODE ANN. § 27-8-26-7 (Michie 1997); 1997 Kan. Sess. Laws 190; OHIO REV. CODE ANN. §§ 1742.42(A), 3901.49(A)(1), 3901.50(A)(1) (Banks-Baldwin 1997).

33. *See* 1997 Ariz. Sess. Laws 229; 1997 Conn. Pub. Acts 97-95; 1997 Haw. Sess. Laws 91; 1997 Ill. Pub. Act 90-25; IOWA CODE ANN. § 729.6.1.c (West 1997); 1997 La. Acts 1418; MINN. STAT. § 72A.139, subd. (2)(b) (1997); N.J. REV. STAT. 10:5-5.oo (1997) (covering genetic discrimination in employment, but the definitions used in the prohibitions of genetic discrimination in health coverage under New Jersey Revised Statutes sections 17:48-6.18, 17:48A-6.11, 17:48E-15.2, 17B:26-3.2, 17B-27-36.2, 26:2J-15.1 do not include gene products); N.Y. CIV. RIGHTS LAW § 79-1.1(a) (McKinney Supp. 1997); 1997 N.C. Sess. Laws 350; R.I. GEN. LAWS § 28-6.7-2 (1997); VA. CODE ANN. § 38.2-508.4(A) (Michie 1997); WIS. STAT. §§ 111.32, 942.07 (1996) (covering genetic discrimination in employment, but the definitions used in the prohibitions of genetic discrimination in health coverage under Wisconsin Statutes section 631.89 do not include gene products).

34. California, New Jersey, and Wisconsin use different definitions in different contexts. *See supra* notes 29 & 33.

35. MD. CODE ANN. INS. § 223.1 (1997).

job."[36] Louisiana includes "all information about genes, gene products, inherited characteristics, or family history/pedigree that is expressed in common language."[37] It is not clear what the Louisiana legislation intended by the last clause—perhaps a comment on scientific expression.

This variety of definitions reflects the difficulty of determining what information should be protected. In a forthcoming article, Joseph S. Alper and Jon Beckwith note that most clinical tests detect abnormal concentrations of biochemical entities, which can provide information about the genes that code for those entities, as well as the functioning of various organs.[38] Thus, practically every clinical test may be considered a test for gene products. The determination whether a test is genetic may depend on the context or purpose of the test: for example, whether cholesterol is tested in an individual with a family history of hypercholesterolemia or as part of a routine physical.[39] A National Institute of Health task force on genetics and health insurance has noted that the categorization of health risk information as genetic or nongenetic is becoming increasingly difficult, and most contents of medical records will soon have genetic significance.[40]

Laws that limit the definition of genetic information to the results of direct tests for gene alterations are easier to implement but may not provide sufficiently broad protection. Employers and insurers in states where such laws are in effect know they cannot use the narrowly defined genetic tests to discriminate. But the laws do not prevent them from substituting indirect tests or family history to obtain information about genetic predisposition (albeit with less precision), and using such information as a basis for discrimination. The scope of protection against genetic discrimination is significantly expanded in the states with definitions that include gene products and family medical history as well as direct genetic test results. Such broad definitions may, however, be impractical to implement; George Annas, Leonard Glanz and Patricia Roche, for example, used a narrow definition of "private genetic information" for their model Genetic

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36. N.H. REV. STAT. ANN. § 141:H-1.IV (1996).

37. 1997 La. Acts 1418 (relevant section codified at LA. REV. STAT. ANN. § 213.7(A)(8) (West 1998)).

38. Joseph S. Alper & Jon Beckwith, *Distinguishing Genetic from Nongenetic Medical Tests: Some Implications for Antidiscrimination Legislation*, SCIENCE AND ENGINEERING ETHICS (forthcoming 1998).

39. *See id.*

40. NIH-DOE WORKING GROUP ON ETHICAL, LEGAL AND SOCIAL IMPLICATIONS OF HUMAN GENOME RESEARCH, GENETIC INFORMATION AND HEALTH INSURANCE: REPORT OF THE TASK FORCE ON GENETIC INFORMATION AND INSURANCE (1993) (available at <http://www.nhgri.nih.gov/About_NHGRI/Der/Elsi/itf.html>).

Privacy Act, arguing that a broader definition would "necessitate the overhaul of well established medical information practices and policies."[41]

B. The Meaning of Genetic Discrimination

It is important to note that whether genetic information is defined narrowly or broadly in the laws barring genetic discrimination, the term generally does not include information about expressed, or existing, genetic disorders. The quintessential feature of genetic discrimination is the use of genetic information about an asymptomatic person. If the disorder related to a genetic characteristic has occurred, discrimination based on the disorder may be unfair but is not customarily considered "genetic discrimination."

Some state laws specifically limit protection to asymptomatic individuals. For example, New York's law barring genetic discrimination in employment protects carriers of recessive traits and persons who have a genetic predisposition "associated with an increased statistical risk of being expressed as a physical or mental disease or disability in the individual *but which has not resulted in any symptoms of such disease or disorder.*"[42] The effect is the same if a law merely prohibits discrimination based on genetic information: an individual with a genetic disorder is protected from discriminatory use of genetic test results, but not from discrimination based on the presence of the disorder itself. Other laws, not specific to genetic discrimination, but instead protective of all persons with disabilities, may prohibit discrimination based on an existing genetic disorder. The laws that focus specifically on genetic discrimination are intended to protect only asymptomatic individuals.

1. Utility of Genetic Discrimination Laws

This conception of genetic discrimination raises a question: why should special protection be provided to asymptomatic individuals who possess a gene associated with a disease? In the case of health insurance, why not protect all persons with indications of future illness, whether or not the indications are genetic, and persons whose need for health coverage is greatest—those who are sick? Unfortunately, universal health coverage is not yet politically feasible in this country, and we appear able to work toward it only incrementally. Indeed, the laws barring genetic discrimination in health insurance are a very slight increment, since they

41. George J. Annas, et al., *The Genetic Privacy Act and Commentary*, Boston: Health Law Department, Boston University School of Public Health (1995), at 48.

42. N.Y. EXEC. LAW § 292, subd. 21-B (McKinney 1993 & Supp. 1997) (emphasis added).

protect only the few persons who purchase individual health coverage. For the great majority of individuals, who are insured by employers or government plans, there is no individual underwriting and little threat of genetic discrimination in health insurance.[43]

The laws barring genetic discrimination in health insurance do not respond to a substantial problem but to a perceived threat of loss of insurance that might hinder genetic researchers' search for human subjects. Removing the basis for this fear of insurance loss may seem a reasonable step, but the possible cost of laws barring genetic discrimination in health insurance should also be weighed. Although the piecemeal approach of barring genetic discrimination may help a few people, it also removes a compelling argument for the ultimate goal of universal health coverage, which would benefit far more people.

2. *Perverse Effects of Genetic Discrimination Laws*

In the case of employment, absolute prohibitions of genetic discrimination ignore the possibility that under certain circumstances, such discrimination might be appropriate to protect the safety of workers or the public. A genetic anomaly might predict a disease that could endanger the public when it first manifests itself too quickly or subtly to detect in advance, or it might indicate a susceptibility to an occupational exposure.

In the first situation, genetic discrimination should be the last resort. If routine physical examinations can detect manifestations of the disease before the public is endangered, there is no need for early exclusion from employment. However, if detection is not possible and the likelihood of harm to the public is significant, the genetic anomaly may be an appropriate disqualification for the position.

Discrimination should also be the last resort in the case of genetic susceptibility to an occupational exposure. The first effort should be to remove the exposure and make the workplace safe for everyone. But if that step is impossible, and the likely result of exposure is a serious, untreatable illness, exclusion of susceptible individuals may be justified. However, the laws barring genetic discrimination in employment generally do not permit any exceptions.

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43. *See* Michael S. Yesley, *Genetic Privacy, Discrimination and Social Policy: Challenges and Dilemmas*, 2(1) MICROBIAL & COMPARATIVE GENOMICS, 19, 26-27 (1997).

IV. SHOULD THE LAW RECOGNIZE PROPERTY RIGHTS IN GENETIC DATA ABOUT INDIVIDUALS?

We return to the question posed at the outset—should the law recognize a property right in genetic data about individuals? A few states have already taken this step,[44] but its ramifications are uncertain. In opposing such legislation, the biotechnology industry is probably concerned that ownership of genetic data might permit the result that eluded John Moore: recovery of the value of the property (cells from his body) that was used without his permission. The California Supreme Court found Moore had a cause of action for the performance of medical procedures without informed consent, because his doctor did not disclose that he was using Moore's cells in research.[45] But the court denied Moore's "novel claim to own the biological materials" and accordingly refused to impose liability for conversion of the cells.[46] In dissent, Justice Mosk noted that if Moore were found to have an ownership interest in the cells, his share in the profit from commercial exploitation of his cells might be substantial, but the remedy allowed by the court for lack of informed consent was "largely illusory."[47] Thus, the penalty for failure to obtain Moore's permission to use his cells in research would have been greater if the court had recognized an ownership interest in the cells.

The value of intangible genetic data about an individual is probably not comparable to the value of an individual's cells from which a commercial product is derived. A class of individuals might have an aggregate claim of significant value for conversion of their data used in product development, if the data were their property and had been used without permission, but this possibility is somewhat remote. Thus, the goal of protecting genetic information is not to preserve any value of the information, but to control its use and disclosure. For this purpose, requiring informed consent is probably sufficient, and the disincentive of potential recovery for conversion of property is unnecessary. Virtually the same informed consent will authorize use of genetic information, whether or not it is considered property. That consent will be granted or withheld on the basis of the individual's attitude toward the use and disclosure of the information, not the amount or lack of remuneration.

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44. *See supra* note 12.

45. *See* Moore v. Regents of the University of California, 793 P.2d. 479, 486 (Cal. 1990), *cert. denied,* 499 U.S. 936 (1991).

46. *See id.* at 487-97.

47. *See id.* at 519 (Mosk, J. dissenting).

V. CONCLUSION

A property right might buttress the obligation of those conducting genetic testing to obtain informed consent, but that obligation has already become entrenched. The growing number of statutes requiring informed consent for the development or disclosure of genetic information, the *Moore* court's reading of the common law requirement of informed consent, and, most recently, the Ninth Circuit's application of constitutional privacy protection to genetic testing make it imperative to obtain an individual's authorization of any genetic testing and use of identified test results. Overlaying an ownership interest would not add to this protection but might create uncertainty about the use of previously collected data, similar to issues surrounding the use of stored tissue samples.

MAINTAINING INCENTIVES FOR BIOPROSPECTING: THE OCCASIONAL NEED FOR A RIGHT TO LIE

By Robert Heidt †

ABSTRACT

Building on a model by Anthony Kronman, the author argues that biotechnological researchers searching for valuable cells should occasionally be allowed to deceive research subjects whose cells prove valuable. The wish to preserve proper incentives for these searches justifies this exception to the law's usual abhorrence of deception. The subject's ability to "hold up" the researcher once the subject learns of his cells' value combined with the law's likely refusal to force an unwilling subject to continue his cooperation with the researcher poses risks for biotechnologists that other producers of information do not face and that the right to deceive helps to alleviate. The author explains the variables that limit the proposed right to deceive, examines arguments against the proposed rule, and describes the current law.

Bioprospecting, the search for valuable cells, also presents three related issues on which the author comments. One issue is whether the subject's assignment of all his rights in his cell samples to the researcher should be enforced ex post when the cells prove valuable. A second issue is whether, in the absence of a clear assignment of rights to the cell samples, the subject or patient should possess a claim against the researcher to a share of revenues derived from those cell samples. A third issue is whether a patient whose samples are used for research or commercial purposes without his express consent should possess some dignitary claim against the researcher regardless of whether the samples have proven valuable. On each issue, the author supports an approach that favors the biotechnological researcher.

TABLE OF CONTENTS

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I. INTRODUCTION

Consider this story:

> A biotechnology[1] company (researcher) searches for individuals with rare cells that will assist it[2] in developing valuable drugs. The search is risky and costly for the researcher. It must collect (typically through drawing a sample of blood) and examine the cells of a great number of research subjects before discovering cells of value. In addition, the researcher must train its employees where to search, send them to remote areas to collect samples, compensate the subjects, and test the samples.
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> Before collecting a subject's cells, the researcher routinely informs the subject of the risks of the collection procedure and obtains the subject's consent to use the cells for research and commercial purposes.[3] Although the subject's motivation is

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1. Biotechnology refers to any technique to modify the products of living organisms. Examples include hybridoma and recombinant DNA technology. Hybridoma technology entails the fusion of two types of cells, an antibody-producing B lymphocyte and a certain tumor cell line (*i.e.,* a myeloma). *See* U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS - SPECIAL REPORT, OTA-BA-337, 31-58 (1987) [hereinafter OTA REPORT]. The resulting immortal hybrid cells, called hybridomas, secrete large amounts of monoclonal antibodies and lymphokines. Because of their exquisite specificity and reduced toxicity, these molecules may help in the treatment of a spectrum of diseases. Recombinant DNA technology (also known as genetic engineering) entails the insertion of genes into microorganisms (typically bacteria) that will express a desired protein which can then be purified. *Id.*

2. Throughout this article, in order to clarify the party being discussed, the researcher is referred to by the impersonal pronoun and the subject by the personal pronoun.

3. For the sake of brevity, the subject's "consent" refers both to the subject's consent that his samples be used for the research and commercial purposes of the researcher, and to the subject's assignment of all his interests in the cell lines and end products developed from his samples to the researcher.

With research governed by the guidelines of the Protection of Human Subjects issued by the Department of Health and Human Services, subjects may not be able to waive their interests in their cells because of the existing ban on the use of exculpatory language in consent agreements. *See* 45 C.F.R. § 46.116 (1998). Because the purpose of

largely altruistic, and the arrangement largely donative, the researcher compensates the subject modestly. For example, the researcher pays the subject's expenses of allowing the collection or performs medical tests of therapeutic value.

After much searching, the researcher finds valuable cells in a subject from an Indian tribe who lives in a remote corner of Alaska.[4] The cell line developed from these cells helps the researcher develop a drug that assists in the treatment of one type of cancer.[5] The value of this successful search to society should be apparent—the few cells needed for the research are infinitely more valuable in the researcher's hands than in the subject's.[6] The discovery of the cells' value effectively increases the world's wealth.

If the researcher successfully maintains an immortal cell line, it would not need any further contact with the subject. It would proceed apace with its use of the cell line without identifying or involving the subject in any way. In particular, it would refrain from alerting the subject that his cells are valuable. Barring accident, the subject would never learn that his cells proved valuable.

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that ban was to preserve a subject's right to sue should he be injured during the research, this impairment of the subject's ability to aid research by clarifying the researcher's rights seems unfortunate. *See Hearings: The Use of Human Biological Materials in the Development of Biomedical Products* 233 (October 29, 1985) (statement of Dr. Charles R. McCarthy, Director, Office for Protection From Research Risks, National Institute of Health).

4. Individuals with valuable cells are found disproportionately among members of isolated groups. *See* OTA REPORT, *supra* note 1, at 54-56. Examples of such groups include the Guyami tribe of northwest Panama (cells useful in retarding the progress of AIDS), the Hugahai tribe in Papua New Guinea (cells useful in combating leukemia) and a remote community in the Sudan (cells useful in avoiding heart disease). *See* Philip L. Bereano, *Patent Pending: The Race to Own DNA—Guaymi Tribe Was Surprised to Discover They Were Invented*, THE SEATTLE TIMES, Aug. 27, 1995, at B5; *Patent Blather: Biotechnology*, THE ECONOMIST, Nov. 25, 1995, at 87; Linda Marsa, *Whose Ideas Are They Anyway: Intellectual Property in the Information Age*, OMNI, Dec. 22, 1995, at 36.

5. Examples of successful end products of biotechnology include: EPO, which prevents anemia during kidney dialysis; Neupogen, which decreases the risk of infection during chemotherapy; and Acromegaly, which aids growth. *See generally* Sandra Cuttler, *The Food & Drug Administration Regulation of Genetically Engineered Human Drugs*, 1 J. PHARMACY & L. 191 (1992).

6. "[B]iological materials involved [in commercial biotechnology] are almost always replenishable and often constitute waste materials, at least from the point of view of the donor." Arthur L. Caplan, *Blood, Sweat, Tears and Profits: The Ethics of the Sale and Use of Patient Derived Materials in Biomedicine*, 33 CLINICAL RESEARCH 448, 450 (1985).

> Unfortunately for the researcher, it is not able to maintain the cell line it has created, and therefore it needs to return to the subject for a further collection.[7] However, when requested to participate on the same terms as before, the subject immediately asks whether the researcher has any reason to believe that his cells are valuable.

How should the law allow the returning researcher to respond? Must it tell the subject the truth—that his cells are valuable? Should the researcher be allowed to lie—by saying there is no more reason to believe the subject's cells are valuable than there was at the time of the first collection?

This article argues for the researcher's right to lie in this situation. Of the reasons supporting the right to lie, the most powerful stem from the subject's ability to hold up the researcher once he suspects his cells are valuable and from the resulting destruction of the researcher's incentive to search.

Not surprisingly, the law, both common and statutory, virtually never tolerates lying. To induce another to promise or to perform based on a deliberate lie about a material matter is to commit fraud.[8] Agreements based on fraud are void,[9] and the fraud may trigger liability in tort,[10] as well as in contract.[11] Considerations from moral to economic call for this hostility to lying, a hostility that appears in many contexts and powers an elaborate variety of legal rules.[12] Without challenging any of these rules,

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7. The probability of maintaining a cell line from a given sample is low. Even with strict adherence to nutrient and temperature requirements, established cell lines can not always be maintained. Contamination and damage during storage is the most common culprit. Interview with Dr. Derrick Stempel of Massachusetts General Hospital (Oct. 3, 1996).

One simplifying assumption throughout this article is that the researcher, perhaps because of its failure to maintain the cell line, is unable to obtain any patent.

8. *See* Ahern v. Scholz, 85 F.3d 774, 792-94 (1st Cir. 1996); *see also* Haberman v. Greenspan, 368 N.Y.S.2d 717, 720 (1975); RESTATEMENT (SECOND) OF CONTRACTS § 162 (1979).

9. *See* Procter & Gamble Co. v. Bankers Trust Company, 925 F. Supp. 1270, 1289 (D. Ohio 1996).

10. *See* RESTATEMENT (SECOND) OF TORTS § 525 (1974); *see also* WILLIAM PROSSER, LAW OF TORTS §§ 105-06 (6th ed. 1994).

11. *See supra* note 8.

12. *See, e.g.*, Shannon v. Russell, 203 B.R. 303, 311-12 (Bankr. S.D. Cal 1996) (reiterating the doctrines of fraud and misrepresentation in a non-dischargeability action); Kahn v. Flood, 550 F.2d 784 (2d Cir. 1977) (perjury invalidates evidence obtained with a search warrant); IND. CODE § 6-3-11 (1997) (criminal liability for submitting false state-

and without suggesting that the researcher should refrain from seeking alternative arrangements that would avoid the need to lie, this article contends that in carefully limited situations, of which the returning researcher's is one, the law's usual hostility toward lying is inefficient and misplaced.

II. THE HOLD-UP PROBLEMS

The subject's direct question about whether the researcher has reason to believe his cells are valuable puts the researcher in a dilemma that impacts the biotechnology industry and all future beneficiaries of this research.[13] If the law requires an answer that leads the subject to suspect the truth, the subject, however altruistic, will be tempted to act against the researcher's interests. Conceivably, the subject could arrange to have himself tested,[14] and having learned the value of his cells, could approach rival biotechnology companies, satisfy them as to the value of his cells, and allow collection of his cells only by the highest bidder. In effect, the subject can hold up the researcher by demanding, "Pay me the full value of my cells or I won't allow you another collection." In this scenario, the subject pockets all rents from the scarcity of his cells, the highest bidding researcher earns the normal competitive profit on the development of the

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ments on tax returns); NEW YORK PENAL LAW § 210.00 (McKinney 1997) (felony to commit perjury during testimony before a court).

One reason fraud is undesirable is because it increases the amount of misinformation in the market and therefore reduces the market's ability to allocate resources efficiently. *See* Michael R. Darby & Edi Karni, *Free Competition and the Optimal Amount of Fraud*, 16 J.L. & ECON. 67 (1973).

13. I do not claim that the dilemma faced by the returning researcher in the story presented rises to the level of a pressing social problem. The stylized story primarily provides a convenient context for applying economic principles. Nevertheless, the Office of Technology has found that uncertainty about how courts will resolve various claims by subjects against researchers who have profited from the subject's cells presents the single greatest obstacle to continuing developments in biotechnology. *See* OTA REPORT, *supra* note 1, at 58. Moreover, previous discussion of the subject's claims has largely ignored the need to preserve the researcher's incentive to search. *See, e.g.*, Roy Hardiman, Comment, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207 (1986); Richard Delgado & Helen Leskovac, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67 (1986).

14. This discussion assumes the suspicious subject can find some way to assess the value of his samples while still retaining his control over the use of the samples for research and commercial purposes. For this assumption to be true, some laboratory, testing service, or research institution must be able to assess the cells' value in return for compensation and must also be willing to refrain from using the cells itself.

end products, and the researcher that discovered the valuable cells is cut out completely. Its risky and costly search goes wholly unrewarded.[15]

The subject's suspicion of his cells' value allows a second holdup as well. Even after the subject provides the returning researcher with a further collection (indeed even when no further collection is necessary), the suspicious source can demand, "Pay me or I will alert your rivals to the value of my cells and deal with them."[16]

The possibility of these holdups presents added risks to a researcher contemplating whether to undertake a search. By undermining the incentive to search, the subject's suspicion drives a wedge between the private and social costs of searching.[17] The amount of private investment in searching diverges more widely from its social product. At considerable loss to society, the amount of searching falls below the optimum.

The hold-up problem can be stated in various ways. One can state the issue as whether to recognize in the researcher a property right in the information it has discovered, namely, that valuable cells exist in this individual. So viewed, the holdup presents the information externality problem that is part of the standard argument for both patents and property rights.[18]

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15. The subject's hold-up problem would not destroy the incentive to search if that search gave the researcher a decisive head start in developing and marketing the end products over the rival companies with which the knowledgeable subject might eventually decide to deal. Just as the need for patent protection is most acute when research is difficult but imitation easy, the need for the right to lie is most acute when the search for valuable cells is difficult but the development of the end products from those cells relatively easy.

16. The subject's threat must be taken seriously even when the researcher has a patent on the cell line derived from the subject's cells. This is because of the severe practical problems of enforcing the patent once an infringer has obtained access to the cell line. *See* Alan J. Lemin, *Patenting Microorganisms: Threats to Openness*, *in* OWNING SCIENTIFIC AND TECHNICAL INFORMATION 196 (Vivian Weil & John Snapper eds., 1989).

17. Of course, society would not want the researcher to search when the expected costs of searching (primarily the costs to the researcher and to the subjects) exceed the expected social value of the search—the latter being the social value of a successful search discounted by the chance the search will not succeed. But as long as the costs of searching are internalized on the searcher, society can rely on the searcher's self-interest to assure that searches which are not cost-justified are not undertaken. The need for the searcher to compensate the subject for his voluntary participation, or to induce that voluntary participation some other way, internalizes the subject's costs of allowing the search unto the searcher. In short, the danger here is not too many searches but too few.

18. Like patents the proposed right to lie subjects the key information, here that this subject's cells are valuable, to the researcher's exclusive control. Assuming the demand curve for the information is negatively sloped, exclusive control imposes some allocative or dead weight loss. Here, for instance, the information once discovered would be most

Alternatively, one can say the hold-up problem arises because the information produced by the researcher—that these valuable cells exist in this individual—is not self-appropriating. Just as a firm that has prepared a competitive bid can lose the value of its preparatory effort if the bid is communicated to a rival who bids one dollar less, the researcher can lose the value of its search once the subject suspects the truth.

One can also state the problem by characterizing the subject whose suspicions are aroused as a free rider on the search efforts of the researcher. The subject's participation in the search was compensated adequately, in the subject's own eyes, by the nominal compensation he received. In contrast, the researcher relies for its compensation on the return from finding valuable cells. By asking his question, the subject can, in effect, exploit the law's condemnation of lying to appropriate that return for himself.[19] Asking, in combination with the law's condemnation of lying, becomes the mechanism for this appropriation. Yet asking, although potentially ruinous to the researcher,[20] is virtually cost-free to the subject. While the windfall to the subject is not a concern, the harm to society from the suppression of the researcher's search is.

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efficiently used if it was distributed to all biotechnology companies, the marginal benefits of distribution clearly exceeding the marginal costs. The dead weight loss primarily consists of the foregone gain from more widespread use of this information. *See* Frank Easterbrook, *Insider Trading, Secret Agents, Evidentiary Privilege and the Production of Information,* 1981 SUP. CT. REV. 309, 313. The case for patents and property rights hinges on the assumption that the gains to society from improved incentives exceed this short-term allocative loss which all quasi-rents create. *But see* Edmund W. Kitch, *The Nature and Function of the Patent System,* 20 J.L. & ECON. 265, 275-80 (1977) (calling for patent protection whenever the information sought is valuable and costly to acquire). Here the social gain from more widespread use of the information seems modest in part because the searching researcher's exclusive possession of the information gives it a powerful incentive to exploit that information vigorously by developing and marketing the end product itself or by transferring the information to some company who can.

19. The National Organ Transfer Act [hereinafter NOTA], 42 U.S.C. § 274(e) (1988), and its state complements, which condemn the sale of body parts, might seem to condemn the subject who attempted the holdup as well. But even if the transaction for the right to collect cells was deemed a sale of the subject's cells, NOTA would not apply. The Act expressly exempts the sale of replenishable tissues such as blood or sperm. In addition, NOTA may only forbid sales for transplantation, rather than research, purposes.

20. If the appropriation fails because the researcher denies reason to believe the cells valuable, the subject by asking will at least set up the researcher for a later suit should the cells prove valuable. Given that asking is costless to the subject, that should be reason enough to ask.

However stated, the problem is familiar. Kronman's famous article pointed out that the law could incent[21] the production of socially valuable information by allowing the producer of the information to trade on it without disclosing it to the other trading parties.[22] When producing socially valuable information is costly, society's wish to incent its production may trump society's usual wish to avoid mistakes by the contracting parties. The wish to avoid mistakes calls for compelling disclosure from the party who can avoid the mistake most cheaply. Invariably, the cheaper mistake-avoider is the party—here the researcher—which already possesses information about which it knows the other party is mistaken—here the true value of the subject's cells—and which can avoid the other party's mistake merely by disclosure. Tolerating nondisclosure by the cheaper mistake-avoider thus becomes the law's mechanism for establishing its property right in the information it produced.

The wish to incent the production of information explains those relatively rare occasions where contracts are enforced despite one party's deliberate failure to disclose material information about which it knows the other party is mistaken. Kronman's prime example was *Laidlaw v. Organ*.[23] There a buyer learned that the British blockade of New Orleans would soon be lifted, and thus that the price of tobacco would soon rise. Using this knowledge, the buyer bought tobacco at the relatively cheap price prevailing before this news became widespread.[24] When the seller refused to deliver at that low price, the buyer sued and prevailed.[25] A still more familiar example where courts do not require disclosure is suggested

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21. The verb, "to incent," while not formally established grammar, enjoys an increasingly accepted status in various industries. The author uses it here because he feels that it most accurately captures the concept he intends to convey. *Eds.*

22. *See* Anthony T. Kronman, *Mistake, Disclosure and the Law of Contracts*, 7 J. LEGAL STUD. 1 (1978); *see also* Victor Brudney, *Insiders, Outsiders and Informational Advantages under the Federal Securities Laws*, 93 HARV. L. REV. 322, 339-43, 371-76 (1979).

23. 15 U.S. (2 Wheat.) 178 (1817).

24. *Id.* at 186.

25. *Id.* Kronman was offering an explanation for why courts did not require disclosure in some mistake cases. *See* Kronman, *supra* note 22. However the modern trend is to require disclosure in all such cases. *See* RESTATEMENT (SECOND) OF CONTRACTS § 153 (1979).

Kronman's model better explains the rationale courts should be using when they refuse to require disclosure than the rationale courts actually use in such cases. Other models, such as the contractarian model suggested by Professor Scheppele, better explain the rationales courts actually use. *See* KIM L. SCHEPPELE, LEGAL SECRETS 124 (1988).

by *Leitch Gold Mines, Ltd. v. Texas Gulf Sulfur.*[26] There a company searching for underground deposits of oil (oilman) discovers oil under the field of a farmer with whom it has never dealt. Naturally, the oilman seeks to buy the right to extract the oil without the farmer suspecting the value of those rights. By consensus, at least among legal scholars,[27] the oilman need not disclose to the farmer the information it has discovered. That is, the law will enforce the contract by which the uninformed farmer transfers the rights to extract to the oilman. Upon discovering his mistake, the farmer might attempt to void the contract on the ground that the oilman did not disclose material information of which it knew the farmer was ignorant, but his attempt will fail.[28] Nor will the law void the contract on the ground that the undisclosed information made the value of the right to extract far greater than the value suggested by the contract price.[29] Here again, allowing nondisclosure incents the search efforts of the oilman by recognizing its property right in the key information its search uncovered, namely, that oil lay under the farmer's field. Of course, our researcher resembles the oilman and our subject resembles the farmer. But while this example may provide a powerful precedent for allowing non-disclosure, no one suggests the law would allow the oilman to lie.[30]

Or rather almost no one. Saul Levmore, while conceding that courts have not yet tolerated lying, points out that the right not to disclose will lose its value without an accompanying right to lie.[31] Mere non-disclosure protects the incentive to search only until the other party learns to ask the key question. In the oilman/farmer case, the key question from the farmer is whether the oilman has any reason to believe oil lies under his field; in our case, the key question from the subject is whether the researcher has any reason to believe the subject's cells are valuable. In the face of the key question, the nondisclosure option becomes useless. At that point, any answer that seems to equivocate or evade—including, in particular, an an-

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26. 1 O.R. 469, 492-93 (1969); *see also* Holly Hill Lumber Co. v. McCoy, 23 S.E.2d 372 (S.C. 1942); Simpson Timber Company v. Palmberg Construction Co., 377 F.2d 380 (9th Cir. 1967).

27. *See, e.g.*, CHARLES FRIED, CONTRACT AS PROMISE 82-84 (1981).

28. *See Laidlaw*, 15 U.S. (2 Wheat.) at 178; *see also In re* Verifone Securities Litigation, 784 F. Supp. 1471 (N.D. Cal. 1992).

29. *See* Files v. Brown, 124 F. 133 (8th Cir. 1903).

30. In *Laidlaw*, Chief Justice Marshall emphasized in dictum that while nondisclosure was permitted, more active measures to mislead, such as a lie, would not be. *Laidlaw*, 15 U.S. at 195. Mere silence in the face of the ignorant party's question may even have been fraudulent.

31. *See* Saul Levmore, *Securities and Secrets: Insider Trading and the Law of Contracts*, 68 VA. L. REV. 117, 139-41 (1982).

swer from the oilman/researcher that the law does not require it to answer—risks signaling the truth.[32] And as we have seen, signaling the truth destroys the incentive to search.

To be sure, an outright, immediate lie may likewise fail to protect the incentive to search should the suspicions of the farmer/subject be otherwise aroused. The farmer may suspect the truth just from the oilman's offer to buy the mineral rights; the subject may suspect the truth just from the researcher's return. Any behavior from the oilman/researcher which the farmer/subject interprets as unexpectedly generous may signal the truth. In Dashiell Hammet's *Maltese Falcon*, Kasper Gutman, the fat man, nullifies his discovery of the falcon by negotiating too softly for its purchase. His uncharacteristically generous offer signals the antique seller, General Kemidov, that his apparently undistinguished black statuette of a falcon possesses greater value than he thinks, prompting him to reexamine it, discover its value, and replace it with a statuette truly undistinguished. The fact that the oilman/researcher lacks any guaranteed method of avoiding the holdup only underscores the importance of allowing them some latitude to minimize the hold-up problem provided their methods stop short of the coercive or invasive.[33]

The researcher's lie is best characterized as a low-cost self-help method by which the researcher can internalize the benefits from its search. When a search yields new information, the searcher's ability to

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32. Granted, a refusal to answer may not arouse the subject's suspicions as much if the researcher has clearly warned the subject from the start that it will never provide feedback about the value of a subject's cells. *See infra* notes 57-58 and accompanying text.

33. Courts have been willing to stretch the law to avoid severe hold-up problems in other contexts. *See generally* RICHARD A. EPSTEIN, SIMPLE RULES IN A COMPLEX WORLD 122 (1995) (denying injunction to resident whose property is polluted by manufacturer).

The power of eminent domain illustrates that the wish to avoid hold-up problems sometimes justifies coercion. Indeed some may feel allowing the researcher to use coercion to obtain a further collection no more odious than allowing it to lie. But while both coercion and lying trigger moral objections, lying seems a less serious offense. The lie still preserves the subject's control over whether he will allow a further collection in return for the nominal compensation offered. The lie merely removes the possibility of significant financial gain as a factor in the subject's decision.

In this context giving the researcher the right to force the subject to provide a further collection (*i.e.*, a private right of eminent domain) will not avoid hold-up problems as successfully a right to lie. For if the exercise of the right to eminent domain alerts the subject to the value of his cells, he will be able to hold up the researcher for payment in return for promising to refrain from providing collections to the researcher's rivals. *See infra* notes 57-58 and accompanying text.

keep the information secret often functions in this manner.[34] Helping an actor use self-help methods like secrecy frequently internalizes benefits better (at lower social cost) than granting the actor more formal legal protection, such as a patent, property, or contract right to the information in question.[35] The social cost of granting more formal rights, especially the cost of establishing, identifying, enforcing, and transferring the rights can easily exceed the negative aspects of legal rules that help an actor keep his information secret.

A straightforward comparison suggests itself. Rules that help an actor keep his information secret should be preferred to more formal legal protection that equally incents the actor's efforts when the negative aspects of the former are less than the cost of the latter. Because there is rarely a need to choose between the former and the latter, the comparison in no way calls for restricting formal legal protection. It does suggest, however, that the value of legal rules designed to assist self-help efforts—here maintaining the secrecy of the information discovered—deserves more appreciation.

Often self-help measures designed to internalize the benefits of an actor's efforts elicit judicial hostility until their function is understood. Antitrust law, for example, advanced enormously when economists described how practices thought to be exclusionary, such as tying and exclusive dealing arrangements, were better conceived as self-help measures to keep free riders from appropriating benefits generated by a firm's efforts.[36] Other self-help methods that incent socially valuable creative efforts remain condemned by judicial opinions that fail to appreciate the method's tendency to economize on the costs of more formal legal protection.[37]

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34. The costs of creating and administering property or contract rights in information often need to be incurred only because the information whose production society wishes to incent could not be kept secret in fact. One who develops a trade secret, say, has no need for any legal protection if he can actually keep what he has developed a secret. The *law* of trade secrets comes into play only when actual secrecy can no longer be maintained. Thus, laws that help an actor keep his information secret in the first place may economize on the costs of laws that are needed only after secrecy is lost. Here, keeping the subject free from any suspicion that his cells have proven valuable avoids all the costs of granting property rights or contractual rights in the key information.

35. Formal property rights in information can be granted through tort doctrines such as unfair competition as well as through trade secret and copyright law.

36. *See, e.g.*, RICHARD POSNER, ANTITRUST LAW: AN ECONOMIC PERSPECTIVE (1976).

37. *See, e.g.*, Fashion Originators Guild of America v. Federal Trade Commission, 312 U.S. 457 (1941) (self-help effort to avoid style piracy condemned as violation of the Sherman Act). In contrast, the courts of England are more inclined to view these self-help efforts favorably. *See* Robert Heidt, *Populist & Economic v. Feudal: Approaches*

Granted, in other contexts the cost of keeping new information secret in order to preserve the incentive to search can itself be high. For example, when the information concerns industrial or scientific know-how and when the many employees needed to exploit that know-how must learn the key information as a byproduct of the production process, the security measures needed to keep the information from rivals can entail considerable costs. In these instances, more formal legal protection may economize on the costs of these security measures. But when the information consists of the identity of the subject whose cells helped establish a useful cell line, the costs of maintaining secrecy are modest. Employees working with the cell line have little or no reason to learn the subject's identity. The know-how acquired about what the cells can do is easily shared without the need to identify the subject. Even the employees involved in testing the cells and discovering their value need not know enough about the subject to be able to identify him.[38]

Given these features of the industry, this article suggests that helping the researcher keep the information secret may incent its search more effectively and cheaply that would more formal legal protection. Part IV builds on this suggestion by showing that one type of more formal legal protection—judicial recognition of the researcher's contract rights—proves inferior to judicial tolerance of the researcher's lie. But first, the article addresses the claim that the researcher can easily finesse the hold-up problems, thus rendering the researcher's lie unnecessary and, for that reason, unjustifiable.

