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Proprietary Rights and the Norms of Science in Biotechnology Research

Rebecca S. Eisenberg†

As basic research in biotechnology yields increasing commercial applications, scientists and their research sponsors have become more eager to protect the commercial value of research discoveries through intellectual property law. Some scientists fear that these commercial incentives will weaken or even undermine the norms that have traditionally governed scientific research. In this Article, Professor Eisenberg examines the interaction of proprietary rights in inventions with these traditional scientific norms. Trade secrecy, she argues, is an undesirable strategy for protection of basic research discoveries because it impedes dissemination of new knowledge to the scientific community. She finds that patent law is in many respects more congruent with scientific norms than trade secrecy because it is premised on disclosure rather than secrecy. Professor Eisenberg demonstrates, however, that the fit between the patent system and the norms and incentives of the scientific community is hardly perfect. Patent law may operate to delay the dissemination of knowledge to other researchers. Moreover, by granting rights to exclude others from using patented inventions for a term of years, the patent system threatens the interest of the scientific community in the free use and extension of new discoveries. Professor Eisenberg concludes that greater sensitivity to the impact of

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† Associate Professor of Law, University of Michigan Law School. I wish to thank Marty Adelman, Ed Cooper, Mel Eisenberg, Julie Gage, Judah Garber, Paul Goldstein, Don Herzog, Dick Kaba, Jim Krier, Rick Lempert, Jessica Litman, Fred Schauer, Jonathan Weinberg, Peter Westen, and Virginia Wise for helpful comments on earlier drafts of this Article.

patent law doctrine on scientific norms will help to reconcile the norms and incentives of these two systems.

INTRODUCTION

The commercial potential of recent advances in biotechnology has substantially increased private investment in basic research in the biomedical sciences.¹ Some academic scientists have viewed this influx of private funding as a mixed blessing. Although it comes at a time when the continuity of public funding for biomedical research is uncertain,² it raises concerns about the potential impact of commercial incentives to protect intellectual property on traditions of open communication and free flow of information within the scientific community.³ Indeed, some scientists have

1. See S. OLSON, *BIOTECHNOLOGY: AN INDUSTRY COMES OF AGE* (1986); Blumenthal, Gluck, Louis & Wise, *Industrial Support of University Research in Biotechnology*, 231 *SCIENCE* 242 (1986). Between World War II and the 1970s, basic research in the biomedical sciences was dominated by public funding. See generally M. KENNEY, *BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX* 13-18 (1986); I. B. SMITH & J. KARLESKY, *THE STATE OF ACADEMIC SCIENCE: THE UNIVERSITIES IN THE NATION'S RESEARCH EFFORT* 11-48 (1977), and sources cited therein.

I use the term "basic research" to refer to "pure" research directed solely toward expanding human knowledge, as opposed to "applied" research directed toward solving practical problems. See *infra* notes 38-47 and accompanying text. I shall argue below that, whatever validity this dichotomy may have in other contexts, it is difficult to maintain in the context of contemporary biotechnology research. See *infra* notes 93-109 and accompanying text.

2. Between 1980 and 1984, industrial funding for research and development at universities and colleges increased 93%, from \$237,025,000 in 1980 to \$457,227,000 in 1984, while federal funding increased only 31%, from \$4,096,029,000 to \$5,386,578,000. NATIONAL SCIENCE FOUNDATION, *NATIONAL PATTERNS OF SCIENCE AND TECHNOLOGY RESOURCES* 65 (1986) (Table 51). Adjusted for inflation, the total investment in research and development at universities and colleges rose only 4% between 1980 and 1983. This extremely modest rise reflects cutbacks in federal funding, particularly in the health area. *Id.* at 12-13.

Since 1980, federal support has increasingly shifted toward defense-related fields at the expense of other categories of research and development. While the federal government's share of total national research and development outlays remained at a relatively constant 46-47% between 1980 and 1986, federal defense-related expenditures rose from 22% of this total in 1980 to an estimated 30% in 1986, while federal civilian-related expenditures fell from 18% in 1980 to an estimated 10% in 1986. *Id.* at 41 (Table 13). During this period, federal research and development funding for national defense increased approximately 183%, from \$14,946,000,000 in 1980 to an estimated \$42,360,000,000 in 1986, while federal funding for health-related research and development increased only 38%, from \$3,694,000,000 in 1980 to an estimated \$5,108,000,000 in 1986. *Id.* at 45 (Table 22). Biomedical research would have fared worse under budgets proposed by the Reagan administration, but Congress has repeatedly approved funding increases significantly greater than the administration's recommendations. See Culliton, *Pressure to Cut the Deficit Creates Uncertainty for Biomedical Research*, 232 *SCIENCE* 564 (1986); Norman, *Science Escapes Brunt of Budget Ax*, 231 *SCIENCE* 785, 787 (1986).

3. See generally *Commercialization of Academic Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. (1981) [hereinafter *Commercialization Hearings*]; D. NELKIN, *SCIENCE AS INTELLECTUAL PROPERTY* (1984); TWENTIETH CENTURY FUND, INC., *THE SCIENCE BUSINESS* (1984) [hereinafter *THE SCIENCE BUSINESS*]; Grobstein, *Biotechnology and Open University Science*, 10 *SCI. TECH. & HUM. VALUES*, Spring 1985, at 55.

Concerns about the impact of industrial funding on biomedical research are by no means confined to the effects of intellectual property law. Other potential problems include distortion of the biomedical research agenda as academic scientists seek to attract corporate sponsors; bypassing of traditional peer review mechanisms in allocating research funds, with consequent deterioration in the quality of research; alteration of the research and subsequent employment opportunities available to graduate students; divided loyalties of faculty affiliated with industry; compromise of university autonomy in

asserted that granting property rights in research discoveries is antithetical to the norms of science.⁴

In this Article I examine the interaction of intellectual property rights with research science norms⁵ in biotechnology-related fields to determine whether the two systems of rules and incentives conflict, and if so, how. Biotechnology research presents an unusual, if not unprecedented,⁶ juxtaposition of the incentives of the patent law system with the norms and

such matters as faculty appointments; and loss of university credibility for impartial expertise on scientific issues. *See generally* M. KENNEY, *supra* note 1; Blumenthal, Gluck, Louis, Stoto & Wise, *University-Industry Research Relationships in Biotechnology: Implications for the University*, 232 SCIENCE 1361 (1986); Markle & Robin, *Biotechnology and the Social Reconstruction of Molecular Biology*, 10 SCI. TECH. & HUM. VALUES, Winter 1985, at 70; Note, *Patent and Trade Secret Protection in University-Industry Research Relationships in Biotechnology*, 24 HARV. J. ON LEGIS. 191, 201-08 (1987); Note, *Ties That Bind: Conflicts of Interest in University-Industry Links*, 17 U.C. DAVIS L. REV. 895 (1984).

4. For example, microbiologist Jonathan King has claimed that concern for preserving proprietary rights is retarding communication among university scientists, thereby undermining a previously shared "professional canon" of promoting the dissemination of knowledge for the public welfare:

The openness, the free exchange of ideas and information, the free exchange of strains, of protein, of techniques, have been a critical component in the creativity and productivity of the biomedical research community. . . .

This freedom of communication stemmed from the fact that all of the investigators shared the same professional canon; the increase of knowledge of health and disease for the general benefit of the citizenry. . . .

Individuals planning to profit personally from commercial development, by, for example, assigning patents to their own firms, tend to cut down communication with their colleagues. . . .

This secrecy is inimical to the function and effectiveness of universities in educating future generations of scientists, as well as retarding the research effort.

Commercialization Hearings, supra note 3, at 62-63 (testimony of Dr. Jonathan King).

5. Throughout this Article I use the word "norms" in a normative rather than descriptive sense. By "research science norms" I mean socially inculcated beliefs within the research science community about how scientists *should* behave, as opposed to descriptions of how they actually *do* behave. *See infra* notes 8-28 and 110-54 and accompanying text.

6. In some fields, such as chemistry and engineering, industrial applications of research have been sufficiently immediate that universities and academic researchers have engaged in industry-sponsored research projects for years. In these areas, researchers have long confronted industry's concern for protecting intellectual property. *See Commercialization Hearings, supra* note 3, at 28-60 (testimony of Dr. Paul Gray); D. DICKSON, *THE NEW POLITICS OF SCIENCE* 89-90 (1984); Servos, *The Industrial Relations of Science: Chemical Engineering at MIT, 1900-1939*, 71 ISIS 531 (1980); Smith & Hounshell, *Wallace H. Carothers and Fundamental Research at DuPont*, 229 SCIENCE 436 (1985). But in other fields, including many fields within the biomedical sciences, the gap between basic and applied research has been wider. *See* Peters & Fufeld, *Current U.S. University-Industry Research Connections*, in NATIONAL SCIENCE BOARD, *UNIVERSITY-INDUSTRY RESEARCH RELATIONSHIPS: SELECTED STUDIES* 1, 20-21 (1982). In these fields, there have been fewer occasions to reconcile conflict between scientific norms and patent law.

The sudden juxtaposition of commercial incentives and scientific norms has been particularly striking in the biomedical sciences, in part because of the strong public interest in health-related research and in part because of the rapid onset and proliferation of university-industry research relationships in biotechnology fields following decades of predominantly public funding. Martin Kenney describes the prevailing attitude among biomedical researchers prior to the biotechnology boom as follows:

The role of the state as a funder of basic (non-commodity-oriented) research fostered a powerful ideology—one of scientists working for the public good to improve the health status of Americans. According to this ideology, industry's motives—especially that of profitability—were suspect, and the applied science orientation of industry was considered to be scientifically uninspiring to scientists.

