

RESEARCH PATHFINDER

BIOTECHNOLOGY AND LAW †

INTRODUCTION

This pathfinder is a research guide to materials that address the various legal issues raised by biotechnology. While it is not exhaustive, it does catalogue and describe selected statutes, cases and literature that will introduce the legal researcher to the area of biotechnology and the law.

Much of the current litigation concerning biotechnology arises from allegations that biotechnological research violates federal environmental and health regulations. Part I lists and describes the various federal statutes that arguably govern genetic engineering, deliberate release experiments and the biotechnology industry generally. It also surveys cases and literature that evaluate this body of federal regulatory law.

Part II covers intellectual property protection of biotechnological inventions. Biotechnological inventions and discoveries may be protected by patent, trade secrets or possibly even copyright laws. The patent section outlines those cases, statutes and commentaries concerning the patent protection of biotechnological inventions. In the landmark case of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the United States Supreme Court held that a genetically engineered bacterium qualifies as patentable subject matter under general federal patent law. Certain varieties of bioengineered organisms may also qualify for protection under the Plant Patent Act or the Plant Variety Protection Act.

Biotechnological discoveries and innovations may also be protected as trade secrets. The United States Supreme Court in *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974), held that federal patent law does not preempt state trade secrets laws. The law of trade secrets originates in state common law, and thus varies from jurisdiction to jurisdiction. Most jurisdictions have long observed the codification of trade secrets law found in RESTATEMENT (FIRST) OF TORTS § 757 (1939). Recently, however, several states have created statutory protection for trade secrets by enacting versions of the Uniform Trade Secrets Act (1979). Whether based on common law or on statute, trade secrets law protects from

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misappropriation any industrial information—including devices, formulae, processes, and techniques—that one maintains as a secret and uses to commercial advantage.

Whether federal copyright law protects biotechnological inventions remains an open question. The language of the Copyright Act clearly extends copyright protection to all original works of authorship fixed in any tangible medium of expression, but it is unclear whether that statute can be drawn to encompass gene sequences "authored" by bioengineers, and embodied in the "medium" of DNA. Courts have not yet considered this question, and legal scholars have debated it vigorously without reaching a consensus. Part II concludes by cataloging the leading works on both sides of this issue.

Part III focuses on the licensing and transfer of interests in biotechnological property. Patents, trade secrets, and copyrights all have the attributes of personal property, and their owners may thus transfer their proprietary rights therein. The commercial potential of biotechnological properties has occasioned complex agreements and joint ventures between research universities and private companies, and between multiple companies engaged in diverse research and development projects. While general principles of technology licensing will largely govern biotechnology licensing agreements, the terms of such agreements should take into account the unique characteristics of organic property, such as mortality and replication. The cases and commentaries mentioned in the licensing section discuss both the general principles and the unique concerns that should be considered in drafting transfer agreements involving biotechnological properties.

Part IV features discussions about the potential tort liability of biotechnology companies and scientists for injuries caused by recombinant DNA products and deliberate release experiments. While the issue of tort liability has not been adjudicated in the courts, it has been explored in the literature cited below.

Part V concludes the pathfinder with a brief list of sources of non-legal information about biotechnology. Those sources provide information about institutions and companies engaged in biotechnological research, as well as both introductory and technical explanations of the techniques used in that research.

I. FEDERAL REGULATION OF GENETIC ENGINEERING AND DELIBERATE RELEASE EXPERIMENTS

A. Statutes

Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1982 & Supp. II 1984).

Governs the registration and experimental use of pesticides, and regulates their transportation, importation, monitoring, and disposal. Protects trade secrets and other commercial information pertaining to pesticides that are disclosed in the course of such registration and regulation.

Federal Plant Pest Act, 7 U.S.C. §§ 150aa-150jj (1982).

Regulates the importation and movement in interstate commerce of all plant pests. Section 150aa(c) defines a plant pest as "any living stage of: Any insects . . . bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organism similar to or allied with [these]." Authorizes the seizure, quarantine, destruction, or disposal of any product or article infested with a plant pest not widely prevalent in the United States, where such product or article creates an extraordinary emergency.

Plant Quarantine Act, 7 U.S.C. §§ 151-167 (1982).

Regulates the importation of all nursery stock, defined as certain plants and plant products for propagation. Section 159 grants the Secretary of Agriculture limited authority to restrict and regulate importation of plants other than nursery stock.

Federal Noxious Weed Act, 7 U.S.C. §§ 2801-2813 (1982).

Regulates the importation and distribution in interstate commerce of any noxious weed. Section 2802 defines a noxious weed as any living stage of a parasitic or other plant that is of foreign origin, is new to or not widely prevalent in the United States, and can directly or indirectly injure American agriculture or public health.

Toxic Substances Control Act, 15 U.S.C. §§ 2601-2629 (1982 & Supp. II 1984).

Regulates chemical substances and mixtures. Section 2602 defines a chemical substance as "any organic or inorganic substance of a particular molecular identity," exclusive of, inter alia, mixtures, pesticides, foods, drugs, or cosmetics. Assigns to manufacturers and processors of chemical substances and mixtures responsibility for developing adequate data concerning the effects of such products on health and the environment. Authorizes the EPA to regulate chemical substances and mixtures that pose unreasonable risks or imminent hazards.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392
(1982 & Supp. II 1984).