III. INTRACTABILITY OF THE HOLD-UP PROBLEMS

One might think the researcher's ability to evade or refuse to answer the subject's question will avoid the hold-up problems. But a subject sufficiently interested in his ticket in the biotechnological lottery may not be so easily put off. To appreciate the intractability of the hold-up problems, imagine the possible discussion between the researcher's chief executive officer (CEO) and the employee responsible for collecting the cells (Collector) after they have learned that the subject's cells are valuable but that a further collection is needed:

> CEO: You know we need to go back to Subject.
> Collector: That's what I heard.

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to Industry Self-Regulation in the United States and England, 34 MCGILL L.J. 39, 50 (1989).

38. *See* OTA REPORT, *supra* note 1, at 52.

CEO: What was he like? Was he altruistic about participating?

Collector: Very much so. Like most in the tribe, he was glad for the chance to help medical research.

CEO: So you don't see any problems in getting him to participate again?

Collector: Oh, I didn't say that. Subject definitely had his eye out for his main chance. He had heard about the *Moore* case somewhere.[39] He knew that very occasionally a person's cells or genes have rare properties that can help in making drugs that are worth millions. He asked if we had any reason to suspect his cells might be especially valuable. Of course, I told him all that we knew then, namely, the chance that his cells were valuable was close to zero. But I barely overcame his skepticism that time. So we can count on him asking the big question again.

CEO: Will he make anything of our coming back to him?

Collector: Sure he will. He's a savvy guy. Our coming back will set off every alarm bell. And I don't think he'll participate until he satisfied his chances are no better than they were before. We'll be lucky to satisfy him with a flat out denial that we have any more reason than before to think his cells are valuable. Though my guess is a flat out lie would suffice.

CEO: There must be a better way than lying. How about ignoring his question and offering him some extra payment?

Collector: If he suspects he's carrying a treasure trove in his veins, a modest extra payment won't persuade him. Once his suspicions are aroused, he'll put us off and think about how to proceed. You can be sure of that. And it won't take him long to

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39. Moore v. Regents of the University of California, 793 P.2d 479 (Cal. 1990), *cert. denied,* 499 U.S. 936 (1991). This famous case was brought by a cancer patient against his doctor and his doctor's associates and employer. *See id.* at 480. In his treatment of the plaintiff over a course of years, the defendant doctor never alerted the plaintiff to the doctor's research interest in the plaintiff's tissues nor did he obtain the plaintiff's consent to any research or commercial use of those tissues. *See id.* at 481. The plaintiff was allowed to believe the tissues were taken solely for therapeutic purposes whereas in fact some tissues were taken solely for research purposes. *See id.* In a dramatic and widely publicized opinion the California Court of Appeals found that the defendant's research constituted the tort of conversion, entitling plaintiff to a share of the revenues from the end products of that research. *See* Moore v. Board of Regents of University of California, 249 Cal. Rptr. 494, 504 (Cal. Ct. App. 1988), *rev'd*, 793 P.2d 479 (Cal. 1990), *cert. denied,* 499 U.S. 936 (1991). In reversing, the California Supreme Court denied plaintiff's claim for a share of the revenues from the end products. *See Moore*, 793 P.2d at 479. But the court held that the doctor, as part of his obligation under the informed consent doctrine, needed to disclose his research interest in any treatment he was recommending. *Id.* at 484-85.

realize he should arrange to have himself tested and to deal with our rivals.

CEO: Why don't we tell him we're only coming back because we mishandled the first collection? That's literally true. After all, it's only our "mishandling" of the cell line that is taking us back to him for another collection.

Collector: He'll still suspect our coming back to him means we've found something special about his cells. And so before allowing the collection, he'll ask whether we have reason to think his cells are valuable. We need to be able to reply to that direct question in a way that persuades him to allow the collection without arousing his suspicions.

CEO: Let's use some new hire to approach him then. Someone who when asked the key question can honestly say "Sorry, I don't know anything about whether your cells have commercial value."

Collector: It's a thought. But my guess is that the moment he knows the request comes from us, he'll insist on talking to someone familiar with our testing of his first collection. He'll probably call you or me and put the question to us. And if we delay talking to him, he'll just get more suspicious and wait us out.

CEO: So if our approaching him arouses his suspicions, how about hiring an independent lab to approach him? They can ask him if he'll allow them to draw some of his blood to be used in medical research. That's certainly true, medical research is what we're about. They could even say the researchers who hired them got his name from a list of people previously willing to give blood samples to help research. That's also true.

Then when he asks the key question, the collector can honestly say he doesn't know what the research entails and certainly doesn't know anything about whether Subject's cells are commercially valuable. Sure, Subject will still be suspicious. But look at the hassle facing him if he tries to follow up his suspicion: he'd need to ask this uninformed collector what company wants the samples, and, of course, that collector can honestly say he doesn't know. He'd then need to contact the collector's employer. But the collector's employer could delay him and, if necessary, eventually say he isn't at liberty to disclose who hired him. Or if he called us to ask if we're behind this latest request, we could delay him or transfer his call to someone working here who knows nothing.

Given his wish to help, and anticipating the hassle he'd face in following up his suspicion, don't you think he'd let us take another sample?

Collector: He could, but I doubt it. He was insistent on getting an answer to his key question the first time. I don't think he would have gone ahead had I said what you want your independent collector to say, namely that he can't answer his question. And no matter how unrelated to our first collection we make your independent's request appear, Subject is sure to wonder why he's being approached again. My guess is he'll insist that this collector put him in touch with someone who knows what was learned about his earlier collection. And he won't go ahead until someone answers his question.

And there's another downside to any plan aimed at evading his key question—the evasions might leave him so suspicious that he won't then believe an outright lie. Right now, my instincts tell me that he would believe a lie. But with any evasions, however well-handled, he's less likely to do so.

CEO: So that's what you suggest—lying right from the start?

Collector: Any other suggestions?

CEO: How about telling him everything? And then offer him a share of our eventual revenues?

Collector: Why should he agree to that? I said he likes to help medical research. I didn't say he was selfless. The moment he knows the truth he has no more reason to deal with us than with any of our rivals. He need only alert our rivals to the value of his cells and wait for everyone in the industry to bid for permission to collect his cells. And the permission will predictably go to the highest bidder, not to the company that sampled his cells and discovered their value originally.

CEO: That scenario leaves us with nothing, absolutely nothing, for our *successful* search. Our rivals will keep bidding until the winning bid allows a competitive return only on the development of the cell line. None of our expense to discover the cell line will ever be recovered. Unless we can lie, Subject can pick our pocket just by asking his question.

Avoiding the hold-up problem is not the only reason for allowing the returning researcher to lie. If such researchers are unable to lie, some may opt to obtain samples from the subject through methods that are even more unseemly and that deny the subject any choice about whether to participate. They may, for instance, surreptitiously seek out samples of the sub-

ject's hair, nails, or expelled bodily fluids.[40] The grave robbings of 19th century England illustrate the methods to which committed researchers have resorted when unfavorable laws impede their work.[41]

By keeping the identity of the source of the cell lines the researcher has developed secret, the right to lie will also help the researcher enforce any patents on those cell lines that are eventually obtained. For an aspiring infringer could not then obtain the patented cell line from the subject. Preventing aspiring infringers from gaining access to a cell line becomes especially important because of the lack of any effective remedy against infringement once the infringer obtains access. A.J. Lemin has explained that once an infringer splices the useful DNA from a prior inventor's cell line into the infringer's genomic construction and finds that the new cells produce large quantities of valuable proteins, enforcement of the patent on the first inventor's cell line becomes problematic:

> These proteins would probably have no direct structural relationship to the pirated DNA. The fact that they were obtained through an infringement of the first inventor's patent would be ascertained only through a complete sequencing of the DNA in the second inventor's newly engineered organism. Since this organism would not be available to the general public, there would be no immediately way of discovering the infringement. Consequently there is no practical way to protect the inventor of the original cell line from accidental or otherwise covert infringement of his patent rights.[42]

This is another example of how toleration for self-help measures advances the goals of more formal legal protection.

IV. THE ABSENCE OF CONTRACTUAL SOLUTIONS

One might think the researcher's dilemma in obtaining a further collection could be solved by careful drafting of the original agreement between the researcher and the subject.[43] The agreement could provide that

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40. *See generally* Valerio Barrad, *Genetic Information and Property Theory,* 87 N.W.U. L. REV. 1037, 1083 (1993).

41. *See* JACQUES BARZUN, BURKE & HARE: THE RESURRECTION MEN (1974).

42. Alan J. Lemin, *Patenting Microorganisms: Threats to Openness*, *in* OWNING SCIENTIFIC AND TECHNICAL INFORMATION 196 (Vivian Weil & John Snapper eds., 1989).

43. Perhaps the surest way for the researcher to avoid the holdup would be to collect enough cells during the initial collection so that extra cells could be stored against the possibility that the cell line could not be maintained. The researcher could then recreate the cell line from the stored supply if necessary, and the subject need never be contacted.

the subject agrees to allow not just the initial collection but a number of further collections as well.[44] With the subject locked in by such a provision, the returning researcher could compel the subject to allow further collections even after the subject knows the value of his cells. Its ability to obtain further cells assured, the researcher could then answer the subject's key question with the happy truth.[45] And if the knowledgeable subject resists the request for a further collection, the researcher could enlist the court's help to enforce the contract provision.

But this approach is likely to fail. No modern court is likely to require an individual to allow another private party to collect bodily fluids from him against his present will no matter how clearly the individual agreed to allow precisely that. One reason is that the policies informing the common law rule against compelling specific performance of personal service contracts would apply.[46] Enforcing a decree that compels the subject to submit further collections by the researcher would require the cooperation of the subject. And the court would need to be prepared to invoke the severe sanctions available for contempt.[47]

The researcher's inability to enforce such a provision suggests why the case for allowing lying in this context is stronger than in the oilman/farmer case. There, the oilman can avoid the hold-up problem by purchasing the right to search and extract at an early stage before it knows of the presence of the oil. At that point, of course, it has no need to lie. And the law's

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Although certain types of cells are more fragile than others, most samples can be frozen and stored. And the survival rate when they are thawed, and recovery attempted, can approach 95%. *See* OTA REPORT, *supra* note 1, at 53.

44. Of course, a researcher who insists that its subjects promise to allow not just the immediate collection but future ones as well will predictably persuade fewer subjects to participate.

45. Telling the subject the truth will still enable the subject to exercise the second holdup, namely, "Pay me or I'll tell your rivals what you've learned and allow collections by them." Even if the original agreement contained an enforceable provision barring the subject from allowing collections by others, the subject's threat to allow such collections *sub rosa* would certainly be credible. Whether explicit or implicit, those threats create a risk for the researcher that it can never eliminate entirely once the subject knows the truth. The wish to avoid this second holdup gives the researcher ample reason to lie despite its contractual protection. For further discussion on the danger presented by the second holdup, see *infra* text accompanying notes 50-52.

46. *See* E. ALLEN FARNSWORTH, CONTRACTS § 12.7, at 836 (2d. ed. 1990).

47. Even if courts do everything within their power to force the subject to allow a further collection, a practical researcher must consider the possibility of the knowledgeable subject flouting the courts' orders by fleeing to another jurisdiction or going into hiding. The knowledgeable subject may hope the researcher stands to gain enough from his cells that it will quickly offer financial payment rather than endure delays or risks or incur enforcement costs.

willingness to enforce the agreement reached then makes all the difference. Once the oilman discovers oil, the court will enforce its right to extract the oil despite the objections of the farmer.[48] Indeed those searching for oil sometimes operate in this fashion, buying the right to search and extract at an early stage before they obtain positive information about the chance of finding oil which, if known, would significantly increase the price for those rights.[49] Technological restraints, in particular their inability to search under land without entering the land, may explain this practice of acquiring mineral rights early. But the oilman's ability to enforce an early agreement against a farmer who later learns information increasing the value of the right to extract may contribute to this practice as well.

Even if a court was willing to force the subject to allow a further collection, the knowledgeable subject retains the power to exercise the second holdup, "Pay me or I'll alert your rivals to my cells' value and deal with them."[50] Because competition from those rivals on the cell line or the end products would reduce the researcher's gain, the subject knows the researcher will be willing to pay to avoid that competition. Accordingly, the astute researcher would also include a provision in the original agreement whereby the subject agreed not to deal with the researcher's rivals.

In one sense this second holdup presents a greater threat to bioprospecting than does the first. For the knowledgeable subject's ability to reduce the researcher's gain from its search by allowing collections by the researcher's rivals exists *even when no second collection is needed.* The ability to exercise the second holdup exists from the moment any subject learns the value of his cells. From that moment, the researcher can do little to prevent the subject and its rivals from dealing with each other in a manner that reduces the value of its discovery. Thus, the second holdup threatens a researcher even when it has maintained an immortal cell line and needs no further cooperation from the subject. The naive may think that such a researcher possessing both the cell line and a contract provision entitling it to the fruits of the cell line needs no further legal assistance and can justly be compelled to inform its subject of the happy news if only to

48. *See* Leitch Gold Mines, Ltd. v. Texas Gulf Sulfur, 1 O.R. 469 (1969).

49. *See* J.P. ALLENBRIGHT, THE TEN DOLLAR WILDCAT 20-24 (1979).

50. The assumption here is that once the knowledgeable subject allows collection by the researcher's rivals and tells those rivals what he knows about the value and characteristics of his cells, the rivals will not face significantly greater costs in exploiting the cells than would the original researcher. Without this assumption, the original researcher may not be hurt by the subject dealing with its rivals. If—to take the extreme case—all rents arise not from the cells' unique characteristics but from the researcher's unique knowledge about how to exploit the cells, giving the cells to rivals would not enable them to compete.

let the subject enjoy the satisfaction of knowing he provided valuable cells. But the knowledgeable subject need never content himself with so little. By exercising this second holdup, he can seriously threaten the researcher's gain. The wish to avoid the second holdup argues powerfully for never requiring a researcher to notify a subject that his cells have value.

To be sure, the subject's gain from this second holdup should fall short of the maximum rents from his cells as long as the original researcher, pursuant to the court's intervention or otherwise, can also obtain possession of the subject's cells. This is because the amount the researcher needs to offer the subject for his promise not to deal with its rivals should be limited to the maximum amount a rival will offer the subject in return for dealing with it. That amount is sure to fall short of the maximum rents from the cells given that the original researcher also possesses the cells and can also develop and market the end products. The most a rival would offer would be the expected duopoly gain, and a rival will only offer that amount if it can somehow be satisfied that the subject will never deal with additional rivals in the future.[51]

This contract provision barring the subject from allowing collections by the researcher's rivals will remain important to the researcher even if courts refuse to enforce the provision that would allow the researcher to take further samples from the subject. If the knowledgeable subject is barred from dealing with the researcher's rivals, the returning researcher should more easily and cheaply persuade the subject to allow it a second collection. The knowledgeable subject can still hold up the researcher for much more payment in return for allowing the second collection than the ignorant subject would receive. But the amount of the holdup should be less than if the knowledgeable subject was free to deal with the researcher's rivals. The problem now resembles that of bilateral monopoly for neither party has a good alternative to dealing with the other.[52] The knowledgeable subject, not being able to turn to the researcher's rivals (at least not lawfully), can only refuse all further collections. And the subject will not find that alternative desirable. After all, allowing the collection

51. *See* JACK HIRSHLEIFER, PRICE THEORY AND APPLICATION 296 (3d ed. 1984).

52. A bilateral monopoly is an example of strategic behavior, the particular focus of game theory. *See* ERIK RASMUSEN, GAMES AND INFORMATION: AN INTRODUCTION TO GAME THEORY (1989). Bilateral monopolies also present the danger that the resource in question—here the cells—will not be transferred to the higher valued use because the parties in attempting to establish their reputation for hard bargaining will never reach agreement. The social loss when, for this reason, no researcher uses the subject's cells is acute.

costs the subject virtually nothing, merely a harmless, simple, and momentary drawing of blood. The offer the subject receives from the researcher will easily exceed those trivial costs. Likewise, the researcher lacks any good alternative to dealing with the subject, not being able to exploit its successful search without further cells.

One might think that the ideal situation for the knowledgeable subject would arise when courts refuse to enforce both the contract provision requiring the subject to allow further collections and the provision barring the subject from allowing collections by others. In fact, however, the subject would prefer the situation where the second provision ("I agree not to deal with rivals") was enforceable but the researcher neglected to include it in the consent agreement. Only that situation will yield the subject the maximum rents from his cells. The reason is that when the second provision is unenforceable, the amount bid by the rival companies will disappoint the subject because the bidders will fear that the subject will allow collections by others later despite his promise to the contrary and despite whatever consideration is paid for that promise. That is, the failure to enforce the second provision prevents the subject from giving a binding promise to allow collection only by the winning bidder. In contrast, with the second provision legally enforceable (putting aside the practical problems of enforcement), the amount bid for the right to collect the subject's cells should increase to the maximum rent. Because this ideal situation for the subject only arises when the researcher foolishly fails to include the second provision in the agreement, the situation is irrelevant to a consideration of whether the astute researcher can structure some contract solution to the hold-up problem. For that reason, it merits no further discussion.

In review, there are a multitude of possible outcomes facing the astute researcher. If the returning researcher must inform the subject of the value of his cells, the researcher can only avoid a holdup if courts enforce contract provisions that (1) assure the researcher future access to the subject's cells on the original terms, and (2) bar the subject from allowing collections by others. If either provision is unenforceable, some hold-up problem exists. If the second provision is enforceable but the first is not, the knowledgeable subject can demand payment in return for allowing the researcher the further collections it is seeking.[53] If the first provision is en-

53. A feature of the science involved here may aid our researcher. For when helpful cells are found in one individual, they are also typically found in at least some of the individual's relatives. This plurality of sources could undermine the ability of any one of them to exercise a holdup. The researcher's stumbling block now becomes the possibility of collusion among knowledgeable sources. For once one source learns of the value of

forceable but the second is not, the subject can demand payment in return for not allowing further collections by others. If neither provision is enforceable, the subject can demand payment in return for either or both desired behaviors, but cannot expect his unenforceable promise to refrain from allowing collections by others to yield much extra payment.

Given that courts are virtually certain to refuse enforcement of the first provision, the importance of enforcing the second provision becomes clear. The bilateral monopoly created when the second provision is enforced should provide the researcher at least some gain from, and therefore some incentive for, its search. In contrast, refusing to enforce the second provision as well as the first leaves the researcher nothing for its search.

However essential for preserving the incentive to search the second provision may be, modern courts are again likely to refuse enforcement.[54] The modern judicial hostility toward any agreements that smack of servitude or of restrictions on a person's freedom to deal with others comes into play.[55] Moreover, the researcher would be asking the court to issue an injunction. And courts traditionally refuse that equitable remedy when the consideration given the promisor, here the subject, has been nominal.[56]

Even if this second provision was legally enforceable, the ease with which blood can be secretly drawn and the source of a cell line hidden bar effective enforcement. Once the subject knows the value of his cells, he

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his cells, his interest lies in contacting his relatives and warning them against allowing any collections. If the relatives all heed this advice and collude with each other, the researcher's dilemma remains as before. Its negotiations with the sources should proceed just as they would if there was a single source.

54. For example, no court will enjoin a subject from allowing collections by medical personnel if therapeutic reasons call for those collections. Nor will a court compel the subject to obtain a contractual promise from those medical personnel not to use the collections for research or commercial purposes. Barring the subject from allowing collections by others, including other researchers, would change prevailing practices and annoy the many subjects who want to work with others. Such a ban, of course, would be unnecessary if the key information is kept secret.

55. *See* CAL. BUS. & PROF. CODE § 16600 (West 1995) (contracts restricting an employee from engaging in a lawful profession, trade, or business are to that extent void); RESTATEMENT (SECOND) OF CONTRACTS § 186 (1979); E. ALLAN FARNSWORTH, CONTRACTS § 5.3, at 16-17 (3d ed. 1992). Commentators have pointed out some of the legitimate purposes which restrictive covenants serve but which courts have overlooked. *See* Edmund W. Kitch, *The Law & Economics of Rights in Valuable Information*, 9 J. LEGAL STUD. 683 (1980) (employment restraints, although generally unenforceable, assist companies in financing the training of employees and in enforcing trade secret laws); Paul H. Rubin & Peter Shedd, *Human Capital and Covenants Not to Compete*, 10 J. LEGAL STUD. 93 (1981) (occupational and geographic restrictions on the seller of a business, although often unenforceable, encourage the development of good will).

56. *See* E. ALLAN FARNSWORTH, CONTRACTS § 12.7, at 836, 869 (2d ed. 1990).

has little reason, apart from his previous promise, to confine his collections to the researcher who discovered his cells' value. The subject may feel driven, perhaps desperately, to find some way to capture for himself more of the value of his cells. Allowing others to collect costs him little. The chance his breach would be detected is remote. His likely penalty should his breach be detected cannot amount to much compared to his likely gain. A contract provision barring a subject from dealing with rival researchers will inhibit only the unusually law-abiding. Even the unusually law-abiding may be able to allow collections by others while maintaining a colorable claim of having acted lawfully by leaving the reach of U.S. law and allowing collection elsewhere.

If the law is not able effectively to police the subject from allowing collections by the researcher's rivals, some may think the law can effectively police the rival researchers from secretly collecting or using the subject's cells. The rival researchers, perhaps, offer deeper pockets and less mobility than the subject and thus provide a more feasible legal target. A lawsuit against them, grounded on their interference with the agreement between the researcher and the subject, may be worth maintaining. But these biotechnology companies need not be the ones who actually collect the subject's cells. Other companies, some of them operating entirely outside the reach of U.S. law, can collect the cells and sell them to the rival researchers without identifying the subject. The subject will face an ongoing temptation to deal with these companies.

One can imagine other attempts to solve the hold up problems contractually. The original contract could provide for revenue sharing between the researcher and the subject should the subject's cells prove valuable. In return, the subject would allow the researcher to collect samples now, and if necessary, in the future, and would also promise not to allow collections by others. More than the provisions discussed previously, those provisions so combined would probably be legally enforceable. But the practical enforcement problems discussed above remain. Having made this deal with the searcher, the knowledgeable subject will be tempted to augment his gain by allowing collections by others, if not within the reach of U.S. law, then outside of it.[57] The subject's mobility and ability to hide his breach separates him from the farmer who knows that his breach will

57. No doubt the revenue sharing agreement could be structured to link the subject's future gains to the researcher's. But while a carefully structured agreement might reduce the subject's temptation to deal with rivals, some temptation will remain as long as the subject can keep his dealings with rivals secret. This research will now suffer from the incentives for inefficient behavior created by divided ownership. *See* RICHARD POSNER, ECONOMIC ANALYSIS OF LAW 82-83 (5th ed. 1995).

be detected, and an injunction against him issued, should he allow extraction of the oil on his farm by a rival of the oilman who discovered the oil.[58]

No contractual solution to the hold-up problems serves the researcher as well as keeping the subject unaware of the value of his cells. From the moment this subject suspects the truth, the researcher loses control of the cell line and its development. The knowledgeable subject becomes a loose cannon whose behavior endangers the researcher's future return. Whatever promises the subject gave at the time of the original collection, the knowledgeable subject can find some way, legally or illegally, within reach of this country's laws or elsewhere, to appropriate much of the gain from the researcher's search. The self-help method of keeping the subject in the dark protects the researcher's incentive to search better than would more formal legal protection—here, the protection afforded by contract law.

The most helpful contract solution would aim not at controlling the suspicious subject but at keeping the subject from ever becoming suspicious. One provision in the consent agreement that recommends itself would state clearly that the researcher will never inform the subject of the value of his cells. Beyond that, the researcher may want to clarify that it will never inform the subject of the specific goals or methods of its research. This advance warning may eliminate a later need for the returning researcher to lie. In response to the subject's direct question, the returning researcher could refer to this policy and decline further comment. While this response may lead some subjects to refuse the requested further collections, fewer subjects should suspect the truth and thus more should participate as they did before than without this advance warning. Many subjects may accept that the researcher, in refusing to answer their question, is merely obeying a general policy rather than hiding its knowledge that their cells are valuable.

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58. Revenue sharing also makes more sense in the oilman/farmer context because the farmer who sells his mineral rights while retaining his fields will learn eventually that his fields contain oil, whereas the subject is much less likely ever to learn of the value of his cells. The farmer's knowledge of the oil's presence may put him in position even at that point in time to harm the oilman's operations through, for example, noncooperation or sabotage. Thus the oilman may feel compelled to obtain the farmer's continuing cooperation, a goal achieved by the revenue sharing agreement. In other words the oilman may need to resort to revenue sharing because it is not able to adopt, as a practical matter, the self-help remedy available to the researcher, namely, keeping the subject permanently in the dark.

V. LIMITING THE PROPOSED RIGHT TO LIE

The preceding discussion suggests the right to lie could be limited to situations where the hold-up problems may destroy all incentive to search and where the searcher's inability to overcome those problems through evasions or contractual commitments is manifest. Other variables limit this proposed right to lie further. First, the right to lie, like Kronman's right to nondisclosure,[59] is only worthwhile when the search it incents is likely to be socially valuable. And the usual proxy for a socially valuable search is that the new information produced is itself likely to be socially valuable. On this ground, Kronman distinguished new information about market conditions (which the discovering party need not disclose) from information about typographical errors in the other party's offer (which the discovering party must disclose).[60] The considerable social value of the researcher's search, acknowledged by the United States Supreme Court in its decision allowing cell lines to be patented, thus distinguishes it from searches for less valuable information.[61] A right to lie designed to incent the researcher's search need not call for a general right to lie.

Indeed, the development of methods to use an individual's cells in the production of valuable drugs provides a vivid example of a technological change that by enhancing the social value of certain activities calls for legal changes designed to better incent those activities.[62] The development of the telegraph and of wireless communication played a similar role in *International News Service v. Associated Press.*[63] There, the Associated Press (AP) successfully attacked its rival's practice of reporting the foreign news AP had gathered. The development of the telegraph and wireless in effect increased the value of gathering foreign news because that news need only be minutes rather than weeks old.[64] Thus, the loss to society from the law's failure to incent the gathering of foreign news increased. And as that social loss increased, the case for incenting those news gathering efforts (in that case, by enjoining a rival from reporting

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59. *See* Kronman, *supra* note 22, at 6.

60. *See id.* at 23.

61. *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (the mere fact that subject matter is "living" does not render it unpatentable).

62. Harold Demsetz has offered the classic explanation of how technological changes that increase the value of certain resources call for legal changes designed to better incent the development of those resources. One such legal change is the recognition of new property rights. *See* Harold Demsetz, *Toward a Theory of Property Rights*, AEA PAPERS AND PROCEEDINGS (May 1967).

63. 248 U.S. 215 (1918).

64. *See id.* at 237.

news gathered by AP) strengthened. The externalization of benefits from the AP's efforts and the resulting poor incentive structure for those efforts that was tolerable when the gathering of such news added little to society's wealth became intolerable when, as a result of the wireless, those news gathering efforts added more value. Just so, the law's failure to incent the researcher's search efforts becomes less tolerable as those efforts, thanks to the developments of modern biotechnology, aid society more.

Requiring that the search incented be costly to the searcher confines the right to lie even more. Scholars have emphasized the relation between the actor's cost of undertaking an activity and the need for the law to internalize to the actor the benefits of his activity.[65] For example, giving the actor a property right in the fruits of the activity—one method of internalizing benefits—becomes more appropriate as the actor's cost of undertaking the activity increases. At bottom the point is a simple one. The more costly the desired activity, the less likely the actor will undertake it in the absence of some assurance that he will reap its benefits. Conversely, the less costly the desired activity, the more likely the actor will undertake it for an independent reason despite the risk that he will not reap its benefits. Thus in *International News* where the Supreme Court granted AP a quasi-property right in the news it gathered, the Court identified as a key factor in AP's favor the huge cost it incurred in creating the AP network.[66] Without legal intervention to enable AP to appropriate the benefits of its efforts, society could not expect future APs to incur such costs, and society would suffer from a suboptimal amount of news gathering. Kronman likewise limited the right to nondisclosure to situations where the search being incented was costly.[67] Only those who had incurred substantial costs in ferreting out new information were free to trade upon it without disclosure. One who obtained the information casually could not. To take Kronman's example, an eavesdropper overhearing new information of which it has reason to believe the other party is unaware must disclose the information to the other party.[68]

Unlike the social value of the search, which will be high for virtually all searches, not all researchers will face high costs in finding an individ-

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65. *See* Armen Alchian & Harold Demsetz, *Some Economics of Property Rights*, 30 IL POLITICO 816 (1965); Armen Alchian & Harold Demsetz, *Production, Information Cost, and Economic Organization*, 62 AM. ECON. REV. 777 (1972); Douglass C. North, *The Rise and Fall of the Manorial System: A Theoretical Model*, 30 J. ECON. HIST. 777 (1971).

66. *See International News*, 248 U.S. at 222.

67. *See* Kronman, *supra* note 22, at 11.

68. *See id.* at 13.

ual with valuable cells. For example, a researcher who is paid by an individual to determine the value of that individual's cells might discover valuable cells at no risk or net expense to itself.[69] Here the risk of the search failing falls not on the researcher but on the subject. And the compensation from the subject adequately incented the researcher's efforts. In this case, there is absolutely no reason to excuse the researcher from honestly reporting the test results to the subject, as the parties agreed. Enforcing such an agreement benefits this research by encouraging individuals who have reason for believing their cells are likely to be valuable to test themselves. Reporting to the individual that his cells are valuable may trigger a holdup but not a hold-up problem. The subject's gain properly incents the subject's search. Not having incurred the costs and risks of searching, the researcher cannot avail itself of legal rules designed to encourage it to undertake those costs and risks. In general, a subject who takes the risks and incurs the costs of self-testing is entitled to whatever compensation, whether in the form of a share of eventual revenues or otherwise, he can induce the researcher to promise.

One can imagine cases short of this extreme example in which the researcher's search costs are so low that the wish to incent the researcher's search will no longer justify a right to lie. A patient may suffer from an abnormal growth of tissues whose cells are disproportionately likely, by several orders of magnitude, to prove valuable. The patient's cells may become available to the researcher through no effort of its own, and the value of the cells may be readily apparent on examination. If in such a case the researcher returns to the subject for a further collection, having found useful cells but having failed to maintain an immortal cell line, and if the subject confronts it with the key question, society's wish to incent searches would not support allowing the researchers to lie. In Kronman's words the researcher, like the eavesdropper, acquired the key information casually, or at least relatively casually compared to a researcher who undertook an expensive and risky search for those with useful cells.[70]

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69. Another example of a low cost searcher would be one who learns the key information—the value of this subject's cells—by eavesdropping or by industrial espionage.

70. *See* Kronman, *supra* note 22, at 14. To be sure, just as the eavesdropper at least incurs the cost of eavesdropping, the lucky researcher has incurred the cost of ascertaining the cells' value. And compelling truthfulness will prevent the eavesdropper and researcher respectively from recouping those costs, thus creating a disincentive for them to incur those costs in the first place. This is a greater concern with the researcher than with the eavesdropper just because ascertaining the value of cells plainly carries greater social value than eavesdropping.

However, the cost of differentiating case by case between the low-cost and high-cost searcher in order to reserve the right to lie to the latter may not be worth the benefit. Such a differentiation imposes significant line drawing and measurement difficulties. A cruder rule that treats as high-cost searchers all searchers who at their own expense and risk examine cells not previously known to be valuable recommends itself when the administrative costs of a more differentiated rule are considered.[71] In effect, such searchers serve as proxy for high-cost searchers.

The previous example of the individual who takes the initiative and incurs the cost and risk of testing himself suggests another limit to the right to lie—the liar must be generally more able to discover the key information than the victim of the lie. For if the cheaper way to identify those with valuable cells is for individuals to search out the value of their cells themselves than for researchers to search for promising subjects, the appropriate legal approach ought to shift fundamentally. In that case, the cheaper way for society to acquire the key information would be to incent individuals either to arrange to search themselves or to gather information about whether self-searching would be cost-justified.

There is no need to consider what legal rules would best further that goal, however, because certain features of this industry suggest that the researcher can generally search at lower cost than can the subject. As a by-product of its research efforts, the researcher acquires some expertise about the family background and profile of traits that might suggest where

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The facts of *Moore v. Regents of the University of California* , 793 P.2d 479, 480-83 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991) suggest the problem. There, a cancer patient, Moore, presented a melon-sized diseased spleen which his doctor, the primary defendant, surgically removed and from which the doctor maintained a cell line of considerable value. The issue discussed here did not arise because the doctor had not obtained Moore's consent to the use of his tissues for research and commercial purposes at the time the tissues were taken. But if Moore had consented, the doctor/researcher had thereafter returned to Moore for further tissues, and Moore had asked the key question, should the doctor have been allowed to lie about the value of Moore's cells? The fact that the doctor came into possession of the cells almost costlessly, indeed almost fortuitously, suggests not. On the other hand, the fact that the doctor had undertaken significant efforts to ascertain the value of the cells, the benefits of which Moore could appropriate if he knew the full truth, suggests the lie should be allowed.

The more precise question then is not whether the researcher's *search* was costly but whether the researcher has undertaken *any* costly and socially valuable efforts the benefits of which the subject will be able to appropriate, and the incentive for which will be destroyed, if the subject is told the truth.

71. *See* Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. LEGAL STUD. 257 (1974) (case by case assessments often less efficient than reliance on blanket rule based on cruder indicia which serve as proxies).

to search. Moreover, in this fast developing field the researcher can more easily keep up to date on new developments that aid searching. Insofar as effective searching calls for testing many individuals, the researcher is better positioned to do that than the subject who can probably test only his family and himself. To be sure, the subject will learn about his family background and traits more cheaply than the researcher. But the subject likely faces prohibitive costs in learning whether his background and traits render him a sufficiently promising subject to justify the cost of self-searching.

The fact that subjects, for whatever reasons, are not likely to search out the value of their cells themselves further heightens the importance of maintaining proper incentives for searching by researchers. As in the oilman/farmer example, the case for allowing the oilman to suppress his knowledge of the oil would lose much of its force if the farmer, left to his own devices, was likely to drill for minerals himself. For the net social loss from failing to encourage the oilman's exploration would then diminish. Thus, the right to lie may be further limited to situations where the liars are more likely to undertake a search for the key information than are the victims of the lie.

Granted, this research would advance faster (though perhaps at disturbingly high costs) if individuals took the initiative to "search themselves" at their own expense. Accordingly, the approach recommended here calls for rewarding those individuals. Still, given the individual's likely inability to assess whether self-searching is worthwhile, and thus his likely failure to self-search, the law can best incent worthwhile searches by incenting the researchers.

The right to lie may be further limited to situations where the lie is unlikely to effect an allocative loss. The right to lie, like Kronman's right to not disclose, suffers from the disadvantage of causing mistakes. Here the subject in reliance on the lie allows a further collection that he might not have allowed had he known the truth. Mistakes by contracting parties harm society by frustrating the tendency of contracts to move resources into the hands of those who value them most highly. Mistaken investors, for example, may misjudge consumer demand and launch ventures that waste society's resources. A buyer of a house who is unaware of the presence of termites may fail to take remedial action until the cost of dealing with the termites is much greater. Absent the mistake, the waste could have been avoided. Various commentators distinguish between mistakes causing these productive or allocative losses and mistakes that merely re-

distribute wealth between the contracting parties.[72] In their view, the law should aggressively strive to penalize allocative mistakes but should be willing to tolerate redistributive mistakes when doing so incents the production of socially valuable information. Thus, the knowledgeable party should be required to disclose material information to the mistaken party when necessary to avoid allocative losses but need not disclose merely to avoid redistributional losses. Applied here, the issue becomes whether the subject would have allowed someone to collect his cells and use them in biotechnology had the subject known of their value. Can we predict with confidence that the cells would have been put to biotechnological purposes rather than remain in the subject or be used for some other purpose? If so, the researcher's lie does not effect any allocative loss, and the case for tolerating the lie is strengthened.

The previous willingness of the subject to allow a collection in return for nominal compensation supports this prediction.[73] The subject's willingness to allow the second collection in return for the same modest compensation conclusively establishes that, when all subjective valuations are counted, his is not the higher valued use of those cells.[74] If the trivial costs to him of allowing the collection are swamped by the modest benefits actually offered (mainly the satisfaction of helping medical research), those costs would be swamped, *a fortiori,* by the substantial benefits that would be offered if he had the knowledge to hold out. Once the cells are known to be valuable in research, they will ultimately be used in research rather than remain in the subject, with or without the lie. The lie merely removes information about the value of the cells from the second consent agreement. It thus allows the subject to grant or withhold consent to the second collection based largely on his subjective feelings about contributing to research which might lead to commercial gain for the researcher. Prohibiting the lie, and thereby allowing the holdup, only

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72. *See, e.g.*, Janet K. Smith & Richard L. Smith, *Contract Law, Mutual Mistake, and Incentive to Produce and Disclose Information,* 19 J. LEGAL STUD. 467, 470 (1990); ROBERT COOTER & TOM ULEN, LAW AND ECONOMICS (2d ed. 1997).