M. KENNEY, *supra* note 1, at 32. In light of this ideology, it is not surprising that the privatization of new knowledge as intellectual property has been resisted in the biomedical research community.

incentives of a basic research community. Given the growing economic significance of research-oriented industries, it seems likely that patent law will have an increasing impact on the conduct of basic research. Thus, the experience of the biomedical research community with patent law may offer a preview of phenomena that will soon become more widespread. If patent law is in fact unsalutary for the conduct of basic research, it would be useful to figure out why.

In Section I, I analyze the divergence between intellectual property law and research science norms as traditionally conceived. I begin by describing a conventional view of the norms of research science concerning the dissemination of new knowledge and the rights of scientists in their discoveries. Against this background, I examine impediments to intellectual property protection for basic research discoveries in the biomedical sciences under traditional patent and trade secret doctrine. In Section II, I analyze the conjunction of the norms and incentives of research science and the rules and incentives of intellectual property in contemporary biotechnology research. First, I describe recent developments that have helped bring about this conjunction. Next, I analyze the operation of scientific norms concerning publication of research results in the specific context of contemporary biotechnology research, as illustrated by the records of a recent controversy within the *Journal of Biological Chemistry*. I then examine patent law doctrine as applied to biotechnology inventions to determine whether and how patent law conflicts with scientific norms in this particular research context. I conclude that, although there are substantial parallels between the two systems, the conjunction may nonetheless cause delay in the dissemination of new knowledge and aggravate inherent conflict between the norms and the reward structure of science.

I. THE TRADITIONAL DIVERGENCE BETWEEN INTELLECTUAL PROPERTY AND SCIENTIFIC NORMS IN BASIC RESEARCH

Given the shared focus of research science and patent law on promoting invention and the dissemination of new knowledge, the proposition that scientific norms and patent laws have coexisted for centuries⁷ without

7. Patent laws have existed in this country since 1790 and in Europe since the 17th century. The origins of patent law are generally traced to the English Statute of Monopolies, 1623, 21 Jac., ch. 3, reprinted in 6 D. CHISUM, PATENTS app. at 8-1 (1987). Patents granted in the American colonies were primarily special enactments of colonial legislatures in favor of individual inventors. B. BUGBEE, GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 57 (1967). The first United States patent statute was enacted in 1790, Patent Act of 1790, ch. 7, 1 Stat. 109-12, and revised in 1793, Patent Act of 1793, ch. 11, 1 Stat. 318-23. A more substantial revision occurred in the Patent Act of 1836, ch. 357, 5 Stat. 117-25, which created a patent office to examine patent applications for conformance to statutory criteria prior to the issuance of patents. The law has since been revised on numerous occasions. See Patent Act of 1839, ch. 88, 5 Stat. 353-55; Patent Act of 1870, ch. 230, 16 Stat. 198-217; Patent Act of 1897, ch. 391, 29 Stat. 692-94; Patent Act of 1903, ch. 1019, 32 Stat. 1225-27; Patent Act of 1928, ch. 730, 45 Stat. 732; Patent Act of 1939, ch. 450, 53 Stat. 1212; Patent Act of 1952, Pub. L. No. 593, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1-376 (1982 &

working out their differences calls for some explanation. Conflict may have been forestalled in the past by mutual avoidance: Particularly in the biomedical sciences, both legal doctrine and scientific norms have discouraged attempts to protect basic research discoveries as intellectual property.

A. *A Traditional View of the Norms of Science*

Some observers have asserted that, prior to the recent growth of commercial interest in biotechnology, neither research scientists nor the institutions funding basic scientific research in the biomedical sciences showed much inclination to pursue patent rights.⁸ Universities, where much of the research was conducted, encouraged the dissemination of research results through publication and occasionally showed a positive aversion to patenting discoveries.⁹

Public sponsorship of basic research permitted university researchers to avoid industrial sponsors who might have exerted pressure to protect intellectual property.¹⁰ Government sponsors gave universities and researchers little incentive to identify patentable inventions or pursue patent rights. While the patent policies of the federal agencies that fund univer-

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Robert Merton traces the origins of the ethos and norms of modern research science back to 17th-century Puritanism. R. MERTON, *The Puritan Spur to Science*, in *THE SOCIOLOGY OF SCIENCE* 228-53 (1973) [hereinafter *THE SOCIOLOGY OF SCIENCE*], originally published as R. MERTON, *Motive Forces of the New Science*, in *SCIENCE, TECHNOLOGY AND SOCIETY IN SEVENTEENTH-CENTURY ENGLAND* 80-111 (1970).

8. *Commercialization Hearings*, *supra* note 3, at 62-63 (testimony of Dr. Jonathan King); *THE SCIENCE BUSINESS*, *supra* note 3, at 30-31 (1984) (background paper by Nicholas Wade). See generally R. MERTON, *The Normative Structure of Science*, in *THE SOCIOLOGY OF SCIENCE*, *supra* note 7, at 275, originally published as *Science and Technology in a Democratic Order*, 1 J.L. & POL. SOC. 115 (1942). Merton cites a handful of counterexamples of prominent research scientists outside the biomedical sciences who have been patent holders, including Einstein, Millikan, Compton, and Langmuir. *Id.* at 275 n.16, citing W. HAMILTON, *PATENTS AND FREE ENTERPRISE* 154 (TNEC Monograph No. 31, 1941).

As recently as 1975, academic scientists Cesar Milstein and Georges Köhler decided not to patent their path-breaking and commercially valuable invention of monoclonal antibody-producing hybridoma cells. See M. KENNEY, *supra* note 1, at 129. Kenney suggests that they may have believed it inappropriate to patent such a potentially life-saving discovery. *Id.*

9. David Dickson quotes a 1934 policy statement by the president and fellows of Harvard University that "no patents primarily concerned with therapeutics or public health may be taken out by any member of the university, except with the consent of the president and fellows; nor will such patents be taken out by the university itself except for dedication to the public." D. DICKSON, *supra* note 6, at 89. Harvard abandoned this policy in 1975 after signing an agreement to give an exclusive worldwide license to Monsanto Corporation for inventions made in the course of research under a 12-year, \$23 million grant from Monsanto to the Harvard Medical School. See M. KENNEY, *supra* note 1, at 58-60, 78; Culliton, *Harvard and Monsanto: The \$23-Million Alliance*, 195 *SCIENCE* 759-63 (1977).

A notable early counterexample to the generalization that universities were averse to patenting discoveries is the University of Wisconsin, which has administered patents and licenses resulting from research discoveries of faculty through a non-profit foundation since 1925. See Blumenthal, Epstein & Maxwell, *Commercializing University Research: Lessons from the Experience of the Wisconsin Alumni Research Foundation*, 314 *NEW ENG. J. MED.* 1621 (1986).

10. As recently as 1982, a National Science Foundation study reported that in many academic fields there appeared to be a "psychological barrier to interacting with industry." Peters & Fusfeld, *supra* note 6, at 39.

sity research varied considerably prior to the Patent and Trademark Act Amendments of 1980,¹¹ a common practice was to require that rights in inventions made in the course of government-sponsored research be assigned to the government.¹² This practice accorded with the prevailing wisdom since World War II that private ownership of inventions made through public funding was contrary to the public interest.¹³

The disinclination to secure patents also had a normative component: It was thought contrary to scientific norms to claim exclusive rights in research discoveries.¹⁴ These norms derive in part from the notion that making new observations available to the scientific community for evaluation and extension in further research facilitates the progress of science.¹⁵ In the biomedical sciences, this notion has been fortified by a belief that new knowledge should be made as widely available as possible in order to serve humanity.¹⁶

A commonly held conception of the norms and incentives that guide the behavior of research scientists is set forth in the writings of sociologist Robert Merton.¹⁷ Merton identifies the overriding institutional goal of sci-

11. Pub. L. No. 96-517, 94 Stat. 3019 (codified at 35 U.S.C. §§ 200-11 (1982)). These revisions established a uniform policy permitting non-profit organizations (defined to include "universities and other institutions of higher education," 35 U.S.C. § 201(i)) and small business firms to retain title to patentable inventions made in the course of government-sponsored research. See *infra* notes 102-08 and accompanying text.

12. See Dobkin, *Patent Policy in Government Research and Development Contracts*, 53 VA. L. REV. 564, 568-84, 591-607 (1967).

13. President's Memorandum, 28 Fed. Reg. 10,943, 10,943-44 (1963); 1 U.S. DEP'T OF JUSTICE, INVESTIGATION OF GOVERNMENT PATENT PRACTICES AND POLICIES: REPORT AND RECOMMENDATIONS OF THE ATTORNEY GENERAL TO THE PRESIDENT 4-5 (1947). See generally Dobkin, *supra* note 12.

14. See *infra* text accompanying notes 17-28.

15. See *infra* text accompanying notes 17-19.

16. See *Commercialization Hearings*, *supra* note 3, at 63 (testimony of Dr. Jonathan King); M. KENNEY, *supra* note 1, at 32.