Prohibits the introduction, delivery, and receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and prohibits the manufacture of such products in any U.S. territory. Regulates the manufacture, packaging, labeling, and advertising of all foods, drugs, devices, and cosmetics marketed in interstate commerce. Governs the approval of all innovative or "new" foods, drugs, devices, and cosmetics, and protects any trade secrets disclosed by an applicant during the approval process.

Occupational Safety and Health Act, 29 U.S.C. §§ 651-678
(1982 & Supp. II 1984).

Provides for the promulgation and enforcement of occupational safety and health standards, and encourages employers to develop new and improved worker safety programs of their own.

Federal Water Pollution Control (Clean Water) Act, 33 U.S.C.
§§ 1251-1376 (1982).

Prohibits the discharge from a point source of any pollutant into American waters without a national pollution discharge elimination system (NPDES) permit. Does not expressly prohibit isolated, non-continuous releases from single sources. Encourages the development and implementation of new processes and technologies for treating wastes and eliminating discharges.

Marine Protection, Research, and Sanctuaries Act, 33 U.S.C.
§§ 1401-1445 (1982 & Supp. II 1984).

Regulates the dumping of all types of materials, and prohibits or strictly limits the dumping of all hazardous materials, both by persons transporting materials from the U.S. to a location outside the U.S., and by persons from outside the U.S. dumping materials in U.S. territorial waters.

Public Health Service Act, 42 U.S.C. §§ 262-272 (1982).

Provides for federal regulation of biological products applicable to the prevention, treatment, or cure of diseases or injuries of man. Empowers the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. Authorizes the extermination or destruction of animals or articles found to be sources of dangerous infection.

National Environmental Policy Act, 42 U.S.C. §§ 4321-4370
(1982 & Supp. II 1984).

Requires all federal agencies to assess the potential environmental effects of any projects they approve or recommend, and to compile a detailed environmental impact statement before approving any project that could significantly affect the environment. In the final

analysis, NEPA imposes on federal agencies only procedural requirements; it defers to those agencies all substantive risk-benefit decision making. Because it governs only the activities of federal agencies, NEPA is inapplicable to the activities of those commercial biotechnology companies that can avoid all but voluntary federal involvement.

Section 4332 of NEPA elaborates the procedural and substantive requirements for the compilation of an acceptable environmental impact statement. This section has provided the statutory basis for much litigation concerning biotechnological experimentation. The leading case in the field is *Foundation on Economic Trends v. Heckler*, 587 F. Supp. 753 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985). There, the Court of Appeals for the District of Columbia upheld an injunction halting a recombinant DNA experiment involving the deliberate release of engineered frost-resistant bacteria onto a row of potatoes, on the grounds that NIH had approved the experiment without first compiling an environmental impact statement as required by NEPA. At the same time, however, the court of appeals vacated the district court's blanket injunction against NIH approval of any other deliberate release experiments, holding that such experiments should be approved upon completion of appropriate environmental impact assessments.

Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901-6987 (1982 & Supp. II 1984).

Regulates the treatment, storage, transportation, and disposal of all solid wastes and all hazardous wastes generated by any agricultural, laboratory, or manufacturing process.

Clean Air Act, 42 U.S.C. §§ 7401-7642 (1982 & Supp. II 1984).

Regulates and controls industrial emissions of a wide variety of air pollutants, including biological materials, that may cause or contribute to public health hazards.

Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. §§ 9601-9657 (1982 & Supp. II 1984).

Imposes liability on any person who releases hazardous substances into the environment from vessels or facilities, and requires such a person to notify the National Response Center as soon as he has knowledge of such a release. Provides authority for the expeditious cleanup of released hazardous substances with monies from the Hazardous Substance Response Trust Fund.

Hazardous Materials Transportation Act, 49 U.S.C. §§ 1801-1813 (1982 & Supp. II 1984).

Grants regulatory and enforcement authority to the Secretary of Transportation to protect the nation against the risks to life and property inherent in the transportation of hazardous materials in commerce.

Exec. Order No. 11,987, 3 C.F.R. 116 (1977), *reprinted in* 42 U.S.C. §4321 app. at 511-12 (1982) (Exotic Organisms).

Orders executive agencies to restrict, to the greatest extent legally possible, the introduction of exotic (i.e., nonnaturally occurring) species into the natural ecosystems of the United States.

B. National Institutes of Health Guidelines

National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules, 49 Fed. Reg. 46,266 (1984), *as amended by* 50 Fed. Reg. 9,760 (1985).

In 1974, the National Institutes of Health ("NIH") chartered the Recombinant DNA Advisory Committee ("RAC") to develop recommendations for the regulation of recombinant DNA research. RAC developed the Guidelines for Research Involving Recombinant DNA Molecules ("Guidelines"), which NIH issued in 1976. 41 Fed. Reg. 27,902 (1976). The original Guidelines have been revised and considerably relaxed many times during the last decade. The current version of the Guidelines appears at 49 Fed. Reg. 46,266 (1984), *as amended by* 50 Fed. Reg. 9,760 (1985).