73. Barring the remote chance that the subject has undergone a conversion since the original collection, the subject is not someone who for religious or other personal reasons strongly opposes the drawing of his blood or any participation in research. Were that the case, the subject would feel his cells were more highly valued in a use other than research. Of course a subject recently converted to an anti-research view remains free to refuse a second collection.

74. In other words, the agreement to allow the second collection creates significant gains from trade, despite the subject's ignorance of the value of his cells. The researcher's lie only affects the terms of that agreement, not the ultimate use of the cells.

redistributes wealth between the subject and the researcher, at the cost of destroying the latter's incentive to search.[75]

One could limit the right to lie further by confining it to situations where that rule is unlikely to lead victims of the lie to duplicate the liar's previous search. Adoption of this proposed right to lie will admittedly reduce the subject's trust in the returning researcher. Because the subject knows that the law allows the researcher to lie, the subject becomes more inclined to self-search. Any rule short of one requiring full disclosure by all parties suffers from the disadvantage of eliciting "defensive" searches by less informed parties to discover information they fear the other parties already know but are not disclosing.[76] Insofar as the nondisclosing parties have already searched out the information, these "defensive" searches duplicate the earlier searches. The greater the resulting social waste, the stronger the case for requiring full disclosure.[77] How can one estimate this waste in each specific context? One indicia is clear: if for any reason the less informed party will not undertake a search despite his fear of being mistaken, no waste will occur. In our context, the question becomes whether a subject who knows the law allows the researcher to lie will undertake the costs of self-searching when he sees the researcher return and hears the researcher deny any knowledge of positive information. What will most research subjects in this position decide? Perhaps one can only guess. However, the tiny percent of people whose cells are actually valuable suggests that the chance of that being the case, even when the researcher has returned to that subject, remains remote.[78] Thus, the expected costs of self-searching probably still exceed the expected benefits. For this reason, a right to lie should trigger only a modest amount of duplicate searching.

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75. The allocative effect of a lie will rarely be so insignificant. False information about the value of securities, for example, moves the price away from the accurate price and thereby inflicts a deleterious allocative effect.

76. *See* Erik Rasmussen & Ian Ayres, *Mutual Mistake*, 22 J. LEGAL STUD. 309 (1993); Levmore, *supra* note 31, at 137-38.

77. At least until the research subjects learn that the law allows the researcher to lie, the researcher's false assurance that it has no reason to think the subject's cells are valuable should deter the subject from searching himself. And to the extent self-searching is wasteful, this effect strengthens the case for allowing the lie. Nevertheless, allowing lying should eventually inspire more self-searching, not less. Once the subject knows he can not rely on the researcher for an honest answer to his question, self-searching becomes his only way to obtain a reliable answer.

78. *See* Thomas P. Dillon, Note, *Source Compensation for Tissues and Cells Used in Biomedical Research: Why a Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628, 631 (1989).

More obvious limits to the right to lie narrow the proposed rule further. Plainly, the researcher could not justify lying about the value of the subject's cells to the tax authorities. Nor could it lie when doing so would increase the amount of misinformation in the marketplace, and therefore reduce the efficiency of the market as a mechanism for allocating resources. For instance, the researcher could not escape its obligations to be truthful which the securities laws impose.

Added together, all the limits suggested here confine the proposed right to lie so narrowly that it might seem to apply to the returning researcher's situation alone. While the right's scope may not be quite so narrow, these limits should allay any concern that embracing the right would compromise the law's condemnation of lying to a significant extent.

VI. ARGUMENTS AGAINST THE PROPOSED RIGHT TO LIE

The proposed right to lie will discourage from participating in this research those potential research subjects who, for whatever reason, wish to learn the value of their cells. Granted, the proposed right leaves these potential subjects free to search themselves at their own expense. But given the cost of that option, the right should effect a net reduction in the number of subjects willing to allow some collection of their cells for biotechnological purposes. Fortunately for this research, however, the low cost to the subject of participating and the substantial number of people willing to participate simply for the satisfaction of advancing medical research should assure an ample supply of subjects and should keep this objection from becoming significant.

Judicial embrace of the right to lie presents a greater concern than the possible disaffection of those interested in their cells' value. The wider audience that currently supports research financially and through other volunteer efforts may start to view researchers, and the research enterprise, in a less generous light. A legal rule chosen in part to encourage this research could easily backfire if it compromises the image of research among this wider audience.

The chance that judicial embrace of the right to lie would sour this wider audience on supporting research is a matter of public perception that cannot be assessed here. One can speculate that the example of the returning researcher lying would hurt the industry more than the courts' tolerance of that lie. Many people must know by now that some biotechnology researchers become wealthy by finding unusual cells and discovering their value. And many people no doubt suspect that certain researchers are driven by that prospect. But that does not mean the public expects the

lie defended here. The only deceit during research many probably expect is that which is required to achieve the immediate research goal. For example, a single blind research project may require misleading subjects who are given a placebo. To be sure, the deceit defended here resembles that deceit in that both advance research. But the public is likely to view the deceit defended here with a more jaded eye. The public is more likely to attribute the returning researcher's lie not to its wish to assure itself some gains from its search, thereby maintaining incentives for that search, but rather to its greedy wish to keep all the gains from the subject's cells to itself.

Lying to the subject may seem especially offensive when compared with the subject's own generous and altruistic behavior. The researcher repays the subject for his willingness to volunteer by lying to him in a way that deprives him of his ticket in the biotechnological lottery.[79] Moreover the researcher, instead of justifying the trust implicitly placed in him by the research subject, seems to be preying on that trust. If the researcher has lied to the subject about the value of his cells, and then brazenly and successfully justified that lie in court, the public may wonder what other matters the researchers may be lying about.

The proposed rule presents other problems than the public relations risk to the industry. The adage "one lie leads to another" suggests one jurisprudential problem: by tolerating the collector's verbal lie, the court would seem to tolerate supplemental lies by other employees of the researcher in more formal settings. Suppose the suspicious subject asks the returning researcher to put in writing its denial of any further reason for believing the subject's cells valuable? A law that tolerates the researcher's verbal denial would seem implicitly to tolerate a written one. Then suppose the subject insists on separate written denials from the researcher's employees who have personally tested his cells? Again, tolerating the company denial presumably requires tolerating individual denials. Yet we can see that the quantum of lying may proliferate quickly. Suppose further that the subject insists the denials be notarized or submitted in a formal affidavit or sworn to under oath? Can the researcher who wishes to comply, and thus allay the subject's suspicions, lie in these more formal settings with equal impunity? Criminal law provides a useful limit here, for courts could recognize an exception to the right to lie when the lie is uttered in a setting where lying is a crime. After all, the wish to pre-

79. *See, e.g.*, Aaron D. Twerski & Neil B. Cohen, *The Myth of Justiciable Causation*, 1988 ILL. L. REV. 600, 620 (reviewing the public's tendency to overrate small chances of large payoffs).

serve the integrity of the law's fact-finding processes warrants condemning lies uttered in the course of formal legal proceedings regardless of the lies' social value otherwise. Thus, lying under oath about a material matter triggers criminal sanctions, without regard to the subject of, or the justifications for, the lie.[80] Moreover, there is nothing remarkable or anomalous about treating lies differently depending on the legal formality of the setting in which they are uttered. Applying this limit, researchers who lie in a setting where the lie is criminal would subject themselves to the usual criminal sanctions.[81] Incenting socially valuable searches is not the law's only mission.

Perhaps the most obvious objection to the right to lie is that it opposes, indeed it seems to be proposed in defiance of, the Kantian principle that one must never treat another person merely as a means to some other end.[82] The researcher who responds to the subject's question with a lie in order to secure the second collection provides a quintessential example of using another merely as a means. Further, the lie denies the subject the choice of whether to donate his valuable cells to research or to attempt to secure for himself at least some of their value. A Kantian might claim that proper respect for the subject as a rational, autonomous, and moral being requires affording him that choice. To deny him that choice by means of the lie is to deny his essential personhood.

The researcher can hardly deny that it is treating the subject as a means, but it can reply that in research on human subjects, subjects are inevitably means to the research goals. That subjects are means is an inherent aspect of the research enterprise. The question for a Kantian, the researcher could argue, is not so much the morality or effect of the deception, but rather how much the subject needs to know to be in position to

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80. The federal statute imposing criminal penalties for perjury requires that the lie be uttered in the course of a formal proceeding. *See* 18 U.S.C.A. § 1621 (West Supp. 1996). Its purpose is to keep the process of justice free from the contamination of false testimony. *See generally* United States v. Manfredonia, 414 F.2d 760 (S.D.N.Y. 1969).

81. Except when the lie of the researcher's employee is uttered in such a formal setting that it constitutes a crime, the proposed right to lie would preclude criminal liability as well as civil. The reasons for guarding the researcher and its employees from civil liability argue as forcefully against criminal liability.

When the lie of the researcher's employee constitutes a crime, the offense lies in polluting society's fact-finding processes. As perjury by a defendant during a civil proceeding does not necessarily call for upholding the civil plaintiff's action, the lie of the researcher's employee, when criminal, need not automatically trigger civil liability to the subject.

82. *See* IMMANUEL KANT, GROUNDWORK OF THE METAPHYSICS OF MORALS 96 (1964).

consent meaningfully to the second collection. Here the subject knows a great deal at the time he gives consent. He knows the researcher with whom he dealt before is asking for a further collection for biotechnological research with possible commercial applications. In addition, the subject knows the time, place, risks, methods used, and terms of the proposed collection. Given what the subject knows, the researcher can argue, the subject is able to make a choice that ratifies his personhood. Thus, Kantian principles are not necessarily offended if he is not told more. It would not be practical, after all, to insist that the subject's choice is only meaningful when the subject knows everything the researcher knows. No one can seriously advance such a stern disclosure requirement.

Arguably, misinformation about harms, risks, and costs to the subject offend Kantian principles more than misinformation about additional benefits. As long as the known benefits suffice to induce the subject's consent, information about additional benefits should be viewed as surplusage. Failure to disclose those benefits or misinformation about them need not nullify consent freely given in the hope of lesser benefits.

The amount the subject knows at the time he consents to the further collection combined with the fact that he retains the option to refuse consent distinguish the lie from more offensive ways of obtaining samples. The lie accords the subject's autonomy greater respect and influence than if the researcher seized the samples surreptitiously or coercively.

Another moral objection to the proposed right to lie is that it countenances bad faith behavior. Such a characterization of the researcher's lie seems especially appropriate given the need for trust in the subject/researcher relationship. But the researcher may reply by calling for a fresh evaluation of the morality of the subject's question and of how that question colors its response. Here, conventional norms fall short, for they dismiss too readily the negative effects of the subject's question. It is common to say, for instance, that "there is no harm in asking," at least when the party being asked is a business with much greater ability to unearth the information sought. But here, asking is anything but harmless. While the subject may ask out of innocent curiosity, his question amounts to an attempted appropriation of the researcher's search. In this respect, asking becomes socially destructive for the same reason as attempted theft. Asking threatens the researcher for other reasons as well. When the researcher honestly answers the question "no" but later discovers the cells' value, then the researcher in a later suit by the subject may be unable to show that it was ignorant of the cells' value at the time it answered the question. Asking thus enables the subject to set up the researcher for a later suit whether he answers honestly or not. Once these effects of the

question are appreciated, the claim that the researcher's lie amounted to bad faith appears in a fresh light. Whether an actor has behaved in good faith or bad cannot be assessed in a vacuum.

Plainly, the Kantian and other moral objections to the proposed rule cannot be answered entirely. But the returning researcher's situation illustrates that the application of existing norms to new technology may yield anomalous effects. While those who violate the law gain a competitive advantage over the law-abiding in many other contexts as well, a law against lying here will give legal violators a particularly significant advantage over the law-abiding. When confronted with the subject's question, the former, appreciating how inappropriate that question is, and how dangerous to its interests an affirmative answer would be, will opt to lie despite the law. And if sued, the researcher will dispute or deny the lie. Rather than experience remorse, such a researcher will rightly disdain the shortsighted law that would insist on an honest answer to a question so inappropriate. In contrast the law-abiding researcher who complies with the law and answers truthfully will suffer for its compliance. And the lesson it will learn, the message that the law will send most clearly, will be that searching is futile where an uncritically conventional law fails to protect the incentive to search.

VII. THE CURRENT LAW

The reverence afforded the common law as the accumulated wisdom from case by case adjudication over time naturally inspires a wish to reconcile one's proposals with that law. But although no court has dealt definitively with the returning researcher who lies, there is little reason to believe that courts will guard the researcher against liability by adopting the right to lie. The subject able to prove that the returning researcher has lied can advance various claims under a number of common law categories.[83] While an exhaustive review of the possible claims triggered by the researcher's lie is beyond the scope of this article, a sampling of claims will illustrate the gap between the proposed rule and the current law.

The subject could claim the researcher is liable in tort for intentional infliction of emotional distress. The subject would need to show that the returning researcher acted in reckless disregard of the emotional distress the subject might suffer from the lie, that the lie foreseeable caused the subject emotional distress, and that the researcher's behavior in lying con-

83. The issue here–whether the researcher's lie is actionable–must be distinguished from the issue of whether the researcher's use of the subject's or patient's cells without their consent is actionable. For discussion of the latter issue, see *infra* part VIII B.

stituted outrageous conduct.[84] To keep this claim from a jury (the first two elements being unproblematic), the researcher would need to satisfy the court that sensible jurors could not deem its behavior "outrageous."[85] But the law's usual abhorrence of lying coupled with the subject's trust in and vulnerability to the researcher probably doom the researcher's claim. And characterizing the researcher's lie as outrageous conduct may expose the researcher to punitive as well as compensatory damages.[86] The danger of this liability brings into relief the importance of courts appreciating the reasons for tolerating the lie. By establishing the lie's social utility, those reasons might persuade a court to rule as a matter of law that the lie was not outrageous, despite its similarity to other deceitful behaviors deemed outrageous. Previous decisions defining outrageous behavior indicate that socially useful activities—from discharging for just cause an aged worker to outbidding at an auction one who is sentimentally attached to item for sale—escape that characterization regardless of the actor's intent or the emotional distress that predictably results.[87]

The subject can attack the researcher's behavior under other tort categories as well. The subject could claim the researcher's lie nullified the subject's consent to the second collection, thereby rendering that collection procedure a battery.[88] This tort action would not require any reliance on the informed consent doctrine.[89] The action relies only on the long-

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84. *See* RESTATEMENT (SECOND) OF TORTS § 46 (1974).

85. "Outrageous" conduct has been defined as "conduct exceeding all bounds usually tolerated in a decent society of a nature which is especially calculated to cause ... mental distress of a very serious kind." WILLIAM PROSSER & W. PAGE KEETON, TORTS § 12, at 60-64 (5th ed. 1984).

86. *See* Kelco Disposal v. Browning-Ferris Industries, 845 F.2d 404 (2d Cir. 1988).

87. *See* Thompson v. Williamson Co., 965 F. Supp. 1026 (M.D. Tenn. 1997) (ruling father can't recover for intentional infliction of emotional distress (IIED) where deputy sheriff shot and fatally wounded mentally disturbed son holding machetes); Coleman v. Special School Dist. No. 1, 959 F. Supp. 1112 (D. Minn. 1997) (school district's firing of principal and dissemination of written statements regarding prior, concealed felony convictions not grounds for IIED); Kraslavsky v. Upper Deck Co., 65 Cal. Rptr. 2d. 297 (Cal. Ct. App. 1997) (no grounds for IIED where employee terminated after refusing to take drug test, even when no individualized suspicion); Gosvener v. Coastal Corp., 59 Cal. Rptr. 2d 339 (Cal. Ct. App. 1996) (no grounds for IIED where supervisor who held safety sensitive position at a dangerous chemical refinery in a residential neighborhood was terminated for being an alcoholic).

88. *See, e.g.*, Mink v. University of Chicago, 460 F. Supp. 713 (N.D. Ill. 1978).

89. The tort of battery requires only that the defendant acts with intent to cause a harmful or offensive contact, or apprehension thereof, and that such a contact results. *See* RESTATEMENT (SECOND) OF TORTS § 13 (1974); *see also* WILLIAM PROSSER & W. PAGE KEETON, TORTS § 9, at 39-42 (5th ed. 1984); *see also* Richard Epstein, *Intentional Harms*, 4 J. LEGAL STUD. 391, 421 (1975).

standing principle that fraud vitiates express consent, here the express consent of the subject to the second collection.

More ambitiously the subject could seek to extend the informed consent doctrine so as to give subjects who allow collections in reliance on lies (or at least lies unrelated to the research goals) a cause of action in tort.[90] Thus far, the doctrine only benefits patients, not research subjects. Informed consent only requires that patients be informed of risks of the proposed treatment and of alternatives to that treatment, not of potential financial benefits.[91] In most states, a violation of the doctrine only gives rise to an action in negligence for injuries from the treatment. Thus, extending the doctrine to behavior like the researcher's, which poses no hidden risk of bodily harm, would stretch the doctrine beyond its personal injury focus.

Perhaps the subject's most obvious and irrefutable claim against the lying researcher—one sounding in tort and contract—would be fraud.[92] Given the researcher's intent to mislead, its awareness that its answer is false, and the likelihood that its false answer contributed to the subject's decision to allow the second collection, the researcher would seem reduced to arguing that the lie did not concern a material matter. The heart of the offer put before the subject, the researcher could argue, was whether the subject was willing to further the researcher's research and commercial purposes by allowing this second collection in return for the nominal compensation. The fact that the subject was highly likely to further those purposes, it could be asserted that the matter lied about was not material to this willingness. Unfortunately for the researcher, the significant chance the subject would have refused to allow the collection on the same terms had the researcher told him the truth establishes the matter's materiality in the eyes of most courts.[93] Once the fraud is established, the subject's remedy might even include an injunction against future production of products derived from the fraudulently acquired cells.[94]

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90. *See, e.g.*, Linda Daniels, *Commericalization of Human Tissues: Has Biotechnology Created the Need for an Expanded Scope of Informed Consent*, 27 CAL. W. RES. L. REV. 209 (1990).

91. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).

92. *See* RESTATEMENT (SECOND) OF CONTRACTS § 159 (1979); RESTATEMENT (SECOND) OF TORTS § 46 (1974).

93. *See* W. Page Keeton, *Fraud, Concealment and Nondisclosure*, 15 TEX. L. REV. 1, 25-26, 31-40 (1936).

94. *See* Papazian v. American Steel & Wire Co., 115 F. Supp. 111, 116 (N.D. Ohio 1957).

One could also attack the lie on the ground that it violates the fiduciary duty which researchers ought to owe to their subjects. The classic fiduciary relationship can be viewed as an implied understanding to share certain risks with the beneficiary who is, in effect, purchasing the fiduciary's information and using the fiduciary as an agent.[95] While such an implied understanding may exist between the researcher and subject as to the risks (physical and emotional) which the subject might face in participating in the research, no such implied understanding would seem to exist as to the financial benefits that might arise from the research.

In support of a fiduciary duty to respond to the subject honestly, the subject might cite the duties Congress imposed on researchers toward subjects when it passed the National Research Act of 1974.[96] That Act required the Office for Protection from Research Risks of the Department of Health and Human Services (then the Department of Health, Education and Welfare) (DHSS) to publish regulations for the protection of research subjects.[97] It also created the National Commission for the Protection of Human Subjects[98] and directed it to hold public hearings every four years and issues findings which, unless rejected by DHSS, were incorporated into new regulations.[99] The regulations primarily protect human subjects by requiring the creation of Institutional Review Boards (IRBs) which must review and approve each research project prior to its being funded by DHSS. In turn, the IRBs focus heavily on satisfying themselves that the researcher has obtained the subject's informed consent. The spirit of those regulations—if not the letter—call for the fullest and most updated disclosure of material matters to researcher subjects.[100] The regulations' oppo-

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95. *See* RESTATEMENT (SECOND) OF AGENCY § 13 cmt. 9 (1958); RESTATEMENT (SECOND) OF TRUSTS § 2 cmt. 3 (1958); RESTATEMENT (SECOND) OF TORTS § 874 (1974); *see also* DEBORAH A. DEMOTT; FIDUCIARY OBLIGATION, AGENCY, AND PARTNERSHIP 4 (1st ed. 1991).

96. *See* National Research Service Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 342 (1974).

97. *Id.* at 352-53.

98. *Id.* at 348.

99. *Id.* at 349.

100. Both the Food and Drug Administration and the Department of Health and Human Services have issued regulations that, where applicable, require researchers to disclose certain information to research subjects. 21 C.F.R. § 50 (1989); 45 C.F.R. § 46 (1998). If those regulations would condemn a researcher's failure to disclose that the subject's cells have been found valuable, they would seem to condemn, *a fortiori*, a deliberate lie about the cells' value.

The regulations focus entirely on assuring that the subject is alerted to risks, including risks of psychological distress, social stigmatization or financial indebtedness. Not surprisingly, a number of provisions suggest that a researcher need not disclose that a

sition to mere non-disclosure by the researcher suggests an abhorrence of any lying, at least any lying not necessary to the research goals.

However, the congressionally imposed obligations on researchers focused on reducing risks, whether physical or emotional, to the subject. Congress stopped short of imposing an obligation on researchers to further the financial well-being of subjects. Likewise the California Supreme Court in *Moore*, while recognizing that a doctor has a fiduciary duty to his patient to inform him when samples are taken solely for research purposes, based that duty on concern for the patient's physical well-being and refused to hold that a doctor has an obligation to concern himself with the patient's financial well-being.[101] Whatever the duties arising from the doctor/patient relationship, no court has yet recognized a fiduciary relationship between a researcher and its subjects.

The subject could attempt to nullify the second agreement under contract principles as well. The Uniform Commercial Code's emphasis on the fundamental importance of good faith supports a sweeping condemnation

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subject's cells have proven valuable. Reflecting the focus on alerting subjects to possible embarrassment, 46 C.F.R. § 101(b)(4) exempts from any obligations "[r]esearch involving the ... study of ... pathological specimens or diagnostic specimens ... if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects." *Id.* Reflecting the focus on alerting subjects to possible physical injury, 46 C.F.R. § 116 (1998) further allows an Institutional Review Board to waive the usual requirement of informed consent when the research involves no more than minimal risks to the subject. Moreover, in 1981, the Department clarified that this waiver may be obtained through an expedited procedure when the research involves the mere collection of blood samples.

On the other hand, some language in the regulations could be interpreted to require researchers who discover that a subject's cells are valuable to alert the subject to their discovery. 46 C.F.R. § 116(b)(5) requires disclosure when "significant new findings [are] developed during the course of the research which may relate to the subject's willingness to continue participation." Similarly, 46 C.F.R. § 116(a)(3) requires that subjects be informed of likely benefits from the research.

These guidelines apply to studies funded by any of the seventeen federal agencies, experiments to prove the efficacy of medicines or medical devices, and research by academics regardless of the source of funds. In addition, California, New York, and Virginia have legislated consent requirement for research not governed by the federal guidelines. None of these statutes expressly require that subjects be notified when their cells are found to be valuable. *See* CAL. HEALTH & SAFETY CODE §§ 24170-24179.5 (West 1986); N.Y. PUB. HEALTH LAW §§ 2440-2446 (McKinney Supp. 1986); VA. CODE ANN. § 37.1 (1979).

101. *See* Moore v. Regents of the University of California, 793 P.2d 479, 482 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991); *see also* Anne T. Corrigan, Note, *A Paper Tiger: Lawsuits against Doctors for Non-Disclosure of Economic Interests in Patients' Cells, Tissues and Organs*, 42 CASE W. RES. L. REV. 565, 583 (1992).

of lies.[102] The subject could also invoke the law of unilateral mistake, despite that law's apparent willingness to forgive non-disclosure in the *Laidlaw* and *Texas Gulf Sulphur* line of cases.[103] Not only do cases like *Laidlaw* stop short of tolerating lying, they probably fail to state the prevailing legal rule even for their own contexts. Despite those cases, the mistaken party—here the subject—can generally void an agreement under the Restatement when the knowledgeable party has reason to know of the other's mistake or has caused it.[104]

That the subject may advance a number of highly promising claims against the researcher does not mean the fate of the proposed right to lie is sealed. The context, like the technology, is fresh. Courts have yet to confront even remotely similar facts. The *Laidlaw* and *Texas Gulf Sulphur* line of cases offer some support for a right to not disclose material information about which one knows the other party to be ignorant as long as that information is the fruit of one's deliberate search. From that right to not disclose, the proposed right to lie is a short step. The need to protect search incentives that supports the former right argues for the latter as well. Indeed, once the other party learns to ask the searching party what it has discovered, the right to not disclose becomes meaningless unless accompanied by the right to lie. However more outlandish the right to lie may seem compared to the right to not disclose, the two rights imply each other.

VIII. RELATED ISSUES

A. Nullifying the Consent Agreement on Behalf of the Subject when the Cells Prove Valuable.

Some may think the most interesting issue bioprospecting presents is whether the original agreement giving the researcher the right to any revenues derived from the subject's cells should be upheld when attacked ex post by a subject who somehow learns that his cells have proven valuable. The specter of the researcher profiting from the subject's cells while the

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102. U.C.C. § 1-203 (1995); *see also* CHARLES FRIED, CONTRACT AS PROMISE (1981) (emphasizing the importance of good faith). The Greeks saw good faith as a universal social force that governed their social interrelationships. *See* FRITZ PRINGSHEIM, THE GREEK LAW OF SALES 87 (1950). Canon law posited good faith in a universal moral norm rather than a social norm. *See* Powel, *Good Faith in Contracts*, 9 CURRENT LEGAL PROBLEMS 21-22 (1956).

103. Laidlaw v. Organ, 15 U.S. 27 (2 Wheat) 178 (1810); Leitch Gold Mines, Ltd. v. Texas Gulf Sulfur, 1 O.R. 469 (1969).

104. *See supra* note 25 and accompanying text.

subject does not may rankle some. They may feel intuitively that the subject should share in any revenues the researcher obtains. And by nullifying the provision in the agreement whereby the subject assigned the researcher the right to use the cells for commercial purposes, the court can use its equitable powers to effect that result.

There seems no reason, however, why the researcher and subject, ex ante, should not be free to enter into binding arrangements that they consider desirable. Nor is there any reason the usual assumption that participants in agreements can protect their own interests should not control here as elsewhere.

The most publicized proponent of nullifying the agreement on behalf of the subject is Thomas Murray.[105] Notwithstanding the warning given the subject before the collection that the samples might be used for commercial purposes, the subject's clear assignment of his rights to the researcher, and the nominal compensation, Murray insists that the original collection be viewed entirely as a gift.[106] Murray privileges gift-giving over agreed-upon exchange in that he invests gift-giving and the gift relationship with special and superior moral significance. According to Murray, it would pollute our moral relation to our bodies, even to our replenishable fluids and cells, and even after we have abandoned them, were others to make use of them save by our gift.[107] And to safeguard the purity of our moral relation to our bodies (themselves a gift), courts should nullify the terms of any agreement concerning bodily materials and enforce instead terms that comply with the norms of gift-giving. What are those norms that so trump the party's wishes? Murray suggests a few: grateful conduct, appropriate reciprocity, and grateful use.[108] Applied here, the grateful use norm maintains that no recipient should unduly prosper from the gift, and if profits do result, some must be dedicated to a public service goal and some must be shared with the subject.[109]

In putting gift-giving on a more elevated moral plane than exchange and then insisting that certain transfers be only by gift, Murray echoes

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105. *See* Thomas Murray, *Gifts of the Body and the Needs of Strangers,* 17 HASTINGS CENTER REPORT 30 (1987); Thomas Murray, *The Gift of Life Must Always Remain a Gift,* 7 DISCOVER, Mar. 1986, at 90; Thomas Murray, On the Ethics of Commercializing the Human Body (1986), (unpublished paper prepared for U.S. Congress Office of Technology Assessment) (on file with author); Thomas Murray, *Who Owns the Body? On the Ethics of Using Human Tissue for Commercial Purposes,* 8 IRB: A REV. OF HUM. SUBJECTS RES. 1 (1986).

106. *See* Murray, *Gifts of the Body and the Needs of Strangers, supra* note 105, at 33.

107. *See id.* at 34.

108. *See id.* at 32-33.

109. *See id.* at 35.

earlier authors, most notably Richard Titmuss.[110] These authors exalt primitive tribes who emphasized gift-giving as a method of establishing networks of reciprocity that bound the community together. They find support for the moral superiority of gift-giving over agreed-upon exchange in the fact that gifts were typically used to satisfy the recipients "needs" rather than his mere "desires." That is, gifts were more often given to avoid starvation than to avoid some lesser dissatisfaction.[111]

Looking at the same anthropological phenomena through an economic lens, Richard Posner punctures this romantic illusion.[112] He explains that gift-giving provided insurance against major losses like starvation in a society where insurance markets were not sufficiently developed for insurance to be otherwise obtained.[113] For example, giving to another whose fields were located elsewhere would create an obligation on the other's part to reciprocate in time of need and thus would diversify against the risk that one's own crops would fail.[114] The well-known tendency for insurance to be sought only against major losses likewise explains the restriction of gift-giving to what Murray calls "needs."[115] As insurance, gift-giving suffers in comparison to the market insurance available in more developed societies. The move away from gift-giving to the agreed-upon exchanges of more developed societies thus appears, at least on this front, as an advance. Murray's views, like those of Titmuss, represent the by-product of a romantic ideology rooted in antipathy toward the market economy and idealization of the primitive.[116]

B. Sharing Revenues in the Absence of an Agreement

When samples come from therapeutic efforts to treat patients rather than from research subjects participating in clearly designated research projects, the patients are not always alerted to the possibility that their

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110. *See* RICHARD M. TITMUSS, THE GIFT RELATIONSHIP (1971); *see also* MARCEL MAUS, THE GIFT (1967); Lori B. Andrews, *My Body, My Property*, 16 HASTINGS CENTER REPORT 28 (1986).

111. *See, e.g.*, TITMUSS, *supra* note 110, at 197.

112. *See* Richard A. Posner, *A Theory of Primitive Society, With Special Reference to Law*, 23 J.L. & ECON. 1, 32 (1980).

113. *Id.* at 33.

114. *Id.* at 34.

115. *See, e.g.*, David Friedman, *What is Fair Compensation for Death or Injury?*, 2 INT'L REV. L. & ECON. 81 (1982) (the diminishing marginal utility of wealth, which lies behind the demand for insurance, is not brought into play by small losses).

116. *See* Scott Cook, *The Obsolete "Anti-market" Mentality: A Critique of the Substantive Approach to Economic Anthropology*, 68 AMER. ANTHROPOLOGY 323 (1966) (responding to Karl Polyanyi, *Our Obsolete Market Mentality*, 3 COMMONWEALTH 109-17 (1947)).

samples may be used for research or commercial purposes.[117] And research subjects who know and consent to the use of their samples for research and commercial purposes may not always have assigned all rights to revenue derived from those samples to the researcher. These "non-consenting"[118] parties (patients) figure significantly in one of biotechnology's most discussed issues: when the samples prove valuable, should the non-consenting patient be entitled to a share of the revenues?[119] While we may prefer that doctors and researchers obtain consent, the better rule in the absence of any agreement assigning the revenues from commercial use to the patient or the researcher would give the patient no right to share in the revenues or to control the course of the research.[120]

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117. The assumption here is that the collector had a therapeutic purpose for recommending that the samples be collected, and that the patient consented to the collection for that purpose. The patient was not asked about, and was presumably unaware of, the subsequent research and commercial use of those samples.

The facts in *Moore* differed significantly. There, apparently, defendants collected some samples with no therapeutic purpose whatsoever. Although allowing those collections subjected the patient to some inconvenience, his physician, one of the defendants, led him to believe the collections were necessary for therapeutic purposes. Moore v. Regents of the University of California, 793 P.2d 479, 481 (1990), *cert. denied*, 499 U.S. 936 (1991).

118. The patient is "non-consenting," despite having consented to the collection for therapeutic purposes, only in the sense that he never consented to any research or commercial use of his samples and never assigned the right to revenues derived from the samples to the researcher. The subject is "non-consenting" because he never assigned the right to revenues derived from the samples to the researcher. The assumption here is that the patient and subject are silent on these matters. Of course, if the patient or subject expressly refuses consent, his wishes should be respected.

Because of the continuing ban on exculpatory provisions in any consent agreement governed by the Department of Health and Human Services guidelines, many research subjects will be non-consenting as the term is used here. *See* 45 C.F.R. § 46.116 (1998). Yet the purpose of the rule banning exculpatory provisions had nothing to do with the subject's commercial rights in the extractions. Its purpose was to preserve a subject's right to sue should he be injured during the course of the research. *See Hearings: The Use of Human Biological Materials in the Development of Biomedical Products* 233 (October 29, 1985) (statement of Dr. Charles R. McCarthy, Director, Office for Protection From Research Risks, National Institute of Health).

119. Of the many commentators discussing the patient's claim, most support the patient's right to share. *See, e.g.*, Mary Taylor Danforth, *Cells, Sales and Royalties: The Patient's Right to a Portion of the Profits*, 6 YALE L. & POL'Y REV. 179 (1988); William Bowlier, Note, *Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts*, 23 HOFSTRA L. REV. 693 (1995); Laura M. Ivey, Comment, Moore v. Regents of the University of California: *Insufficient Protection of Patient Rights in the Biotechnological Market*, 25 GA. L. REV. 489 (1991).

120. Although *Moore* provides one precedent for denying the patient's claim to the revenues, there is no discrete statutory or common law that deals specifically with this

First, giving the patient a share will not encourage socially desirable behavior. It will not, for example, encourage the patient to act in a way that would increase the value of his cells. Giving people a right to the earnings from their native talent incents them to develop those talents. But there are no such developmental behaviors by which the patient can add value to his cells. The patient either possesses valuable cells or does not. His possession of such cells is a matter of his genetic endowment and not of any behavior the law can influence.

To be sure, with a default rule that recognized the patient's right to share, patients will feel more enthusiastic about allowing collections for therapeutic purposes. At least they will be much less likely to object should they learn their samples were subsequently used for research and commercial purposes. And if, as a result, more samples are available to researchers, that would be some reason for letting the patient's share. But the therapeutic reasons alone will persuade patients to allow the overwhelming majority of these collections, and there is no need to give the patients the extra incentive of a possible share in far-removed revenues.

Moving from the context of the patient to that of the research subject whose consent agreement was silent about the right to revenues, one could argue that a default rule recognizing the subject's right to share would give the subject greater incentive to participate in the research project. The resulting greater willingness of subjects to participate should lower search costs. But the savings should be modest if, as appears to be the case, many subjects are willing to allow collections without this incentive. Given the generous spirit of so many subjects, the extra incentive of a possible share seems unnecessary. It may look unkind to deny subjects a right to share in the revenues on the ground that most of them are generous and altruistic enough to participate in the research anyway. But this is just another application of the general principle that the law need not incent low cost activities that the actor is likely to undertake for independent reasons despite his inability to internalize the benefits.[121]

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issue. Nor is it clear whether the issue should be treated as one of property, tort, contract, patent, or trade secret law. Certainly a patient seeking a share of the profits could advance his claim under a wide variety of legal theories.

121. One might think granting subjects a right to share would encourage persons not only to participate in the researcher's project, but also to self-search, in other words, to undertake the initiative and risks of testing themselves. If searching is better conducted by persons self-searching, this would provide a further reason for giving subjects a right to share. One must distinguish, however, between participating with the researcher's project and taking the initiative and bearing the risk of self-searching. Recognizing the right to share encourages the first but not the second. Instead, denying the right to share better encourages the second. Self-searching with a view toward allowing collection by

By awarding the subject a share of the revenues, the law should reduce the need interested subjects may feel to self-search.[122] That effect would strengthen the case for sharing if self-searching was a wasteful and high-cost method of finding valuable cells and if many subjects, denied the right to share, would resort to it. While the first condition is met (the subject being a higher-cost searcher than the researcher),[123] denying the subject the right to share is unlikely to induce much self-searching, wasteful or otherwise, given the long odds against having valuable cells that face a subject who has no particular reason to believe his cells valuable. Thus, recognizing the subject's right to share realizes little savings on this score.