17. These writings are collected in THE SOCIOLOGY OF SCIENCE, *supra* note 7. Merton is often cited in descriptions of the traditional ethos of research science. See, e.g., D. DICKSON, *supra* note 6, at 90 n.115; J. GASTON, ORIGINALITY AND COMPETITION IN SCIENCE 5-6 & *passim* (1973); THE SCIENCE BUSINESS, *supra* note 3, at 29-30; Garfield, *Citation Measures of the Influence of Robert K. Merton*, 39 TRANSACTIONS N.Y. ACAD. SCI. SERIES II 61 (1980), and sources cited therein. The picture Merton paints of the scientific community has been criticized, however, as inaccurate and misconceived. See, e.g., J. RAVETZ, SCIENTIFIC KNOWLEDGE AND ITS SOCIAL PROBLEMS 311-12 (1971); Mulkay, *Sociology of Science in the West*, 28 CURRENT SOC. 1, 43-64 (1980), and sources cited therein; Stehr, *The Ethos of Science Revisited*, in THE SOCIOLOGY OF SCIENCE 172 (J. Gaston ed. 1978), and sources cited therein.

The fact that scientists may depart from Merton's norms in practice does not necessarily mean that they lack normative authority within the scientific community. Nicholas Wade explains:

Academic scientists quite regularly depart from the norms of universalism, communism, and disinterestedness—usually in the pursuit of personal recognition. Vigorously asserting one's claim to a discovery, even at the expense of others' legitimate claims, is surely not disinterested, and may not even be justified, but it is probably not in itself a serious threat to the purity or progress of science. Indeed, such behavior is part of the competitive attitude that characterizes many of the fastest-moving arenas of scientific inquiry. And the intensity of glory-seeking is sometimes moderated by the need to observe at least the appearance of Mertonian norms; thus *The Double Helix*, James Watson's account of the competition to discover the structure of DNA, occasioned a major stir within the scientific community not so much because it described unusual behavior but because it publicly acknowledged motives that scientists usually reserve

ence as "the extension of certified knowledge."¹⁸ The methodology for achieving this goal is empirical research. Merton describes four interrelated norms that derive from the institutional goal and the methodology: universalism, communism, disinterestedness, and organized skepticism.¹⁹ "Universalism" means that the veracity of claimed observations is to be determined on the basis of impersonal criteria without regard to the identity of the scientist who makes the observation. Since what is true in one laboratory will also be true in another, all scientists, regardless of their personal qualities or national or institutional affiliations, may draw on and contribute to the same body of certified knowledge.²⁰ "Communism" means that scientific findings are a product of social collaboration and should be dedicated to the scientific community. All discoveries build on what has been learned previously and contribute to what may be learned in the future.²¹ "Disinterestedness" means that scientists should seek truth rather than seeking to further their own interests by advancing spurious claims.²² "Organized skepticism" means that the scientific community should subject the claims and beliefs of its members to empirical scrutiny before accepting them as true.²³

Merton describes a scientific reward structure that fortifies these norms. The scientific community rewards those who make original contributions to the common stock of knowledge by giving them professional recognition.²⁴ The emphasis on originality creates pressure to publish as quickly as possible in order to avoid being forestalled by others who are doing competitive research on the same problems.²⁵ Upon publication, scientists lose exclusive use of their scientific property. The reward structure of science thereby reinforces Merton's norm of communism. By offering recognition and esteem to those who contribute to its shared body of knowledge,

for private confessions.

THE SCIENCE BUSINESS, *supra* note 3, at 30.

The presence of a norm is indicated by community embarrassment and disapproval at its violation. For example, in acknowledging violations of scientific norms concerning the sharing of new knowledge in the biomedical sciences, Jonathan King stresses that such behavior is frowned upon: "I don't mean to say there isn't professional jealousy [sic]. We have ambition and we have fame and recognition, but it is considered a departure from the normal and you are embarrassed when it comes out. It is not what you are supposed to be doing." *Commercialization Hearings*, *supra* note 3, at 63. For evidence that Merton's norms continue to influence how researchers in the biomedical sciences believe they ought to behave, see *infra* notes 112-54 and accompanying text.

18. R. MERTON, *The Normative Structure of Science*, in THE SOCIOLOGY OF SCIENCE, *supra* note 7, at 267.

19. *Id.*

20. *Id.* at 270-73.

21. *Id.* at 273-75.

22. *Id.* at 275-77.

23. Merton defines organized skepticism as "[t]he temporary suspension of judgment and the detached scrutiny of beliefs in terms of empirical and logical criteria." *Id.* at 277. This skepticism is applied to societal assumptions about the world as well as to claims of other scientists. *Id.* at 277-78.

24. R. MERTON, *Priorities in Scientific Discovery*, in THE SOCIOLOGY OF SCIENCE, *supra* note 7, at 286, originally published in 22 AM. SOC. REV. 635 (1957).

25. R. MERTON, *Behavior Patterns of Scientists*, in THE SOCIOLOGY OF SCIENCE, *supra* note 7, at 325-27, originally published in 105 PROC. AM. PHIL. SOC'Y 470 (1961).

the scientific community insures that scientists' self-interest will coincide with the public good.²⁶

This reward structure also reinforces Merton's norm of disinterestedness, in that publication involves submitting research results to the scrutiny of other scientists. Efforts to gain recognition by making false claims are unlikely to succeed; false claims may be exposed if other scientists are unable to replicate the fraudulent results.²⁷

According to this model, both the norms and the rewards of science promote prompt disclosure of new discoveries through publication. Upon publication, the scientist's observations enter the public domain, permitting the scientific community to check the veracity of her claims and to build upon them in further research.²⁸ To the extent that it might interfere with publication of new claims or limit the ability of other scientists to use published knowledge, intellectual property law has been perceived within the scientific research community as conflicting with the traditional norms and rewards of science.

B. *Traditional Intellectual Property Protection for Basic Research Discoveries*

At the same time, legal doctrine has discouraged the protection of basic research discoveries in the biomedical sciences as intellectual property. In most fields of technology, intellectual property protection can be obtained through the federal patent system, state trade secrecy law, or actual secrecy.²⁹ Limitations on patentable subject matter and requirements for patentability have operated, however, to exclude basic research discoveries

26. Merton believed that proprietary rights in discoveries conflicted with the scientific norm of communism, R. MERTON, *supra* note 18, at 275, but in fact a similar communal value may be reflected in the patent law policy of requiring disclosure and ultimate dedication to the public as the *quid pro quo* of a patent monopoly. See *infra* text accompanying notes 155-206.

27. See generally *Fraud in Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. 19-24, 55-58, 352-55 (1981) (testimony of Dr. Philip Handler, Dr. John C. Long, and Dr. Patricia Woolf, respectively) [hereinafter *Fraud Hearings*].

28. The only "payment" owed by users of the published research is citation to the original author. J. RAVETZ, *supra* note 17, at 247, 255. The frequency of citation to a publishing scientist's work is a measure of the esteem in which it is held. *Id.* at 257.

29. A notable exception to this general rule is computer software, which may be protected under the copyright statute but not under the patent statute. See Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959 (1986); Davidson, *Protecting Computer Software: A Comprehensive Analysis*, 1983 ARIZ. ST. L.J. 611; Samuelson, *CONTU Revisited: The Case Against Copyright Protection for Computer Programs in Machine-Readable Form*, 1984 DUKE L.J. 663; cf. *Diamond v. Diehr*, 450 U.S. 175 (1981) (processes incorporating computer programs may be patented, although computer programs themselves may not be patented). For an argument that genetically engineered organisms are works of authorship entitled to copyright protection, see Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH. L. REV. 191 (1982).

Recently, Congress has provided *sui generis* copyright-like protection for semiconductor chip masks. Semiconductor Chip Protection Act of 1984, Pub. L. No. 98-620, 98 Stat. 3347 (codified at 17 U.S.C. §§ 901-14 (Supp. III 1985)). See generally *Symposium: The Semiconductor Chip Protection Act of 1984 and Its Lessons*, 70 MINN. L. REV. 263 (1985).

from patent protection. Even without patent protection, some basic research discoveries can be protected through the law of trade secrecy. Depending on the scope of permissible subject matter under applicable state law, however, basic research discoveries may not qualify for legal protection as trade secrets either, although they might still be protected as a practical matter through a program of actual secrecy. Both forms of secrecy require substantial nondisclosure, thereby preventing researchers from attaining recognition and conflicting with traditional scientific norms.

1. *Doctrinal Impediments to Patent Protection*

A patent gives an inventor³⁰ the exclusive right to make, use, and sell the invention in the United States for a period of seventeen years.³¹ At the end of this period, the invention becomes freely available to all. To qualify for patent protection, an invention must fall within patentable subject matter³² and must satisfy the further statutory requirements of novelty,³³ utility,³⁴ and nonobviousness.³⁵ In exchange for the property rights conferred by the patent system, the inventor must disclose her invention to the public.³⁶ Insofar as patent law not only permits but even requires disclosure, it is more congruent with scientific norms than either legal trade secrecy or actual secrecy.³⁷ Nonetheless, patent protection has often been unavailable for basic research discoveries in the biomedical sciences.

Traditional patent law doctrine has confined the reach of patent protection to inventions in applied technology, as distinguished from basic scientific research. This focus on applied technology derives in part from the language of the Constitution, which authorizes Congress "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."³⁸ This provision is traditionally read distributively. Under this reading, the function of the patent law is to promote the progress of "useful Arts" (i.e., applied technology) by securing exclusive rights to

30. Patent applications must generally be made by the inventor or inventors, 35 U.S.C. §§ 111, 115, 116 (1982), although in some instances persons other than the inventor who have proprietary interests in the invention may apply for a patent. 35 U.S.C. §§ 117, 118 (1982). Patents and patent applications may be assigned by the inventor to someone else. 35 U.S.C. §§ 152, 261 (1982).

31. 35 U.S.C. §§ 154, 271(a) (1982); see *infra* notes 207-14 and accompanying text.