The Guidelines apply to all recombinant DNA research conducted at or sponsored by an institution that receives from NIH *any* support for recombinant DNA research. Section III of the Guidelines classifies all recombinant DNA experiments into four groups according to the precautionary measures and approval processes required for each. The most stringently regulated and closely reviewed class of experiments includes those involving (1) the deliberate formation of recombinant DNAs containing genes for the biosynthesis of toxic molecules lethal to vertebrates, (2) the deliberate release into the environment of any organism containing recombinant DNA, (3) the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire it naturally, or (4) the deliberate transfer into human subjects of recombinant DNA or DNA derived from recombinant DNA.

Section IV of the Guidelines authorizes NIH to suspend, limit, or terminate its financial assistance to any institution that engages in *any* recombinant DNA experiment in noncompliance with the standards set forth in the Guidelines. Although the Guidelines are neither binding nor enforceable on those research enterprises that do not receive NIH funds, sections IV-D-5 and VI of the Guidelines encourage those individuals, corporations, and institutions not otherwise covered by the Guidelines to conduct their recombinant DNA experiments in compliance with Guidelines standards. To further encourage voluntary compliance, section IV-E protects the proprietary data of commercial organizations that follow the standards and procedures of the Guidelines.

C. Articles

Korwek & de la Cruz, *Federal Regulation of Environmental Releases of Genetically Manipulated Microorganisms*, 11 RUTGERS COMPUTER & TECH. L.J. 301 (1985).

Evaluates the authority of both the FDA and the USDA to regulate environmental releases of genetically manipulated microorganisms under selected federal statutes, including the National Environmental Policy Act. Observes that our present lack of knowledge about whether or to what extent biotechnology poses environmental hazards makes difficult both the application and the evaluation of such federal statutes. Argues that the current remedial regulations seem adequate until unique hazards are identified.

Schiffbauer, *Regulating Genetically Engineered Microbial Products Under the Toxic Substances Control Act*, 15 ENVTL. L. REP. (ENVTL. L. INST.) 10,279 (Sept. 1985).

Examines and evaluates favorably the authority of the FDA to regulate bioengineering under 15 U.S.C. §§ 2601-2629.

Jones, *Genetic Engineering in Domestic Food Animals: Legal and Regulatory Considerations*, 38 FOOD DRUG COSM. L.J. 273 (1983).

Discusses possible approaches to regulating gene splicing and hybrid food animal products under existing federal statutes.

McChesney & Adler, *Biotechnology Released From the Lab: The Environmental Regulatory Framework*, 13 ENVTL. L. REP. (ENVTL. L. INST.) 10,366 (Nov. 1983).

Reviews the federal statutory framework for regulating and controlling the environmental effects of bioengineering. Focuses primarily on the regulation of deliberate releases of organisms, but considers the regulation of biotechnological waste products as well.

McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461 (1983).

Discusses possible uses of a broad spectrum of federal regulatory authorities and statutes in regulating the bioengineering industry.

Korwek, *FDA Regulation of Biotechnology as a New Method of Manufacture*, 37 FOOD DRUG COSM. L.J. 289 (1982).

Argues that an article of biotechnological manufacture is entitled to the same regulatory status as a counterpart article of non-biotechnological manufacture, assuming that such counterpart articles share a structural identity.

Rosenblatt, *The Regulation of Recombinant DNA Research: The Alternative of Local Control*, 10 B.C. ENVTL. AFF. L. REV. 37 (1982).

Discusses the regulatory climate surrounding biotechnology industries following *Chakrabarty*. Considers the Recombinant DNA Ordinance of Cambridge, Mass. as a model for local regulatory schemes.

Karny, *Regulation of Genetic Engineering: Less Concern About Frankensteins but Time for Action on Commercial Production*, 12 U. TOL. L. REV. 815 (1981).

Reviews three legal mechanisms for the regulation and control of genetic engineering: the NIH Guidelines, tort law, and various federal health, safety and environmental statutes. Concludes with a comprehensive proposal for the federal regulation of bioengineering.

Korwek, *OSHA Regulation of Industrial Applications of Recombinant DNA Technology*, 50 U. CIN. L. REV. 284 (1981).

Evaluates the authority of OSHA under the Occupational Safety and Health Act to regulate industrial applications of biotechnology in the workplace.

Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, 21 JURIMETRICS J. 264 (1981).

Describes the history and substance of the NIH Guidelines. Argues that the FDA has neither the legal authority nor the practical capability to impose the Guidelines on private industry.

Korwek & Trinker, *Perspectives on the FDA Status of Drug Products Manufactured by the Recombinant DNA Technique*, 36 FOOD DRUG COSM. L.J. 517 (1981).

Addresses the regulatory issues that arise when recombinant DNA techniques are used to manufacture generic copies of FDA-approved drugs.

Talbot, *Introduction to Recombinant DNA Research, Development and Evaluation of NIH Guidelines, and Proposed Legislation*, 12 U. TOL. L. REV. 804 (1981).