Compared to the meager social benefits of assigning the patient a share of revenues, the costs society would incur from this default rule are striking. Measuring the patient's share of the revenues would entail substantial costs.[124] A court would need to identify the contribution, if any, of the patient's cells to the end product. But many laboratory transformations over a long period of time separate the original extraction from the end product.[125] Research results are typically a series of several joint efforts with specimens provided by several individuals.[126] Moreover, the cells of some individuals may have contributed merely by educating the researcher about the kind of genetic material that might express the desired protein product. The cells of others might have helped merely by educating the researcher how to make hybridomas or monoclonal antibodies in the first place. That is, neither those cells nor the cell line derived from them constitute any physical part of the end product. How then can the contribution of those cells be measured? Even if the right to share was (rather arbitrar-

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the highest bidding researcher then becomes the only way a person can realize for himself the value of his cells. In general, the more the law favors researchers over subjects, the more the law encourages persons to self-search and keep all researchers out of the search as much as possible.

We see the same principle at work in the oilman/farmer case where rules favoring oilmen drive the suspicious farmer to take the initiative and the risks of hiring a geologist to ascertain the value of his mineral rights. If such self-searching is socially desirable, that is an argument for the law favoring the oilman. If such self-searching is not socially desirable, say because it duplicates previous testing or is otherwise wasteful, that is an argument for the law favoring the farmer. Assuming that the costs of self-searching exceed the benefits, the case for a right to share is marginally strengthened by that rule's tendency to reduce self-searching.

122. *See id.*; *see also supra* notes 76-78 and accompanying text.

123. For discussion of why the researcher can search at lower cost than the subject, see *supra* notes 73-74 and accompanying text.

124. *See* OTA REPORT, *supra* note 1, at 54.

125. *See id.*

126. *See id.*

ily) limited to patients whose cells constitute some physical part of the end product, a number of patients could typically claim a right to share. Often there will be no way to assess the relative contribution of each patient's cells. As the Office of Technology Assessment found, "A determination of the contribution of any single individual to the marketable end product would be speculative."[127]

One could reply that the measurement problems should diminish in the face of a clear rule recognizing the patient's right to share, because researchers would react to that rule by negotiating the patient's share at the time of the collection. But the negotiations thus induced, which will sometimes need to occur around the patient's hospital bed, impose costs of their own. Perhaps the greatest cost stems from the delay of research that may result if the two sides hold out for a greater share. But even when negotiations proceed smoothly, the negotiating costs may be substantial compared to their benefits in light of the many patients whose collections researchers may wish to examine and the tiny percent of these negotiated agreements that will ever be used. Indeed researchers can argue that the cost of the negotiations needed to allocate the right to revenue should be analogized to the cost of transferring property rights from a lower to a higher valuing user.[128] As the costs of transferring those rights increase, perhaps because of the number of agreements needed, the case for recognizing the lower valuing user's property right—and thus compelling the transfer in the first place—weakens. For these reasons and others discussed below,[129] it is surprisingly unclear whether society wants to require researchers to negotiate with patients for use of their cells. There is little

127. *Id.* at 41. The costs of identifying the patient's contribution resemble the prohibitive identification cost of patenting the ideas generated by basic research. With the passage of time it becomes increasingly difficult to identify the products in which the basic ideas are embodied. Here identifying the contribution of the patient's cells to various end products becomes increasingly difficult. *See* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 67 (4th ed. 1993).

128. The property rights issue arises, for example, when a landowner sues for trespass an airline that has flown at a high elevation over his property. One reason for ruling for the airline, and thus refusing to recognize the landowner's property right to the airspace above his land, is to avoid the cost of negotiating the many agreements that would be needed for the airline to obtain the consent of all landowners over whose land its route would pass. *See* Thomas W. Merrill, *Trespass, Nuisance and the Costs of Determining Property Rights,* 14 J. LEGAL STUD. 13 (1985).

129. *See infra* notes 143-152 and accompanying text.

point to embracing a pro-plaintiff rule in order to induce negotiations which cost more than the benefits they provide.[130]

The record-keeping required to measure the patient's share also imposes costs. To keep a court from overestimating shares, researchers would need to keep track of patients, cell lines, the patients' contribution to each cell line, the role of each cell line in developing the end products, and the sales of the end products to which each cell line contributed. Studies involving the development of cell lines can take years to complete and commercial application even longer. The cost of keeping records of the origin of all the cell lines involved cannot be ignored. In light of the small percent of cell lines that ever yield revenues, these record-keeping costs may dwarf the revenues that researchers are eventually compelled to share.

No doubt the greatest cost of recognizing the patient's right to share comes from the possible effect of that rule on the behavior of researchers. Before the patient's claim to a share of revenues is clearly recognized or rejected, the usual costs of legal uncertainty burden the researcher. The researcher faces the specter of the law seizing a substantial share of its revenues and branding it as a converter or thief in the process. That specter also warns off any would-be purchaser of the cell line for the purchaser cannot be sure what rights, or what liability, it will be buying. The researcher's fear of these lawsuits may sour its enthusiasm and drive its energies and investments elsewhere. As Hamlet said of another fear, "enterprises of great pitch and movement, with this regard their currents turn awry, and lose the name of action."[131]

Eliminating the legal uncertainty by ruling in the patient's favor will of course further reduce the incentive for the researcher's endeavors. The chance of a loss of revenue should a patient discover that his cells have been used now becomes a certainty. Moreover, recognizing the patient's right to share in effect divides the ownership of the cell lines, thereby inflicting the usual costs of divided ownership.[132]

Recognizing the patient's right to share the revenues implies some right in the patient to control the course of the research. Thus, the possible harm from the patient's right to control argues against the right to share. And the divergent interests between the patient and researcher render that

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130. The Office of Technology Assessment found that "transaction costs are likely to dwarf the cost of payment to ... individuals [whose cells contribute to commercial gain.]" OTA REPORT, *supra* note 1, at 31.

131. WILLIAM SHAKESPEARE, HAMLET, act III, sc.1, lines 86-88.

132. For a summary of the inefficiencies of divided ownership, see RICHARD POSNER, ECONOMIC ANALYSIS OF LAW 120 (5th ed. 1995).

harm all too likely. For example, the patient's interest might oppose the widespread practice among researchers of exchanging newly acquired information and tissue samples freely.[133]

Notwithstanding the utilitarian grounds for a default rule favoring the researcher, some will say the patient becomes entitled to a share of the revenues on grounds of fairness just because use was made of his cells. To let the researcher profit from those cells but not the patient seems unjust.[134] This claim will often lose some of its appeal when the use of the patient's cells is examined more closely. In genetic engineering, for example, the patient's cells may serve only to educate the researcher about what kind of genetic material will express the desired protein product.[135] Genetic engineering typically leads not only to the modification of cells but to the development of organisms that have never existed in nature separate from other organisms. In this sense those organisms are new. To be sure, the patient's cells have contributed to that organism. But the patient's contribution does not differ significantly from that of subjects whose cells led researchers to learn the methods of genetic engineering originally.

The contribution of the patient's cells to the end product nevertheless provides a more compelling equitable ground for granting the patient a share than does the patient's behavior. The relatively passive behavior of allowing the collection requires little effort and less preparation. In both respects, it contrasts sharply with the strenuous and elaborately grounded behavior of the researcher who must find the cells, identify their value and develop the end product. Why equity demands a windfall for the passive at the expense of the active is not self-evident. At bottom, the patient's equitable claim relies on the lottery mentality which champions claims based on a wild fortuity over claims based on value added through extensive preparation, careful planning, and painstaking effort. Fueled by a populist fervor, the lottery mentality favors claims of ordinary folk over claims of entrepreneurs or educated professionals regardless of the effect of recognizing those claims on society.

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133. *See* Alan J. Lemin, *supra* note 16, at 197.

134. *See* OTA REPORT, *supra* note 1, at 43-44. John Rawls is one philosopher who would oppose allowing the subject a share of the revenues. Rawls justifies rewarding the born lucky only when society has reason to expect that the reward will motivate the born lucky to significant added efforts that benefit the community as a whole. JOHN RAWLS, A THEORY OF JUSTICE, 102-104 (2d ed. 1971).

135. *See* OTA REPORT, *supra* note 1, at 43-44.

C. Whether Researchers Should be Required to Obtain a Patient's Consent to Research and Commercial Use

The default rule proposed in the preceding subsection, by denying the patient a right to share in the revenues, will certainly invite researchers to refrain from notifying patients that samples taken from them for therapeutic purposes will also be used for research and commercial purposes.[136] For the researcher's failure to notify will not give the patient a claim for any revenues directly or indirectly derived from the collections. Given that default rule, the question becomes whether the law should put any pressure whatsoever on researchers to alert patients to the possible research and commercial use. For example, the law could afford the nonconsenting patient some claim against the researcher short of a claim for a share of the revenues, the hope being that the lesser claim will suffice to induce the researcher to obtain the patient's consent.[137]

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136. Again, the situation in *Moore* differs from that discussed here in several respects. In *Moore*, some collections were undertaken with no therapeutic purpose in mind at all, yet the patient was allowed to believe the collections were solely for therapeutic purposes. Moore v. Regents of the University of California, 793 P.2d 479, 492 (1990), *cert. denied,* 499 U.S. 936 (1991). Moore was treated purely as a research subject, yet he was led to believe he was purely a patient.

One rule *Moore* establishes is that when the doctor's only purpose of a collection is to aid research, the doctor should inform the patient of that fact. Federal regulations, where they govern, also support this rule for they require that consent to research use be obtained where samples are taken from patients *primarily* for research purposes. *See* 46 C.F.R. § 110(b) (1998). But this rule leaves open the issue here where researchers merely use material collected for therapeutic purposes.

Moore also clarifies the information a doctor must provide in order for a patient to give informed consent to the doctor's recommended treatment. Under *Moore*, doctors who have research interests in the treatment they recommend must alert the patient to those research interests, at least when those interests might have influenced their decision about what treatment to recommend. *Moore,* 793 P.2d at 479. The knowledge of the doctor's research interests bears on the patient's decision about whether to seek a further opinion regarding the recommended treatment and also on his decision about which doctor should administer the treatment. Without knowledge of the doctor's other interests, *Moore* holds, the patient's decision to consent to the doctor's recommended treatment cannot be an informed one. *Id.* at 508.

So understood, the ruling in *Moore* only affects those involved in the patient's treatment. The ruling puts no obligations on researchers or pathologists not involved in the treatment who merely gain access to the samples afterwards.

137. For instance, the researcher's negligent or deliberate failure to obtain the patient's consent might be held to afford the patient an action for the modest damages stemming from the indignity he suffers because his samples are used in ways he would not have approved. *See, e.g.*, Alan Meisel, *A "Dignitary Tort" as a Bridge between the Idea of Informed Consent and the Law of Informed Consent,* 16 LAW MED. & HEALTH CARE 210, 211-14 (1988); Anne T. Corrigan, Note, *A Paper Tiger: Lawsuits Against*

At least two considerations call for requiring researchers and cooperating health care professionals to obtain the patient's consent to research and commercial use. First, some patients will object to research or commercial use of their samples on religious grounds or on other grounds of principle.[138] Their dignitary interest in avoiding offensive uses of their cells deserves respect. Like the property owner who puts a subjective value on his property that is much higher than the market value, that subjective valuation ought to be taken into account in deciding the optimal use of the samples. There is a welfare loss, after all, when samples are used for research even though their utility for that purpose is swamped by the disservice that use causes the patient. And the patient's subjective valuations will only come into account if the patient's consent must be obtained. Moreover, so few patients are likely to refuse consent that their refusals should not interfere significantly with the research.

Second, in the vast majority of cases the researcher should be able to obtain the patient's consent to research and commercial use easily, at least when the researcher asks early enough, namely, before the patient suspects his cells have a significant chance of being valuable. Another sentence in the notification given patients upon their arrival at the hospital or in the

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Doctors for Non-Disclosure of Economic Interests in Patients' Cells, Tissues and Organs, 42 CASE W. RES. L. REV. 565 (1992). The court in *Moore* recognized a similar dignitary action against an uninformed patient's doctor. *Moore*, 793 P.2d at 508. To be sure, the doctor not only failed to inform his patient that his samples might be used for research and commercial purposes, he also misled his patient into believing that certain collections were for therapeutic purposes when in fact they were solely for research purposes. The court further limited the action by basing it on the fiduciary duty doctors owe to all their patients. *Id.* at 511. Thus researchers who have no contact with the patient would have no duty to warn of the possible research and commercial use.

Despite these distinctions, *Moore* gives some support to the notions that patients should be informed when research or commercial use of their samples is contemplated and that courts should recognize some action for the modest indignity when the samples of uninformed patients are so used.

138. A devout Catholic woman with ovarian cancer might object to the use of her removed ovary for the development of oral contraceptives. Similarly, an Orthodox Jew who believes that it is good to bury the parts of the body in the same area where the body itself will rest after death might not want her organs to be sent to a research facility. A person morally opposed to war might not want her cells to be used in experiments regarding the effects of chemical warfare, while an animal rights activist would object to the use of her tissue in the development of painful skin tests to be used on live animals.

Sharon N. Perley, Note, *From Control Over One's Body to Control Over One's Body Parts: Extending the Doctrine of Informed Consent*, 67 N.Y.U. L. REV. 335, 346 (1992).

consent form which the patient needs to sign for his treatment may be all that is needed.[139]

Moreover, the court in *Moore* has already found illegitimate one reason for the reluctance of doctors to mention to patients the possibility of research and commercial use.[140] That reason is the doctor's wish to appear exclusively devoted to the patient's health rather than involved in some research use of the patient's samples. Doctors may fear that any hint of divided loyalty risks rupturing their relationship with the patient and thereby endangering the patient's therapy. Regardless of whether this fear is warranted, the court in *Moore* brushed this fear aside and held that the patient is entitled to be informed when his doctor has a research interest in his recommended therapy.[141]

Research hospitals that do not routinely alert patients to the possible research or commercial use of their extractions defend their practice on several grounds.[142] They claim that mentioning the possibility of commercial use to the patient excites unwarranted curiosity and unreasonable hopes and invites further inquiries from the patient about the research.[143] The burden of supplying each patient with all the information he demands may become significant. Occasionally, a patient also may insist on controlling the course of any research that would use his samples.[144] In an effort to assure that their samples are examined for possible commercial value, some patients may falsify their medical history. Thus, mentioning this possibility adds an element of complexity in obtaining samples that may imperil the therapeutic goals that called for the collections originally.[145] How patients in fact react to mention of this subject, and whether mentioning it would impede therapy or research, is something the health care professionals and researchers are better positioned to assess than a

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139. Research hospitals usually provide notice on admission and do not seek informed consent until treatment. *See* ROBERT LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 111-113 (1986).

140. *See Moore,* 793 P.2d at 485.

141. *See id.* at 511.

142. *See* Eleanor S. Glass, Note, *Restructureing Informed Consent: Legal Theory for the Doctor-Patient Relationship*, 79 YALE L.J. 1537 (1970); Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966).

143. *See supra* note 100.

144. For the argument that patients should have the right to control the course of research by putting restrictions on the use of their samples, see Perley, *supra* note 138.

145. The possibility that therapeutic goals will suffer from informing patients about research use contradicts the holding of *Moore,* for the court there held that alerting patients to their doctor's research interests furthered therapeutic goals by giving the patient a sounder basis for picking a doctor, requesting a second opinion and allowing treatment. *Moore,* 793 P.2d at 496.

judge would ever be. They are better able, after all, to see the patient's reaction when the topic is broached and the patient's consent requested.

Moreover, a law requiring consent would need to indicate how much information researchers need to convey about the research use intended. Need they describe only the goals or the methods as well? How specifically must the goals and methods be described? Under the informed consent doctrine, the test of materiality governs which risks of treatment must be disclosed. And that test requires disclosure of risks to which a reasonable person would attach significance.[146] However, given the widely divergent views about research that patients possess, a researcher will be hard pressed to identify the information about its research that patients will find significant.

Once consent is required, it follows that patients can at least attempt to condition their consent on the researcher's promise to adhere to certain research goals and methods of which the patient approves. Respect for the patient's autonomy in this regard will present further issues. Will courts enforce, for example, a patient-imposed requirement that the patient's cells only be used in research designed to benefit certain races?

Because the patient is consenting to the collection on therapeutic grounds, the research use requires no added invasion of the patient's bodily integrity. Nor does the research use expose the patient to any additional risk of harm. The lack of additional risk argues against an extension of the informed consent doctrine because that doctrine is driven by the wish to assure patients the power to decide whether to incur the risks of doctor-recommended treatment. The patient's decision-making power in that regard would in no way be impaired by research use of his samples.

While research use is more common, the patient's samples will so rarely lead to a commercial use that requiring consent to this use from every patient seems unduly burdensome.[147] As the chance of using this consent becomes more remote, the cost of obtaining the consent, though

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146. *See* Canterbury v. Spence, 464 F.2d 772, 786 (D.C. Cir. 1972).

147. The Department of Health administrators responsible for the federal regulations protecting human subjects cite the remote chance of commercial gain as the primary reason for not requiring researchers to alert subjects to the chance of such gain. *See Hearings: The Use of Human Biological Materials in the Development of Biomedical Products* 233, 263 (October 29, 1985) (statement of Dr. Charles R. McCarthy, Director, Office for Protection From Research Risks, National Institute of Health). Those regulations, in particular the ban on exculpatory provisions, may discourage researchers from mentioning that research or commercial use is possible. For those regulations do not allow patients to give up any rights they may have to the cell lines or end product derived from their samples. This effect of the regulations was surely unintended. *See supra* note 121.

small with each collection or patient, approach and eventually exceed the benefits. It would be foolish for the law to insist that researchers prepare for the possibility of samples having commercial value if the number of times that preparation will be put to use is trivial. When the chance of a contingency becomes sufficiently remote, the law should not insist that the parties provide for that contingency ex ante. Much of contract law, for example, aims to establish default rules for contingencies so remote that it is not sensible for the parties to provide for them. With such contingencies, it may not be wise for the law to require agreement.

Thus, courts should be surprisingly hesitant before insisting, through even the mildest remedy, that researchers alert patients from whom a collection is recommended on therapeutic grounds that some research or commercial use of the sample collected is also possible.[148] Arguably, the use of the samples should be classified with other research involving patients for which consent is not required, such as passive behavioral observations or the anonymous tabulation of routine data like body temperature, blood pressure, height, and weight.

IX. CONCLUSION

Previous commentators have discussed the respective claims of the subject and researcher by asking essentialist questions such as whether the subject's cells in essence constitute the subject's property.[149] Once the

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148. For the current U.S. law on whether patients who have consented to samples on therapeutic grounds need to be informed of possible research and commercial use, and their consent for such use obtained, see Catherine A. Tallerico, Note, *From Control Over One's Body to Control Over One's Body Parts: Extending the Doctrine of Informed Consent,* 67 N.Y.U. L. REV. 335 (1992); Catherine A. Tallerico, *The Autonomy of the Human Body in the Age of Biotechnology,* 61 U. COLO. L. REV. 659, 673-74 (1990).

In Canada, cells from placentas are routinely used for commercial purposes without the patient's knowledge or consent. Cells collected during amniocenteses, circumcision and psychosurgery are routinely used for research without patient knowledge or consent. Bernard M. Dickens, *The Control of Living Body Materials,* 27 U. TORONTO L.J. 142, 155 (1977).

149. *See generally* RUSSELL SCOTT, THE BODY AS PROPERTY (1981); Richard Gold, *Owning Our Bodies: An Examination of Property Law and Biotechnology,* 32 SAN DIEGO L. REV. 1167 (1995); Lori B. Andrews, *My Body, My Property,* 16 HASTINGS CENTER REPORT 28 (1986); Paul Matthews, *Whose Body? People as Property,* 36 CURRENT LEGAL PROBLEMS 193 (1983); Bernard M. Dickens, *Living Tissue, Organ Donors, and Property Law: More on* Moore, 8 J. CONTEMP. HEALTH L. & POL'Y 73 (1992); Phillippe Ducor, *The Legal Status of Human Materials,* 44 DRAKE L. REV. 195 (1996); Michelle B. Bray, Note, *Personalizing Personalty: Toward a Property Right in Human Bodies,* 69 TEX. L. REV. 209 (1990); Daniel M. Wagner, Comment, *Property Rights in the Human Body: The Commercialization of Organ Transplantation and Biotechnology,*

essentialist questions are answered, analogies and metaphors to existing legal categories take over. Through such reasoning, the subject emerges with causes of action that vary from conversion[150] to assessment[151] to confusion,[152] to violations of his rights of commerciality,[153] privacy[154] or informed consent.[155] While the behavior of the returning researcher who lies has not yet been discussed, those who resolve legal issues by relating concepts and looking for the preexisting legal categories that bear the closest resemblance to the behavior in question will confidently condemn that behavior as fraud.

This article has argued that the sensible, socially apt, and efficient rules are to allow the returning researcher to lie, to enforce faithfully any agreements which assign rights to the researcher, and to resolve ambiguities in favor of the researcher. The contentions rest on an examination of the economics of developing these biologic resources. That focus rejects all essentialist claims.[156] That focus pays no heed to whether existing legal concepts like fraud can be expanded to apply to the researcher's behavior, nor to whether the rules that seem most sensible are required by the law of property or of informed consent. While the law elsewhere may be driven by policies that operate here as well, this focus discusses those policies directly and does not cast about for the legal metaphors that fit the context here with the least Procrustean stretching or collapsing. New technologies often challenge courts to alter the legal environment so the technology can better flourish. This technology will suffer needlessly if courts regulate it based on formal resemblances to issues of the past.

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33 DUQ. L. REV. 931 (1995); *see also* Margaret Radin, *Property and Personhood,* 34 STAN. L. REV. 957 (1982) (Radin is perhaps the most well known proponent of the essentialist approach to concepts like property).

150. *See Moore*, 793 P.2d at 479.

151. *See* Allen B. Wagner, *The Legal Impact of Patient Materials Used for Product Development in the Biomedical Industry*, 33 CLINICAL RESEARCH 444, 445 (1985).

152. *See* Thomas Murray, *Gifts of the Body and the Needs of Strangers,* 17 HASTINGS CENTER REPORT 30 (1987).

153. *See* Roy Hardiman, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue,* 34 UCLA L. REV. 67 (1986).

154. *See* Mary T. Danforth, *Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits,* 6 YALE L. & POL'Y REV. 179 (1988).

155. *See* Perley, *supra* note 138; Richard Delgado & Helen Leskovac, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67 (1986).

156. In support of this focus, see RICHARD POSNER, OVERCOMING LAW 387-405 (1995).

DID CONGRESS ACTUALLY CREATE INNOVATION MARKETS?

By Lawrence B. Landman[†]

ABSTRACT

The antitrust enforcement agencies claim that they protect competition in markets in which innovation is itself the "product." Congress seems to support the agencies' attempts to regulate competition in these innovation markets. When, in 1984, Congress enacted the National Cooperative Research Act, it told the agencies and courts to protect competition in "properly defined, relevant research, development ... markets."

Yet, as this article shows, the agencies have actually protected competition, not in innovation markets, but rather in future goods markets. In other words, the agencies have identified markets in which the relevant firms probably will compete in the future. In the appropriate cases, the agencies have acted to protect competition in these future markets. The agencies have, for example, required merging firms to license technology. The agencies hope that competitors will use this technology to stop the merging firm from monopolizing the future market.

The antitrust enforcement agencies explain how they define an innovation market most importantly in their 1995 Intellectual Property Licensing Guidelines, and in a law review article written by two then-high ranking DOJ officials. This article analyzes the agencies' innovation market methodology. The article shows that this methodology allows the agencies to find, not innovation markets, but rather future goods markets.

TABLE OF CONTENTS

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I. IN 1984 CONGRESS ENDORSED THE IDEA OF RESEARCH AND DEVELOPMENT MARKETS

A. Introduction: The National Cooperative Research Act

According to some,[1] the National Cooperative Research Act[2] (the Act) created a concept of "research and development markets" (R&D markets). To encourage firms to work together, the Act lowers the antitrust liability of certain joint ventures. The Act also requires courts to apply the rule of reason to appropriate joint ventures. Finally, the Act defines the rule of reason which courts should apply to these joint ventures.

The Act incorporates what it calls research and development markets into its definition of the rule of reason. It says that when analyzing appropriate joint ventures, courts should: "tak[e] into account ... competition in properly defined, relevant research, development ... markets."[3]

The NCRA incorporated R&D markets into American law in 1984. Since then the United States Department of Justice (the DOJ or Department) and the Federal Trade Commission (the FTC, and, together, the agencies) claim to have found R&D markets in many cases.[4] In these cases the agencies have thus developed the concept which the NCRA created. And since the agencies have taken many years to develop this concept, it is now appropriate to examine how the agencies have in fact de-

1. *See, e.g.*, Christine A. Varney, *Antitrust and the Drive to Innovate: Innovation Markets in Merger Review Analysis*, 9 ANTITRUST 16, 17 n.7 (1995).

2. National Cooperative Research and Production Act of 1993, 15 U.S.C. §§ 4301-05. (1993) (formerly National Cooperative Research and Production Act, 15 U.S.C. §§ 4301-05 (1984)).

3. *Id.* § 4302.

4. *See infra* parts IV-V.

veloped this concept. In particular, it is now appropriate to see if, and how, the agencies have actually defined an R&D market.

The agencies claim that they have found R&D markets when examining many kinds of transactions in addition to joint ventures.[5] Yet, for three reasons, the agencies' attempts to find R&D markets when examining these other transactions will greatly influence how the agencies define R&D markets when examining joint ventures subject to the Act. First, the agencies must apply the same market definition policies when examining different types of transactions. Second, unlike in some other contexts, the agencies and the courts clearly have the authority to find an R&D market when examining a joint venture subject to the Act. Third, in its report accompanying the Act, Congress endorsed the idea that firms compete in R&D markets—and endorsed it broadly. Thus, the legislative history implies that the agencies are implementing the will of Congress when they find R&D markets in contexts beyond joint ventures. For all of these reasons, the way the agencies define an R&D market in contexts other than joint ventures will have a direct impact on how the agencies define an innovation market when interpreting the NCRPA.

B. Structure and Conclusion of the Article

1. *Congress Supports Agencies' Policy of Finding Innovation Markets.*

This article first examines how the National Cooperative Research Act incorporated into American law the idea that firms compete in R&D markets. The article shows that, regarding joint ventures subject to the Act, the statute clearly gives the agencies, and courts, authority to find R&D markets. And since Congress instructed the agencies to find R&D markets when analyzing these joint ventures, the agencies could reasonably conclude that Congress also supports their attempts to find R&D markets when they examine other types of transactions.

2. *Agencies' Methodology*

Second, the article analyzes the methodology the agencies have developed to allow them to find R&D markets. The article shows that this methodology allows the agencies to actually find, not R&D markets, but rather future goods markets. In other words, the agencies have developed a methodology which only allows them to identify a future market for goods which do not yet exist. They have not developed a methodology which allows them to find the broad R&D market which the NCRPA

5. *Id.*

seems to authorize the agencies to find, and which, using the term "innovation market," they themselves claim to find.

3. Cases Applying Methodology

Third, the article analyzes representative cases in which the agencies claim to have found innovation markets. The article shows that, consistent with the limited methodology which the agencies have actually developed, the agencies have in fact not found innovation markets in these cases. They have, by contrast, found future goods markets.

4. Officials' Statements

Lastly, the article reviews officials' statements regarding innovation markets. While these officials have certainly given the impression that the agencies find broad innovation markets, close examination of their statements reveals that even these officials acknowledge that the agencies find future goods markets rather than innovation markets.

5. Conclusion: Agencies Have Not Been Able to Define an R&D Market

The agencies are correct when they say that firms compete on innovation as well as price. But, this article concludes, the agencies have not been able to use this broad economic concept to define an innovation market. The article shows that while the agencies have tried to do this, they have developed a methodology which actually only allows them to find a future goods market. Yet, because firms do compete to innovate, this article does not criticize the agencies' attempts to regulate competition in future goods markets.

The article further shows that the agencies have not been able to define a market in which innovation is itself the "product." Firms' innovation efforts only compete against each other if the firms are trying to develop the same future good. To analyze the firms' innovation efforts, the agencies must define the goods the firms are trying to produce. Thus, they must determine if the firms will compete in the future when they both sell this good. Thus, this article concludes, while the agencies have coined the appealing term "innovation market," they have in reality only regulated future goods markets.

Finally, this article examines how the agencies should interpret the NCRPA provision which allows them to find R&D markets. It therefore does not examine other legal theories, such as potential competition, which may allow the agencies to find future goods markets in other contexts. This article simply reaches the narrow conclusion that the agencies

should acknowledge that they have not been able to find innovation markets and that they have only found future goods markets.

II. THE NATIONAL COOPERATIVE RESEARCH ACT: CONGRESSIONAL SUPPORT FOR RESEARCH AND DEVELOPMENT MARKETS

A. Congress' Broad Endorsement of the Concept of R&D Markets

When enacting the National Cooperative Research Act, Congress clearly endorsed the idea that, in the appropriate case, the agencies should regulate competition in innovation markets. The Act says that when analyzing the appropriate joint venture, the authorities should apply a rule of reason which "tak[es] into account all relevant factors affecting competition, including, but not limited to, effects on competition in properly defined, relevant research, development, product, process, and service markets."[6]

Further, the Act's legislative history broadly supports the idea that firms compete in innovation markets. Congress enacted the Senate version of the relevant bill. The Senate report accompanying the Act endorsed the idea that the authorities should regulate competition to innovate. The report says:

> Competition is as important in R&D as it is in any other commercial endeavor. Indeed, in many industries, particularly those that are based on rapidly evolving technology, competition in R&D may be crucial to success. Motivated by the benefits of getting ahead of one's competitors as well as the threat of falling behind, firms in such industries have strong incentives to be the first to develop new processes and products.[7]

The Senate report also tries to help courts define an R&D market. The report states that

> [T]o be included in the relevant R&D market, firms must have the ability and incentive, either individually or in collaboration with one another, to undertake R&D comparable to that of the joint program in question. In this context, "incentive" is measured by an objective standard. Firms need not currently compete with one another at the production or marketing stage. Market shares in current markets or in projected future markets will not

6. 15 U.S.C. § 4302 (1993).
7. S. REP. NO. 98-427 § 202 (1984).

> be determinative of a firm's ability and incentive to compete in a relevant R&D market. Rather, what is crucial to evaluating R&D competitiveness are the facilities, technologies, and other assets to which firms have access.[8]

B. Neither the Act Nor the Legislative History Define an R&D Market

The Act, however, does not define an R&D market. Indeed the Act seems to implicitly recognize that Congress could not define an R&D market. The Act says that the courts should analyze *properly defined* research and development markets, but never, itself, provides any such definition. This broad endorsement, without an accompanying definition, implies that Congress could not define an innovation market. Indeed, the agencies have also been unable to define an innovation market.

III. THE AGENCIES' UNSUCCESSFUL ATTEMPTS TO DEFINE A RESEARCH AND DEVELOPMENT MARKET

In their 1995 Joint Intellectual Property Licensing Guidelines (I.P. Guidelines) the agencies explain how they analyze intellectual property licensing agreements.[9] The I.P. Guidelines also explain, rather briefly, how they define an innovation market. Also in 1995, two high-ranking DOJ officials, Richard Gilbert and Steven Sunshine, wrote an influential law review article on innovation markets. In their article these authors explained that the agencies will find innovation markets when examining transactions in addition to license agreements. In their article the authors explained why the agencies try to find innovation markets, and also developed a methodology which, the authors claim, allows the agencies to find these innovation markets.[10] The following year two FTC attorneys wrote yet another law review article, in which they endorsed Gilbert and Sun-

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8 *Id.* § 202.

9. *See Department of Justice and Federal Trade Commission Antitrust Guidelines for the Licensing of Intellectual Property*, 4 Trade Reg. Rep. (CCH) ¶ 13, 132 (1995) [hereinafter *I.P. Guidelines*].

10. Richard J. Gilbert & Steven C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 ANTITRUST L.J. 569 (1995). When the authors wrote this article they were Deputy Assistant Attorney Generals for, respectively, Economics and Mergers. Further, Dr. Gilbert headed the task force that drafted the *I.P. Guidelines*, and Mr. Sunshine participated actively in this effort. The authors, therefore, to some extent, wrote on behalf of the DOJ. *See* Robert J. Hoerner, *Innovation Markets: New Wine in Old Bottles?*, 64 ANTITRUST L.J. 49, 52 n. 14 (1995).

shine's innovation market analysis.[11] Together, the I.P. Guidelines and Gilbert and Sunshine's law review article explain how the agencies define an innovation market.

A. Intellectual Property Guidelines

The I.P. Guidelines define an innovation market, but do so only to a very limited extent. According to these Guidelines, firms compete in a separate innovation market to make better products or provide better services. Clearly, firms compete in markets for goods and services. Just as clearly, firms compete in technology markets, by, for example, licensing comparable technologies. The I.P. Guidelines say that, in addition to these markets, the market to develop better products is itself a separate market which antitrust authorities can identify.[12] Innovation, say the I.P. Guidelines, is itself the "product" of this innovation market. Furthermore, they say, firms must not monopolize this innovation market.

The I.P. Guidelines build on the market definition policies of the agencies' 1992 Horizontal Merger Guidelines (Merger Guidelines).[13] These Merger Guidelines state that a firm has market power if it can raise the price of a good without causing a significant number of customers to buy other goods instead.[14] Similarly, the I.P. Guidelines say that a firm has market power in an innovation market if it can lower its R&D spending without causing other firms to correspondingly increase their R&D investments.[15] The I.P. Guidelines also require the agencies to consider other factors, such as the unique research capabilities of the relevant firms, before concluding that they have market power.[16] Finally, the I.P. Guidelines require the agencies to consider how the transaction may improve innovation efficiencies.[17]

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11. Thomas N. Dahdouh & James F. Mongoven, *The Shape of Things to Come: Innovation Market Analysis in Merger Cases,* 64 ANTITRUST L.J. 405 (1996). When they wrote this article, the authors were staff attorneys with the Office of Policy and Evaluation of the Bureau of Competition of the FTC. The authors therefore, to some extent, wrote on behalf of the FTC.

12. *I.P. Guidelines*, ¶ 20, 738.

13. *See 1992 Department of Justice and Federal Trade Commission Horizontal Merger Guidelines*, 4 Trade Reg. Rep. (CCH) ¶ 13,104 [hereinafter *Merger Guidelines*].

14. *Id.*

15. *I.P. Guidelines*, *supra* note 9, § 3.2.3.

16. *Id.*

17. *Id.*

B. Gilbert and Sunshine's Attempt to Define an Innovation Market

Gilbert and Sunshine wrote their influential law review article in the same year that the agencies issued their I.P. Guidelines. In their article the author expanded upon the I.P. Guidelines. The authors further explained how the agencies protect competition in innovation markets. In their article Gilbert and Sunshine developed a five-step methodology which, the authors say, allows the agencies to find an innovation market. These five steps are: (1) to identify the R&D which is the product of the innovation market; (2) to identify competition in the R&D product market, (3) to analyze competition from downstream goods; (4) to analyze increase in R&D concentration and firms' incentives innovate; and (5) to assess R&D efficiencies. This section analyzes each of these five steps and shows that this methodology does not actually allow the agencies to find an innovation market. Instead it allows the agencies to find no more than a future goods market.

To find an innovation market the agencies must identify "innovation." Innovation is the product of the innovation market, but is also intangible. Because innovation is intangible, Gilbert and Sunshine use tangible surrogates to represent innovation. More specifically, Gilbert and Sunshine use R&D programs to represent innovation. However, as these authors recognize, to identify the appropriate specific type of innovation the agencies must identify the appropriate specific R&D program. Yet, as this section will show, by requiring the agencies to identify these specific R&D programs, the authors have actually limited the agencies to regulating the future markets for the goods these programs are trying to develop.

1. Step 1: Identify the R&D which is the Product of the Innovation Market

Gilbert and Sunshine say that when defining an innovation market the agencies should first identify the specific product which the firms' R&D programs are trying to develop.[18] As the authors explain:

> 1. *Identify the Overlapping R&D Activities of the Merging Firms.* The definition of a relevant R&D product market begins with the identification of the set of overlapping R&D activities of the merging firms. Such activities are economically relevant only if they may lead to improved products or processes. Thus, it is necessary to establish that the outcome of a proposed set of R&D activities can have a significant impact in one or more

18. *See* Gilbert & Sunshine, *supra* note 10, at 594.

> relevant downstream product markets as a precondition for including the R&D activities in a relevant innovation market.[19]

To identify these overlapping R&D activities, the agencies must: (1) identify the products or processes the firms are trying to develop; and (2) determine either that the products to be developed will compete in a future goods market, or that the processes to be developed will change the nature or price of products which will compete in a future goods market[20]

This conclusion follows because the authors say that the relevant R&D activities will only raise antitrust concerns if they impact at least one downstream product market.[21] This implies that the agencies will only examine R&D programs which are trying to create new or improved products. The authors also say that the agencies should only define an innovation market if these programs "overlap." R&D programs will only overlap if they are both trying to develop the same new or improved product.