32. 35 U.S.C. § 101 (1982).

33. 35 U.S.C. §§ 101, 102 (1982).

34. 35 U.S.C. §§ 101, 112 (1982).

35. 35 U.S.C. § 103 (1982); *Graham v. John Deere*, 383 U.S. 1, 13-19 (1966).

36. 35 U.S.C. § 112 (1982).

37. Cf. *Commercialization Hearings*, *supra* note 3, at 79 (testimony of Dr. William Raub, National Institutes of Health) ("[M]any biomedical scientists, perhaps most, regard the patent process as a means of institutionalized secrecy, whereas it is in fact a time-tested way to assure broad and ready access to proprietary information."); see also *infra* notes 162-206 and accompanying text (comparing disclosure under patent system with disclosure motivated by scientific norms).

38. U.S. CONSR. art. I, § 8, cl. 8.

"Inventors" in their "Discoveries," while the function of the copyright law is to promote the progress of "Science" (i.e., knowledge in general) by securing exclusive rights to "Authors" in their "Writings."³⁹ So understood, the Constitution only authorizes Congress to extend patent protection to inventions in applied technology.

Congress has accordingly defined patentable subject matter to limit patent protection to applied technology. The present patent statute defines as patentable subject matter "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."⁴⁰ Applying this definition and its predecessors in earlier legislation, the cases have denied patent protection to theoretical or abstract discoveries,⁴¹ laws of nature, products of nature,⁴² principles, abstract ideas, mathematical formulae, and algorithms.⁴³ Patents are issued only for the discovery of new means to achieve useful results.⁴⁴ To the extent that basic research discoveries comprise explanations for existing means of achieving useful results or principles that are only put into practical use later by the work of others, they may not be protected by patent.⁴⁵

Patent law doctrine further restricts the patentability of basic research discoveries through the requirement that a patent applicant make a disclosure demonstrating that the invention is "operable and capable of use" before a patent will issue.⁴⁶ This requirement impedes the patenting of basic research discoveries in two ways. First, if technical problems remain to be solved before the discovery may be put to practical use, it may not yet be patented. Second, an invention with no demonstrated "utility" may not be patented, however interesting and significant it may be to research scientists. The Supreme Court has held that a patent applicant must demonstrate a specific and substantial utility for a claimed invention. The

39. See, e.g., *In re Bergy*, 596 F.2d 952, 958-59 (C.C.P.A. 1979), *aff'd sub nom.* *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) ("[T]he constitutionally-stated purpose of granting patent rights to inventors for their discoveries is the promotion of progress in the 'useful Arts,' rather than in science. . . . [T]he present day equivalent of the term 'useful arts' employed by the Founding Fathers is 'technological arts.'"). See generally 1 D. CHISUM, *supra* note 7, § 1.01 n.9 (1987) (Congress may enact patent legislation only to promote "useful arts," not to promote "science" or knowledge in general).

40. 35 U.S.C. § 101 (1982).

41. *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1938); *In re King*, 801 F.2d 1324, 1328 (Fed. Cir. 1986); 1 D. CHISUM, *supra* note 7, § 1.01.

42. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

43. *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63 (1972).

44. 1 D. CHISUM, *supra* note 7, § 1.01.

45. *Id.* § 1.03[2]. As Chisum remarks, some courts have noted the irony of denying patent protection to the discoverers of fundamental scientific principles, while extending protection to "those lesser geniuses who put such discoveries to practical uses." *Id.* (quoting opinion of Frank, J., in *Katz v. Horni Signal Mfg. Corp.*, 145 F.2d 961, 961 (2d Cir. 1944)). The Supreme Court has justified the distinction on the ground that scientific principles are the "basic tools" of science and technology. *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). Judge Frank has offered another rationale: Great scientists are not motivated by pecuniary gain, so the prospect of a patent monopoly will not enhance their productivity. *Katz*, 145 F.2d at 961.

46. This requirement derives from 35 U.S.C. §§ 101, 112 (1982). See 1 D. CHISUM, *supra* note 7, at § 4.04.

fact that the claimed invention "may be an object of scientific research" does not satisfy the utility standard.⁴⁷ Thus, under existing law, many basic research discoveries are not yet ripe for patent protection.

Even in the area of applied technology, patent protection for inventions in the biomedical sciences has been retarded by cases holding that medical and agricultural processes may not be patented.⁴⁸ While the rationale for these cases is not entirely clear,⁴⁹ at least one court seems to have believed that a patent monopoly on methods of medical treatment is contrary to the ethics of medical doctors and the public interest:

Doctors and surgeons have seldom thought it desirable to patent their new procedures for human relief. . . . The professional ethics of doctors and surgeons are more consistent with the widespread use of their medical and surgical discoveries for the benefit of mankind than in obtaining a monopoly to control their discoveries for personal commercial advantage. In this respect it would seem also that public interest is here involved.⁵⁰

Finally, prior to the Supreme Court's 1980 decision in *Diamond v. Chakrabarty*,⁵¹ patent protection for biological materials was retarded by the longstanding belief that living organisms and cells were unpatentable products of nature.⁵² One explanation for this limitation on patentable

47. *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966).

48. See generally 1 D. CHISUM, *supra* note 7, § 1.03[3], and cases cited therein. Medical *products* (such as drugs), as opposed to medical *processes*, may be patentable. See *Ruskin v. Coe*, 58 F. Supp. 424 (D.D.C. 1945).

49. The origin of the rule that medical procedures may not be patented is apparently the holding in *Morton v. New York Eye Infirmary*, 17 F. Cas. 879 (S.D.N.Y. 1862) (No. 9865). The inventors in that case discovered that ether could be used as an anesthetic for patients undergoing surgery. The court acknowledged that the inventors had made one of the "greatest discoveries of modern times," but concluded nonetheless that it was not a patentable invention: "A discovery may be brilliant and useful, and not patentable. . . . The new force or principle brought to light must be embodied and set to work, and can be patented only in connection or combination with the means by which, or the medium through which, it operates." *Id.* at 884. The court followed similar reasoning in *Wall v. Leck*, 66 F. 552 (9th Cir. 1895), extending the exclusion from patent protection to agricultural methods.

In *Ex parte Brinkerhoff*, 24 Comm'r Ms. Dec. 349 (1883), reprinted in 27 J. PAT. OFF. SOC'y 797, 798 (1945), the Commissioner of Patents offered another rationale for excluding medical procedures from patent protection—that the effectiveness of such treatments is uncertain, and granting a patent might have a tendency to deceive the public into believing that the method is more foolproof than it is.

Subsequent decisions have retreated somewhat from the rules of *Morton* and *Brinkerhoff*, extending patent protection to a skin test for detecting the susceptibility of a human being to scarlet fever, *Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628 (S.D.N.Y. 1930), and a method of injecting medications by a pressure jet, *Ex parte Scherer*, 103 U.S.P.Q. (BNA) 107 (P.T.O. Bd. App. 1954).

50. *Martin v. Wyeth, Inc.*, 96 F. Supp. 689, 695 (D. Md. 1951), *aff'd*, 193 F.2d 58 (4th Cir. 1951).

51. 447 U.S. 303 (1980); see *infra* notes 60-66 and accompanying text.

52. See generally 1 D. CHISUM, *supra* note 7, § 1.02[7][a]-[b], and cases cited therein; Biggart, *Patentability, Disclosure Requirements, Claiming and Infringement of Microorganism-Related Inventions*, in GENETICALLY ENGINEERED MICROORGANISMS & CELLS: THE LAW & THE BUSINESS C (I. Kayton ed. 1981) [hereinafter GENETICALLY ENGINEERED ORGANISMS].

Prior to *Chakrabarty*, two federal statutes provided intellectual property protection for new plants. The Plant Patent Protection Act of 1930, 46 Stat. 376 (codified at 35 U.S.C. §§ 161-164 (1982)),

subject matter is that in order to be patentable a product must be new, and naturally-occurring organisms are not new.⁵³ New *processes* using preexisting naturally-occurring products could be patented, but the *products* themselves could not.⁵⁴ An applicant who seeks a patent monopoly on a naturally-occurring product would deprive the public of the use of something "which nature has produced and which nature has intended to be equally for the use of all men."⁵⁵

The Supreme Court's decision in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*⁵⁶ suggested a broader, if somewhat less coherent, limitation on patentable subject matter under the "products of nature" doctrine. The claimed invention in that case was a combination of selected strains of naturally-occurring bacteria. When inoculated into leguminous plants, the bacteria enabled the plants to fix nitrogen from the air.⁵⁷ Although the mixture of strains was a new product in that the selected strains did not naturally occur in combination, the Supreme Court held the patent invalid. The precise basis for the decision is unclear. Justice Douglas, writing for the majority, suggested both that the invention was a product of nature outside the scope of patentable subject matter⁵⁸ and that the combination of species failed to satisfy the nonobviousness or "invention" requirement.⁵⁹

extended patent protection to asexually reproduced plants, and the Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542 (codified at 7 U.S.C. §§ 2321-2583 (1982)), allowed breeders of sexually reproduced plants to obtain patent-like protection from the Department of Agriculture.

53. Once the patent applicant has modified the product in any significant respect from its naturally-occurring state, this "product of nature" objection would seem to be overcome, since the claimed invention would then be a "manufacture" or "composition of matter" and thus within the statutory subject matter. 1 D. CHISUM, *supra* note 7, § 1.02[7][a].

54. *In re Mancy*, 499 F.2d 1289, 1294 (C.C.P.A. 1974) (distinction between new products and new processes); *Guaranty Trust Co. of New York v. Union Solvents Corp.*, 54 F.2d 400, 411 (D. Del. 1931) (same).