Provides an introduction to the nature of recombinant DNA research and the history of its regulation by the NIH.

D. Comments and Notes

Comment, *Regulating the Environmental Release of Genetically Engineered Organisms: Foundation on Economic Trends v. Heckler*, 12 FLA. ST. U.L. REV. 891 (1985).

Describes and evaluates current federal mechanisms for regulating deliberate release biotechnological experiments, including those mechanisms available to the EPA, the NIH, and the USDA. Presents the background for and an analysis of the district court decision in *Foundation on Economic Trends v. Heckler*.

Comment, *Regulation of Genetically Engineered Foods Under the Federal Food, Drug, and Cosmetic Act*, 33 AM. U.L. REV. 899 (1984).

Discusses the authority of the FDA to regulate genetically engineered foods under FFDCA.

Comment, *Protection for Trade Secrets Under the Toxic Substances Control Act of 1976*, 13 U. MICH. J.L. REF. 329 (1980).

Describes and evaluates the system by which federal agencies protect the confidential information and trade secrets that they collect pursuant to the requirements of TSCA.

Note, *An Overview of FDA Regulation of Biotechnology Derived Products: Dealing with the Collision of Science and Society*, 11 RUTGERS COMPUTER & TECH. L.J. 501 (1985).

Outlines the authority of the FDA to regulate various types of biotechnological products under the Federal Food, Drug, and Cosmetic Act, and describes the FDA's "cautious, flexible" approach to regulating the biotechnology industry.

II. INTELLECTUAL PROPERTY PROTECTION OF BIOTECHNOLOGICAL INNOVATIONS

A. Patent

1. Statutes

35 U.S.C. §§ 100-104, 111-122 (1982 & Supp. II 1984).

Sections 101-104 provide that a person may secure patent protection for any invention or discovery of a process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, that is new and useful (§ 101), novel (§ 102), and nonobvious (§ 103).

Sections 112-115 delineate the necessary enabling requirements of the patent application, which include a written specification of the invention and its manufacture (§ 112), a drawing (§ 113) or a model or specimen (§ 114) of the invention, and the inventor's oath that he believes himself to be the original inventor of the subject matter in question (§ 115). The specification requirement obliges an inventor to disclose his invention in a manner that will enable a person skilled in the art of that invention to make and use the same.

Plant Patent Act, 35 U.S.C. §§ 161-164 (1982).

Defines the conditions under which a person who invents or discovers and asexually reproduces a distinct and new variety of plant, including cultivated spores, mutants, hybrids and certain newly found seedlings, may obtain patent protection for that plant.

Plant Variety Protection Act, 7 U.S.C. §§ 2321-2583 (1982 & Supp. II 1984).

Provides breeders of novel varieties of sexually reproduced plants (other than fungi, bacteria, or first generation hybrids) with trade protection in the form of certificates of plant variety protection.

2. Cases

Diamond v. Chakrabarty, 447 U.S. 303 (1980).

The United States Supreme Court held that a live, human-made organism constitutes a patentable "manufacture" or "composition of matter" within the meaning of 35 U.S.C. § 101.

In re Lundak, 227 U.S.P.Q. 90 (Fed. Cir. 1985).

The Court of Appeals for the Federal Circuit held that 35 U.S.C. § 112 does not require a patent applicant whose written specification of a new cell line refers to that cell line to deposit a sample of his invention prior to filing an application for its patent. Rather, § 112 permits him to deposit his sample after filing his application but before the issue of his patent.

Ex Parte Hibberd, 227 U.S.P.Q. 443 (PTO Bd. Pat. App. & Inter. 1985).

The PTO Board of Appeals and Interferences held (1) that the Plant Patent Act and the Plant Variety Protection Act do not narrow the scope of patentable subjects protected under the general utility patent statute, (2) that these plant specific acts do not represent the exclusive forms of patent protection for the plant life they protect, and (3) that tissue cultures are not "plants" within the meaning of the Plant Patent Act.

Ex parte Jackson, 217 U.S.P.Q. 804 (P.O. Bd. App. 1982).

The Patent Board Office of Appeals held that inventors of a microbiological process who deposit their microorganisms in a national repository may claim patent protection not only for the processes that utilize those microorganisms, but also for any mutations of those microorganisms.

In re Argoudelis, 434 F.2d 1390, 168 U.S.P.Q. 99 (C.C.P.A. 1970).

The Court of Customs and Patent Appeals held that 35 U.S.C. § 112 requires a valid enabling disclosure of a microbiological process to include a deposit in a national repository of a sample of the microorganism used in that process.

3. Texts

1 D. CHISUM, PATENTS §§ 1.02[7][d] & 1.05 (rev. ed. 1986).

Section 1.02[7][d] discusses the extent to which living organisms constitute patentable subject matter. Section 1.05 describes the system of Plant Patent protection.