2. *Step Two: Identify Actual and Potential Competition in the R&D Product Market*

a) Actual Competition

Gilbert and Sunshine's second step requires the agencies to analyze other firms' R&D programs. These are R&D programs which other firms either are performing or could perform. This is the logical second step, and is an extension of the previous step. The agencies must look to see if other firms are performing the "same" R&D (which is R&D to make the same future good). If many other firms are performing the same R&D, then these firms make the innovation market competitive, and, the transaction will therefore probably not raise antitrust concerns. As the authors say:

> 2. *Identify Alternative Sources of R&D.* The purpose of this step is to identify the R&D activities that are reasonable substitutes for the activities of the merging firms. This corresponds to the evaluation of demand substitution in the Merger Guidelines. In the case of innovation, the "product' is R&D directed to particular new products and processes, which entails a set of activities including the required scientific skills and equipment. Because the product is a set of activities, rather than a particular good or service, it is both analytically and practically easier to

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19. *Id.* at 595.

20. A "future goods market" includes a market in which firms sell the same goods at a lower price.

21. *See* Gilbert & Sunshine, *supra* note 10, at 595-96.

> identify the firms that possess the capabilities to supply these activities, rather than attempt to categorize each activity separately.[22]

Perhaps unintentionally, the authors, in reality, ask the agencies to analyze a future goods market. The authors cannot help but do this. In this paragraph the authors ask the agencies to perform analysis equivalent to the demand substitution analysis which the 1992 Merger Guidelines require regarding traditional goods markets.[23] This step requires the agencies to identify other firms which are making the same product as are the firms involved in the relevant transaction.[24] If enough other firms are also selling the relevant product, then the agencies can approve the relevant transaction.

This paragraph also states that R&D programs are the "product" of an innovation market. As the authors acknowledge, the agencies cannot identify this "product" directly. The authors therefore establish an awkward system of surrogates, in which one item stands for another. After establishing this system of surrogates the authors develop a methodology which allows the agencies to find no more than a future goods market.

Because R&D is the "product" of the innovation market, say the authors, the quantity and quality of firms' R&D assets represent the R&D which firms can "produce." The authors define R&D assets to include both physical and mental assets. Most importantly, the authors say that, if firms have the same R&D assets, then they produce the same R&D "product."

According to the authors, firms produce the same R&D "product" if they have the same R&D assets. They also say that firms have the same R&D assets if they can use these assets to make the same future goods. Thus, the authors imply, firms compete against each other in an innovation market if they both have assets which will probably allow them to make the same future good.

Yet if the authors say that the relevant firms compete against each other because the firms will probably both be able to make the same future good, then the authors are actually saying that the firms compete against each other because they both will compete against each other in the same future goods market. The authors have therefore developed a awkward methodology which actually only allows the agencies to find a future goods market.

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22. *Id.* at 595.
23. *See Merger Guidelines*, *supra* note 13, § 1.3.
24. *See* Gilbert & Sunshine, *supra* note 10, at 595.

b) Supply Substitution and Potential Competition

In their second step Gilbert and Sunshine are not only trying to identify firms which currently compete in an innovation market, but also firms which may do so in the future. In the second paragraph of this step, therefore, the authors ask the agencies to perform analysis equivalent to the Horizontal Guidelines' supply substitution and potential entry analyses. As the authors expand in their description of the second step:

> A reduction in R&D by a monopolist in the assumed set of activities may be unprofitable because there are many alternative sources of R&D, so that a firm would not want to risk losing the R&D race, or because other firms would respond by increasing their R&D activities, with the result that the monopolist would be less likely to succeed in introducing new or cheaper products. Evaluating these alternatives parallels the evaluation of alternatives available to consumers in the delineation of downstream product markets. As in that analysis, it would be reasonable to include not only those firms that currently possess the necessary specialized assets for R&D, but also those firms that could be expected to acquire those assets within a reasonably short time period in response to a small but significant and nontransitory reduction in R&D. This corresponds to the evaluation of supply substitution and entry in the Merger Guidelines.
>
> In many market circumstances there is so much serendipity in research and development that it is impossible to predict the sources of innovation with reasonable certainty. It is unlikely that combining the R&D activities of the merging firms would have a significant impact on innovation in these circumstances. The delineation of innovation markets should be limited to markets in which R&D directed towards particular new products or processes requires specific assets that are possessed by identified firms. If innovation directed to particular products or processes does not require specific assets, entry into R&D would be easy and the innovation market would be competitive. If such innovation does require specific assets, it may nonetheless be inappropriate to delineate an innovation market if the firms that possess those assets cannot be reliably identified to provide sufficient certainty as to the proper boundaries of the innovation market.

In their footnote 63, the authors add the following:

> Evaluating competitive effects necessarily requires a forecast into the future which becomes more uncertain with a longer time

> horizon. These uncertainties are likely to be overwhelming for forecasts of competitive effects from innovation that extend beyond several years. In estimating whether a firm would be able to acquire the assets necessary to engage in R&D, a two-year horizon would be consistent with the analysis of entry in the Merger Guidelines.[25]

c) Analysis: Agencies Cannot Identify Firms Which Offer Alternative Sources of Supply, or Potential Competitors

Gilbert and Sunshine base their definition of an innovation market on the 1992 Horizontal Merger Guidelines.[26] These Merger Guidelines require the agencies to identify firms which could, in response to the appropriate price rise, readily produce alternative sources of supply, usually within one year.[27] The Merger Guidelines also require that the agencies analyze barriers to entry, and thereby determine whether potential competitors could enter the market, usually within two years.[28] In the paragraph above, Gilbert and Sunshine require the agencies to perform an equivalent analysis.

In this step Gilbert and Sunshine combine what the 1992 Merger Guidelines divide into two analytical steps.[29] The authors ask the agencies to determine if the relevant transaction will harm competition in an innovation market.[30] To do this the agencies must determine the level of competition in the innovation market. And to determine this level of competition, the agencies must, among other things, determine whether enough firms, which are not currently performing the relevant R&D, could perform this R&D in the future. If these firms could perform the R&D, then either the threat that they may do so will restrain a firm from exercising monopoly power in the innovation market, or, if the firm does exercise such power, then these other firms will perform the relevant R&D and enter the market. In either case, Gilbert and Sunshine believe, these firms will keep the innovation market competitive.

Since the authors are trying to develop an innovation market methodology, they appropriately combine supply substitution and entry analysis. Innovation is such an unusual product that the agencies will find it difficult enough to determine which firms may, in the future, perform the relevant

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25. *Id.*
26. *See generally Merger Guidelines*, *supra* note 13.
27. *Id.* § 1.3.
28. *Id.* § 3.2.
29. *See* Gilbert & Sunshine, *supra* note 10, at 595.
30. *Id.*

R&D. The agencies certainly will not be able to determine whether these firms will enter the R&D market within one or two years, as the Merger Guidelines ask the agencies to do regarding currently existing goods. By combining these analyses the authors allow the agencies to avoid making this very difficult determination.

Because the authors combine the two steps of the Merger Guidelines into one, they make it as easy as possible for the agencies to identify potential competitors in the innovation market.[31] Yet, as easy as the authors make this analysis, they still ask the agencies to do what the agencies cannot do. The agencies cannot define potential competitors who may enter an innovation market.

Potential competitors in an innovation market are firms which could, in the future, try to develop the relevant good. Firms compete in a current innovation market, not when they produce the relevant good, but when they invest in the appropriate R&D and try to produce that good. Thus firms trying to produce the relevant good are already competing in the innovation market.

A potential competitor into an innovation market is a firm which may invest in the appropriate R&D, and which therefore may try to produce the relevant good. Firms enter innovation markets when they invest in the appropriate R&D. Therefore, any firm which may, in the future, invest in the appropriate R&D is an potential competitor into the relevant innovation market.

In this step Gilbert and Sunshine's methodology breaks down. Just about any firm may, in the future, try to produce just about any good. Firms which do not even currently exist may, in the future, try to produce a particular good. The agencies cannot practicably identify firms which may, in the future, try to produce particular goods. Thus, the agencies cannot identify potential competitors of an innovation market.

Furthermore, a firm may also be a potential competitor in an innovation market even if it never intends to produce the relevant good. The firm may intend only to develop the technology which would allow a manufacturer to produce the relevant good. Specifically, it may intend to develop, and then license, the relevant technology. Indeed, many so-called R&D firms develop technology and then license this technology to manufacturers or other firms. Any number of these R&D firms may, in the future, decide to perform the relevant R&D. Thus, such firms may decide,

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31. The Merger Guidelines require the agencies to analyze only the barriers to entry to a market. In the usual case, therefore, the agencies do not identify potential competitors. *See Merger Guidelines, supra* note 13, § 3.1.

in the future, to enter the relevant innovation market. Almost all of these R&D firms are therefore potential competitors of an almost infinite number of innovation markets.

Gilbert and Sunshine implicitly recognize that the agencies cannot identify potential competitors of an innovation market. While the authors require the agencies to identify firms which could enter an innovation market, in which R&D is the "product," the authors also recognize that the agencies cannot actually identify this R&D "product." The authors therefore use as a surrogate for the R&D "product" the physical and knowledge assets which firms need to perform R&D. Thus, to identify potential entrants into an R&D "product" market, the authors ask the agencies to identify firms which could acquire the physical and knowledge assets they would need to perform the relevant R&D.[32]

Gilbert and Sunshine recognize that the agencies will not normally be able to identify such firms. As they say, "there is so much serendipity in research and development that it is impossible to predict the sources of innovation with reasonable certainty."[33] Thus, they continue, "[t]he delineation of innovation markets should be limited to markets in which R&D directed toward particular new products or processes requires specific assets that are possessed by identified firms."[34]

Gilbert and Sunshine therefore acknowledge that the agencies will usually not be able to identify potential entrants into an imagined R&D "product" market. The authors only require the agencies to find an innovation market if the agencies can identify the specific firms which possess the assets they need to develop the relevant goods. Thus Gilbert and Sun-

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32. *See* Gilbert & Sunshine, *supra* note 10, at 595.

33. *Id.* at 596.

34. *Id.* In this passage, therefore, the authors acknowledge that the barriers to entry to an innovation market are so low that the number of potential competitors of the innovation market will always be infinite. If it is impossible to predict the sources of innovation, then it is impossible to predict which firms will successfully innovate. And if it is impossible to predict which firms will successfully innovate, then it certainly is impossible to predict which firms will even try to innovate.

Thus, even if Gilbert and Sunshine did not require the agencies to identify potential competitors, the agencies still could not use the authors' methodology. Even if, consistent with the 1992 Merger Guidelines, the authors only asked the agencies to identify the likelihood of entry into the innovation market, the agencies still could not find innovation markets. Because the agencies will never be able to say which firms, or even how many firms, may even try to innovate, the agencies will never be able to say that entry into the innovation market is so unlikely that they can conclude that the market is not sufficiently competitive. In other words, because an infinite number of firms may try to develop a given innovation, an innovation market will always have an infinite number of potential competitors.

shine ask the agencies to identify the firms which can or will be able to develop the relevant goods.

By limiting their analysis to firms which could manufacture the relevant goods, Gilbert and Sunshine have defined, not an innovation market, but a future goods market. To repeat, a firm competes in an innovation market when it invests in R&D which would allow a manufacturer to make the relevant good. To compete in an innovation market a firm does not need to produce any good. And a potential competitor in an innovation market is a firm which may, in the future, invest in the relevant R&D. Gilbert and Sunshine's potential competition analysis, however, does not require the agencies to identify firms which may invest in the relevant R&D. Instead it requires the agencies to identify firms which have the relevant assets and may therefore be able to produce the relevant goods. Thus Gilbert and Sunshine's methodology actually requires agencies to identify potential competitors who may enter, not an innovation market, but rather a future goods market.

In some cases the agencies fear that the relevant firms may control intellectual property rights, or standards, which may allow the firms to keep other firms out of the relevant market. In these cases the agencies may be able to identify the potential competitors of the innovation market, because the potential competitors of the future goods market may also be the potential competitors of the innovation market.

If firms, not competing in a particular goods market, realize that the firms already in this market could use intellectual property rights or standards to keep others out of the market, then the currently non-competing firms will not try to enter the goods market. Because they will not try to enter the appropriate goods market, they will not invest in the appropriate R&D to try to develop the good. These firms will therefore not be potential competitors of either the future goods market or the innovation market.

In these patent or standard cases however, although the agencies can identify the potential competitors of the innovation market, the agencies still cannot apply Gilbert and Sunshine's innovation market methodology. First, Gilbert and Sunshine do not limit their methodology to cases involving patents or standards. Second, the agencies cannot analyze firms' incentives to innovate, as Gilbert and Sunshine also ask the agencies to do.[35] Third, as the discussion of *Sensormatic Elecs. Corp.*[36], and *Ciba*

35. *See infra* notes 55-59 and accompanying text.

36. Sensormatic Elecs. Corp., 60 Fed. Reg. 5428 (F.T.C. 1995). For discussion of the case, *see infra* text accompanying notes 104-119.

Geigy/Sandoz[37] explains in greater detail, other principles of antitrust law (not innovation market analysis) already give the agencies authority to stop firms from acquiring intellectual property rights, or from developing standards in ways which may harm competition, including competition to innovate.

In conclusion, Gilbert and Sunshine's methodology actually requires the agencies to find, not an innovation market, but rather a future goods market. The authors know that, in reality, the agencies cannot identify a market in which innovation is the "product." The authors therefore develop a complex series of surrogates. They first use R&D programs as a surrogate for innovation itself. They then use the assets firms need to perform this R&D as a surrogate for these R&D programs. Finally, Gilbert and Sunshine say that the agencies should only find an innovation market if the agencies can identify all the firms which will, for the foreseeable future, be able to obtain the assets they need to perform the relevant R&D.

The authors ask the agencies to identify firms which are investing in R&D programs which will allow them to make the same future products. The authors are therefore asking the agencies to identify firms which compete in the same future goods market. Since this is what the authors are actually asking the agencies to do, then this is what the authors should say they are asking the agencies to do.

Nonetheless, the agencies should analyze future goods markets. The agencies should ensure that a current transaction will not harm future competition. The simple, direct, and clear way to protect future competition is to protect competition in future goods markets. In fact, because this is the simple and appropriate way of protecting future competition, it is in fact the method Gilbert and Sunshine themselves actually use.

d) Timing of Market Entry

As a post-script, it bears emphasis that, when the agencies analyze possible future market developments, they must do so within a specific period of time. If the agencies are, for example, trying to determine if a firm will enter a future goods market, then they must determine whether the firm will enter the market, if at all, then within a specific period of time. Since the further into the future the agencies look the more speculative their analysis becomes, the agencies must limit the number of years into the future in which they will try to anticipate whether firms will, for example, try to enter the future goods market.

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37. Ciba Geigy Ltd., FTC File No. 961-0055 (Dec. 5, 1996). For discussion of the case, *see infra* text accompanying notes 120-127.

Gilbert and Sunshine say that the agencies should only look two years into the future. The authors borrow this time limit from the 1992 Horizontal Merger Guidelines. These Guidelines say that when trying to determine whether barriers to entry will keep potential entrants out of a given market, they agencies will generally try to determine if these possible potential entrants would enter the market within two years.

When analyzing future goods markets, however, the agencies actually look more than two years into the future. In *Upjohn-Pharmacia,* for example, the FTC anticipated market developments seven years into the future.[38] Because market conditions vary widely from case to case, and, in particular, the Federal Government subjects pharmaceutical products to a long and cumbersome approval process which does allow the agencies to reasonably anticipate future market developments more than two years into the future,[39] the agencies correctly ignore Gilbert and Sunshine's two year time limit.

3. Step Three: Competition from Goods

Gilbert and Sunshine's third step requires the agencies to analyze the actual and potential competition from what Gilbert and Sunshine call downstream markets. As the authors continue:

> *3. Evaluate Actual and Potential Competition from Downstream Products.* In addition to competition from alternative technologies, a second reason why a reduction in R&D may be unprofitable for a hypothetical monopolist is actual and potential competition from downstream products. Innovation permits the hypothetical monopolist to increase its share of downstream markets and be more profitable. A downsized R&D program would make it more difficult for the R&D monopolist to enter new markets where it does not presently compete. If the resulting loss of competitive opportunities would exceed any savings in R&D expenditures so that a reduction in R&D would not be profitable, a merger or acquisition would not have an adverse impact on the level of R&D effort. In this circumstance, a merger or other combination would not adversely affect incentives to invest in R&D. This may be true even if the firm were a monopolist in all of the substitutes for the R&D activities of the merging firms.[40]

38. Upjohn Co., 60 Fed. Reg. 56,153 (F.T.C. 1995) (complaint at " 5").
39. *See* Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321.
40. Gilbert & Sunshine, *supra* note 10, at 596.

In this third step, the authors ask the agencies to analyze the relevant firms' incentives to perform R&D. In particular, they ask the agencies to determine whether a combined firm, which would presumably enjoy monopoly power in an innovation market, would maintain its previous level of R&D investments because it wanted to enter "downstream markets."

Gilbert and Sunshine do not define these downstream markets. Though the authors clearly use this term to refer to markets for goods which already exist, they do not make clear whether downstream markets are markets for goods which the firms are trying to enter directly, or are other markets which the new technology may also allow the firms to enter. This article will therefore examine both of these markets. For the sake of clarity, the article will call the markets which the new technology may also allow the firms to enter, "opportunistic markets."

a) Markets for Goods the Firms are Trying to Enter Directly

Markets for goods which the firms are trying to enter directly are future goods markets. Even if another firm is making the good, one or both of the firms involved in the relevant transaction may not currently produce the good. These firms may be investing in R&D with the hope of one day entering the market.

b) Opportunistic Markets: Markets for Goods Other Than the Markets the Firms are Trying to Enter Directly

For the following reasons the authors may, in this step, want the agencies to analyze markets for goods other than the markets the firms are trying to enter directly:

First, in an earlier section of their law review article, before explaining their innovation market methodology, the authors explained that innovation market analysis allows the agencies to analyze the effects of R&D on opportunistic markets. The authors hypothesized that two merging firms were developing a new smelting process, which, if successful, would allow them to lower the cost of making aluminum ingot, and thereby lower the cost of the lawn furniture they made. The authors used this example to show that if the firms developed this better smelting process, then its invention would allow the firms, not only to improve their aluminum lawn furniture business, but also to enter new markets, such as the market for automobile parts.

Second, this is the only step in the authors' analysis in which the agencies could analyze effects comparable to the automobile parts market in the authors' example. Thus, the authors probably expect the agencies to examine such effects in this step.

Third, the authors want to examine firms' incentives to innovate. By examining the firms' ability to enter these related markets, the authors presumably hope to fully capture the firms' incentive to innovate.

Thus, if the authors expect the agencies to examine opportunistic markets in this step, then they must expect the agencies to perform the following two step analysis. The agencies must be able to: (1) identify the other markets the firms may be able to enter; and (2) analyze the competitive conditions of these markets both currently and in the future. This is an extremely complex analysis. In fact, it is an overly complex analysis. This section will analyze each of these two steps. The section will show that the agencies cannot perform this overly complex analysis.

i) Identifying the Other Markets the Firms May Be Able To Enter

The agencies will have great difficulty identifying other markets the firms may be able to enter. This step requires the agencies to be even more prescient than a firm's own strategic planners. It requires the agencies to identify markets, other than the markets the firm is actually trying to enter, which the relevant technology will also allow the firm to enter. The firms' own strategic planners may not know which markets these are, or, for that matter, whether any such markets exist. And even if strategic planners or agency analysts did identify such opportunistic markets, any conclusion he or she may reach regarding the firm's ability to enter one or more of these opportunistic markets, and its success in these markets, would be speculative at best. The firms could enter an almost infinite number of opportunistic markets, including markets for products which do not yet exist.

Moreover, if the agencies were able to identify any such opportunistic markets, then they would only have identified other future goods markets. Opportunistic markets are markets which the relevant firms may be able to enter after they combine their R&D programs. Because the firms may compete in these markets in the future, these markets are, in fact, future goods markets. Thus when the agencies identify opportunistic markets, they actually identify future goods markets.

Gilbert and Sunshine's methodology already allowed the agencies to identify these opportunistic markets. This article's analysis of their second step showed that when they asked the agencies to find markets in which R&D is the "product," the authors established a system of surrogates which in reality ask the agencies to find future goods markets. The author's second step did not limit the number of future goods markets the agencies could find. If, in a given case, a firm were developing technology

which would allow it to enter more than one future goods market, then the agencies could simply analyze the effects of the transaction on these several future goods markets. In fact, in *Ciba Geigy* the FTC identified four future goods markets.[41]

ii) Analyze the Conditions of this Market Both Currently and in the Future

Undertaking an analysis of current (and future) conditions in opportunistic markets seems very complex. Unfortunately, as complex as this part of Gilbert and Sunshine's methodology may seem, it actually adds very little to the authors' overall analysis. This step requires the agencies to analyze the current market conditions of markets which the relevant firm may enter. Because these markets already exist, this part of the analysis clearly relates to markets for already existing goods. Thus this part of the analysis asks the agencies to analyze markets for already existing goods.

In step one, however, the authors implicitly already asked the agencies to analyze markets for already existing goods. At the outset, the authors asked the agencies to analyze markets for goods which the firms' R&D programs were trying to develop. If other firms already made these goods, then, implicitly, this step already asked the agencies to consider these already existing goods when the agencies analyzed the relevant goods market.

On the other hand, this part of the analysis does ensure that the agencies analyze these currently existing markets. It also ensures that the agencies analyze opportunistic markets. Thus, this step guarantees that the agencies will analyze all relevant markets, and, to that extent, adds to Gilbert and Sunshine's methodology. But this rather modest contribution does not lead the agencies to find innovation markets.

With regard to future conditions in the markets, the agencies cannot determine how most markets will develop. If, however, the agencies were able to anticipate how a particular market would probably develop, and they analyzed future competition in this market, then they would simply be analyzing competition in a future goods market.

c) Incentives

Gilbert and Sunshine ask the agencies to identify opportunistic markets because the authors want the agencies to analyze the relevant firms' incentives to innovate. The authors ask the agencies to determine whether

41. *See infra* text accompanying note 121.

opportunistic markets create such a strong incentive to innovate that they will encourage even an innovation market monopolist to invest in R&D. The authors therefore ask the agencies to evaluative the innovation market monopolist's incentives to innovate. However, as the following analysis of step four shows, the agencies cannot determine an innovation market monopolist firm's incentives to innovate.

4. *Step Four: Concentration of R&D, and Incentives to Invest in R&D*

In step four Gilbert and Sunshine ask the agencies to do two things. The authors ask the agencies to: (1) analyze shares of innovation markets, and (2) analyze innovation market monopolists' incentives to invest in R&D. Their methodology, however, does not allow the agencies to achieve either of these goals. The agencies cannot determine a firm's share of an innovation market and also cannot analyze firms' incentives to invest in R&D.

As the authors explain their fourth step:

> *4. Assess the Increase in Concentration in Research and Development and Competitive Effects on Investment in R&D.* A relevant innovation market is established when the analysis identifies the set of R&D activities for which a hypothetical monopolist would profit by a small but significant and nontransitory reduction in R&D. Having defined the innovation market, an analysis of a merger involving R&D must consider whether the merged firm's share of R&D is sufficient to affect the total level of R&D in that market, and whether there are any particular factors (in addition to competition from downstream products analyzed in Step 3) that affect the likelihood that the merger may have an impact on competition. The proper measure of the merged firm's share of innovation activity will depend upon individual circumstances. Expenditures on research and development can be used *if the expenditures can be localized to R&D leading to the relevant new products or processes.* In other situations, the level of activity (such as production) or the level of assets may be better correlated with the probability that a firm will be a successful innovator. (For example, production levels, or appropriately weighted past production levels, may be a reasonable measure of a firm's position on a learning curve and thus its ability to introduce new process innovations.) If firms in the identified population of innovators are equally likely to be successful, the proper measure would assign each firm an equal market share.

> As discussed in Part V above, adverse impacts on R&D are more likely to occur from the unilateral exercise of market power by a merged firm that controls a large share of an innovation market. Collusion in R&D is difficult, especially if an innovation would be likely to have a significant impact on existing competitive relationships.[42]

a) Share of Innovation Market

The authors believe that the agencies should only challenge a transaction if it would give a firm market power in an innovation market. To determine if a transaction will give a firm such market power, the agencies must therefore determine the firm's market share in the innovation market. Yet the agencies have difficulty enough determining shares of traditional product markets. The agencies cannot determine shares of markets in which the "product" is intangible innovation.

i) Money Invested in R&D

Gilbert and Sunshine ask the agencies to analyze several criteria which, the authors say, allow the agencies to determine firms' shares of innovation markets. The first criteria the authors ask the agencies to analyze is the amount of money the relevant firms are investing in R&D programs. But, as Gilbert and Sunshine had previously established, the agencies should only consider R&D programs which are directed towards producing the same future good. The authors therefore actually ask the agencies to determine how much money each firm is investing in its efforts to enter the relevant future goods market. The authors are say that this level of investment strongly indicates how successful the relevant firms are likely to be in the future goods market.

The authors have once again developed an awkward methodology. The authors ask the agencies to determine how much money the relevant firms are investing in R&D. They say that this reflects the firms' shares of the innovation market. The authors then, in effect, say that the firm's share of the innovation market indicates how successful its innovation efforts are likely to be. Thus, the larger the firm's share of the innovation market, the more likely the firm is to develop and sell the relevant good. In effect, the authors say that the more money the firm spends to develop a future product, the larger the firm's share of the future goods market will be.

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42. *See* Gilbert & Sunshine, *supra* note 10, at 596-97 (footnotes omitted and emphasis added).

This analysis does not add to the author's overall methodology. Step one already required the agencies to analyze the relevant firms' R&D programs. This step four asks the agencies to determine how much money the relevant firms are investing in these R&D programs. But the agencies already should have done this when, pursuant to step one, they analyzed the firm's R&D programs. Thus, in this step, the authors merely ask the agencies to repeat the analysis of step one.

Furthermore, the agencies cannot anticipate future market shares, even of future goods markets. The agencies have difficulty enough anticipating which markets will exist in the future. Neither they, nor firms themselves, can anticipate how much of a good, which does not even yet exist, any firm may eventually sell. The agencies cannot assume that, because a firm is spending a lot of money to develop a good, that it will therefore sell a lot of that good in the future.[43]

In the cases the agencies have actually decided, they have not been able to determine shares of future goods markets. In these cases the agencies have identified the firms which they believed would probably compete in then future goods markets. The agencies have then, in effect, assumed that these firms would have equal shares of the future market. This was the only reasonable assumption the agencies could make.

ii) Other Criteria for Determining Market Share

The authors list other criteria which, they say, allow the agencies to determine a firms' share of an innovation market. The I.P. Guidelines list other, similar, criteria. The agencies, however, cannot use these criteria to determine a firm's share of an innovation market.

This section first describes the criteria both Gilbert and Sunshine and the I.P. Guidelines say the agencies should use to determine a firm's share of an innovation market. This section will then show that the agencies must apply these criteria narrowly, if at all.

These market share criteria explain which firms are competing in the innovation market. They therefore actually define the innovation market. Just as the previous section showed that the agencies could only analyze R&D programs which were trying to develop the same future products, this section will show the agencies can only apply these criteria narrowly. And yet, by applying these criteria narrowly, the agencies find, not innovation markets, but rather future goods markets.

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43. *See* Richard T. Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 ANTITRUST L.J. 20, 33-36 (1995).

One should note at this point that the I.P. Guidelines and Gilbert and Sunshine use similar, and consistent, market share criteria. In fact, the I.P. Guidelines and the authors develop generally consistent methodologies.[44] Gilbert and Sunshine were both high DOJ officials when they published their law review article, and when the agencies issued their I.P. Guidelines. Gilbert and Sunshine wrote their article not only to explain why the agencies incorporated innovation market analysis into the I.P. Guidelines, but also to explain why the agencies will find innovation market when analyzing transactions beyond license agreements. Lawyers have therefore correctly come to see Gilbert and Sunshine's article as an important explanation of both the I.P. Guidelines and the agencies' general innovation market policy.

This section will address each of the market criteria in turn: (1) specialized assets; (2) R&D expenditures under the I.P. Guidelines; (3) buyer and seller assessments; and (4) firms' incentives to invest in R&D.

(1) One market share factor is possession of certain specialized assets. To perform the relevant R&D, firms must have the appropriate equipment and other physical assets, and must also have the appropriate knowledge and skills. Gilbert and Sunshine call this equipment and skills "physical and knowledge assets". Gilbert and Sunshine reason that if firms must use these specific physical and knowledge assets to perform the relevant R&D, then only firms which have these specific assets can participate in a particular innovation market. The authors call these specific assets "specialized assets." They believe the agencies can identify these "specialized assets," and, further, that by doing so the agencies can identify all the participants in a particular innovation market.

The authors distinguish between physical and knowledge assets. A firm's physical assets are the buildings, machinery, and related equipment which it owns or controls. Gilbert and Sunshine reason that if firms need specific machinery to develop a new good, or an improved version of an existing good, then only those firms which currently own or control such machinery could participate in the current innovation market. For example, Gilbert and Sunshine reason that only firms which manufacture heavy-duty transmissions are able, not only to make the transmissions they currently sell, but also to even try to make better heavy-duty transmissions. Thus, say the authors, only firms which currently make heavy-duty

44. As another example, both the *I.P. Guidelines* and Gilbert and Sunshine say that they fear that an innovation market monopolist will retard the pace of research and development. *See I.P. Guidelines*, *supra* note 9, § 3.2.3; Gilbert & Sunshine, *supra* note 10, at 590-93.

transmissions participate in the current innovation market to make better heavy-duty transmissions.[45]

Gilbert and Sunshine also apply this reasoning when analyzing what they call "knowledge assets." A firm's knowledge assets are the knowledge and skills it controls. In some cases only certain firms will have the knowledge and skills firms need to make a new or improved version of a good. Only these firms, Gilbert and Sunshine reason, compete in the innovation market. For example, only firms currently making heavy-duty transmissions have the knowledge and skills any firm would need to make better heavy-duty transmissions.

According to the authors, if a firm's market share for products it is currently producing and selling accurately reflects its strength and importance in the industry, then the agencies should consider the firm's current market share when assessing its share of the related innovation market. The firm's current production, the authors reason, usually reflects rather well the specialized machinery and skills which the firm controls. Thus, reason the authors, by examining a firms' current production, the agencies will usually be able to determine the nature and extent of any specialized assets the firm may control, and therefore determine its share of the related innovation market. The authors are in effect asking the agencies to use a firm's share of the current goods market as its share of the innovation market.

(2) Another market share factor under the I.P Guidelines is R&D expenditures. According to the I.P. Guidelines, when determining a firm's share of an innovation market, the agencies should also consider the firms "shares of research and development expenditure."[46] This phrase is ambiguous. The Guidelines may be asking the agencies to consider either the total amount of money the firms are investing in R&D, or they may be asking the agencies to consider only the amount of money the firm is investing in the relevant R&D program.

If the Guidelines mean to ask the agencies to determine how much money, relative to other firms, the firms is spending on total R&D, then the agencies must believe that the total amount of money a firm invests in R&D reflects, to some degree, its general ability to innovate.[47]

The Guidelines may, however, be asking the agencies to determine how much money, relative to other firms, the develop the relevant future good. This is in fact what Gilbert and Sunshine ask the agencies to do.

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45. *See* Gilbert & Sunshine, *supra* note 10, at 588.
46. *I.P. Guidelines, supra* note 9, § 3.2.3.
47. *See id.*

(3) A third market share factor is buyer and seller assessments. The agencies themselves note that when determining shares of an innovation market, they will ask the opinions of buyers, competitors, and others who participate in markets for related goods. The I.P. Guidelines say that the agencies will "seek evidence of buyers' and market participants' assessments of the competitive significance of innovation market participants."[48] The agencies also say that, if they have difficulty determining how much money the relevant firms invest in R&D, then they will give particular weight to the assessments of these buyers and sellers.[49]

(4) Finally, when estimating a firm's share of the relevant R&D market, the agencies will analyze the firm's incentive to invest in R&D. But since the agencies are analyzing R&D programs which are trying to develop specific future goods, they must analyze the firms' incentives to develop these specific future goods. Gilbert and Sunshine therefore actually ask the agencies to analyze the firms' incentives to develop specific future goods.

iii) Evaluation: Market Share Analysis Relates to Specific Products

When the agencies analyze the amount and quality of a firm's specialized physical and knowledge assets, they are actually analyzing the firm's ability to make a specific good in the future. They are analyzing how well the firm will be able to compete in the future when it develops and sells that good; in other words, they are determining whether a firm will be able to compete in a future goods market, and if so, what market share they expect the firm to achieve.

Thus, when analyzing either a firm's specialized assets or its current share of a market for existing goods, the agencies are determining what share of a future goods market they expect the firm to achieve. The specialized assets are, by definition, specialized, if not unique. Other firms cannot readily purchase these specialized assets. Thus, the firm that possesses such assets has a greater ability to make a specific good in the future.

Similarly, if the agencies can only use a firm's current market share to indicate the firms' future market performance if the agencies are analyzing a future goods markets. If the agencies are measuring a firm's current market share, then they must be counting how much of a specific product the firms are selling. If the agencies believe that this will help them de-

48. *Id.*
49. *See id.*

termine the firm's future market performance, then they must be examining a future market for goods which are at least related to the goods the firm is currently selling. Most likely, the agencies are examining the future market for improved versions of the good the firm is currently selling. This is probably the relevant future goods market.

With regard to the second factor (R&D expenditures, the agencies will not be able to determine how the firm's *total* R&D expenditure effects the firm's likelihood of developing any particular future good. Firms invest in many different forms of R&D. A large firm may, for example, invest vast sums to develop or improve hundreds of different products. The agencies cannot analyze the antitrust implications of all these potential R&D programs. Nor can the agencies assume that, because a firm is trying to develop products other than the products relevant to the transaction it is analyzing, that the firm is therefore more likely to develop the goods relevant to the agencies' analysis. This reasoning implies that large firms always innovate better than small firms which is, of course, not true.

Furthermore, if, when trying to determine a firm's share of an innovation market, the agencies try to determine how much money, relative to other firms, the firm is investing in the relevant R&D program, then the agencies will face two analytical difficulties. First, they will have difficulty determining how much money the firm has actually invested in the relevant R&D program. Many firms invest a great deal in R&D. They spend this money to try to develop many new products and processes. The agencies will have great difficulty deciding how to allocate this possibly large expenditure over all the many R&D programs into which the firms may invest. Second, the agencies cannot assume that a firm which invests more in R&D will innovate faster or better. The correlation between the amount of money a firm spends on R&D and its success as an innovator is, at best, weak.[50]

As discussed above, the agencies also say that, in the appropriate case, they will also ask the appropriate buyers and sellers to assess firms' shares of an innovation market.[51] But to do this, the agencies must assume that they have indeed defined an innovation market. As this article shows, however, the agencies have not been able to define an innovation market. And if, without defining an innovation market, the agencies ask buyers and sellers to evaluate firms' shares of an innovation market, the agencies would merely have passed the problem of defining an innovation market to the buyers and sellers. Further, before the agencies can ask buyers and

50. *See* Rapp, *supra* note 43, at 33-36.

51. *See I.P. Guidelines, supra* note 9, § 3.2.3.

sellers, they must decide which buyers and sellers to ask. The agencies will naturally ask those who buy or sell the appropriate good. The agencies must therefore define the appropriate good, and when they do so they will have defined a future goods market.

That the agencies can only apply these criteria to future goods markets is a needed limit on their application of the definition of an innovation market. If the agencies apply these criteria more broadly, then they must also expand their definition of the innovation market beyond the future goods market. And if the agencies do this, then they cannot limit the definition of an innovation market. No principal or rule of logic will constrain the agencies' definition. The agencies could then include just about any firm in the innovation market. The agencies will then be able to act illogically, and arbitrarily.

Gilbert and Sunshine, and the I.P. Guidelines, actually recognize that the agencies must limit their analysis. They therefore require the agencies to include within the innovation market only specific, narrowly defined, R&D assets. Furthermore, in the I.P. Guidelines the agencies say that the agencies "will delineate an innovation market only when the capabilities to engage in the relevant research and development can be associated with specialized assets or characteristics of specific firms."[52]

This limited application stands in contrast to the rhetoric of the agencies and the fears of antitrust lawyers. Antitrust lawyers fear innovation markets because the agencies have created the impression that their methodology gives them broad and unrestrained powers.[53] Gilbert and Sunshine themselves say that firms may compete in an innovation market even if they "are not likely potential competitors."[54] And as this article will also show in greater detail, agency officials seem to endorse this view.[55]

But, despite the agencies' rhetoric, they have, for the most part, acted with restraint. They have not exercised the broad powers innovation market analysis seems to give them. This article therefore asks the agencies to state clearly and unequivocally that they will not act arbitrarily. It concludes by asking the agencies to acknowledge that they have not exercised the broad powers innovation market methodology seems to give them, and they will not exercise these broad powers in the future.