55. *Ex parte Latimer*, 1889 Dec. Comm'r Pat. 123, 125 (1889).

56. 333 U.S. 127 (1948).

57. Different species of bacteria were effective for different crops, and multiple strains existed within each species. The patentee was the first to identify strains of bacteria that could be combined without inhibiting one another's effectiveness, permitting farmers to buy a single mixed culture inoculant usable for multiple crops. *Id.* at 129-30.

58. "The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none." *Id.* at 130.

59. [T]here is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough.

Id. at 132.

In a concurring opinion, Justice Frankfurter suggested a more cogent basis for holding the patent invalid—that the patent claims were overly broad in extending to any mixture of compatible strains, rather than just the particular mixture derived by the patentee, and that the same failure to identify the particular compatible strains used by the patentee also made the description of the invention inadequate. *Id.* at 133-35. The description problem for inventions requiring the use of living organisms is now generally resolved by depositing cultures of the organisms in recognized depositories. *See infra* notes 167-78 and accompanying text.

Thirty-two years later, in *Diamond v. Chakrabarty*,⁶⁰ the Supreme Court held in a five to four decision that a living, genetically-engineered microorganism itself fell within the statutory categories of patentable subject matter as either a "manufacture" or a "composition of matter." The majority held that living things are not categorically excluded from patent protection, noting that the relevant distinction is "not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."⁶¹ While the *Chakrabarty* decision makes plain that the subject matter of patents extends to genetically-engineered microorganisms and that living things are not per se excluded from patent protection, the Supreme Court did not reach the issue of whether naturally-occurring microorganisms that have been newly isolated or purified also fall within the ambit of "manufactures" or "compositions of matter."⁶²

Since the *Chakrabarty* decision, the Patent and Trademark Office (PTO) has extended patent protection to plants⁶³ and indicated that non-naturally-occurring polyploid oysters would be patentable if the invention were nonobvious.⁶⁴ The Commissioner of Patents recently issued a notice announcing that the PTO "now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 USC 101."⁶⁵ The Commissioner of

60. 447 U.S. 303 (1980).

61. *Id.* at 313. Chakrabarty modified an existing bacterial strain by introducing new deoxyribonucleic acid (DNA) plasmids into a bacterial cell, thereby giving the organism the capacity to break down multiple components of crude oil. In so doing, he "produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility." *Id.* at 310. The Court concluded that the resulting organism "is not nature's handiwork, but [Chakrabarty's] own." *Id.*

62. A companion case, *In re Bergy*, involved a claim to a biologically pure culture of an organism occurring in nature only in impure form. 563 F.2d 1031 (C.C.P.A. 1977), *vacated sub nom.* Parker v. Bergy, 438 U.S. 902 (1978), *on remand*, *In re Bergy*, 596 F.2d 952, *cert. granted sub nom.* Parker v. Bergy, 444 U.S. 924 (1979), *vacated and remanded with instructions to dismiss as moot sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980). The Court of Customs and Patent Appeals held that the claims in both *Chakrabarty* and *Bergy* recited patentable subject matter. 596 F.2d at 952. Dicta from the Court of Customs and Patent Appeals in *In re Bergy* rejected the argument that a "biologically pure culture" of an organism existing naturally only in impure form is an unpatentable product of nature, *id.* at 972-73, but so far no appellate court holding has resolved the issue. The Patent and Trademark Office (PTO) has been issuing patents on such organisms, and it seems likely that the Court of Appeals for the Federal Circuit would follow the *Bergy* dicta if the issue were to arise. See *generally* South Corp. v. United States, 690 F.2d 1368 (Fed. Cir. 1982) (Court of Appeals for Federal Circuit will consider prior decisions of Court of Customs and Patent Appeals binding as precedent).

63. *In re Hibberd*, 227 U.S.P.Q. (BNA) 443, 444 (P.T.O. Bd. App. & Int. 1985). Plants may also qualify for more limited protection under the Plant Patent Act, 35 U.S.C. §§ 2321-2364 (1982), or the Plant Variety Protection Act, 7 U.S.C. §§ 2321-2583 (1982). The Plant Patent Act grants "the right to exclude others from asexually reproducing the [protected] plant or selling or using the plant so reproduced," 35 U.S.C. § 163, while the Plant Variety Protection Act grants the right "to exclude others from selling the [protected] variety, or offering it for sale, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom . . ." 7 U.S.C. § 2483(a).

64. *In re Allen*, 2 U.S.P.Q.2d (BNA) 1425 (P.T.O. Bd. App. & Int. 1987).

65. *Nonnaturally Occurring Non-Human Animals Are Patentable Under § 101*, 33 Pat. Trade-mark & Copyright J. (BNA) No. 827, at 664 (Apr. 23, 1987).

Patents cited *Chakrabarty* for the proposition that Congress intended the subject matter of patents to "include anything under the sun that is made by man," but reiterated that products found in nature may not be patented.⁶⁶

In short, although patent protection has previously been unavailable for basic research discoveries in general and for those in the biomedical sciences in particular, the trend of recent authority is towards increasing availability of patent protection for biotechnology-related inventions.

2. *Doctrinal, Practical, and Normative Impediments to Protection Through Secrecy*

Even in the absence of patent protection, however, inventors can sometimes protect their research discoveries through some form of secrecy. The term "trade secrecy" is often used ambiguously⁶⁷ to refer to two different types of protection: legal trade secrecy and actual secrecy. Legal trade secrecy affords a remedy in tort to persons who disclose certain kinds of information in confidence against those who breach this confidence or who otherwise misappropriate the information. Actual secrecy is a practical, nonlegal strategy for protection that may be effective in circumstances where not all of the legal requirements for trade secrecy protection have been satisfied.⁶⁸ Since in many jurisdictions legal trade secrecy doctrine might exclude from protection research discoveries not yet put to use in a

66. *Id.* It is not clear at this time whether Congress will permit the new policy of the PTO on the patentability of non-naturally-occurring, non-human animals to go into effect. Shortly after the Commissioner's announcement, the Senate adopted an amendment to a supplemental appropriations bill, H.R. 1827, 100th Cong., 1st Sess. (1987), that would have barred the use of funds appropriated for fiscal year 1987 "for the purpose of granting any patent for vertebrate or invertebrate animals, modified, altered, or in any way changed through engineering technology, including genetic engineering." *Id.*, amendment no. 245, 133 CONG. REC. S7268 (daily ed. May 28, 1987); see *Senate Votes Moratorium on Patenting of Animals*, 34 Pat. Trademark & Copyright J. (BNA) No. 833, at 124 (June 4, 1987). The Senate amendment was stricken, however, in conference, after the PTO indicated that it would not grant patents on animals during the remainder of fiscal year 1987. 100th Cong., 1st Sess., 133 CONG. REC. H5654 (daily ed. June 27, 1987) (Joint Explanatory Statement of the Committee of Conference); 34 Pat. Trademark & Copyright J. (BNA) No. 838, at 277 (July 16, 1987). A currently pending House bill would impose a two-year moratorium on the issuance of animal patents. H.R. 3119, 100th Cong., 1st Sess., 133 CONG. REC. H7206 (daily ed. Aug. 5, 1987); see *House Bill Would Impose Two-Year Moratorium on Patenting Animals*, 34 Pat. Trademark & Copyright J. (BNA) No. 841, at 351 (Aug. 6, 1987). In the meantime, the House Subcommittee on Courts, Civil Liberties and the Administration of Justice has held hearings on the animal patenting issue. See *House Panel Holds Third Hearing on Animal Patents*, 34 Pat. Trademark & Copyright J. (BNA) No. 845, at 460 (Sept. 3, 1987); *House Panel Resumes Hearings on Animal Patenting Issue*, 34 Pat. Trademark & Copyright J. (BNA) No. 840, at 321 (July 30, 1987); *Hearing Ponders Patentability of Genetically Altered Animals*, 34 Pat. Trademark & Copyright J. (BNA) No. 835, at 191 (June 18, 1987).

67. For example, Roman Saliwanchik states that "[a]n inventor has the right to hold any invention in secret as a trade secret." R. SALIWANCHIK, *LEGAL PROTECTION FOR MICROBIOLOGICAL AND GENETIC ENGINEERING INVENTIONS* 9 (1982) (emphasis added). This statement is clearly incorrect if he means to refer to legal trade secrecy, see *infra* text accompanying notes 68-88, yet his use of the terms "right" and "trade secret" suggests that it is indeed legal protection that he has in mind.

68. Actual secrets may also receive legal protection outside of trade secrecy law, through laws against trespass or theft.

business, actual secrecy may offer the only feasible strategy for protecting such discoveries.

Trade secrecy is usually governed by state common law, although an increasing number of jurisdictions have enacted statutory trade secret protection,⁶⁹ and a handful of federal statutes protect trade secret rights once they have accrued under state law.⁷⁰ Trade secret doctrine varies somewhat among jurisdictions, but the basic requirements are similar in most states. State law generally limits the permissible subject matter of trade secret protection⁷¹ and further requires that the owner of a trade secret demonstrate some measure of actual secrecy,⁷² reasonable efforts to maintain secrecy,⁷³ and misconduct by the defendant in acquiring, using, or disclosing the trade secret.⁷⁴

In most jurisdictions, the permissible subject matter is quite broad, but it does have limits that potentially exclude basic research discoveries. The definition in the first Restatement of Torts,⁷⁵ which many jurisdictions follow,⁷⁶ is susceptible to such a construction:

A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers [I]t is not simply information as to single or ephemeral events in the conduct of the business A trade secret is a process or device for continuous use in the operation of the business. Generally

69. See *infra* note 79; ARK. STAT. ANN. §§ 70-1001-1007 (1985); IDAHO CODE §§ 48-801 to -807 (1984); MASS. ANN. LAWS ch. 93, §§ 42, 42A (Law. Co-op. 1982); N.M. STAT. ANN. §§ 30-16 to -24 (1978); N.C. GEN. STAT. §§ 66-152 to -157 (1985).