I. COOPER, BIOTECHNOLOGY AND THE LAW (rev. ed. 1985).

Presents an exhaustive discussion of all aspects of the patent law as it relates to biotechnology. Sections 8.02-8.17 examine all facets of the Plant Patent Act. Sections 9.01-9.06 consider the possible application of the Plant Variety Protection Act ("PVPA") to bioengineered microorganisms, and describe the relationship between the PVPA

and the international Union for the Protection of New Varieties of Plants ("UPOV") Convention. Section 9.05 includes a useful summary comparing the three means of protecting new plant varieties under the patent law.

4. Articles

Ihnen, *Patenting Biotechnology: A Practical Approach*, 11 RUTGERS COMPUTER & TECH. L.J. 407 (1985).

Illustrates with hypothetical cases how to draft a biotechnological patent application as broadly as possible while nevertheless presenting a valid claim.

Hamburg, *Board of Appeals Holds that Claims Reciting Bacterial Strains Cannot Be Broader than the Specific Strains Deposited, With the Exception of Mutations*, 81 PAT. & TRADEMARK REV. 419 (1983).

Briefly reports on the *Jackson* decision and its implications for the deposit and disclosure requirements of 35 U.S.C. § 112.

Bent, *Patent Protection for DNA Molecules*, 64 J. PAT. OFF. SOC'Y 60 (1982).

Discusses the strategy of seeking biotechnology patents by filing patent claims that recite DNA polymers instead of or in addition to claims that recite genetically modified cells.

Smith, *The Promise of Abundant Life: Patenting a Magnificent Obsession*, 8 J. CONTEMP. L. 85 (1982).

Discusses *Chakrabarty* as an impetus to biotechnological research and development. Argues that the "obsessive" quest for scientific mastery of the genetic code has the potential to prevent much suffering and improve human life.

Behringer, *Microorganisms Patents: United States Supreme Court Opens Door to Patenting of Human-Made Bacteria*, 63 J. PAT. OFF. SOC'Y 128 (1981).

Discusses questions about the scope of patent protection for microorganisms following *Chakrabarty*, including whether either induced mutant strains of bacteria or biologically pure cultures of newly discovered wild-type microorganisms might be patentable subject matter.

Schlosser, *Patenting Biological Inventions*, 12 U. TOL. L. REV. 925 (1981).

Describes the American system of patent protection for biotechnology following *Chakrabarty*. Discusses various foreign systems of protecting biotechnology, as well as the international treaties protecting biotechnological innovations abroad, including the Budapest Treaty, the New Patent Cooperation Treaty, and the International Convention for the Protection of New Varieties of Plants.

Sparrow, *An International Comparative Analysis of the Patentability of Recombinant DNA-Derived Organisms*, 12 U. TOL. L. REV. 945 (1981).

Compares the reasoning of the *Chakrabarty* court with the reasoning of the European Patent Office with respect to questions about the patentability of biotechnological products, and concludes that both lines of reasoning lead to similar outcomes.

Cooper, *Arzberger Under the Microscope: A Critical Reexamination of the Exclusion of Bacteria From Plant Patent Protection*, 78 PAT. & TRADEMARK REV. 59 (1980), reprinted with modifications in 7 RUTGERS J. COMPUTERS TECH. & L. 367 (1980).

Argues that bacteria and other microorganisms are entitled to protection under the Plant Patent Act (35 U.S.C. 161-164). Contends that the decision in *In re Arzberger*, 112 F.2d 834 (C.C.P.A. 1940), which held that bacteria is not a "plant" within the meaning of the Plant Patent Act, is an anachronism that the courts will continue to ignore.

Cooper, *The Patent System and the New Biology*, 8 RUTGERS J. COMPUTERS TECH. & L. 1 (1980).

Surveys both the field and the future of the patent law as it applies to biotechnology following *Chakrabarty*.

5. Comments and Notes

Comment, *Patenting Microorganisms: Working the Bugs Out of the International Depository Authority*, 14 CAL. W. INT'L. L.J. 49 (1984).

Calls for a uniform system of international patent protection for biotechnological inventions. Discusses the Budapest Treaty and the International Depository Authority.

Comment, *Innocuous Inoculum or Perilous Parasite? Encouraging Genetic Research Through Patent Grants: A Call For Regulation and Debate*, 18 SAN DIEGO L. REV. 263 (1981).

Critically examines *Chakrabarty*, and suggests several grounds on which authorities could conceivably deny patent protection to the products of genetic research.

Note, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That is the Question*, 52 FORDHAM L. REV. 592 (1984).

Criticizes the imposition of the present Section 112 deposit requirement on biotechnology patent applications. Argues that a deposit is in most cases unnecessary because a written specification alone will suffice to disclose the invention. Recommends revisions of the deposit requirement to avoid the costs of unnecessary deposits, to delineate clear deposit standards, and to limit the scope of patent protection to the particular invention specified or deposited.

Note, *Patent Protection for Microbiological Processes: Has In re Argoudelis Been Mutated?*, 1984 WIS. L. REV. 1679.

Examines in detail the enabling disclosure requirements of 35 U.S.C. § 112. Discusses the *Argoudelis* and *Jackson* decisions.

Note, *Building a Better Bacterium: Genetic Engineering and the Patent Law After Diamond v. Chakrabarty*, 81 COLUM. L. REV. 159 (1981).