With respect to the final factor mentioned above, the agencies cannot analyze an innovation market monopolist's incentives to innovate. Of

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52. *Id.*
53. *See infra* notes 130-145 and accompanying text.
54. *See* Gilbert & Sunshine, *supra* note 10, at 570.
55. *See infra* notes 130-145 and accompanying text; *see also* Varney, *supra* note 1.

course the agencies can, and should, assume that firms want to earn profits, and that, to earn profits, they will enter various markets. The agencies therefore should assume that if, to enter a market, a firm must innovate, then it may at least try to do so. But Gilbert and Sunshine ask the agencies to do more than this. These authors ask the agencies to determine if an innovation market monopolist will suppress innovation. Gilbert and Sunshine fear that if firm monopolizes an innovation market, then it will use its monopoly power to cut back on its R&D investments.

But the agencies cannot evaluate a firm's incentives to suppress innovation. Innovation provides benefits which are not only great, but also varied. Because an innovation may offer a firm so many different benefits, the agencies cannot evaluate a firm's incentives to develop this innovation. Indeed, the agencies cannot evaluate the incentives to innovate of either a theoretical innovation market cartel, or of a theoretical individual innovation market monopolist.

A firm may have what Gilbert and Sunshine regard as monopoly power in an innovation market. As mentioned above, the authors fear that this monopoly power will allow the firm to cut back on its R&D investments. According to Gilbert and Sunshine, a firm with monopoly power in an innovation market will not worry that competitors will produce better products, and the innovation market monopolist will therefore not itself try to innovate.

But, equally plausibly, the firm's monopoly power may give it a greater incentive to innovate. No firm may yet sell the good the firm is trying to develop, or no firm may yet sell the improved version of the good which the firm is trying to develop. If the firm develops this product or improvement, then it will presumably enjoy a monopoly in the future market. It will therefore be able to earn monopoly profits in the future goods market. And the opportunity to earn monopoly profits creates a greater, not a lesser, incentive to innovate.

Furthermore, as Gilbert and Sunshine recognize in step two of their methodology, new technology may allow a firm to expand into one or more new markets.[56] These markets may be completely new; in other words, they may be markets for products which do not yet exist. Or they may be markets which are new to the firm: that is, markets for products which exist, but in which the relevant firm does not yet compete. In either case, the opportunity to expand into these new markets will encourage the firm to invest in the appropriate R&D. These markets provide an incentive to innovate.

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56. *See* Gilbert & Sunshine, *supra* note 10, at 585-86.

To analyze a firm's incentives to innovate, the agencies must therefore determine which new markets the firm may be able to enter. However, as discussed above, the agencies cannot confidently determine which markets successful innovators may enter. In fact, the firm itself may have only a general idea of which markets its new technology may allow it to enter. It may even have only a general idea of what the technology it is trying to develop will be able to do. If the firm itself has only a general idea of what its new technology may be able to do, or what new market it may be able to enter, then the firm will not be sure whether it should try to develop the technology. And if the firm cannot know what it should do, then certainly a federal agency will not know what it should do. The agencies will therefore not be able to determine the firm's incentives to innovate.

Even Gilbert and Sunshine acknowledge that competitors are not likely to agree to uniformly reduce their R&D investments.[57] Further, Gilbert and Sunshine acknowledge that, even if firms do form such an innovation cartel, the cartel will very likely fall apart. As Gilbert and Sunshine say:

> The conditions required to sustain a collusive agreement, however, are particularly difficult to satisfy when the coordinated activity is research and development. Firms are likely to benefit in different ways from a successful R&D program and agreement over the "spoils" of coordinated R&D activity is likely to be difficult. Monitoring will also be difficult since R&D typically involves private information. A firm that succeeds in an R&D program gains a substantial advantage over its competitors and retaliation by its unsuccessful rivals may be difficult or even impossible. In addition, when R&D does not require specialized assets, any collusive agreement to suppress R&D will be vulnerable to entry from innovators that are not members of the agreement.[58]

Still, some firms have suppressed technologies.[59] Gilbert and Sunshine, and the agencies, legitimately fear that, in the future, other firms may also suppress technology. But the agencies have already acted to stop firms from suppressing technology. The law already gives the agencies power to stop firms from inappropriately suppressing technology. Thus, Gilbert and Sunshine do not need to develop convoluted innovation mar-

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57. *Id.* at 591-92.

58. *Id.* at 591.

59. *See* United States v. Automobile Manufacturers Assoc., 307 F. Supp. 617 (C.D. Cal. 1969); McDonald v. Johnson & Johnson, 537 F. Supp. 1282 (D. Minn. 1982).

ket analysis to give the agencies the power to stop firms from suppressing technology.

iv) Research Regarding Process Technologies

This article has so far discussed innovations which would allow a firm to develop new or improved goods. A firm may, however, be trying to develop a new process, which would allow it to make, at lower cost, goods it already sells.

Just as firms usually try to develop new products, so too do they usually try to develop new process technologies. New process technologies allow firms to make the same goods, but at lower cost. New process technologies therefore allow firms to lower their prices, expand their market shares, and increase their profits. Firms therefore usually try to develop new process technologies.

If the agencies should ever hypothesize that, in a particular situation, a firm would not seek to develop a new process technology, then the agencies must believe that the relevant firm cannot use the technology to expand its market share or increase its profits. The agencies must also believe that neither the firm's competitors, nor its potential competitors, will, for the foreseeable future, develop comparable technology. This situation is very unlikely to arise. Thus, even an innovation market monopolist is overwhelmingly likely to try to develop new process technology.

Further, if the agencies should ever fear that a firm is suppressing process technology, then their fears must relate to a current goods market. New process technologies allow firms to make, more efficiently, already existing goods. Thus if a process technology were to affect any market, then it must affect a market for already existing goods. The agencies would therefore fear that the relevant firms were harming competition in a current goods market. Thus, the agencies should respond to their concerns using traditional antitrust law, not innovation market analysis.

5. Step Five: Efficiencies

Lastly, Gilbert and Sunshine require the agencies to evaluate any efficiencies the merger may generate. As the authors say:

> 5. *Assess R&D Efficiencies.* The final step in the analysis of a merger or other combination that might affect investment in R&D is to evaluate the consequences for the efficiency of R&D. It is clearly not sufficient to end the evaluation with a determination only of the likelihood that the combination will reduce R&D effort. The relevant competitive concern is whether the combination will have an adverse impact on innovation, for which

> R&D is only an input. The analysis must consider whether the merger or other combination affords efficiency benefits that enhance the likelihood or value of innovation. This requires evaluating the potential for exploiting complementary R&D assets and scale economies in R&D as well as for eliminating redundant R&D programs.[60]

Firms may indeed enter into transactions which improve R&D efficiencies. Gilbert and Sunshine should therefore ask the agencies to examine R&D efficiencies. But, as the agencies themselves acknowledge, the agencies cannot readily assess those R&D efficiencies. The agencies acknowledged this when, in April 1997, they revised the efficiencies section of their 1992 Horizontal Merger Guidelines. The revised efficiencies section states, "Other efficiencies, such as those relating to research and development, are potentially substantial but are generally less susceptible to verification and may be the result of anticompetitive output reductions."[61]

When the agencies made this admission they already had great experience analyzing innovation markets, and therefore, presumably, possible R&D efficiencies. The agencies had issued their 1995 I.P. Guidelines two years earlier. The FTC had also already held its hearings on the "New, High-Tech Global Marketplace," at which numerous witnesses discussed innovation markets.[62] Indeed the FTC staff had issued a report based on these hearings.[63] Perhaps most importantly, the agencies issued these revised guidelines after they had decided many cases in which they claim to have found innovation markets.

In these revised efficiency guidelines, therefore, the agencies made an important admission. After they had gained a great deal of experience analyzing innovation markets, the agencies publicly acknowledged that have great difficulty analyzing R&D efficiencies. In other words, the agencies acknowledged that they have great difficult applying one of the five steps of Gilbert and Sunshine's innovation market methodology.

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60. *See* Gilbert & Sunshine, *supra* note 10, at 597.

61. Department of Justice and Federal Trade Commission, *Revision To Horizontal Merger Guidelines* (Apr. 8, 1997) (*available in* 1997 WL 166999 (D.O.J.)).

62. Federal Trade Commission, *Hearings on Global and Innovation-Based Competition* (Dec. 13,1995) <http://www.ftc.gov/speeches/other/speech.htm>.

63. *See* ANTICIPATING THE 21ST CENTURY: COMPETITION POLICY IN THE NEW HIGH-TECH, GLOBAL MARKETPLACE, A REPORT BY THE FEDERAL TRADE COMMISSION STAFF (1996).

C. The Authors' Aluminum Ingot Example

Gilbert and Sunshine offer an example which they believe illustrates why the agencies should use innovation market analysis.[64] This example, however, actually illustrates why the agencies cannot use the innovation market methodology. Thus, even the example by which the authors attempt to show why the agencies should apply their innovation market methodology actually demonstrates why the agencies cannot, in fact, do so.

To illustrate the value of the innovation market methodology, Gilbert and Sunshine analyze a market with only two integrated producers of aluminum ingot. One producer operates in the United States and the other in Europe. Both produce their own ingot, and each uses this ingot to make both aluminum cable and lawn furniture. Both compete in a world aluminum cable market, but each sells lawn furniture only in its domestic market. Neither firm intends to enter the other's lawn furniture market, nor does either firm believe that the other will expand into its domestic lawn furniture market. No other firms compete in any of these markets. Thus only these two firms compete in the cable market, and each enjoys a monopoly in the lawn furniture market.[65]

1. Effect of Merger

a) Products: Only Cable Market Affected

Gilbert and Sunshine say that if these firms were to merge, then, applying standard antitrust analysis, the agencies would only analyze the aluminum cable market, in which both firms competed. But, the authors say, standard antitrust analysis would not lead the agencies to analyze the lawn furniture market. Before the merger, each firm enjoyed a monopoly in this market, and after the merger each firm would still enjoy its monopoly. Standard antitrust law would therefore lead the agencies to conclude that the transaction did not affect the lawn furniture market.

b) Innovation: Cable and Lawn Furniture Markets

Gilbert and Sunshine believe that because standard antitrust analysis does not lead the agencies to analyze the lawn furniture market, it does not lead the agencies to analyze the full affects of this hypothetical merger. To show this, the authors further assume that prior to the merger each firm was performing R&D to develop a new smelting process. This smelting process would lower the cost of producing aluminum ingot. The authors

64. *See* Gilbert & Sunshine, *supra* note 10, at 581-86.
65. *See id* at 581-82.

then analyze how the merger would affect the new merged firm's incentives to innovate. Further, they analyze how the new incentive structure would affect both the cable market and the lawn furniture market.

The merger, say the authors, would clearly lower the merged firm's incentive to innovate in the cable market. Before the merger, each firm competed against the other, and therefore sought to increase its market share. Each firm therefore sought to lower its price, and its production costs. But, say the authors, this merger would create a monopoly, and the new monopolist would not try to increase its market share. It would therefore not try to develop new low cost production techniques. It would not innovate.

Further, say the authors, if the merged firm faced a lower incentive to innovate, then not only would it not only fail to develop lower priced cable, it would also fail to develop lower priced lawn furniture. If the two firms had invested sufficiently in R&D so they could lower the cost of producing aluminum ingot, then they would produce at lower cost not only aluminum cable, but also lawn furniture. Because they would have lowered the cost aluminum ingot, which is the most important material they use to make lawn furniture, and could also have sold lawn furniture at a lower price. Their innovation would therefore have benefited, not only aluminum ingot consumers, but also lawn furniture consumers.

The authors stress that if the firms had innovated, then, even if the firms had remained monopolists, they still would have lowered the cost of producing lawn furniture. The authors also say that if the two firms did not merge, but had continued to innovate, then they would not only have been able to make aluminum ingot at lower cost, but they would also have been able to expand into other markets. Their lower cost production methods may allow them to sell, for example, auto parts at competitive prices.

Gilbert and Sunshine claim that in this example the two unmerged firms were competing in a current innovation market. The firms were currently competing to develop ways to make less expensive aluminum ingot, say the authors. And only if the agencies analyze this current innovation market will they fully understand all the consequences of the firms' possible merger.

2. Analysis

This example does not, however, show that the agencies should use Gilbert and Sunshine's innovation market analysis. The authors offer an unrealistic example, and one which shows that innovation market analysis does not in fact add to conventional antitrust analysis.

The example is unrealistic because it assumes not only that the firms are monopolizing their respective lawn furniture markets, but also but also that they will continue to do so. In reality, many firms sell lawn furniture in both Europe and the United States, and many more firms could enter these markets. Perhaps more importantly, in both Europe and the United States, markets for similar goods are competitive. The authors offer no reason why the agencies will analyze cases in which markets for these similar goods will not be competitive.

If the firms respective lawn furniture markets were competitive, then the firms would have faced a strong incentive to innovate in this market. The firms would want to produce goods a lower cost, and then either underprice their competitors, or increase their profits. Further, the firms would fear that their competitors would either also produce lower cost aluminum ingot, and therefore also lower cost lawn chairs, or would be able to buy lower cost aluminum ingot from producers who had developed a comparable smelting process. In either case, the firms' competitors would have been able to sell lower priced lawn furniture. And, fearing that this might happen, the firms would have an incentive to sell lower priced lawn furniture as soon as possible.

The example implies that the agencies will use innovation market methodology to help them analyze a transaction involving firms which are monopolizing their respective downstream markets. Yet in none of the cases in which the agencies say they found innovation markets have the agencies claimed that firms monopolized downstream markets. The example therefore implies that, in the cases the agencies actually decided they did not need to find innovation markets.

Even if the relevant firms do monopolize markets comparable to the lawn furniture market, this example still shows that innovation market analysis adds nothing to traditional antitrust analysis. Traditional antitrust analysis itself covers the merger the authors describe. The agencies would not allow two firms to merge, and then monopolize a given market.

Traditional antitrust law would require the agencies to challenge this merger, among other reasons, because the law posits that monopolies do not innovate as fast or as well as competitive firms. Traditional antitrust law therefore already requires the agencies to ensure that these firms faced the appropriate incentive to innovate. The agencies did not need Gilbert and Sunshine innovation market methodology to ensure that the firms faced the appropriate incentive to innovate.

Finally, the merger did not necessarily lower the firms' incentive to innovate. Even if the firms had obtained the monopoly in the aluminum cable market, they still may have tried to develop the lower cost smelting

process. If the firms had been able to develop lower cost aluminum ingot, then they would have been able to earn more money in the aluminum cable and lawn furniture markets. They would have been able to either sell the same amount of these goods, but at a greater profit, or, more likely, they would have been able to sell more of these products. They also may have been able to enter new markets, such as the auto parts market. All these opportunities to earn more money gave the merged firm, albeit a monopoly, an incentive to innovate.

IV. CASES

A. Introduction

1. The Agencies Find a Future Goods Market

The following section reviews representative cases in which innovation market advocates claim that the agencies found an innovation market. As this analysis will show, however, in none of these cases have the agencies actually find an innovation market. In all of these cases the agencies instead found future goods markets. Thus, rather than find a market in which innovation was itself the "product," the agencies instead analyzed a future market for goods which did not yet exist.

This part divides the cases into three categories. The first section of this part analyzes cases in which both parties already made the relevant good, such as transmissions. Thus, in these cases, the agencies examined the future market for a better version of the existing good, such as the market for better transmissions.

The second section analyzes cases in which one of the parties already made the relevant good. In these cases the agencies feared that the transaction would remove a potential competitor from the market. The agencies believed that the relevant firm would compete in the future goods market, and they would not let the transaction remove this competitor from the future goods market.

The third section analyzes cases in which no firm yet made the relevant good. In these cases as well, the agencies analyzed, not innovation markets, but rather future goods markets. They feared that the transaction would remove competition from the future goods market and that, if the firms were to combine their R&D efforts or to merge, then, rather than compete in the future, the firms could monopolize the future goods market.

2. *Patent Acquisition and Standards*

In two of these cases the agencies also analyzed the intellectual property portfolios the relevant firms would acquire.[66] In these cases the FTC feared that the transaction would give the relevant firm such a broad portfolio of intellectual property rights that it could stop other firms from entering the relevant market. The FTC thus feared that the combined firm could use its intellectual property rights to monopolize the future market. This section will show that while the FTC may very well have legitimately feared that the combined firm would monopolize the market, it did not find an innovation market in these cases, just as it did not find an innovation market in the other cases. With respect to the cases involving intellectual property, the agencies may have expanded the law regarding how firms acquire intellectual property rights, but they did not find innovation markets.

In one case the FTC may also have feared that the transaction would allow the relevant firms to develop standards which they could then use to keep potential competitors out of the relevant market.[67] In this case as well, the FTC may indeed have correctly seen an antitrust problem, but to respond to the problem the FTC did not need to, and did not, find an innovation market.

3. *European Decisions*

The European Commission has also analyzed many of the same cases in which the American antitrust authorities found future goods markets. In these cases the European Commission also found future goods markets.[68] Unlike its American counterparts, however, the European Commission does not even claim it has found innovation markets.

The American agencies should examine the European Commission's decisions. In this area, not only does the European Commission analyze cases similar to those the American agencies analyze, but it has even analyzed many of the same cases. By implication, if the European Commission could not find an innovation market, then: (1) neither can the American authorities; and (2) the European Commission is doing explicitly what the Americans are doing implicitly.[69]

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66. *See* Ciba Geigy Ltd., FTC File No. 961-0055 (Dec. 5, 1996); Sensormatic Elecs. Corp., 60 Fed. Reg. 5428 (F.T.C. 1995).

67. *See* Sensormatic Elecs. Corp., 60 Fed. Reg. 5428 (F.T.C. 1995).

68. *See* Lawrence B. Landman, *Innovation Markets in Europe,* 19 EUR. COMPETITION L. REV. 21 (1998).

69. *Compare* John Temple Lang, *European Community Antitrust Law: Innovation Markets and High Technology Industries*, 20 FORDHAM INT. L. REV. 717 (1997) (the

B. Joining of Two Competitors in the Current Goods Market

1. General Motors—ZF Friedrichshafen[70]

In this case the DOJ opposed ZF Friedrichshafen's (ZF) attempt to buy the Allison transmission division of General Motors (GM).[71] GM and ZF together controlled about 90% of the world's heavy-duty automatic transmission market.[72] In Europe, the firms were the largest producers of heavy-duty automatic transmissions for commercial and military vehicles.[73] In the United States, however, the firms competed in only two small markets, those for automatic transmissions for busses and refuse trucks.[74]

GM had dominated the American heavy-duty automatic transmission market until ZF entered the American market in 1985. When ZF entered the market, it offered customers a better transmission. In response GM invested $500 million to develop still a better transmission. In this way the firms developed a pattern of competing to innovate. The DOJ did not want the acquisition to eliminate this competition to innovate which clearly benefited American consumers.

The DOJ alleged that the firms competed, not only in the narrow bus and refuse truck transmission markets, but also in a broad innovation market to make better transmissions. The DOJ feared that the transaction would harm competition in markets beyond the two narrow existing goods markets: that the merger would slow the rate at which the firms developed better automatic transmissions. It therefore alleged that the firms competed in the broad innovation market to make better transmissions.

European Commission can and has analyzed incentives to innovate), *with* Lawrence B. Landman, *The Economics of Future Goods Markets,* 21 WORLD COMPETITION L. & ECON. REV. 63 (1998) (like the Americans, the Europeans too cannot analyze a firm's incentives to innovate in the manner innovation market analysis requires).

70. United States v. General Motors Corp., No. 93-530 (D. Del. filed Nov. 16, 1993).

71. *See id.*

72. *See id.* at 2. Paragraph 42 of the complaint first assigns to each firm the same share of the alleged innovation market that it has of the related goods market. The paragraph then assigns GM over 75% of the innovation market, and ZF 14% of this market.

73. *See* Dahdouh & Mongoven, *supra* note 11, at 431. These authors and the complaint refer to the market for medium and heavy duty automatic transmissions. For the sake of simplicity, this article will use the term "heavy duty" to mean both "medium and heavy duty."

74. *See* United States v. General Motors Corp., No. 93-530 (D. Del. filed Nov. 16, 1993) (complaint at ¶ 19-34).

Critics of the innovation market concept question whether the DOJ needed to allege that in this case the parties competed in an innovation market.[75] According to these critics, DOJ already alleged a sufficiently serious antitrust violation when it alleged that the transaction would harm competition in the two narrow goods markets. These critics say that the Department did not need to also allege that the firms competed in an innovation market.

The DOJ feared, however, that the transaction would not only harm competition in these two narrow markets, but also that it would harm competition in the broad transmission market. Yet if the DOJ had only alleged that the firms competed in these two narrow markets, then ZF would simply have sold GM's businesses in these two narrow markets, and then completed its purchase of GM's division. By alleging that the firms competed in a broad innovation market, the DOJ forced ZF to respond to its broader antitrust concerns.

In this case, as in all the other cases, the antitrust authority actually regulated, not an innovation market, but a future goods market. Yet in this case the firms competed against each other, not only in a future goods market, but also in a current goods market. The firms competed against each other to sell many different types of transmissions.

But while the firms competed against each other to sell these many types of transmissions, they did so in *Europe*.[76] However an *American* antitrust authority wanted to regulate the transaction. The DOJ therefore used what it claimed to be innovation market analysis to actually regulate a future goods market. By regulating that future goods market, the DOJ actually regulated the related current goods market. Thus, because the current goods market was in Europe, the American agency actually used the innovation market concept to assert jurisdiction over a European current goods market.

a) ZF and GM Competed in a Current Goods Market, and Therefore Also in a Future Goods Market

In this case DOJ did not have to imagine that the two firms would compete against each other in the future. At the time of the transaction ZF and GM both sold heavy duty transmissions, and tried to sell these transmissions to the same customers. The firms competed against each other in the current goods market for heavy duty automatic transmissions. And if

75. *See* Rapp, *supra* note 43, at 19-20, 23.

76. *See* Richard J. Gilbert, Remarks Before the FTC Hearings on Global and Innovation-based Competitions, Washington, D.C. (October 25, 1995) (available at <http://www.ftc.gov/opp/global/GC102595.htm>).

these two competitors planned to combine their businesses, then the appropriate antitrust authority should of course ensure that they not do so in a way which would harm competition.

Whenever an antitrust authority ensures that a market is competitive it ensures that firms compete to innovate. While conditions naturally vary from industry to industry, to at least some extent all firms use not only lower prices, but also innovation, as a competitive weapon. Thus all competitive markets to some extent force firms to innovate. Thus even if the antitrust authorities use only the traditional tools of antitrust analysis, and, for example, only measure prices, they will nevertheless, to some extent, also insure that firms compete to innovate. Thus all current competitors to some extent also compete in a future –goods market.

ZF and GM therefore competed against each other in both current and future goods markets. The firms certainly competed in the current heavy-duty automatic transmission market. And because the firms also tried to make better transmissions, the firms also competed in the related future goods market for better heavy-duty automatic transmissions. In fact, ZF and GM's history of competing to innovate shows that the two firms competed in this future goods market.

b) American Authorities Did Not Have Jurisdiction Over the Current Goods Market

If two firms dominate any market, and one tries to buy the other, this potential purchase will naturally raise antitrust concerns. And because all current competitors to some extent also compete against in a related future goods markets, if one dominant firm tries to buy another, this potential purchase may also raise antitrust concerns in the related future goods market. Thus when the appropriate antitrust authority reviews this potential purchase, it may analyze, not only the relevant current goods market, but also the related future goods market.

GM and ZF did compete against each other. They competed against each other, not only in the current goods market, but also in the related future goods market. Thus when the appropriate antitrust authority reviewed ZF's attempt to buy GM's division it would probably have analyzed, not only the relevant current goods market, but also the related future goods market. But, with the exception of the two narrow product markets, these two firms competed in a current goods market in Europe. Thus, while the *appropriate* antitrust authority should indeed have analyzed how ZF's potential purchase of GM could have affected, not only the current goods market, but also the future goods market, that antitrust authority was in Europe.

As this implies, the DOJ should not have asserted jurisdiction over this case. The DOJ, however, wanted to regulate the transaction. DOJ therefore used the innovation market concept so it could plausibly assert jurisdiction. But the Department should not have done so.[77]

The DOJ alleged that innovation spillover effects allowed it to take jurisdiction in this case. While the Department does indeed correctly point out that the transaction may affect the broad American future goods market for automatic heavy duty transmissions, the transaction may affect the broad future goods markets for heavy duty transmissions, not only in the United States, but throughout the world. In fact, almost all transactions affect both the appropriate current goods market and the related future goods market. Such future goods markets are often worldwide. The DOJ's reasoning thus allows almost all antitrust authorities to assert jurisdiction over almost all transactions.

The international antitrust system must appropriately divide jurisdiction over the many transactions in which firms engage throughout the world. Each antitrust authority must therefore regulate transactions which affect current goods markets within its territory. Because GM and ZF competed in the broad current goods market in Europe, the appropriate European antitrust authority, and not an American antitrust authority, should have asserted jurisdiction over both the current goods market, and the related future goods market.

The appropriate European antitrust authority would have ensured that the transaction did not improperly lower competition in both the current goods market and the future goods market. And, by keeping these markets competitive, it would have ensured that market forces drove the relevant firms to innovate. The DOJ should therefore not have used the innovation market concept to assert jurisdiction over this transaction. It should have relied on the European antitrust authority to do the job.

Two FTC attorneys who wrote a law review article endorsing the Gilbert and Sunshine model, Thomas N. Dahdouh and James F. Mon-

77. The European Commission's threat to block Boeing Corp.'s merger with McDonnell Douglas strained relations between the European Union and the United States. At one point the United States seemed on the verge of a trade war with Europe. Vice President Al Gore, for example, threatened to "take whatever action is appropriate" to stop the Commission from blocking the merger. *See EU/US Clash Over Airline Merger*, GLOBAL COMPETITION REVIEW, June/July 1997, at 5. All this occurred in a case where the European Commission clearly had jurisdiction. One shudders when contemplating the White House's reaction if the Europeans had found that Boeing and McDonnell Douglas competed in a global innovation market, and on this basis blocked the transaction.

goven, argued that the DOJ was the appropriate entity to challenge the transaction because of the transaction's effect on the European current goods market, alleging that the sale would have had a spillover effects on "a global innovation market."[78] But, these authors concluded, "it made sense, both as a matter of comity and of common sense, to challenge the most troubling aspect of the transaction directly."[79]

The DOJ should not, however, have asserted jurisdiction over this case. Regarding comity, because the transaction affected the European goods market much more than it did the American market, the Americans should have let the Europeans analyze this transaction. Regarding common sense, the DOJ should not have used the innovation spillover effects to create a doctrine which gives almost any antitrust authority jurisdiction over almost any transaction.

c) The DOJ Analyzed, Not an Innovation Market, But a Future Goods Market, and, Through it, the Current Goods Market

In this case the DOJ used the innovation market concept to regulate the European current goods market. Had the firms competed in a broad American heavy duty transmission market, then the DOJ would not have needed innovation market analysis to challenge the transaction. The relevant firms dominated their market, and traditional antitrust analysis would therefore have allowed the DOJ to challenge this transaction. But because the firms competed in Europe, and the DOJ did not have jurisdiction over the current goods market, the DOJ could not apply this traditional antitrust analysis.

Because the DOJ wanted to regulate the European current goods market, but could not do so directly, it did so indirectly. It regulated what it called an innovation market. But the innovation market DOJ purported to regulate mirrored the European current goods market. Thus while the DOJ claimed to regulate the innovation market, it actually regulated the European current goods market.

Finally, in this case the DOJ did not, in fact regulate an innovation market. It regulated the future goods market for better automatic transmissions. In this case, as in all the others, it could not find an innovation market. It could not, for example, identify potential competitors who might enter the innovation market.

78. Dahdouh & Mongoven, *supra* note 11, at 431.
79. *Id.*

i) Complaint Uses Market Shares of Current Goods Market As Surrogate for Shares of What it Calls an Innovation Market

The DOJ's complaint simply uses the innovation market as a surrogate for the European current goods market. Most importantly, its complaint assigns to each firm the same share of the innovation market that it finds that firm had of the current goods market. Thus while the complaint found that the combined firm would dominate the innovation market, it does so only because it found that the combined firm would dominate the European current goods market.

Thus while claiming to regulate the innovation market, the DOJ actually regulated the European current goods market. In the typical case, the DOJ would simply analyze the current goods market. But in this case DOJ did not have jurisdiction over the current goods market. It therefore used what it called innovation market analysis to regulate the current goods market.

In the very first paragraph of its complaint, the DOJ expressed its true concerns. In this first paragraph the DOJ said that GM and ZF are "the two largest manufacturers of medium and heavy automatic transmissions in the world ... ZF and Allison [GM] are each other's main competitors ...." The complaint then concluded by observing that, "market shares in the Innovation Market can be approximated by the number of units produced worldwide by each manufacturer ...."[80]

ii) What DOJ calls an Innovation Market is Actually a Future Goods Market

In this case the DOJ could not find an innovation market; it in fact regulated the future goods market for better heavy duty automatic transmissions. The complaint said that GM and ZF firms were two of only a small number of firms which could, in the future, make better heavy duty automatic transmissions. The complaint also alleged that no firms could enter the innovation market in the foreseeable future. Thus the complaint actually alleged that GM and ZF were two of only a small number of firms which could compete in the future goods market for better heavy duty automatic transmissions.

When the complaint alleged that no other firm could enter the innovation market in the foreseeable future, it actually alleged that no firm could enter the future goods market in the foreseeable future. As explained

80. United States v. General Motors Corp., No. 93-530 (D. Del. filed Nov. 16, 1993) (complaint at ¶ 42).

above,[81] to enter an innovation market where innovation is itself the "product," a firm need only be trying to develop the future good. If a firm is investing in R&D, then, even if it is not producing the relevant good, it is still "producing" innovation. It is therefore competing in the innovation market. Thus when the DOJ says that no firm will be able to *make* automatic transmissions in the foreseeable future, it is saying that for the foreseeable future no firm will be able to enter the future goods market. It is not saying that no firm will be able to enter the innovation market.

The DOJ clearly used Gilbert and Sunshine's innovation market methodology to help it draft its complaint. The Department issued its complaint before the authors had published their methodology, but nevertheless while the authors held a high office in the Department. Unfortunately, as the preceding section showed, the authors' methodology breaks down, among other reasons, because the agencies cannot identify potential competitors who might enter an innovation market.[82]

Accordingly, in this case the DOJ could not identify potential competitors who might enter the relevant innovation market. Specifically, the DOJ could not identify the potential competitors who may enter the innovation market to make better heavy duty automatic transmissions. Firms enter an innovation market when they try to make the relevant good. Since innovation is the product of the innovation market, when firms try to make the relevant good they are currently competing in the relevant innovation market. Potential competitors of the innovation market are thus firms which may, in the future, try to develop the relevant good. Accordingly, potential competitors of the transmission innovation market are firms which may, in the future, try to make better the appropriate transmission.

When the DOJ alleges that no firm will enter the automatic transmission innovation market, it implicitly claims that no firm will, within the foreseeable future, even try to make better automatic transmissions. In its complaint the DOJ does not actually make this claim, nor could it plausibly do so. If the market offered high enough returns, or if the current seller were earning high enough monopoly profits, then other firms may try to enter the market. Other firms may also develop technology which would allow them to make either better transmissions, or current quality transmissions at lower cost. If the market offered a sufficient incentive, then other firms, such as other car, truck, or military equipment manufac-

81. *See supra* text accompanying notes 31-32.

82. *See supra* text accompanying notes 42-62.

turers may try to enter the automatic heavy duty transmission market, either separately or jointly.

Given sufficient time, these new competitors might be able to manufacture transmissions.[83] Other car, truck, or military equipment firms, for example, own manufacturing equipment, and might be able to use this equipment to produce transmissions. Alternatively, the firms could buy manufacturing equipment from the same firms which supply GM and ZF. These new entrants could hire engineers, including engineers GM or ZF previously employed. These firms could also hire academic researchers familiar with the latest technology. They might also develop entirely new transmission technology, develop a new method of distributing transmissions, or try to compete in only part of GM or ZF's current goods market.

These firms, or other firms, may also try to enter the market in still other ways.[84] In short, no one, including DOJ analysts, could know which firms, if any, may, in the future, try to enter the relevant market. To review the logic step-by-step: (1) because firms trying to make new transmissions are already competing in the relevant innovation market, firms which may, in the future, try to develop new transmissions are potential competitors of the innovation market; (2) because the DOJ could not know which firms, if any, may, in the future, try to make new transmissions, it could not know which firms, if any, may, in the future try to enter the automatic transmission innovation market; (3) because the DOJ could not know which firms may enter the automatic transmission innovation market, it could not identify the potential competitors of the innovation market; and (4) because the DOJ could not identify the potential competitors of the innovation market, it could not define the innovation market.

d) Conclusion

The DOJ should not have regulated this transaction. While the DOJ did raise legitimate antitrust concerns, it raised concerns which the antitrust authority holding jurisdiction over the relevant current goods market should have addressed. Because the DOJ did not have jurisdiction over this current goods market, it should not have regulated this transaction.

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83. This period could be longer than the two year period the *Merger Guidelines* use, and which Gilbert and Sunshine say the agencies should adopt. In *Upjohn* the FTC anticipated events seven years into the future. *See supra* text accompanying note 38.

84. *See Subway to the Sky: How a Reserved Canadian Turned a Family Snowmobile Firm into the Nearest Challenger to Boeing and Airbus*, THE ECONOMIST, August 23, 1997, at 52; *see also* Meherdad A. Baghai, et al, *The Growth Philosophy of Bombardier*, 2 MCKINSEY QUARTERLY 4 (1997).

To plausibly assert jurisdiction in this case, the DOJ claimed to regulate, not the current goods market, but rather the related innovation market. But the DOJ's analysis of this innovation market simply reflects its analysis of the current goods market. Therefore, while claiming to regulate the innovation market, the DOJ actually regulated the current goods market. Thus, the American antitrust agency regulated the European current goods market.

Finally, in this case the DOJ did not even regulate an innovation market. It actually regulated the future goods market for better automatic transmissions. The DOJ could not, for example, identify potential competitors of the innovation market. It could not therefore define the innovation market.

2. *Flow International*[85]

Six months after the DOJ challenged ZF's purchase of GM's transmission business, it also challenged Flow International's purchase of Ingersoll-Rand's Waterjet Cutting Systems Division. This case presented the DOJ with facts very similar to those of *GM-ZF*. In this case, as in the *GM-ZF* case, one dominant firm sought to buy another dominant business unit. In this case, however, both firms operated in the United States. Unquestionably, DOJ had jurisdiction in this case.

a) Current Goods Market

As the complaint itself alleged, this transaction would have "combin[ed] the nation's only two major manufacturers of ultra-high pressure waterjet intensifier pumps."[86] Just as in *GM-ZF*, the combined firm would control 90% of the relevant market. The DOJ would not let allow the combined firm to obtain a virtual monopoly. In this case, therefore, the DOJ acted primarily to protect competition in the current goods market.

b) Future Goods Market or Innovation Market

While the DOJ acted primarily to preserve competition in the current goods market, it did to some extent also preserve competition in the future goods market. The future goods market in this case is the market for better ultra-high pressure waterjet pumps. If the two firms did join together, then they would indeed dominate this future market for better pumps.

Yet this observation, while theoretically correct, adds little to the DOJ's case. The law already allowed the DOJ to block a transaction which would give one firm 90% of the relevant current goods market.

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85. United States v. Flow Int'l Corp., No. 94-71320 (E.D. Mich. filed Apr. 4, 1994).
86. *Id.* (complaint, at ¶ 1).

Thus while the DOJ may claim that in this case it also preserved the firms' competition to make better ultra-high pressure waterjet pumps, this claim, while theoretically correct, adds very little to the Department's already very strong case.

3. Shell-Montedison[87]

In this case the FTC reviewed Shell's and Montedison's plans to combine their polypropylene businesses into a joint venture. Both Shell and Montedison produced polypropylene and licensed polypropylene technology. Shell, through its own businesses, and through its American joint venture with Union Carbide, controlled one of the world's two marketable polypropylene technologies. Montedison, through its own businesses and through a cooperation agreement with Mitsui, controlled the world's other marketable polypropylene technology.