70. See, e.g., Freedom of Information Act, 5 U.S.C. § 552b(c)(4) (1982) (exempting trade secrets from disclosure obligation of government agencies); Trade Secrets Act, 18 U.S.C. § 1905 (1982) (prohibiting disclosure of trade secrets by federal employees).

71. See, e.g., *SI Handling Systems v. Heisley*, 753 F.2d 1244 (3d Cir. 1985); *American Alloy Steel Corp. v. Ross*, 149 Cal. App. 2d 215, 308 P.2d 494 (1957); *Revcor, Inc. v. Fame, Inc.*, 85 Ill. App. 2d 350, 228 N.E.2d 742 (1967).

72. See, e.g., *SI Handling Systems v. Heisley*, 753 F.2d 1244, 1256 (3d Cir. 1985); *K-2 Ski Co. v. Head Ski Co.*, 506 F.2d 471, 473-74 (9th Cir. 1974); *Emery Co. v. Marcan Prod. Corp.*, 389 F.2d 11, 16 (2d Cir. 1968); *Koehring Co. v. E.D. Etnyre & Co.*, 254 F. Supp. 334, 339 (N.D. Ill. 1966).

73. See, e.g., *Revcor, Inc. v. Fame, Inc.*, 85 Ill. App. 2d 350, 355, 228 N.E.2d 742, 745 (1967).

74. See, e.g., *E.I. duPont de Nemours & Co. v. Christopher*, 431 F.2d 1012, 1014-15 (5th Cir. 1970), *cert. denied*, 400 U.S. 1024 (1971); *Franke v. Wiltscchek*, 209 F.2d 493, 500 (2d Cir. 1953).

75. RESTATEMENT OF TORTS, § 757 comment b (1939).

76. See, e.g., *Ruesch v. Ruesch Int'l Monetary Servs.*, 479 A.2d 295 (D.C. 1984); *Koch Eng'g Co. v. Faulconer*, 227 Kan. 813, 610 P.2d 1094 (1980); *Engineered Mechanical Servs. v. Langlois*, 464 So. 2d 329 (La. Ct. App. 1984); *Jet Spray Cooler v. Crampton*, 385 N.E.2d 1349 (Mass. 1979); *Delta Filter Corp. v. Morin*, 108 A.D.2d 991, 485 N.Y.S.2d 143 (N.Y. App. Div. 1985); *Felmlee v. Lockett*, 466 Pa. 1, 351 A.2d 273 (1976).

The *Restatement (Second) of Torts* covers neither trade secrets nor the broader topic of "Miscellaneous Trade Practices" under which trade secrecy was subsumed in the first Restatement. See 4 RESTATEMENT (SECOND) OF TORTS 1-2 (1979).

it relates to the production of goods, as, for example, a machine or formula for the production of an article.⁷⁷

This definition could be read to exclude information about ongoing research on the ground that it has not yet ripened into "a process or device for continuous use in the operation of a business."⁷⁸

The definition of "trade secret" under the Uniform Trade Secrets Act⁷⁹ is considerably more amenable than the Restatement definition to a construction that permits protection of knowledge generated in the course of scientific research. Section 1(4) of the Act defines "trade secret" as follows:

"Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

(i) derives independent economic value, present or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and

(ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

As the Commissioners' Comment to this definition makes clear, the Uniform Trade Secrets Act goes beyond the Restatement to extend trade secret protection both to information not yet put to use and to negative information.⁸⁰ Thus, in those jurisdictions that have enacted the Uniform Trade Secrets Act, trade secret protection may be more readily available

77. RESTATEMENT OF TORTS, *supra* note 75, at § 757 comment b.

78. Another type of research information that might be denied protection under a strict reading of the Restatement is "negative information," such as data on failed experiments. A researcher might well wish to keep such information secret, since knowing to avoid these dead ends might save a competitor time and money. Yet this kind of information could be viewed as "simply information as to single or ephemeral events in the conduct of the business" and therefore not protectible as a trade secret.

79. The Uniform Trade Secrets Act was approved by the National Conference of Commissioners on Uniform State Laws in 1979, and approved again with amendments in 1985. UNIF. TRADE SECRETS ACT, 14 U.L.A. 537-51 (1980 & Supp. 1986). It has been adopted by state legislatures in California, CAL. CIV. CODE §§ 3426-3426.10 (West 1984), CAL. CIV. PROC. CODE § 2019(e) (West 1987); Connecticut, CONN. GEN. STAT. ANN. §§ 35-50 to -58 (West 1983); Delaware, DEL. CODE ANN. tit. 6, §§ 2001-2007 (1986); Indiana, IND. CODE ANN. §§ 24-2-3-1 to -8 (West 1982); Kansas, KAN. STAT. ANN. §§ 60-3320 to -3330 (1983); Louisiana, LA. REV. STAT. ANN. §§ 51:1431-1439 (West Supp. 1984); Minnesota, MINN. STAT. ANN. §§ 325C.01-.08 (West 1980); Montana, MONT. CODE ANN. §§ 30-14-401 to -409 (1985); North Dakota, N.D. CENT. CODE §§ 47-25.1-01 to -08 (1983); and Washington, WASH. REV. CODE §§ 19.108.010-.940 (1981).

80. The pertinent language of the Commissioners' Comment reads as follows:

The definition of "trade secret" contains a reasonable departure from the Restatement of Torts (First) definition which required that a trade secret be "continuously used in one's business." The broader definition in the proposed Act extends protection to a plaintiff who has not yet had an opportunity or acquired the means to put a trade secret to use. The definition includes information that has commercial value from a negative viewpoint, for example the results of lengthy and expensive research which proves that a certain process will *not* work could be of great value to a competitor.

UNIF. TRADE SECRETS ACT § 1 comment, 14 U.L.A., at 543 (emphasis in original).

for research discoveries than it is in jurisdictions that follow the Restatement definition.

The requirements of actual secrecy and reasonable efforts to maintain secrecy create considerable practical difficulties. Although absolute secrecy is not required,⁸¹ the claimed trade secret may not be generally known or readily ascertainable by proper means.⁸² Efforts to maintain secrecy are costly and may be foiled.⁸³

Microorganism cultures are especially difficult to maintain as trade secrets because they are easily stolen without detection and propagate rapidly. A small sample of a culture can supply a competitor with bountiful quantities of commercially valuable organisms. The practical difficulty involved in protecting such materials as trade secrets is illustrated by a notorious early biotechnology trade secret case involving microorganism cultures used by American Cyanamid to produce antibiotics and steroids. Although the cultures were maintained as proprietary materials within the company, employees purloined sample cultures of the microorganisms from an American Cyanamid research facility and sold them to foreign pharmaceutical firms. The incident led to criminal convictions of two American Cyanamid employees⁸⁴ as well as civil trade secret actions for damages.⁸⁵

The final requirement of a trade secret claim—wrongdoing by the defendant in acquiring, using, or disclosing the trade secret—further limits the effectiveness of trade secrecy as a strategy for protection in competitive research fields. This requirement insulates from liability anyone who derives the trade secret through independent research,⁸⁶ reverse engineer-

81. Trade secrecy is not lost through disclosure in the course of a confidential relationship or pursuant to an agreement to keep the secret—indeed, the law of trade secrets protects the confidentiality of such disclosures.

82. See, e.g., *SI Handling Systems v. Heisley*, 753 F.2d 1244 (3d Cir. 1985); *K-2 Ski Co. v. Head Ski Co.*, 506 F.2d 471 (9th Cir. 1974); *A.H. Emery Co. v. Marcan Prod. Corp.*, 389 F.2d 11 (2d Cir. 1968); *Sandlin v. Johnson*, 152 F.2d 8 (8th Cir. 1945); *Juliano v. Hobart Mfg. Co.*, 200 F. Supp. 453 (D. Mass. 1961), *aff'd*, 303 F.2d 830 (1st Cir. 1962).

83. See, e.g., *E.I. duPont de Nemours & Co. v. Christopher*, 431 F.2d 1012 (5th Cir. 1970), *cert. denied*, 400 U.S. 1024 (1971). Typical measures include labeling documents or laboratory notebooks "Confidential," limiting disclosure on a "need to know" basis, and obtaining confidentiality agreements from employees and other persons to whom disclosure is made. See Sobel, *Preserving Trade Secret Protection*, in *PRACTISING LAW INSTITUTE, PATENT, COPYRIGHTS, TRADEMARKS, & LITERARY PROPERTY COURSE HANDBOOK SERIES NO. 224, PROTECTING TRADE SECRETS* 567 (1986) [hereinafter *PROTECTING TRADE SECRETS*].

84. *United States v. Bottone*, 365 F.2d 389 (2d Cir.), *cert. denied*, 385 U.S. 974 (1966) (criminal prosecution under National Stolen Property Act).

85. *American Cyanamid Co. v. Sharff*, 309 F.2d 790 (3d Cir. 1962) (civil contempt proceeding against defendant who refused to answer questions in deposition in civil action for misappropriation of trade secrets); *American Cyanamid Co. v. Fox*, 140 U.S.P.Q. (BNA) 199 (N.Y. Sup. Ct. 1964) (civil action for misappropriation of trade secrets and breach of employment agreement).