Discusses *Chakrabarty* against the background of prior law. Explores some of the unique problems persons seeking patents for biotechnological inventions confront in defining and disclosing their inventions in patent claims.

Note, *The Patentability of Living Matter: Hey Waiter, What's Chakrabarty's Pseudomonas Bacterium Doing Back in the Supreme Court's Soup*, 37 WASH. & LEE L. REV. 183 (1980).

Written just before *Chakrabarty*, this note describes the patent law prior to that decision, and argues that microorganisms should be regarded as patentable subject matter.

B. Trade Secrets

The legal protection of trade secrets is generally governed by the common law of the individual states, most of which subscribe to the codification of trade secrets law found in RESTATEMENT (FIRST) OF TORTS § 757 (1939). More recently, however, some jurisdictions have given statutory protection for trade secrets by enacting their own versions of the Uniform Trade Secrets Act (1979).

1. Statutes and Cases

RESTATEMENT (FIRST) OF TORTS § 757 comment b (1939).

Presents the most often-quoted definition of a trade secret as any formula, pattern, device, or compilation of information that one both uses continuously to competitive advantage in one's business and keeps secret from one's competitors.

Restatement (Second) of Torts (1978) did not even attempt a revision of this definition of trade secret, which is so widely accepted that it is in most jurisdictions difficult to find a modern trade secrets case that does not to some extent rely upon it.

UNIF. TRADE SECRETS ACT §§ 1-13, 14 U.L.A. 541 (1980 & Supp. 1986).

Defines a trade secret as any information, including a formula, pattern, compilation, program, device, method, technique, or process that is both economically valuable because of its secrecy, and maintained as a secret by the reasonable efforts of its owner. Departs from the Restatement definition by eliminating the requirement that the information be *continuously* used in business.

At least nine states have enacted versions of the Uniform Trade Secrets Act, and several others have drafted legislative proposals for similar enactments. Texts of the UTSA and of its state-enacted versions may be found both in M. JAGER, *TRADE SECRETS LAW* apps. A1 & A2 (1985), and in 12B *Business Organizations, MILGRIM ON TRADE SECRETS* apps. A & AA (rev. ed. 1985).

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974).

This is the leading trade secrets case. In *Kewanee*, the United States Supreme Court held that federal patent law does not preempt state trade secrets law, at least to the extent that such trade secrets law does not conflict with the operations of federal patent and copyright laws. The *Kewanee* Court recognized that the protection of trade secrets promotes research and the dissemination of knowledge, and maintains commercial ethics.

2. *Texts and Articles*

I. COOPER, *BIOTECHNOLOGY AND THE LAW* § 11.01 (rev. ed. 1985).

Discusses trade secrets protection of biotechnological cultures and know-how, and offers a brief, useful comparison of patent and trade secrets protection.

M. EPSTEIN, *MODERN INTELLECTUAL PROPERTY* (1984).

Includes several chapters about trade secrets law. Chapter 10 is devoted to the subject of protecting biotechnology, and features a section addressed to the unique issues that arise from the application of trade secrets law to biotechnology.

M. JAGER, *TRADE SECRETS LAW* (1985).

Presents a comprehensive discussion of all aspects of trade secrets law, including the various legal theories used by courts to protect trade secrets, the ownership rights to trade secrets, and the interface of trade secret law with patent and copyright laws. Includes appendices that specify the trade secrets laws of the individual states, and that furnish sample licenses and confidential disclosure agreements.

12-12B *Business Organizations, MILGRIM ON TRADE SECRETS* (rev. ed. 1985).

Discusses in detail all aspects of trade secrets: definition, contractual and quasi-contractual protection, taxation, antitrust considerations, federal regulations, interface with patent and copyright laws, and licensing. Appendices include a table of cases, the text of the UTSA, state statutes, and a list of selected articles.

Leuzzi, *Process Inventions: Trade Secret or Patent Protection*, 66 J. PAT. OFF. SOC'Y 159 (1984).

Outlines the relevant considerations for deciding whether to pursue patent or trade secret protection for one's process inventions.

C. Copyright

1. Statutes

17 U.S.C. §§ 101-118 (1982 & Supp. II 1984).

Defines the subject matter and scope of copyright. Section 102 extends copyright protection to original works of authorship fixed in any tangible medium of expression from which they may be perceived or reproduced, and withholds protection from any idea, procedure, process, system, method of operation, concept, principle, or discovery.

17 U.S.C. §§ 901-902 (Supp. II 1984).

Governs the protection of semiconductor chip products. May be of interest because the analogy between computer programs and gene sequences is an important element in the argument that the latter are entitled to copyright protection.

2. Texts and Articles

I. COOPER, *BIOTECHNOLOGY AND THE LAW* § 11.02 (rev. ed. 1985).

Argues at length that copyright protection is not available for gene sequences or molecules, and that the supposed analogy between gene sequences and computer programs is misconceived.

Goldstein, *Copyrightability of Genetic Works*, 1984 *BIO/TECH.* 138.

Explores the analogy between gene sequences and computer programs, and presents the main arguments for and against extending copyright protection to gene sequences.