As the firms originally planned their joint venture, Montedison would contribute its entire polypropylene business, but Shell would contribute only its own polypropylene business, and not its interest in its joint venture with Union Carbide. The firms would thus create Europe's, and the world's, leading polypropylene producer. The joint venture would control both of the world's marketable polypropylene technologies.

a) European and American Authorities

This is one of several cases which both the American and European authorities reviewed. By comparing how both of these authorities analyzed these same transactions, one can clearly see how both authorities analyze innovation markets. In this case the European authorities did not find an innovation market, and, as in all the other cases, did not claim to find such a market. But in this case the FTC also did not actually claim that it found an innovation market.

b) Remedies

The European Commission, which issued its decision first, required Montedison to create a separate polypropylene technology licensing business, in which Shell had no interest.[88] The Commission expected this independent business to compete against both of Shell's two polypropylene joint ventures. The European Commission also required Montedison to invest enough into R&D to ensure that this independent firm would innovate and thus continue to compete against Shell's polypropylene interests.

87. Montedison S.p.A., 60 Fed. Reg. 5,414 (F.T.C. 1995).

88. Shell-Montecatini, Case No. IV/M. 269 (June 3, 1994), O.J. L.332/48 (Dec. 22, 1994).

The FTC imposed a stronger remedy.[89] It ordered Shell to sell all its polypropylene interests aside from its interest in the Montedison joint venture. The FTC therefore, in effect, ordered Shell to sell its interest in its American joint venture with Union Carbide. The FTC also ordered Mitsui to stop cooperating with Montedison and the Shell-Montedison joint venture.

c) Rationale For Authorities' Decisions

In this case the FTC and the European Commission analyzed markets for both polypropylene and polypropylene technology. The FTC alleged that the firms competed in two current markets, one for polypropylene itself, and one for licensing polypropylene technology. Since both the polypropylene and the polypropylene technology already existed, these were both current goods markets. The two authorities alleged that the transaction would improperly allow the joint venture to dominate both of these current goods markets.

Both authorities found that firms in the polypropylene licensing business competed to develop better polypropylene technology. Both authorities therefore found that firms in this market competed to innovate. Yet while both authorities found that the firms competed to innovate, neither alleged that the firms competed in an innovation market.

Even Dahdouh and Mongoven do not claim that in this case the FTC found an innovation market.[90] Those authors do say that if the FTC had merely analyzed the market to license currently existing technology, then it would not have fully appreciated how this transaction would harm competition. To fully appreciate how the market would develop as the firms improved their polypropylene technology, they argue, the FTC also had to analyze the firms' competition to improve their technologies.

The FTC could, and did, analyze this competition to innovate without finding an innovation market. The market for the improved polypropylene technology is, in this case, the future goods market, or, more accurately,

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89. The Commission probably expected the FTC to issue this order. The Commission and FTC had discussed possible remedies in this case, and, at the parties' request, the European Commission reserved the right to change its decision should the FTC issue an order, as it did in fact do, making the Commission's order superfluous. *See* Robert Pitofsky, *International Antitrust: An FTC Perspective,* TWENTY-SECOND ANNUAL PROCEEDINGS OF THE FORDHAM CORPORATE LAW INSTITUTE 1, 7-8 (B. Hawk ed., 1996); *see also* Shell-Montecatini, *supra* note 88, at point 121.

In fact, in light of the FTC's decision the Commission did allow Montedison to bring its separate polypropylene business back into its joint venture with Shell. Shell-Montecatini, O.J. No. L.294 (Nov. 19, 1996).

90. Dahdouh & Mongoven, *supra* note 11, at 433.

the future technology market. Dahdouh and Mongoven say that in this case the FTC must analyze this future market. The authors do not say that the FTC should find an innovation market. In fact, as mentioned above, in this case the FTC, like the European Commission, did not find an innovation market.

As this case shows, without finding an innovation market the agencies can analyze future market developments. In this case, the FTC, without finding an innovation market, was able to analyze future market developments. In fact, as this section will show, if the FTC had tried to apply Gilbert and Sunshine's innovation market methodology, it would still have found only a future goods market.

d) The FTC Could not Apply the Gilbert and Sunshine Methodology

i) Identify Overlapping R&D Activities

The relevant firms in this case performed overlapping R&D. Both were trying to improve their polypropylene technology.

ii) Identify Alternative Sources of R&D

In the short run, no other firms were likely to license polypropylene technology. Thus, if the firms combined their technologies, they would then have been able to dominate the current goods market, and probably also the future goods market. In other words, the FTC could legitimately conclude that for the foreseeable future no other firms would enter the future goods market.

However, as the European Commission's decision makes clear, other firms did control other polypropylene technologies.[91] While at the time these firms had only very small market shares, they were presumably trying to improve their technologies. If the incentives were great enough, then, over time, these other firms may have been able to develop licensable polypropylene technologies.

The FTC could therefore identify the potential competitors who might enter the future goods market, but it could not identify potential competitors who might enter the innovation market. The firms trying to improve their polypropylene technology were potential competitors of the future goods market. These firms were also currently competing in the current innovation market.

91. *See supra* text accompanying note 88.

Firms not trying to improve their polypropylene technology, but which may try to do so in the future, were also potential competitors of the innovation market. Other firms, who controlled, or who might develop, comparable technologies were also potential competitors of the innovation market. The FTC could not reasonably identify all these firms which might, in the future, try to develop or improve polypropylene technology. The FTC could therefore not identify the potential competitors of the innovation market.

iii) Evaluate Competition From Downstream Products

Since Shell and Montedison controlled the two marketable polypropylene technologies, these firms controlled the relevant products. In this case, therefore, downstream products did not apply competitive pressure in any relevant market.

iv) Assess Increase in Concentration in R&D

In this case the FTC could not analyze the joint venture's incentive to innovate. Perhaps the joint venture would already have enjoyed such a large market that it would not try to improve its technology. But even if the joint venture had enjoyed a large market share, it may nevertheless still have tried to improve its technology. The joint venture may, for example, have wanted to sell its improved technology to its old customers. If the joint venture improved its technology it might have been able to sell its better technology to more customers. It may have been able to expand its share of the market for polypropylene itself. Also, if the joint venture had improved its technology, then it may have been able to enter markets for technology related to polypropylene technology, or other opportunistic markets.[92] In short, the FTC could not have determined how, if at all, the joint venture would seek to expand its polypropylene business. It therefore could not have evaluated the joint venture's incentives to innovate.

Even if the FTC could not have analyzed the joint venture's incentives to innovate, the FTC still correctly challenged this transaction. Traditional antitrust law required the FTC to stop the firms from monopolizing the polypropylene technology market. Thus, in this case the FTC acted, not because the firms tried to monopolize an innovation market, but because the firms tried to monopolize the current goods market.

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92. For the definition of an opportunistic market, see *supra* text accompanying note 40.

v) Assess Efficiencies

No evidence indicates that this transaction would generate R&D efficiencies. Such efficiency gains would, in any case, not justify allowing these firms to create a monopoly in the polypropylene technology market.

C. Current Goods Maker Purchases Potential Competitor

1. Wright Medical Technology[93]

a) Background of the Case

Before it attempted to buy Orthomet, Wright Medical Technology already controlled 95% of the orthopedic hand implant market.[94] Orthomet controlled a patent which would allow it to develop the next generation of hand implant. Unsurprisingly, the FTC would not allow Wright to purchase its only potential competitor.[95]

In this case the FTC protected competition in the future goods market. It preserved the possibility that Orthomet may sell the next generation of hand implant and the possibility that Orthomet may compete against Wright Medical in the future hand implant market. But the FTC did not find an innovation market.

In this case as well, if the FTC had applied Gilbert and Sunshine's innovation market methodology, then it would simply have analyzed the future goods market. As the following analysis shows, in this case as well the FTC could not find an innovation market.

b) The FTC Could Not Apply the Gilbert and Sunshine Methodology

i) Identify the overlapping R&D Activities

The firm's R&D activities overlapped in the market for orthopedic hand implants. This is the future goods market.

ii) Identify Alternative Sources of R&D

The complaint alleged that no other firms could make hand implants. However, if Wright Medical were earning high enough monopoly profits, then other firms would certainly want to enter the hand implant market.

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93. Wright Medical Technology, Inc., 60 Fed. Reg. 460 (F.T.C. 1995).

94. *See* Rapp, *supra* note 43, at note 85.

95. *See* Commissioner, Federal Trade Commission, Mary L. Azcuenaga, Intellectual Property and Antitrust: A Perspective from the FTC, Speech before the American Law Insitute-American Bar Association, San Francisco, California (1995) (available at <http://www.ftc.gov/speeches/azcuenaga/ali-aba.htm>).

These possible competitors could include firms currently manufacturing, among other things, other medical devices, automated machinery, or robotic equipment.

Firms which were not performing the relevant R&D at the time of this transaction might do so in the future. They might base their future research on technologies different from those of Wright Medical or Orthomet's, and perhaps even on technologies which do not yet exist.

Thus, in the future, many firms might try to enter the hand implant market. And these firms, by trying to enter the hand implant market, would be providing alternative sources of R&D. The FTC could not identify all these firms which might, in the future, invest in the relevant R&D. The FTC, therefore, could not identify all the all potential competitors who might enter the innovation market, and not find the innovation market.

On the other hand, the FTC may very well have correctly alleged that Orthomet was Wright Medical's only potential competitor. Because Wright already controlled 95% of the market, and was trying to buy the only firm which could challenge it in the foreseeable future, then, almost by definition, no other firm could, for the foreseeable future, compete in the future orthopedic hand implant market. Thus in this case the FTC appropriately protected competition in the future goods market.

iii) Evaluate Competition From Downstream Products

Since Wright controlled 95% of the current goods market, other downstream products offered very little current competitive pressure.

iv) Assess Increase in Concentration in R&D

The FTC could not know how Wright Medical's purchase of Orthomet would affect Wright Medical's incentives to innovate. Perhaps the combined firm would have felt that, because it enjoyed monopoly power, it did not need to innovate. On the other hand, even after it had purchased Orthomet, Wright Medical may still have tried to improve its technology. It may have wanted to do so for any number of reasons. It may have wanted to sell better implants to users of its current products. Or it may have wanted to expand into other markets, such as the market for other types of implants. Wright Medical could expand its business in an almost infinite number of ways. The FTC could not know, how, if at all, Wright Medical may, in the future, choose to expand its business.

v) Assess Efficiencies

As in *Shell/Montedison,* the FTC did not explain what efficiencies, if any, it thought this transaction would generate. The FTC, undoubtedly correctly, did not believe that this transaction would generate efficiencies that would justify allowing Wright Medical to purchase its only potential competitor.

2. Boston Scientific[96]

In this case, Boston Scientific, SCIMED and CVIS planned to combine their businesses. Boston Scientific and CVIS together controlled 90% of the market for intravascular ultrasound catheters (IVUS). SCIMED, the FTC alleged, was the most likely potential entrant into this market. SCIMED was investing in the relevant R&D, had developed a prototype product, and, the FTC said, would probably have entered the market within 2-3 years.

This transaction raised serious antitrust concerns in the current and future goods markets. Two of the relevant firms together controlled 90% of the current goods market. Further, the transaction would combine these two firms, which dominated the current goods market, with their most likely future competitor. Therefore standard antitrust analysis, and not innovation market analysis, required the FTC to challenge this transaction.

This case is similar to *Wright Medical.* Just as the FTC could not apply Gilbert and Sunshine's innovation market methodology in that case, so too could it not apply the author' methodology in this case. In this case as well the FTC could not identify potential competitors of the innovation market, and it could not analyze the combined firm's incentives to innovate.

D. No Current Goods Market, Potential Competitors Combine

Of the three categories of cases, this category offered the antitrust authorities their greatest challenge. This category presented the authorities with cases in which no firm yet made the relevant good, but the relevant firms were trying to make the good. Thus, while the firms did not compete in the current goods market, they may, if they did not combine their businesses, compete in the future goods market.

96. Boston Scientific Corp., 60 Fed. Reg. 12,948 (F.T.C. 1995).

1. Glaxo-Wellcome[97]

In early 1995 the British pharmaceutical firm Glaxo bought its rival Wellcome. Glaxo sold, among other products, the world's most effective anti-migraine drug. Doctors injected this drug into patients. Wellcome was one of several firms trying to develop a comparable anti-migraine drug, but one which patients could ingest orally. Glaxo was also trying to develop an oral version of its drug.

a) The FTC and European Commission Define Future Goods Market Differently

In this case the FTC and the European Commission found that the firms competed in different future goods markets. The FTC defined the market much more narrowly than did the Commission. By defining the future goods market so narrowly, the FTC left no doubt that it found a future goods market, and not an innovation market.

The FTC found that the firms competed in, what it called an innovation market, to develop only the oral version of the anti-migraine drug. The FTC therefore found that the firms were competing to develop a product which did not yet exist. As the FTC analyzed this case, therefore, the firms did not compete in a current goods market.

The European Commission, by contrast, found that the firms competed in a broader market. The European Commission did not distinguish between oral and injectable forms of the drug. Both forms of the drug, the European Commission found, competed against each other. Therefore, according to the Commission, Wellcome was trying to enter a market in which Glaxo already operated.

Additionally, the European Commission found that, besides Wellcome, "at least two" other major pharmaceutical firms were close to developing a competitor to Glaxo's anti-migraine drug. The Commission recognized that, of these R&D projects, Wellcome's might be the only one which succeeds. Thus the Commission realized that if it approved the merger, then the market may lose its only future competitor to Glaxo's new anti-migraine drug.

Recognizing the European Commission's concerns, and possibly anticipating the FTC's future order, Glaxo volunteered to grant to a third party an exclusive license to either Wellcome's or its own anti-migraine R&D program, but Glaxo reserved the right to decide which program it would license. The European Commission, however, concluded that because Wellcome was one of several firms investing in the relevant R&D,

97. Glaxo plc., 60 Fed Reg. 16,139 (F.T.C. 1995).

the effect of removing Wellcome from the market would be "limited." Therefore, the European Commission may very well have approved the merger even if Glaxo had not agreed to license one of the R&D programs.

b) FTC Analyzed a Future Goods Market, Not an Innovation Market

The FTC defined a narrower market than did the European Commission. The FTC found that the firms competed in a narrow future goods market to develop an oral version of the drug. The European Commission, by contrast, found that the firms competed in a broader market which included both the existing injectable form of the drug Glaxo already sold, and the oral form of the drug the firms were trying to develop.

This difference shows that the FTC found a future goods market, and not an innovation market. In fact, the FTC analyzed a very narrow future goods market. If the FTC had actually analyzed an innovation market, then it would have evaluated the firms' broad ability to innovate. Yet the FTC does not even claim that in this case it evaluated the firms' abilities to innovate, either generally or specifically, regarding anti-migraine drugs. In this case the FTC did nothing more than analyze a very narrow future goods market.

c) The FTC Could Not Apply Gilbert and Sunshine's Methodology

As in other cases, the FTC could not apply Gilbert and Sunshine's innovation market methodology.

i) Identify the Overlapping R&D Activities

As the FTC analyzed the firms' R&D activities, both firms were trying to develop the oral version of the drug. The firms therefore competed in the oral anti-migraine drug future goods market.

ii) Identify Alternative Sources of R&D

The complaint alleges that no other firms offered alternative sources of R&D. However, while the FTC might credibly claim that, for the foreseeable future, no firm would enter the future goods market, it could not claim that no firm would enter the innovation market.

The agencies find it particularly easy to identify potential entrants into current and future pharmaceutical markets. Federal agencies test possible new pharmaceutical products for many years. This testing process allows the antitrust agencies to see which drugs firms are trying to develop, and which drugs these firms may therefore be able to sell in the future. Thus,

the testing process allows the agencies to identify potential competitors of current and future pharmaceutical markets. It does not, however, allow the agencies to identify potential competitors of an innovation market. A firm trying to develop a new drug is a potential competitor in the appropriate drug market. But if the firm is trying to develop the new drug, then it is currently "producing" innovation; it is competing in the current innovation market. Potential competitors of the innovation market are firms which may, in the future, try to produce the appropriate drug. And the testing process does not allow the agencies to identify such firms.

Thus, in this case, the agencies could not identify potential competitors of the anti-migraine innovation market. Many other firms may in the future, try to develop anti-migraine drugs. To develop these drugs firms may use technology similar to the technology Glaxo and Wellcome use, or they may use entirely new technology. They may even develop new ways of treating migraine headaches, or may not even use drugs at all.

iii) Evaluate Competition From Downstream Products

The drugs Glaxo and Welcome were trying to develop were so clearly superior to the drugs other firms sold that the FTC did not consider these other drugs to be comparable products. Thus no downstream products exerted competitive pressure in the oral anti-migraine market.

iv) Assess Increase in Concentration in R&D.

While in this case the FTC could not determine the merged firms' incentives to innovate, if it had attempted to do so, then it would have concluded that the merger would probably increase those incentives. If the merged firm could develop an oral version of its drug, then it could expand its anti-migraine drug market. For example, if it could sell an oral, rather than an injectable, form of the drug, then children and others who might prefer an oral form of the drug would probably be much more likely to use the product. Most patients would rather swallow a pill than be injected with a hypodermic needle. And if the merged firm sold a drug which consumers could more easily use, then it would sell more of its product.

If the merged firm developed an oral version of the drug, then it may also be able to enter other markets. It may be able to develop oral versions of other drugs. The firm may also be able to develop a lower strength, over the counter, version of its oral drug. In short, while the agencies can never definitively analyze a firm's incentives to innovate, the evidence in this case does not show that the merger would lower the firms' incentives to innovate.

The FTC acted in this case to stop the merged firm from monopolizing the future goods markets. Even if the FTC had developed an opinion regarding the merged firm's incentives to innovate, this opinion seems to have played no role in the FTC's analysis of this case.

v) Assess Efficiencies.

In this case, as in the other cases, the FTC did not explain what efficiencies, if any, it thought this transaction would generate. Again, efficiency considerations appear to have played no role in the FTC's evaluation of this case.

2. Upjohn-Pharmacia[98]

Later on in 1995, two other pharmaceutical firms, Upjohn and Pharmacia, also merged. These companies were trying to develop, among other things, new treatments for solid tumors. Neither firm yet sold the relevant drug.

a) European Commission: Future Market is Competitive

In this case the European Commission did not see an antitrust problem.[99] The European Commission concluded that, even though both firms based their research programs on the same class of compounds, their R&D efforts would not necessarily overlap. The European Commission said that the drugs the two firms were trying to develop may offer alternative therapies, and would therefore not necessarily compete against each other in the future. The Commission also found that three other firms were doing similar research. It concluded that while the firms were performing similar solid tumor research, their R&D programs did not raise antitrust concerns.

b) FTC: Future Goods Market Not Competitive

Unlike the European Commission, the FTC found that the firms did in fact compete to develop treatments for solid tumors.[100] The FTC found a

98. Upjohn Co., 60 Fed. Reg. 56,153 (F.T.C. 1995).

99. Case No. IV/M. 631 (Sept. 28, 1995).

100. The FTC said that, worldwide, only "a very small number" of firms were engaged in research similar to that of the merging firms. The FTC also said that because the information was highly confidential it could not disclose how small this number was. Presumably the FTC discovered the same three other research programs the European Commission discovered, and, therefore, unlike the Commission, the FTC considered three to be a very small number. This would be consistent with the *I.P. Guidelines'* statement that the agencies will probably challenge a transaction unless at least 4 competitors were doing similar R&D. *See Analysis of Proposed Consent Order to Aid Public Comment*, 60 Fed. Reg. 56,159 (F.T.C. 1995); *I.P. Guidelines*, *supra* note 9, at § 3.2.3 ex.

separate innovation market, and ordered Upjohn to divest specific technology. In this case the FTC saw an antitrust problem where the European Commission saw none.

c) The FTC Could Not Apply Gilbert and Sunshine's Methodology

In this case, as in the other cases, the FTC could not use Gilbert and Sunshine's innovation market methodology. In this case, the FTC found, not an innovation market, but a future goods market.

i) Identify the Overlapping R&D Activities

According to the FTC's analysis, the firms' R&D activities overlapped. Both firms were trying to develop treatments for solid tumors. This is therefore the future goods market.

ii) Identify Alternative Sources of R&D

The complaint alleges that there were no alternative sources of R&D. As explained above,[101] the long and cumbersome federal drug approval process does allow the antitrust agencies to identify potential competitors of future pharmaceutical markets. It does not, however, allow the agencies to identify potential competitors of innovation markets. Thus, in this case, while the FTC could identify competitors who might enter the future goods market, it could not identify potential competitors of the relevant innovation market.

iii) Evaluate Competition From Downstream Products

Since no downstream products existed, no downstream products could exert any competitive pressure.

iv) Assess Increase in Concentration in R&D

While the FTC can never analyze, with complete confidence, a firm's incentives to innovate, if it had done so in this case, it would have, yet again, concluded that the merged firm faced strong incentives to innovate. The merged firm was on the verge of developing a life-saving drug which no competitors sold. Since consumers are willing to pay rather significant sums for drugs which save their lives, if the merged firm were able to develop this drug, and no other firms sold the drug, it could sell the drug quite profitably. In short, the merged firm faced a great incentive to de-

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4; *see also supra* text accompanying note 97 (where, in Glaxo-Wellcome, the European Commission implied that it would find a market with only two other competitors sufficiently competitive).

101. *See supra* text accompanying note 97.

velop this life-saving drug as soon as possible, and thereby earn monopoly rents as soon as possible.

In truth, the FTC acted in this case, as it did in the other cases, because it feared that the merged firm would dominate the future goods markets. If the FTC had developed any beliefs regarding the merged firm's incentives to innovate, then, again, these beliefs played no role in its analysis of the case.

v) Assess Efficiencies

In this case the FTC did not explain what efficiencies, if any, it thought this transaction would generate. Again, efficiency considerations probably played no role in the FTC evaluation of this case.

3. American Home Products[102]

The FTC also claims to have found an innovation market when reviewing American Home Products Corp. (AHP) purchase of American Cyanamid Co. Both firms were trying to develop a vaccine against Rotavirus infections in humans. The merging firms were two of only three trying to develop this vaccine. The FTC ordered AHP to sell its R&D program.

The FTC analyzed this case in much the same way that it analyzed other cases, particularly *Upjohn-Pharmacia.* In this case, just as in *Upjohn-Pharmacia,* the FTC could neither identify potential competitors of the innovation market, nor could it analyze the merged firm's incentives to innovate. Therefore, just as the FTC could only identify a future goods market and not an innovation market in *Upjohn-Pharmacia*, the FTC in this case could only identify a future goods market and not an innovation market.

In this case the FTC could not identify all potential competitors of the relevant innovation market. While the federal drug testing process allowed the FTC to identify firms which were currently trying to develop Rotavirus vaccines, it did not allow the FTC to identify firms which were not yet trying to develop such vaccines, but which might try to do so in the future.

The FTC also could not analyze the merged firms' incentives to innovate. If the merged firm were to develop its new vaccine, then it would be the only firm selling the vaccine. It would be a monopoly seller of a very valuable drug, and would therefore earn substantial profits. Therefore just

102. American Home Prods. Corp., 59 Fed. Reg. 60,807 (F.T.C. 1995).

as the merged firm in *Upjohn-Pharmacia* faced a great incentive to innovate, so did the merged firm in this case.[103]

4. Sensormatic[104]

a) Firms Agree to Sell Assets and Patents

In this case the FTC analyzed a rather complex transaction. The firms involved in this transaction, Knogo Corp. and Sensormatic Corp., manufactured and sold anti-shoplifting systems. To use these systems, retailers put the appropriate sensors and alarms at the exits to their stores, and attached the appropriate markers to their products. When customers paid for a product, store clerks removed the electronic marker from the product. If, however, a shopper should happen to walk out of a store without paying for a product, then the electronic marker would sound the alarm.

In 1994 Knogo Corp. was developing a next generation anti-shoplifting system. This new system, which Knogo based on its Super-Strip technology, would allow manufactures, rather than retailers, to attach the electronic markers to the appropriate products. Manufactures could not only attach markers on products more efficiently than could retailers, they could also attach markers on products to which retailers could not attach markers. The new system would therefore allow retailers to protect more of their products, and at a lower cost.

Sensormatic was trying to develop its own new anti-shoplifting system, but nevertheless sought to acquire Knogo's SuperStrip technology. Knogo originally planned to sell to Sensormatic all of its assets outside North America. Knogo also planned to license to Sensormatic the exclusive right to its SuperStrip patents not only in North America, but throughout the world. Knogo, however, intended to continue to use its SuperStrip technology within North America. Finally, the firms agreed to grant each other royalty-free cross-licenses, in which each agreed to tell to the other of any improvements either may make to the SuperStrip technology.

b) The FTC Feared the Agreement Was Anticompetitive

The FTC feared that the transaction might lower the firms incentives to innovate. In doing so, the FTC expressed as many as four separate con-

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103. The European Commission also reviewed this transaction. It did not, however, discuss the market for vaccines and Rotavirus infections in humans. It therefore, apparently, did not see any antitrust problem in this market. *See* Case No. IV/M. 500 (Sept. 19, 1994).

104. Sensormatic Elecs. Corp., 60 Fed. Reg. 5428 (F.T.C. 1995).

cerns. First, the FTC feared that because the agreement required each firm to share with the other any improvements it may make to its technology, the agreement lowered each firm's incentives to innovate. Each firm would be less inclined to improve its technology, the FTC reasoned, because it would have to share this improvement with the other firm.[105]

Second, the FTC believed that the parties had agreed to share patent rights in a way which would harm competition. The FTC feared that the firms would use their patents to exclude others from the market. The complaint alleged that other firms would not even try to develop comparable anti-shoplifting systems "because of patent protection for important technology and the time required to develop the requisite technical skills to compete in the [innovation market]."[106]

Third, the FTC feared that the agreement would encourage the firms to improperly agree among themselves to develop one anti-shoplifting system standard. Before the transaction Sensormatic was trying to develop its own anti-shoplifting system, which, like Knogo's, would require manufactures to attach markers to their products.[107] The FTC therefore reasoned that to use these or similar systems, manufactures and retailers would have to agree to one uniform standard. The FTC feared that Knogo and Sensormatic, realizing that the industry would eventually use one system with one standard, would not try to develop two competing systems. Yet the FTC wanted Knogo and Sensormatic to each invest in its own system. This competition to innovate, the FTC believed, would drive the firms to develop the best system.[108]

Fourth, the FTC may also have feared that after the transaction the firms remaining in the industry would collude to affect the standard the

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105. *See id.* (complaint, at ¶ 16). This complaint alleges that the transaction would lower only *Knogo's* incentive to innovate. The complaint does not allege that the transaction would lower *Sensormatic's* incentive to innovate. Apparently the FTC felt that, because the cross-license provision forced Knogo to share the fruits of its R&D efforts with Sensormatic, the provision lowered Knogo's incentive to invest in the R&D in the first place. This reasoning is plausible, but should apply equally to Sensormatic, which would have to share the fruits of its R&D efforts with Knogo. While this limited allegation, which related only to Knogo, may have been sufficient to allow the FTC to consider how the cross-license agreement effected the transaction, this article will nevertheless assume that the logic of the allegation applies equally well to both firms. The article will therefore assume that the FTC feared that the agreement would lower each firm's incentive to innovate.

106. *Id.* (complaint, at ¶ 14).

107. Dahdouh & Mongoven, *supra* note 11, at 424.

108. Sensormatic Elecs. Corp., 60 Fed. Reg. 5428 (F.T.C. 1995) (complaint, at ¶ 16).

industry developed. [109] According to this hypothesis, each of the firms trying to develop SuperStrip-like anti-shoplifting systems would realize that if the industry did not adopt its standard, then, firstly, it would not be able to sell products in the future, and, secondly, that the products it had already sold would become useless. The FTC may have feared that the firms would act to keep the equipment they had already sold usable, and that to protect this installed base the firms would, in some unexplained way, collude as they developed the necessary standards. Perhaps the FTC feared the firms would collude to suppress the development of the new technology. Whatever the FTC feared, it did not express the basis for that fear clearly.

In response to these fears, the FTC only allowed Knogo to grant Sensormatic the non-exclusive right to its SuperStrip technology. The FTC therefore preserved Knogo's right to license its SuperStrip technology to other competitors. The FTC hoped that this action would prevent Sensormatic and Knogo from monopolizing the future market for the next generation of anti-shoplifting system.

c) FTC Analyzed a Future Goods Market, Not an Innovation Market

In this case the FTC analyzed a future goods market, not an innovation market. The FTC analyzed the future goods market for the next generation of anti-shoplifting system. As the following analysis shows, once again in this case the FTC could not use Gilbert and Sunshine's methodology to find an innovation market.

The FTC first defined the future goods market, which in this case was the market for improved anti-shoplifting systems. The FTC then analyzed this market, and did so using traditional antitrust law concepts. The FTC feared that this transaction would harm competition in as many as four separate ways. To analyze each of these concerns the FTC applied the appropriate traditional antitrust concept. The FTC did not find an innovation market.

First, the FTC feared that the cross-license agreement would lower each firm's incentives to innovate. However, as the I.P. Guidelines make clear, traditional antitrust law certainly allows antitrust authorities to insure that firms do not enter into cross-license agreements which reduce the firms' incentive to innovate.[110]

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109. *See* Dahdouh & Mongoven, *supra* note 11, at 426-27.

110. *See I.P. Guidelines*, *supra* note 9, § 5.4.

Regarding the FTC's second fear, the law also already allows the antitrust authorities to stop firms from entering into patent license agreements which lower their incentives to innovate.[111] In fact, FTC attorneys Dahdouh and Mongoven acknowledge this themselves.[112]

Regarding the FTC's third fear, antitrust law has also traditionally allowed the agencies to ensure that firms do not develop standards in a way which harms competition. The law has always prohibited firms from using standards to improperly monopolize markets.[113]

Dahdouh and Mongoven suggest that the FTC also feared that the firms remaining in the industry would collude to retard the development of technology and standards. If such a fear were justified, then, as even Dahdouh and Mongoven themselves acknowledge, the FTC already had the authority to respond appropriately.[114] As these authors acknowledge, the agencies and courts have, in a number of cases, stopped firms from improperly suppressing technology.[115]

Thus the FTC could use traditional antitrust law to respond to all its concerns in this case. To regulate this transaction the FTC did not need to, and did not, find an innovation market.

d) Applying Gilbert and Sunshine's Methodology Shows That the FTC Did Not Find an Innovation Market

As with all the other cases, in this case the FTC did not find an innovation market. Furthermore, as this section shows, the FTC could not apply Gilbert and Sunshine's methodology just as it could not in the other cases.

i) Identify the Overlapping R&D Activities

The firm's R&D activities overlapped in the market for the next generation anti-shoplifting system, one which would allow manufacturers to attach the appropriate markers directly to their products. This was the future goods market.

ii) Identify Alternative Sources of Competition.

As the FTC itself acknowledged, other firms were trying to develop comparable anti-shoplifting systems. Thus other firms competed in what

111. *Id.* § 5.5.

112. *See* Dahdouh & Mongoven, *supra* note 11, at 424.

113. *See* James J. Anton and Dennis A. Yao, *Standard-Setting Consortia, Antitrust, and High-Technology Industries,* 64 ANTITRUST L.J. 247 (1995).

114. Dahdouh & Mongoven, *supra* note 11, at 426.

115. *See also supra* text accompanying note 59.

the FTC would call an innovation market. In fact, the FTC does not allege that the innovation market was concentrated.

Further, other firms, which, at the time of the transaction were not trying to develop anti-shoplifting systems, may in the future have tried to develop such systems. In the future these other firms may have tried to enter the market—unless patent rights or standards blocked them. Yet, as explained above, traditional antitrust law already allowed the FTC to determine whether the firms were trying to use patent rights or standards to improperly block access to the market. Gilbert and Sunshine's innovation market methodology adds nothing to this analysis.

iii) Evaluate Competition From Downstream Products

No firm yet produced the improved anti-shoplifting system Knogo and Sensormatic, and other firms, were trying to develop. Other firms did however produce anti-shoplifting equipment, and, as the analysis of step four shows, the FTC did believe that this installed base would affect the firms' incentive to innovate.

iv) Assess Increase in Concentration in R&D.

Regarding the allegations the FTC did make, the FTC did not analyze the firms' incentives to innovate in the systematic way Gilbert and Sunshine require. Gilbert and Sunshine expect the FTC to determine whether the agreement would increase or decrease each firm's incentives to innovate. But the FTC did not definitively state what this agreement would do to those incentives. In fact, the FTC alleged, in effect, that the agreement both increased and decreased the firms' incentives to innovate.

On the one hand, the FTC alleged that the agreement would lower the firms' incentives to innovate. The agreement required each firm to tell the other of any improvements it may make to the SuperStrip technology. The FTC feared that the agreement would therefore lower each firm's incentives to innovate.

On the other hand, the FTC also feared that the agreement would allow Sensormatic and Knogo to work together to establish the industry standard. To establish this standard the firms must be the first to perfect and sell the next-generation anti-shoplifting system. To be the first into the market, the firms would have to work hard and fast, and innovate quickly. Thus when alleging that the firms wanted to establish the industry standard the FTC implicitly alleged that the firms would work hard and fast, and therefore faced a strong incentive to innovate.

The complaint also alleged that the agreement may cause the firms to lower the number of research and development tracks they pursue. It does

not follow, however, that even if the firms were to invest in a smaller number of R&D tracks, that they therefore faced a lesser incentive to innovate. The firms could simply focus their R&D efforts on the most promising technology, and then work hard to develop that technology.

The complaint also alleges that the agreement may have allowed the firms to use the SuperStrip patents to stop other firms from entering the relevant market. If the firms were able to do this, then they would in fact have faced a great incentive to innovate. As soon as they sold the next generation system, they would earn monopoly profits. The opportunity to earn monopoly profits creates a great incentive to innovate.

Dahdouh and Mongoven discuss the FTC's possible fear that this transaction may allow all the firms in the industry to collude regarding the development of standards. The complaint, however, made no such allegation. The FTC probably did not make this allegation because it is so implausible. Even Gilbert and Sunshine themselves acknowledge that firms are very unlikely to collude in an innovation market.[116]

The complaint does, however, allege that collusion might allow Sensormatic to unilaterally reduce innovation efforts, but this allegation is implausible. Apparently, the FTC did not believe that the transaction would lower Knogo's ability to reduce its innovation effort. It is not clear why the FTC believed that the agreement would lower only Sensormatic's ability to unilaterally lower its R&D efforts, and not Knogo's. If the FTC feared that both firms would collude, then it obviously feared that the two firms would work together, and it did not fear that only Sensormatic would reduce its innovation efforts.

If the FTC actually feared that the agreement would increase Sensormatic's ability to unilaterally lower its R&D efforts, this fear does not seem reasonable. Even under the parties' original agreement, Knogo still retained the right to use its patents and other intellectual property rights in North America. Thus Knogo could have continued to innovate, and develop better products, within North America. Since the original agreement allowed Knogo to continue to innovate, the agreement does not seem to increase Sensormatic ability to unilaterally reduce its innovation efforts.

Further, to the extent that either Sensormatic alone, or Sensormatic and Knogo together, could have actually colluded to reduce their R&D efforts, the FTC could have attacked such conduct. To do so, it would not need to allege that the firms competed in an innovation market.[117]

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116. *See* Gilbert & Sunshine, *supra* note 10, at 597.

117. *See supra* text accompanying note 59.

v) Assess Efficiencies.

Again in this case the FTC did not explain what efficiencies, if any, this transaction may generate. Thus, once again, the FTC does not seem to have analyzed any possible R&D efficiencies. In fact, the FTC only alleged that the agreement would harm an innovation market within North America. But innovation market advocates have always claimed that such markets are worldwide.[118] In fact, FTC Commissioner Mary L. Azcuenaga dissented from the FTC's finding that the relevant innovation market was only in the United States and Canada. Commissioner Azcuenaga said that by focusing only on North America, the FTC "exclude[d] from the market the potentially important research activity of at least one European firm."[119]

The FTC limited the market to North America because it found only a future goods market. In this case the FTC focused on the American market for the next generation of anti-shoplifting systems. While the FTC felt that Canadian firms may affect the American future goods market, it did not feel that European firms would affect the future American market. It therefore ignored European firms' attempts to develop the next generation anti-shoplifting system.

5. Ciba Geigy-Sandoz[120]

a) R&D Competition Unclear

When Ciba Geigy and Sandoz merged to create Novartis, they created a firm with control of over $80 billion in assets, and the world's second largest pharmaceutical firm. When reviewing this merger the FTC analyzed, among other things, the firms overlapping R&D programs. The FTC saw antitrust problems regarding, among other things, the firms' gene therapy R&D programs. Neither firm sold, but both firms were trying to develop, gene therapy products.