86. See, e.g., *Speedry Chem. Prods. v. Carter's Ink Co.*, 306 F.2d 328, 330 (2d Cir. 1962) (right to independent discovery of secret has long history); *Greenberg v. Croydon Plastics Co.*, 378 F. Supp. 806, 812 (E.D. Pa. 1974) (others in field who arrive at independent discovery may use plaintiff's trade secret).

ing,⁸⁷ or information obtained from publicly available sources.⁸⁸ Once the "secret" becomes generally known to other scientists through independent discovery, the first discoverer loses protection. Thus, even where state law extends protection to research discoveries, the protection may not last for long.

Trade secrecy presents a further problem for scientists who are conditioned by traditional scientific norms and rewards. The parsimonious hoarding of information necessary to maintain secrecy interferes with scientific communication and frustrates the pursuit of scientific recognition. Public disclosure, such as publication in a scientific journal or presentation of a paper, ends actual secrecy and with it trade secret protection.⁸⁹ Moreover, publication violates the requirement that the owner of the trade secret take reasonable efforts to maintain its secrecy.⁹⁰

While both trade secrecy and actual secrecy foreclose scientific recognition in exchange for protection that may prove fragile and short-lived, trade secrecy may be more disruptive of scientific communication than actual secrecy. Actual secrecy is only one of the elements of a trade secret claim; compliance with the other requirements, such as reasonable efforts to maintain secrecy, may also impede scientific communication. A public disclosure that facilitates reverse engineering may be enough to terminate the right to enforce a trade secret claim⁹¹ even before it ends actual secrecy.⁹² If researchers who wish to earn recognition in the scientific com-

87. See, e.g., *Smith v. Dravo Corp.*, 203 F.2d 369, 375 (7th Cir. 1953) (person may legally obtain trade secret through inspection and analysis of product).

88. *Sinclair v. Aquarius Elec.*, 42 Cal. App. 3d 216, 226, 116 Cal. Rptr. 654, 661 (1974) (by definition, trade secret is something which has not been placed in public domain).

89. See, e.g., *Fishing Concepts, Inc. v. Ross*, 226 U.S.P.Q. (BNA) 692, 695 (D. Minn. 1985) (disclosure of claimed trade secret in advertising textbook ends status as trade secret).

The more typical avenue for terminating trade secrecy through public disclosure is the sale of a product from which the secret can be reverse engineered. See, e.g., *Midland-Ross Corp. v. Sunbeam Equip. Corp.*, 316 F. Supp. 171, 177 (W.D. Pa.), *aff'd*, 435 F.2d 159 (3d Cir. 1970) (sale of product ends trade secrecy where nature of trade secret is ascertainable by inspection of product). *But cf.* *Smith v. Dravo Corp.*, 203 F.2d 369 (7th Cir. 1953) (fact that trade secret could have been discovered through inspection of product does not preclude trade secret action against defendant who instead obtained and used information improperly); *Tabor v. Hoffman*, 118 N.Y. 30, 23 N.E. 12 (1889) (surreptitious duplication of patterns for manufacture of pump actionable notwithstanding fact that patterns could be derived from pumps themselves with sufficient time and effort); *Classic Instruments v. VDO-Argo Instruments*, 73 Or. App. 732, 700 P.2d 677 (Ct. App. 1985) (use of blueprints communicated in confidence was actionable notwithstanding fact that trade secrets could be ascertained from product sold on open market).

90. The content of this requirement varies with the circumstances of each case. Disclosure to persons who have no need to know the secret, or who are not obligated to maintain its confidentiality, ends trade secret protection. *Sandlin v. Johnson*, 152 F.2d 8 (8th Cir. 1945); *Crown Indus. v. Kawaner Co.*, 335 F. Supp. 749 (N.D. Ill. 1971). Requiring reasonable efforts to preserve secrecy serves to alert potential misappropriators to the owner's claim of trade secrecy and to weed out spurious after-the-fact claims of trade secrecy involving information that has been freely disclosed.

91. See *Van Prods. Co. v. General Welding & Fabricating Co.*, 419 Pa. 248, 264-65, 213 A.2d 769, 778 (1965) (patent specification destroys trade secrecy after patent granted).

92. For example, suppose the scientists at American Cyanamid who discovered the tetracycline-producing microorganisms had wanted to gain recognition for their discovery in the scientific community through publication, but the company was unwilling to release the microorganism culture to the public. The company might have permitted publication of a description of the research, provided that

munity can publish general descriptions of their research while keeping essential aspects of their inventions to themselves, they may find actual secrecy to be a more agreeable strategy than legal trade secrecy.

II. CONJUNCTION OF INTELLECTUAL PROPERTY AND BASIC RESEARCH IN BIOTECHNOLOGY

A. *Developments Bringing About the Conjunction*

Scientists working in biotechnology-related fields are increasingly likely to be concerned simultaneously with the norms and rewards of research science and the rules and incentives created by intellectual property law.⁹³ Research involving recombinant DNA and hybridoma technologies can create new organisms with the capacity to make desired products.⁹⁴ The obvious commercial potential of these technologies has attracted the interest of industrial sponsors.⁹⁵ The products of biotechnology research are often readily commercialized—especially when the research is conducted in affiliation with commercial companies.

The interest of industrial sponsors in biotechnology research is not confined to product development. In this field, the traditional dividing line between basic and applied research is blurred. Not only has the historical time lag between the two collapsed, but it has become difficult to characterize given research problems as belonging in one category or the other.⁹⁶

the microorganism itself were withheld from the public. In so doing, the company might have compromised its position in the event of a subsequent trade secret action. Arguably, the publication would have constituted a failure to use "reasonable efforts to maintain secrecy" or made the invention "readily ascertainable by proper means." Nonetheless, even without a legal trade secret remedy, American Cyanamid might have been able to maintain the microorganism culture as an actual secret for a while by keeping it within the company.

93. See generally Grobstein, *supra* note 3.

94. Recombinant DNA technology can alter the genetic information of cells, enabling the cells to make desired proteins. Every living cell contains genetic information in the form of deoxyribonucleic acid (DNA) inherited from the progenitors of the organism of which that cell is a part. When cells replicate, the new cells in turn inherit a copy of the parent cells' DNA. DNA is a long molecule in the form of a double helix composed of two chains of subunits called nucleotides. One of the components of each nucleotide is a base, of which there are four different kinds: adenine, guanine, cytosine, and thymine. DNA provides the cell with instructions on how to make the proteins it needs to survive. These instructions are coded in the sequence in which the four bases occur. Each group of instructions corresponding to an individual protein is called a gene and comprises a small portion of one chain of the DNA molecule. All organisms use the same genetic code for protein synthesis, although different organisms make different proteins in accordance with the different DNA sequences in their cells. Recombinant DNA technology involves taking genetic information from one cell and splicing it into the DNA of another cell—or even combining the DNA of two different organisms. In this manner, simple, single-celled organisms such as bacteria can be programmed to make human proteins. The recombinant organism can then be used as a living factory to make the protein encoded in the cloned gene. See W. KEETON, *BIOLOGICAL SCIENCE* 63–64, 665–66 (3d ed. 1980).

Hybridoma technology involves the fusion of antibody-producing lymphoid cells with tumor cells to create new cell lines that can make desired antibodies.

95. A 1984 study reveals that industry may be funding as much as one-quarter of all biotechnology research in universities, with nearly one-half of all biotechnology companies funding such research. Blumenthal, Gluck, Louis & Wise, *supra* note 1.

96. For example, cells contain more genetic information than they actually use. Learning what causes cells to "express" certain genes and not others would not only answer major questions in

Academic and industrial researchers are often working on the same or closely related problems, whether competitively or collaboratively.⁹⁷ Noteworthy scientific discoveries are made in industrial laboratories, and patentable inventions are made in university laboratories.

In addition, the capital markets are placing a dollar value on intellectual property long before a product is ready for market. The prospectuses that high technology companies use to attract investment capital advertise the companies' affiliations with university facilities and researchers.⁹⁸ These affiliations enhance the companies' credibility with investors. They also supply companies with a window on new scientific developments, which further expedites commercialization.⁹⁹ Sometimes the scientists themselves have equity interests in the companies sponsoring their work.¹⁰⁰ Even if they do not, however, research scientists tend to be more aware of the legal and commercial rights arising out of their work when their sponsors take an interest in those rights.

When industry funds basic research, the scientists and universities involved may be contractually bound to preserve patent rights in sponsored research. But even publicly funded research is increasingly likely to be protected as intellectual property. Many universities have in-house patent or licensing departments or use the services of outside patent development organizations.¹⁰¹ The 1980 Patent & Trademark Act Amendments¹⁰² encourage universities to patent and license inventions made in the course of government-sponsored research. Under this legislation, universities must report any invention which "is or may be patentable"¹⁰³ to the sponsoring agency within a reasonable time; if they do not, the government may receive title to the invention.¹⁰⁴ Universities may elect to retain patent rights, subject to a non-exclusive license to the agency for use of the invention,¹⁰⁵ but only if they agree to file timely patent applications once their research results have been published.¹⁰⁶ Government "march-in rights," through which the sponsoring agency can license the university's inven-

biology, but might also suggest ways of facilitating the manufacture of desired proteins or suppressing the expression of disease-causing genes. This knowledge would therefore be valuable to both scientists and industry.