Kayton, *Copyright in Living Genetically Engineered Works*, 50 *GEO. WASH. L. REV.* 191 (1982).

Argues that copyright protection of the original works of genetic scientists is both available and constitutional, and that copyright may furnish the optimal legal protection for such material.

Comment, *Protecting Trade Secrets Through Copyright*, 1981 *DUKE L.J.* 981.

Examines the practice of placing a copyright notice on trade secrets. Concludes that because copyright protects expressions rather than ideas, copyright provides no additional protection for trade secrets, and so should not be sought.

III. LICENSING LIFEFORMS

A. Statutes and Cases

35 U.S.C. §§ 261-262 (1982).

Provides that patents shall have the attributes of personal property, and that patents or applications for patents, or any interests therein, shall be legally assignable by means of written instruments.

7 U.S.C. §§ 2531-2532 (1982).

Provides that plant varieties protected under the PVPA shall have the attributes of personal property, and that an application for a certificate of plant variety protection or any interest in a variety shall be assignable by means of a written instrument.

17 U.S.C. §§ 201-205 (1982).

Provides that copyrights shall have the attributes of personal property, and may be transferred in whole or in part by any means of conveyance or by operation of law. Distinguishes ownership of copyrights from ownership of the material objects that embody copyrighted works. Governs the termination, execution, and recordation of transfers of copyright ownership.

Aronson v. Quick Point Pencil Co., 440 U.S. 257 (1979).

The most recent United States Supreme Court trade secrets decision. In *Aronson*, the Court held that federal patent law does not preempt state contract law, and that the enforcement of contracts concerning unpatentable inventions is consistent with the policy of encouraging invention that underlies trade secrets law.

Moore v. Regents of the University of California, No. C 513755 (Cal. Super. Ct. L.A. filed Sept. 11, 1984).

A case whose pleadings are currently undergoing amendment, *Moore* might well establish some precedents that will interest biotechnology researchers, licensors, and licensees. The plaintiff in *Moore* is a leukemia patient who has been treated successfully at the University of California at Los Angeles. Plaintiff's treatment entailed the removal of his diseased spleen. University scientists subsequently used cells from his removed spleen to develop a new productive cell line, which they patented. Plaintiff brings suit claiming that he is entitled to proprietary rights in that patented cell line. Plaintiff argues that although he did sign informed consent forms surrendering to the University of California all rights to his spleen, he did not thereby give valid consent because the University did not inform him that his spleen could be used to develop a commercially valuable product.

The *Moore* case figures to raise issues about a person's ownership rights in his body tissues, about ownership rights in patents, and about disclaimers and informed consent clauses. For an outline of

the history of and the issues in *Moore*, see Culliton, *Mo Cell Case Has Its First Court Hearing*, 226 SCIENCE 813 (1984).

B. Texts

5 D. CHISUM, PATENTS §§ 22.01-22.03[5] (rev. ed. 1986).

Discusses the relationship between the concept of ownership of patent rights and the concept of invention, the ownership of patent rights to inventions created in the context of an employment relationship, and the transfer of patent rights.

I. COOPER, BIOTECHNOLOGY AND THE LAW §§ 7.01-7.05 (rev. ed. 1985).

Describes the ownership rights to biotechnology patents, particularly to those patents arising out of joint ventures between private industry and universities. Discusses the university's interests in products developed by its scientists, and the involvement of university scientists in commercial research.

M. JAGER, TRADE SECRETS LAW §§ 8.01-8.03, 11.03 (1985).

Sections 8.01-8.03 discuss ownership rights to trade secrets, particularly to those trade secrets developed in the context of employment relationships. Section 11.03 outlines the common law restrictions on the rights of an owner to license his trade secrets, including restrictions on product prices, territory, duration, quantity, and field of use.

12A Business Organizations, MILGRIM ON TRADE SECRETS (rev. ed. 1985).

Sections 9.01-9.05 review the legal characteristics pertinent to licensing of various sorts of industrial properties, including patents, trade secrets, and copyrights. These sections describe the owner's transferable rights in such properties, the procedural and substantive requirements of such transfers, and the remedies available to the injured owner. Section 9.06 discusses complex and hybrid licensing of multiple and diverse industrial properties. Section 10.01 concerns trade regulations and antitrust principles applicable to the licensing of industrial properties. Section 11.01 outlines some prelicense steps designed to overcome antitrust impediments and effect better negotiations. Sections 12.01-12.04 discuss practical considerations about drafting licensing agreements.

3 M. NIMMER, NIMMER ON COPYRIGHT §§ 10.01-10.15 (rev. ed. 1985).

Provides a comprehensive treatment of assignments, licenses, and other transfers of property rights in copyrighted works. Includes discussions of, *inter alia*, the divisibility of copyrights, transfer formalities, recordation of transfers, construction of transfer agreements, implied and negative covenants, and remedies.

C. Articles

Karny, *Biotechnology Licensing*, 8 LICENSING L. & BUS. REP. 1 (1985).