Gene therapy may offer doctors entirely new ways to treat cancer and other debilitating diseases. Gene therapy may allow doctors to create modified genes, and then insert these modified genes into their patients' cells. But while gene therapy looks very promising, no firm yet sells any gene therapy product. Ciba Geigy and Sandoz were the leading firms investing in gene therapy R&D and trying to develop these gene therapy products.

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118. *See, e.g.*, Gilbert & Sunshine, *supra* note 10, at 594-95.

119. Statement of Commissioner Mary L. Azcuenaga, concurring in part and dissenting in part, 60 Fed. Reg. 5428, 5431 (F.T.C. 1995).

120. Ciba Geigy Ltd., FTC File No. 961-0055 (Dec. 5, 1996).

The FTC alleged that this merger would harm competition in both a broad gene therapy R&D market, and would also harm competition in four specific gene therapy future goods markets. In the first paragraph of the section of its complaint in which it defined the relevant markets, the FTC first alleged that the merger would harm competition in the broad market "for research and development of gene therapies."

After alleging that the transaction would harm competition in this broad gene therapy market, the complaint then alleged that the merger would harm competition in four specific gene therapy future goods markets. The complaint said:

> Specific gene therapy product markets, in which the effects of the proposed merger may be analyzed include the research, development, manufacture and sale of:
>
> (a) herpes simplex virus-thymidine kinase ("HSV-tk") gene therapy for the treatment of cancer;
>
> (d) HSV-tk gene therapy for the treatment of graft versus host disease;
>
> (c) gene therapy for the treatment of hemophilia; and
>
> (d) chemoresistance gene therapy[121]

According to the complaint, the FTC anticipated that the market for these products, and for other gene therapy products, would grow over the coming years. The FTC did not expect the regulatory authorities to allow firms to sell any gene therapy products until the year 2000, but, said the complaint, after that year the market would grow significantly.

In this case the FTC clearly found four future goods markets. The complaint alleged that the firms competed in the four specific gene therapy future goods markets. Specifically, the complaint alleged that the firms competed in the market for the "research, development, manufacture and sale of ..." these products.

The FTC therefore clearly saw the firms' research and development efforts as a part of the firms' efforts to manufacture and sell the relevant products. The FTC analyzed not only the firms' R&D efforts, but also the firms' future efforts to sell products based on these R&D efforts. The FTC therefore alleged that the merger would harm competition, not in a separate R&D, or innovation, market, but rather in future goods markets.[122]

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121. *Id.* (complaint at part IV).

122. One could make this point about other cases as well. In *Upjohn-Pharmacia*, for example the FTC also alleged that the transaction would harm the market for "research, development, manufacture and sale. Upjohn Co., FTC 60 Fed. Reg. 56, 153 (F.T.C.

The FTC may also have feared that the merger would allow Novartis to stop other firms entering the future gene therapy market.[123] According to the FTC, Ciba Geigy and Sandoz were the two firms leading the effort to develop gene therapy products.[124] These firms, the FTC said, controlled vital gene therapy intellectual property. While the FTC acknowledged that it could not know what patents Novartis would eventually receive, it nevertheless concluded that the firm could use its intellectual property, including the patents Ciba Geigy and Sandoz already owned, to hinder or block entry into the relevant market.

The FTC feared that Novartis would not license its gene therapy intellectual property. Novartis would lead the gene therapy R&D effort, and, the FTC reasoned, would not want other firms to close the R&D gap. It would therefore not license its intellectual property to other these research firms, the FTC said. The FTC thus concluded that the merger would improperly allow Novartis to block access to the broad future gene therapy market. It therefore ordered Novartis to offer non-exclusive licenses of essential gene therapy intellectual property. Yet, to issue this order, the FTC did not need to, and did not, find an innovation market. The FTC often regulates how firms acquire and combine intellectual property rights.[125] In this case the FTC exercised its traditional authority in this area. It did not find an innovation market.

The FTC feared that this transaction would harm competition in two separate ways. The FTC feared that Novartis would dominate the four specific future goods markets it identified. The FTC also feared that the merger would give Novartis such a broad portfolio of intellectual property rights that it could block access to the future gene therapy market. To re-

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1995). In this case, however, the FTC alleged that the firms competed in a broad gene therapy market. It is therefore particularly important to note that in this case that the FTC alleged, not only that the firms competed in the broad gene therapy market, but also that they competed in the four specific future goods markets.

123. The first paragraph of the relevant part of the complaint says that: "One relevant line of commerce in which to analyze the effects of the proposed merger is gene therapy technology and research and development of gene therapies, including *ex vivo* and *in vivo* gene therapy. Specific gene therapy products, in which the effects of the proposed merger may be analyzed include the research and development, manufacture and sale of: [the four specific product markets]." Ciba Geigy Ltd., FTC File No. 961-0055 (Dec. 5, 1996) (complaint at part IV). Thus the complaint does not clearly state that the general research and development market is a market separate and distinct from the four specific product markets.

124. *Id.* at part V.

125. *See I.P. Guidelines*, *supra* note 9, § 5.4.

spond to either of these concerns, however, the FTC did not need to, and in fact did not, find an innovation market.

b) The FTC Could Not Apply the Gilbert and Sunshine's Methodology.

Applying the five steps of Gilbert and Sunshine's methodology shows that, again, in this case the FTC did not find an innovation market.

i) Identify the Overlapping R&D Activities

Both firms were trying to develop the four specific gene therapy treatments which the complaint identified. In this case, therefore, the FTC identified four specific future goods markets.

In addition, in this case the FTC also feared that the merger would give Novartis such a broad patent portfolio that it could stop other firms from entering the broad gene therapy market. Yet the FTC could address this concern using its authority to regulate how firms acquire intellectual property rights. To respond to its concerns the FTC did not need to find an innovation market.

ii) Identify Alternative Sources of R&D

In all the previous cases, except possibly *Sensormatic*, the FTC could not identify competitors who might enter the relevant innovation market. Because innovation is the "product" of an innovation market, a firm is competing in an innovation market if it is trying to develop the relevant good. It is competing in the innovation market even if it is not producing the relevant good. Potential competitors of an innovation market are therefore firms which may, in the future, try to develop the relevant good. Since the FTC can usually not know which firms may, in the future, try to produce the relevant good, it can usually not identify potential competitors of an innovation market.

In this case, however, the FTC may have been able to identify potential competitors of the innovation market. In this case the FTC could plausibly claim that it could identify all the firms which would, in the future, try to develop the relevant good. No firm, the FTC could plausibly assert, would try to enter the relevant innovation market; no firm would even try to develop the relevant future goods because, if it develops these goods, then Novartis would stop it from selling the goods. And firms, knowing they will not be able to sell the goods, will not try to develop the goods in the first place. Thus, in this case the FTC could plausibly claim that it could identify competitors who might enter the innovation market: that is, none at all.

Yet in this case the FTC still cannot claim that it found an innovation market. The FTC can only plausibly claim that it was able to identify the potential competitors of the innovation market because Novartis might be able to use its broad intellectual property portfolio to stop other firms from entering the market. But, without finding an innovation market, the FTC could respond to its fear that Novartis would use its intellectual property rights in an anticompetitive manner. It could use its traditional authority to regulate how firms acquire intellectual property rights. Thus even if the FTC could in this case claim that it identified all the potential competitors of the innovation market, this claim, though plausible, still does not lead to the conclusion that the FTC found an innovation market.

iii) Evaluate Competition from Downstream Products

Because no firm yet sold any gene therapy products, there were no downstream products in this case.

iv) Assess Increase in Concentration in R&D

In this case the FTC could not analyze the merged firm's incentives to innovate. In fact, the FTC imposed on Novartis a remedy which may actually have lowered its incentive to innovate. The FTC believed that Novartis was on the verge of developing new treatments for debilitating, previously untreatable diseases. As in *Upjohn-Pharmacia*, the merged firm in this case would earn very substantial profits if it were the only firm selling its life-saving product. Thus the merged firm, Novartis, faced a strong incentive to develop and sell its products as soon as possible, and thereby earn monopoly profits as soon as possible.

If the remedy the FTC imposed on Novartis affected its incentive to innovate, then the FTC in fact lowered these incentives. The FTC required Novartis to license intellectual property rights. This order, the FTC hopes, will increase the competition Novartis will face when, in the future, it sells gene therapy products. This competition will force Novartis to charge a lower price for these products, and therefore earn a lower return from its current and future R&D investments. Since the order will lower the return Novartis will enjoy from its future R&D efforts, the order actually lowers Novartis' incentive to innovate.

If the FTC issued an order which may lower Novartis' incentive to innovate, then clearly the FTC did not issue the order because the FTC wanted to increase Novartis' incentive to innovate. Rather, the FTC is-

sued its order because it wanted to insure that Novartis would not monopolize the relevant future markets.[126]

v) Assess Efficiencies.

In this case, yet again, the FTC did not explain what efficiencies, if any, it thought this transaction would generate. Thus efficiency considerations probably played no role in the FTC's assessment of this case as well.

c) European Commission Decision

i) Analyzed Market Access

In this case the European Commission analyzed what it called the "future market" for gene therapy products.[127] It analyzed whether Novartis would be able to use its patent portfolio to block access to the broad gene therapy market. It did not find an innovation market.

The European Commission said that the merger would allow Novartis to dominate this future market if: (1) Gene therapy were to prove successful; (2) Competitors were unable to develop gene therapy treatments which did not infringe Novartis' patents; and (3) Novartis were granted the broad patents for which the merging firms had applied.

The Europe Commission then analyzed each of these three conditions. Regarding the first, the Commission began by observing that whenever it analyzed a future market it would not know if the firms would ever sell the relevant good. Yet in this case, the Commission concluded, the firms' research looked very promising, and that the Commission should therefore analyze competition in a future gene therapy market.

Regarding the second condition, the Commission again recognized that it was dealing with uncertainty. Competitors may be able to develop gene therapy treatments which did not infringe Novartis' patents, but they may not, the Commission said.

Regarding the third condition, the Commission yet again said that it was dealing with uncertainty. It said that it could not know if Novartis would receive the broad patents for which Ciba Geigy and Sandoz had applied. But, said the Commission, the firms may have created a barrier to entry simply by applying for the broad patents. The Commission feared

126. When the FTC protected competition in these future markets, it simply did what it always does. It acted to ensure that the market was competitive, and would therefore, hopefully, drive the relevant firms to innovate. *See* Landman, *supra* note 69.

127. *See* Ciba Geigy/Sandoz, Case No. IV/M.737 (July 17, 1996), O.J.L.201 (July 29, 1997).

that possible competitors may hesitate to develop technology which Novartis' patents may prohibit them from using.

Focusing on the risk that Novartis' broad patents would stop others from entering the gene therapy market, but realizing that it was dealing with a high level of uncertainty, the Commission concluded that, "[I]t cannot therefore ultimately be said with sufficient probability that the merger will on any future market lead to the creation or strengthening of a dominant position."[128]

Possibly anticipating the FTC's actions, the merging firms had already agreed to license the technology its European patents covered. Aware of this promise, the Commission approved the merger.

Thus, in this case the European Commission determined whether the merger would give Novartis such a broad patent portfolio that it could stop other firms from entering the relevant market. Because the Commission could not know what European patents Novartis would eventually receive, it could not conclude that the patent portfolio would necessarily allow Novartis to stop other firms from entering the future market. The European Commission therefore imposed on Novartis no remedy.

ii) The European Authority and United States Authority Analyzed Future Market Access

In this case both the United States and European authorities analyzed whether Novartis would be able to use its intellectual property rights to block access to the broad future gene therapy market. Ciba Geigy and Sandoz held different patent rights on different sides of the Atlantic, and the two antitrust authorities therefore reached different conclusions. In this case the European Commission analyzed what it called a "future market." It did not find an innovation market. This suggests that the FTC also analyzed whether Novartis could use its intellectual property portfolio to block access to the relevant market, and also did not find an innovation market.

6. Conclusion

In none of these cases have the agencies found innovation markets. In none of these cases were the agencies able to apply Gilbert and Sunshine's innovation market methodology. The agencies were neither able to identify potential competitors of the innovation market, nor were they able to analyze the relevant firms' incentives to innovate. The European Commission analyzed many of the same cases which the American authorities

128. *Id.* at point 106.

also analyzed. The European Commission, however, does not claim to have found an innovation market in these cases. And just as the European Commission was not able to find an innovation market, the American authorities were unable to find an innovation market.

V. OTHER ACTIONS: R&D PART OF GOODS MARKET

The agencies' recent actions also show that they do not in fact find separate innovation markets. In several recent cases the agencies have alleged that various firms competed in research and development markets. The relevant agency has always alleged, however, that this research and development market was a part of a series of markets including the current goods market. In these cases, therefore, the relevant agency clearly saw its alleged research and development market as a part of the relevant current goods market. This section reviews a representative sample of this cases, in which the FTC did not even allege that the firms competed in a *separate*, research and development, or innovation, market.

A. Ciba Geigy-Sandoz

In addition to alleging that the Ciba Geigy-Sandoz merger would harm competition in the market for gene therapy products, the FTC also alleged that the merger would harm competition in the markets for corn herbicides and pest control products. Regarding both markets the FTC's complaint alleged that the firms competed in markets for the "research, development, manufacture and sale" of the relevant product.

Both firms were already selling products in both of these markets, and thus both firms were competing in the relevant current goods market. The FTC therefore did not add to its case when it alleged that the firms also competed regarding research and development. The FTC simply alleged the truism that whenever firms compete in a current goods markets, they compete not only on price, but also on innovation.

B. Lockheed Martin-Loral[129]

The FTC alleged that Lockheed Martin's purchase of Loral Corp. would harm competition in research and development. Yet while the FTC made these allegations, it, yet again, did not find an innovation market.

The FTC alleged that this transaction would harm markets for the "research, development, manufacture, and sale" of 10 different products. But these products, and therefore the markets for these products, already existed. Therefore, just as the FTC's research and development allegations

129. Lockheed Martin Corp., 61 Fed. Reg. 18732 (F.T.C. 1996).

regarding corn herbicide and pest control products did not strengthen the FTC's claim in *Ciba Geigy*, neither did the research and development allegation strengthen the FTC's claim in this case.

The FTC also alleged that various aspects to the transaction would allow Lockheed Martin to obtain competitors' trade secrets and other proprietary information. The FTC alleged that the transaction would therefore lower these competitor's incentive to innovate. Again, while the FTC may have made an accurate allegation, it did not make one which lead it to find an innovation market.

The law protects firms' proprietary information. It seeks to encourage firms to develop this information, and thereby to innovate. If a firm believes that its competitor will obtain whatever proprietary information it may develop, then the firm may indeed not develop the information. Thus, to encourage firms to innovate, the FTC should indeed insure that firms can protect their secrets. But, again, the law has always allowed the FTC to do this. Gilbert and Sunshine's innovation market methodology adds nothing to this analysis.

C. Boeing-Rockwell[130]

The FTC objected to certain aspects of the Boeing Company's purchase of the Aerospace and Defense Business of Rockwell International Corp. In its complaint the FTC alleged that the firms competed in the markets for the "research, development, manufacture and sale" of three specific products: High Altitude Unmanned Air Vehicles, Space Launch Vehicles, and Space Launch Vehicle Propulsion Systems.

Again in this case the FTC did not find that the firms' research and development efforts formed a separate market. On the contrary, the FTC simply alleged that the transaction would harm competition in the markets for these three already existing goods, including harming competition to improve these goods. It did not allege that the firms competed in a separate innovation market.

The FTC also alleged that the transaction would allow Boeing to obtain confidential information, to which it should not have access. Once again, the FTC should resolve this matter as it feels is appropriate. To do so, however, it does not need to find an innovation market.

130. The Boeing Company, 61 Fed. Reg. 66038 (F.T.C. 1996).

VI. AGENCIES RECOGNIZE THAT THEY ONLY FIND FUTURE GOODS MARKETS

A. Introduction

Various agency officials have actually endorsed this article's analysis. These officials have acknowledged that the agencies find only future goods markets. But some of these officials have used terms and qualifying language which has obscured this important reality. These terms and qualifiers have created the inaccurate impression that the agencies find innovation markets.

B. Federal Trade Commission

1. Report on "High-Tech Global Marketplace"

a) "Defined With Respect to an Ultimate Goods Market"

In its highly publicized 1996 report on the "New High-Tech Global Marketplace,"[131] the FTC staff recognized that the agencies actually analyze future goods markets, and not innovation markets. The FTC issued the report after holding related hearings in 1995. At the hearings various witnesses argued for, and against, the idea that the agencies should find innovation markets. The FTC staff's report summarized the debate, and also tried to defend the idea that the agencies should find innovation markets. Yet the report also made the following very telling observation:

> In terms of how to define the scope of an "innovation market, the *IP Guidelines* approach of focusing on "research and development directed to particular new or improved goods or processes" seems most useful. One witness suggested that access to specialized assets could also be the basis for identifying substitutable innovation efforts and for assessing the relative competitive significance of market participants. Such an approach has received some attention. This approach might well be sufficient to cabin the agency's analysis, yet the issue ultimately would lead back to the potential existence of a good. This is, in asking whether a firm possessed "specialized assets," one would need to ask: "specialized assets necessary to produce what types of goods?" At the moment, it seems inevitable that an innovation market will be defined with respect to an ultimate goods market, such as "R&D directed at [a class of products]."[132]

131. FEDERAL TRADE COMMISSION STAFF, *supra* note 63.

132. *Id.* at 34 (citations omitted).

b) This Conclusion is Inconsistent With the I.P. Guidelines

While the FTC claims to base this conclusion on the I.P. Guidelines, this conclusion is actually inconsistent with those Guidelines. The Guidelines try to explain how and when the agencies will find an innovation market. They define an innovation market in the same way Gilbert and Sunshine do. Example three of the Guidelines, for example, says that the agencies will try to analyze firms' incentives to innovate. Thus when the FTC acknowledges that, in trying to define an innovation market, it must inevitably define, not an innovation market, but an "ultimate goods market, " the FTC acknowledges that it finds, not an innovation markets, but rather a future goods market.

c) The Complete Report Obscures This Important Conclusion

While the FTC staff did make this candid admission, it did so reluctantly. The report generally defends the innovation market concept. The report even qualifies this passage. One of the footnotes omitted from the above quotation refers to a previous passage in the report which defended the idea that the FTC can preserve competition in a market for core competencies.[133]

Some innovation market advocates believe that the FTC can not only find an innovation market, but also that by doing so it can protect competition in an imagined market for core competencies. Thus when the FTC defends the idea that it can protect competition in a market for core competencies, it defends the idea that it can protect competition in innovation markets.[134]

2. Commissioner Azcuenaga: "Future Competition in a Specific Product"

In her recent speech *Antitrust and Intellectual Property: Recent Highlights and Uncertainties*[135] FTC Commissioner Mary L. Azcuenaga reviewed the development of the innovation markets concept in the United States. In doing so she in effect acknowledged that the agencies have always analyzed a future goods market, not an innovation market.

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133. *Id.* at 34, n.119.

134. *Accord* Dennis A. Yao and Susan S. DeSanti, *Innovation Issues Under the 1992 Merger Guidelines*, 61 ANTITRUST L.J. 505, 510-11 (1993).

135. Commissioner, Federal Trade Commission, Mary L. Azcuenaga, Speech before the American Law Institute-American Bar Association, Ritz-Carlton Hotel, Boston, Massachusetts, (April 24, 1997) (available at <http://www.ftc.gov/speeches/azcuenaga/aliaba97.htm>).

To begin her discussion Commissioner Azcuenaga reviewed the cases in which the agencies developed the innovation market concept. The Commissioner noted that even before the agencies had developed the innovation market concept, they had alleged that various transactions would harm competition in R&D. The Commissioner offered *Roche Holdings*[136] as an example of such an early case. In *Roche Holdings* the FTC alleged that the parties competed to develop CD4-based therapeutics to treat Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome. The *Roche Holdings* complaint alleged that the proposed merger would eliminate potential competition in the market to develop this product. Thus, in that case, the FTC alleged that the firms competed in the future goods market for CD4-based therapeutics. The FTC did not allege that the firms competed in an innovation market.

Then, Commissioner Azcuenaga said, the agencies developed the innovation market concept. She showed how the I.P. Guidelines and *Sensormatic* contributed to the development of the concept. The Commissioner also noted that many questioned whether the agencies should try to find innovation markets. In particular, she noted Richard Rapp's broad criticism of the concept.[137] She also noted that some have questioned whether firms can actually monopolize innovation markets.

Commissioner Azcuenaga then went on to defend the FTC. When defending the FTC from Dr. Rapp and the others critics Commissioner Azcuenaga said:

> The critiques of the innovation market theory raise serious questions regarding how far it should be pursued, at least given our current knowledge. Nonetheless, the valid criticisms of the theory seem to apply to its application in a broad sense to the concept of innovation. They do not seem to undercut our antitrust concerns for future competition in a *specific product* that is already under development. Almost all the FTC cases have involved research and development by a very few firms of a pharmaceutical product to remedy a particular disease or condition. The Commission has focused on future competition to manufacture and sell the *particular drug* in question and not the general level of research or development in the pharmaceutical industry.[138]

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136. Roche Holdings Ltd., 113 F.T.C. 1086 (1990).

137. *See* Rapp, *supra* note 43.

138. Azcuenaga, *supra* note 135 (emphasis added). Commissioner Azcuenaga repeated this analysis in December 1997 when she said that the FTC is "continuing to allege a diminution of competition in research and development markets for specific prod-

Commissioner Azcuenaga is correct. Her statement says, in effect, that the agencies have not actually extended their analysis beyond that of *Roche Holdings*. The agencies continue to analyze, not an innovation market, but a future goods market.

3. Director Baer: "This Important Innovation Market."

At the same time that FTC Commissioner Azcuenaga offered her analysis, the director of the FTC's Bureau of Competition, William J. Baer, offered his analysis of innovation markets. At first glance, Director Baer seems to have contradicted Commissioner Azcuenaga. Yet, on closer examination, one discovers that Director Baer's analysis, while confusing, is actually consistent with that of Commissioner Azcuenaga, and of this article.

In his *Report from the Bureau of Competition*,[139] Director Baer seemed to state that the agencies find innovation markets as the I.P. Guidelines develop and define the concept. In his report Director Baer discussed *Ciba Geigy* at length. He said that the FTC acted to "preserve competition in this important innovation market." Director Baer continued:

> The *Ciba-Geigy* case illustrates the important role antitrust can play in protecting competition in R&D. This is not new, but it has some prominence—some would say notoriety—in recent years. The renewed focus on R&D competition is probably attributable to several factors. First, the *Intellectual Property Guidelines,* issued in 1995, drew attention to the concept of innovation markets. Second, there has been a substantial amount of recent merger activity in certain markets where antitrust may be particularly important in preserving R&D competition, such as pharmaceuticals and defense. Third, there is an increased appreciation of the importance of preserving incentives for strong rivalry in the race to produce new and improved products in key markets. Research and development, and innovation, are critically important to the competitiveness of our markets, both domestically and internationally. Moreover, R&D competition is critically important not only in saving dollars in the purchase of

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ucts." Commissioner, Federal Trade Commission, Mary L. Azcuenaga, Panel Discussion on Technological Innovation, International Trade and Competition Policy, Remarks before the Japan Fair Trade Commission 50th Anniversary Symposium, Tokyo, Japan (December 1, 1997) (available at <http://www.ftc.gov/speeches/azcuenaga/japan97.htm>).

139. Director, Bureau of Competition, Federal Trade Commission, William J. Baer, Federal Trade Commission Before the American Bar Association Antitrust Section Spring Meeting 1997, Washington, D.C., (April 9-10 1997) (available at <http://www.ftc.gov/speeches/other/abaspg97.htm>).

> new products, but also in saving lives and ensuring our national security.[140]

a) Closer Look: Agencies Find Future Goods Market

A close examination of Director Baer's comments, however, reveals that the director actually agrees with this article's analysis. Despite the passage quoted above, the director actually, indirectly, endorsed the conclusion that the agencies find only future goods markets. When defending the FTC, the director said:

> Our cases will show that we have intervened in innovation market transactions under carefully limited circumstances—namely, where few firms possess the specialized assets or characteristics needed to compete successfully in the market. It is only in that situation that a merger is likely to result in a substantial loss of R&D competition.[141]

Indeed, Director Baer is correct. The agencies have only acted when the merging firms had the same specialized assets. And, as this article has shown, to determine which firms had the same specialized assets the agencies had to determine which firms may sell the same products in the future. In other words, the agencies had to define a future goods market.

4. Baer and Azquenaga: FTC Found an Innovation Market in Ciba Geigy

Both Commissioner Azquenaga and Director Baer seem to say that the FTC found an innovation market in *Ciba Geigy*. Yet neither of these two officials actually show that the FTC found an innovation market in this case.

a) Baer: Agencies Stop Firms From Improperly Using Patents

In the passage quoted above Director Baer implies that the FTC found an innovation market in, among other cases, *Ciba Geigy*. Yet, despite the Director's seemingly broad endorsement of innovation markets, Director Baer actually does agree with this article's conclusion that the agencies find future goods markets. Director Baer acknowledged that in *Ciba Geigy* the FTC acted to stop firms from using their intellectual property rights to harm competition. Director Baer said that, "Because of the patent portfolios of Ciba Geigy and Sandoz, competitors could be blocked from

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140. *Id.* (footnotes omitted).

141. *Id.*

commercial development."[142] Director Baer therefore explained that the FTC acted to ensure that Novartis could not block other firms from entering the relevant market.[143]

Thus, according to Director Baer, the FTC acted because it feared that Novartis would use its broad patent portfolio to improperly block access to the relevant market. Yet, as this article has shown, the FTC could respond to this fear without finding an innovation market. Director Baer's analysis of this case, therefore, does not show that in *Ciba Geigy* the FTC found an innovation market.

b) Commissioner Azcuenaga

Along with Director Baer and this article, Commissioner Azcuenaga also said that in this case the FTC acted to stop Novartis from using its broad patent portfolio to block other firms from entering the relevant market. Commissioner Azcuenaga said that "the language of the complaint and the remedy suggest that the breath of the patent may have been a concern."[144] Thus the Commissioner also recognized that the FTC acted to ensure that Novartis could not use its broad patent portfolio to stop other firms from entering the relevant market.

Commissioner Azcuenaga also recognized that in this case the FTC found four specific future goods markets. The Commissioner said that:

> the complaint alleged four research and development product markets relating to gene therapy for specific medical conditions, similar to other recent Commission orders involving research and development markets. The antitrust concern was that in each of four markets the merger combined two firms with competing products in the FDA pipeline ....[145]

In other words, Commissioner Azcuenaga acknowledged that the FTC alleged that the firms competed, not in innovation markets, but in future goods markets.

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142. *Id.*

143. *Id.* Director Baer repeated these remarks in November 1997, saying of *Ciba Geigy*: "There were relatively few potential competitors for this technology, because the merging firms controlled critical patents." Director, Bureau of Competition, Federal Trade Commission, William J. Baer, New Myths and Old Realities: Perspectives on Recent Developments in Antitrust Enforcement, Address before the Bar Association of the City of New York, New York, (November 17, 1997) (available at <http://www.ftc.gov/speeches/other/bany.htm>).

144. Azcuenaga, *supra* note 135.

145. *Id.*

In her speech, however, the Commissioner also said that in *Ciba Geigy* the FTC may have found an innovation market. The Commissioner said that the FTC may have found an innovation market in this case because "the complaint alleges increased barriers to entry and altered incentives to license patents."[146]

It does not follow, however, that simply because the FTC discussed barriers to entry and incentives to license patents that it therefore found an innovation market. First, courts, and the agencies, regulate how firms acquire patents exactly because they fear that if firms acquire too broad a patent portfolio, then they will use this broad patent portfolio to erect barriers to entry to the relevant market. The law responds to the fear that the firms will monopolize the relevant market, and, as monopolists, will face a lower incentive to innovate. Thus whenever the agencies analyze patent acquisitions they analyze barriers to entry, but they do not find innovation markets. Second, innovation market methodology, so its supporters say, allows the agencies to regulate firms' incentives to innovate. These supporters do not even claim that innovation market analysis allows the agencies to regulate firms incentives to license already existing technology.[147]

C. Department of Justice

1. Patent Pool

Joel Klein, the Assistant Attorney General of the Antitrust Division of the U.S. Department of Justice, has also recently discussed innovation markets.[148] He too seems to have endorsed the idea that the agencies find innovation markets. Yet, once again, close examination of this high official's analysis shows that his endorsement was far from ringing.

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146. *Id.*

147. Commissioner Azquenaga did not say that in *Ciba Geigy* the FTC feared that the agreement would lower Novartis' incentives to innovate. Yet even if the FTC did harbor such fears, it still does not follow that the FTC found an innovation market in this case. The agencies stop firms from using patents, and other intellectual property rights, to monopolize markets because the agencies fear that, as monopolists, the firms will face a lesser incentive to innovate. Therefore, whenever the agencies analyze the scope and breath of any patent or patent acquisition they inevitably consider the relevant firms' incentives to innovate.

Further, in this case, as in all these so-called innovation market cases, the FTC could not analyze the merged firm's incentives to innovate, at least not in the manner innovation market analysis requires. *See supra* text accompanying notes 43-59.

148. Acting Assistant Attorney General Joel I. Klein, Department of Justice: Cross-Licensing and Antitrust Law, Address before the American Intellectual Property Law Association (May 2, 1997).

Assistant Attorney General Klein described the antitrust concerns cross-license agreements raise. In particular, Mr. Klein discussed the complex antitrust history of the Manufacturers Aircraft Association. To resolve various conflicting patent claims, at the time manufacturers first started to build commercial aircraft, almost all aircraft manufacturers agreed to pool their patents. When discussing then-Attorney General Gregory's 1917 opinion regarding the antitrust aspects of this arrangement, Mr. Klein said the innovation market concept would have helped Attorney General Gregory analyze the patent pool. The current Assistant Attorney General specifically cited, with approval, the innovation market section of the I.P. Guidelines.

2. Innovation Markets Analysis Adds Nothing to the Law

Yet, in fact, the innovation market section of the current I.P. Guidelines would not have helped Attorney General Gregory in 1917. Firstly, and most obviously, Attorney General Gregory did not need the help. Without the Guidelines' assistance the former Attorney General reached what the current Assistant Attorney General believes was the correct decision. Secondly, and very relatedly, the law already in 1917 addressed, in quite an appropriate fashion, the antitrust issues which concern Assistant Attorney General Klein today. Just as Attorney General Gregory could address the relevant antitrust issues in 1917 without using innovation market analysis, so Assistant Attorney General Klein can—80 years later—address the relevant issues without using innovation market analysis. Innovation market analysis adds nothing that was not in the law 80 years ago.

Thirdly, and finally, the aircraft technology patent pool of that case did not even raise a true innovation market issue. It raised issues relating to current and future goods markets. The Attorney General analyzed how the patent pool would affect the current goods market, which was the market for the then-current generation of commercial aircraft. Indirectly, the Attorney General also analyzed the future goods market, which was the market for the next generation of aircraft. The Attorney General certainly did not analyze competition among firms that were "not likely potential competitors" in a goods market.[149] The firms already competed against each other.

3. More Aggressive Current Enforcement

Assistant Attorney General Klein did say that his Department may have reached a different decision today than Attorney General Gregory

149. Gilbert and Sunshine say competition in an innovation market relates to firms that are not likely potential competitors. *See supra* text accompanying note 55.

reached in 1917. The United States at that time was fighting World War I, and therefore bought many airplanes. For the sake of national security, therefore, the United States wanted manufacturers to build airplanes as quickly and cheaply as possible. Today the United States is not fighting a war and the DOJ has different priorities. Today, said the Assistant Attorney General, the Department would have worried more about whether the patent pool lowered incentives to innovate. Therefore, today, the Department may not have made the same decision it did in 1917.

In reality the Assistant Attorney General is saying that, regarding intellectual property rights, the Department enforces antitrust law more aggressively now than it did in 1917. While the DOJ has always used antitrust law to limit the extent to which patent holders could exercise their patent rights, it has over time varied the extent to which it has limited these rights.[150] At the moment the Department may very well be enforcing antitrust law more aggressively than it did in 1917. This aggressive attitude may even have lead the Department to develop and defend the innovation market concept. But even if the Department is more aggressive, and even if it says it finds innovation markets, this does not mean that the Department actually finds innovation markets.

VII. AGENCY STATEMENTS CREATE CONFUSION AND OPPOSITION

A. Attorneys Cannot Advise on Innovation Markets

When high agency officials make statements such as these, they create the false impression that the agencies find innovation markets.[151] This impression causes great anxiety among attorneys. When firms consider entering into a transaction, they naturally ask their lawyers whether they will violate any laws if they do so. Attorneys must be able to tell their clients if they should enter into a particular transaction. But if the agencies may find that firms compete in an innovation market, even if they are not even likely potential competitors in a future goods market,[152] then attorneys will not be able to give their clients sound advice. Attorneys will not know when the agencies will find an innovation market, or which firms the agencies will find compete in this innovation market.

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150. Steven P. Reynolds, *Antitrust and Patent Licensing: Cycles of Enforcement and Current Policy,* 37 JURIMETRICS J. 129 (1997).

151. *See, e.g.*, Neil Campbell and Jeffrey Roode, *The 'Highest Common Denominator' Effect*, GLOBAL COMPETITION REVIEW, Aug.-Sept. 1997, at 29 (explaining how the FTC applied Gilbert and Sunshine's innovation market methodology in *Ciba Geigy*.)

152. *See* Gilbert & Sunshine, *supra* note 10, at 570.

Further, the agencies should not expect attorneys to find and analyze innovation markets. The agencies, the creators of this innovation market concept, can themselves not find innovation markets. If the creators of the innovation market concept can themselves not find innovation markets, then attorneys in private practice will certainly not be able to find such markets.

B. Attorneys Can Advise on Future Goods Markets

Although attorneys cannot determine if their clients compete in an innovation market, attorneys usually can determine if their clients compete in a future goods market. Like many areas of the law, attorney's advice in this area will never be completely free of doubt. Nevertheless, attorneys can clearly explain to their clients the concept of a future goods market. And, working with their client, attorneys will usually be able to determine, to a reasonable degree, whether their client competes in a future goods market.

C. Innovation Market Opponents Recognize Agencies' Legitimate Antitrust Concerns

James Kobak, Jr. has adeptly expressed the opposition of many to innovation markets:

> [I]nnovation markets might be described as the newly hypothesized "dark matter" of the antitrust cosmos. Like dark matter, there is little empirical evidence about innovation markets; like dark matter, they are notoriously difficult to explore in the absence of actual transactions; and like dark matter, if they do exist, they will enormously affect the size, scope, and future of the antitrust universe ....
>
> Some call this a search for a will-o'-the-wisp: a market that virtually cannot exist under any customary legal or economic definition of the "relevant market." It is also a search for a market where only the most fragmentary and speculative data may exist. Not only is the burden of the search enormous, but the reliability of what is found may be highly suspect at best.
>
> The innovation market concept goes beyond these relatively familiar [areas of antitrust law]. (footnotes omitted)[153]

Yet Kobak also recognizes that in this area the agencies do at times raise legitimate antitrust issues:

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153. James Kobak, Jr., *Running the Gauntlet: Antitrust and Intellectual Property Pitfalls on the Two Sides of the Atlantic*, 64 ANTITRUST L.J. 341, 360-61, (1996).

> [N]o one would contend that R&D and its fruits are never an important dimension of competition; ordinary market analysis should take some account of R&D efforts and their present and reasonably predictable impact on existing competition.[154]

VIII. CONCLUSION: TO RESPOND TO THEIR CRITICS, THE AGENCIES SHOULD CLEARLY STATE WHAT THEY DO

Director Baer, Assistant Attorney General Klein, and other officials have for the past several years made numerous statements which create the false impression that the agencies actually find innovation markets. In reality, of course, the agencies do not find innovation markets. The agencies are not applying the innovation market methodology the I.P. Guidelines describe, and which Gilbert and Sunshine and Dahdouh and Mongoven develop. The agencies find no more than future goods markets.

The agencies should respond to their critics. The agencies should respond because their actions show not only that the critics are correct, but also that the agencies can validly defend themselves. The agencies' actions show that the critics correctly attack innovation markets; the agencies have never actually found an innovation market. But the agencies' actions also show that in this area the agencies have generally acted reasonably, and with restraint. To respond to their critics the agencies should acknowledge that they find, not innovation markets, but rather future goods markets.

154. *Id.* at 361.

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INTELLECTUAL PROPERTY AND CONTRACT LAW IN THE INFORMATION AGE: THE IMPACT OF ARTICLE 2B OF THE UNIFORM COMMERCIAL CODE ON THE FUTURE OF INFORMATION AND COMMERCE