Discusses the licensing and transfer of biotechnology through both formal licensing agreements and informal letter agreements. Considers how the various unique aspects of biotechnology should inform the negotiation and drafting of licensing agreements, and furnishes some sample forms for such agreements.

Ku, *Licensing DNA Cloning Technology*, in 3 THE LAW AND BUSINESS OF LICENSING: LICENSING IN THE 1980S 3G-69 (R. Goldscheider & T. Arnold rev. ed. 1985).

Relates the history and legal strategy of Stanford University's licensing of the "Cohen-Boyer" patent properties developed by its scientists.

Misrock, Coggio & Dulak, *The Exercise of Patent Rights Through Multiple Exclusive Field-of-Use Licensing*, 11 RUTGERS COMPUTER & TECH. L.J. 301 (1985).

Discusses field-of-use patent licensing generally. Describes and argues for the permissibility of employing multiple *exclusive* field-of-use licensing of biotechnological discoveries. Sketches the relevant antitrust restrictions on such licensing arrangements.

Payne, *Know-How Licensing — Definition, Duration and Disposition*, in 1981 LICENSING LAW HANDBOOK 35 (B. Brunsvold ed. 1981), *reprinted in* 1 THE LAW AND BUSINESS OF LICENSING: LICENSING IN THE 1980S 2A-169 (R. Goldscheider & T. Arnold rev. ed. 1985).

Surveys both the mechanisms and the rationale for the licensing of trade secrets. Presents overview of relevant case law. Discusses the licensing both of trade secrets and of nonproprietary know-how.

IV. TORT LIABILITY FOR BIOTECHNOLOGY PRODUCTS

Karny, *Genetic Engineering Presents Possibility of Tort Liability*, *Legal Times*, Oct. 31, 1983, at 14.

Discusses the potential tort liability of genetic engineering enterprises under theories of strict liability for hazardous activities, strict products liability, and negligence. Considers the possibility of licensor negligence.

Comment, *Strict Product Liability for Injuries Caused by Recombinant DNA Bacteria*, 22 SANTA CLARA L. REV. 117 (1982).

Outlines the difficulties in proving negligence in the event of a biotechnological accident or injury, and examines the limits and arguments in favor of holding the bioengineering industry strictly liable in tort for all injuries it may cause.

Comment, *Creation of Life: A New Frontier for Liability?*, 13 PAC. L.J. 99 (1981).

Argues that bioengineers and manufacturers should be held strictly liable in tort for all injuries caused by biotechnological processes and products, both because genetic engineering is an abnormally dangerous activity, and because bioengineered microorganisms are animals with known vicious or dangerous tendencies. Argues against governmental tort immunity for genetic researchers affiliated with state-sponsored laboratories or institutions.

V. REFERENCE MATERIALS ON BIOTECHNOLOGY AND GENETIC ENGINEERING

J. COOMBS, *THE BIOTECHNOLOGY DIRECTORY 1985: PRODUCTS, COMPANIES, RESEARCH AND ORGANIZATIONS* (1985).

A comprehensive guide to biotechnology both in the United States and worldwide. Includes listings and descriptions of the various information services, governmental bodies, non-commercial organizations, and companies concerned with or engaged in biotechnological research and development.

The following texts provide a general introduction to genetic engineering and biotechnology techniques:

AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, *BIOTECHNOLOGY AND BIOLOGICAL FRONTIERS* (P. Abelson ed. 1984).

A. EMERY, *AN INTRODUCTION TO RECOMBINANT DNA* (1984).

P. HACKETT, J. FUCHS & J. MESSING, *AN INTRODUCTION TO RECOMBINANT DNA TECHNIQUES: BASIC EXPERIMENTS IN GENE MANIPULATION* (1984).

RECOMBINANT DNA RESEARCH AND THE HUMAN PROSPECT (E. Hanson ed. 1983).

R. OLD & S. PRIMROSE, *PRINCIPLES OF GENE MANIPULATION: AN INTRODUCTION TO GENETIC ENGINEERING* (3d ed. 1985).

C. PHELPS & P. CLARKE, *BIOTECHNOLOGY* (1983).

S. PRENTIS, *BIOTECHNOLOGY: A NEW INDUSTRIAL REVOLUTION* (1984).

The following texts provide technical discussions of biotechnology and recombinant DNA research techniques:

MECHANISMS OF DNA REPLICATION AND RECOMBINATION (N. Cozzarelli ed. 1983).

R. DAVIS, D. BOTSTEIN, J. ROTH, ADVANCED BACTERIAL GENETICS: COLD SPRING HARBOR LABORATORY (1980).

RECOMBINANT DNA METHODOLOGY (J. Dillon, A. Nasim & E. Nestman eds. 1985).

ADVANCES IN GENE TECHNOLOGY: MOLECULAR GENETICS OF PLANTS AND ANIMALS (K. Downey ed. 1983).

P. GARLAND & R. WILLIAMSON, BIOCHEMISTRY OF GENETIC ENGINEERING (1979).

EXPERIMENTAL MANIPULATION OF GENE EXPRESSION (M. Inouye ed. 1983).

J. WALKER, TECHNIQUES IN MOLECULAR BIOLOGY (1983).