97. D. DICKSON, *supra* note 6, at 74-77; Blumenthal, Gluck, Louis & Wise, *supra* note 1; Grobstein, *supra* note 3.

98. *Commercialization Hearings*, *supra* note 3, at 7 (testimony of Dr. Donald Kennedy); *see, e.g.*, CALGENE, INC., PRELIMINARY PROSPECTUS 25, 28-29 (May 23, 1986); INTEGRATED GENETICS, INC., AMENDMENT NO. 1 TO FORM S-1, at 17, 22, 25-26 (filed with SEC Apr. 24, 1986).

99. Peters & Fusfeld, *supra* note 6, at 34-36.

100. Blumenthal, Gluck, Louis, Stoto & Wise, *supra* note 3, at 1364.

101. M. KENNEY, *supra* note 1, at 74-77; Blumenthal, Epstein & Maxwell, *supra* note 9; Williams, *Business Aspects of Biotechnology* 25, in *GENETICALLY ENGINEERED ORGANISMS*, *supra* note 52.

102. Pub. L. No. 96-517, 94 Stat. 3019 (1980) (codified at 35 U.S.C. §§ 200-212 (1982)).

103. *See* 35 U.S.C. § 201(d); *see also* 35 U.S.C. § 202(c)(1).

104. *See* 35 U.S.C. § 202(c)(1).

105. *See* 35 U.S.C. § 202(c)(4).

106. *See* 35 U.S.C. § 202(a), (c)(2), (c)(3).

tions itself if the university fails to do so, encourage universities to exploit their patents.¹⁰⁷ The statute also requires universities to share patent royalties with inventors.¹⁰⁸ This personal financial stake gives researchers an incentive to be alert to patent rights.

Finally, most biotechnology research makes use of patented inventions.¹⁰⁹ Thus, even researchers who have no interest in protecting their own intellectual property run up against the intellectual property system when they try to gain access to the inventions of others.

In short, intellectual property law pervades contemporary biotechnology research, causing significant concern about the impact of secrecy and exclusive rights on the behavior of research scientists in fields where scientific norms call for publication and dedication of research results to the public.

B. *The Norms of Science in Contemporary Biotechnology Research*

Wholly apart from any conflict between the law of intellectual property and traditional scientific norms, contemporary biotechnology research presents scientists with a conflict between scientific *norms* and scientific *rewards*. As we have seen, in theory these norms and rewards are congruent: Publication of original research results both rewards the publishing scientist with professional recognition and satisfies the norm of permitting other scientists to replicate one's research results. But for research involving the use of unique biological materials, such as bacterial strains and other types of self-replicating cells, publication in writing alone may not be sufficient to satisfy this replicability norm. To replicate the authors' results, subsequent investigators may need access to identical materials.¹¹⁰

By sharing access to unique materials, however, the publishing scientist not only enables other scientists to replicate her claims; she also allows them to compete with her more effectively in making new discoveries. The professional advantage that exclusive access to unique research materials gives her may motivate her to retain exclusivity for as long as possible in order to maximize the discoveries for which she can claim priority.

Of course, scientists in other fields of research also run the risk of losing future claims to priority when they publish their current research results. But at some point reluctance to help the competition is likely to be overcome by desire to earn recognition for priority of discovery, which is established through prompt publication. Delaying publication may handicap the competition, but the dilatory scientist thereby runs the risk that some-

107. See 35 U.S.C. § 203.

108. See 35 U.S.C. § 202(c)(7)(C).

109. Cf. Fox, *Patents Encroaching on Research Freedom*, 224 SCIENCE 1080 (1984) (discussing concern in biotechnology research community about impact of restrictions on research use of patented products and processes).

110. See *infra* notes 112-46 and accompanying text.

one else will publish first and get all the credit. So long as scientists must publish their results in a form that permits replication in order to earn recognition for priority, the reward structure of science operates to reinforce scientific norms.

In biotechnology, however, the requirement of publication is a less effective mechanism for enforcing scientific norms than in some other fields. As noted above, replication of research using unique biological materials generally requires access to more than the published text. Since the materials themselves cannot be made a part of the text, publishing scientists could conceivably gain recognition through publication without sharing their materials. Withholding materials is a relatively inconspicuous departure from scientific norms. It occurs after publication and is not apparent from the written text.¹¹¹ Thus, publishing scientists with exclusive access to such materials have an opportunity to gain recognition while retaining a future advantage over their research competitors. This conflict between norms and incentives is aggravated when the materials (or the discoveries they facilitate) have potential commercial value.

The records of a controversy that arose when a team of scientists from a commercial biotechnology firm submitted a manuscript to the *Journal of Biological Chemistry* (JBC) in the summer of 1980 dramatically illustrate this conflict.¹¹² The JBC, a scientific journal that frequently publishes reports of research using biological materials, had a policy requiring authors to make available to other researchers any biological materials referred to in published manuscripts.¹¹³ The manuscript submitted by the commercial scientists reported the development of a recombinant organism containing a newly synthesized gene.¹¹⁴ The authors described in detail how they synthesized the DNA insert. But in response to a question from

111. A publication may designate expressly that materials are available from an independent source, such as a cell culture depository, but the absence of such a designation does not necessarily mean that the author would be unwilling to supply the materials. Some authors would rather supply the materials themselves in order to be sure of the identity and viability of the sample. See *infra* note 178.

112. The subject of commercial biotechnology commanded considerable public attention at this time, which roughly coincided with the Supreme Court's *Chakrabarty* decision and the initial public offering of stock by Genentech, Inc. See Hamilton, *Biotech's First Superstar*, BUS. WEEK, Apr. 14, 1986, at 68.

113. This "availability" policy was set forth as Instruction #c.4 in the written instructions to authors, published in each new volume of the JBC, as follows:

THE MICROORGANISMS AND TISSUE CULTURE STRAINS referred to in a manuscript should be identified by an American Type Culture Collection number, or that of a comparable collection. If this is not possible, it is understood that the authors will make the particular strains used available to interested investigators upon request. Well mapped strains of *Escherichia coli* should be sent to the *E. coli* Genetic Center at Yale University.

255 J. BIOLOGICAL CHEMISTRY 2-3 (1980).

114. The authors reported the transformation of a well-known strain of bacteria with a recombinant DNA plasmid containing a newly synthesized gene. There were thus a number of different biological materials "referred to" in the manuscript: the original bacterial strain, the original plasmid, the synthesized gene, the recombinant plasmid containing the synthesized gene, and the transformed bacterial strain containing the recombinant plasmid. In keeping with the JBC's policy, the original bacterial strain was identified by a collection number.

an editor, they indicated that their company's policy prevented them from giving out the recombinant strain.

This event prompted an extensive discussion of the journal's "availability" policy at a meeting of the JBC editorial board,¹¹⁵ culminating in an informal vote of approximately seventy-five percent in favor of retaining the policy¹¹⁶ and twenty-five percent opposed.¹¹⁷

The editorial board decided to seek the advice of an ad hoc committee¹¹⁸ consisting of six academic scientists and two industry scientists on the following question: "Should this Instruction to Authors be retained as is,

115. The content of this discussion is summarized in an enclosure to Letter from William F. Harrington to Nathan O. Kaplan (July 11, 1980) [hereinafter Summary] (on file at *Yale Law Journal*). Dr. Harrington is on the faculty of the McCollum-Pratt Institute, The Johns Hopkins University. Dr. Kaplan is a professor in the Department of Chemistry, University of California at San Diego.

116. Arguments raised in favor of retaining the availability policy emphasized three core norms:

1. *Replicability*. Scientists should publish their research claims in a form that permits replication so that the scientific community can verify their claims: "Once an experiment is published anyone should be able to reproduce it, otherwise it is worthless and might as well just not be published." Summary, *supra* note 115. Replication requires access to the publishing scientist's unique materials.

2. *Dedication*. Publishing scientists should make their scientific advances available to the public:

[T]he act of publishing is the giving of a scientific advance to the public in a form which permits other scientists to reproduce the experiments. . . . [T]o withhold any necessary ingredient which is not generally available is morally equivalent to withholding essential information from the text of the publication and authors should in general be required to make available to other scientists those rare materials that go into the published experiments.

Id. This dedication norm is violated by withholding essential information or rare materials that the author is able to supply.

3. *Progress*. Scientists should publish their research in a form that facilitates the progress of science: "The work cannot be repeated or extended without the availability of the strain or culture." *Id.* (emphasis added).

117. Arguments raised against the policy included:

1. *Inconsistency*. The policy is inconsistent in that it requires authors to make living materials available but does not require authors to make non-living materials available:

We don't require distribution of organic compounds. . . . [A] complicated organic synthesis is more difficult to repeat than a DNA recombination experiment. . . . [I]t would be enough to insist (as in all other experiments) that enough experimental detail be given to know what was done and to permit, in most cases, repetition by a knowledgeable investigator.

Id.

The editors acknowledged parenthetically that "this [repetition] could not be done if a rare cell line from a clinical case is involved." *Id.*

2. *Free riders*. The policy permits free riders to benefit from the work of authors without compensating them:

Such a rule forces an investigator in a university to supply his strain to a profit-making organization without any financial return to his laboratory or university, regardless of the amount of profit eventually received. A similar argument concerns a single investigator developing a special strain after years of work. (One suggestion . . . is that the rule have a time-delay of one or two years before a culture has to be deposited)

Id.

3. *Nonenforceability*. The policy would be difficult or impossible to enforce. If the JBC were to enforce the policy and other journals did not, authors would choose to publish elsewhere:

[W]ould some authors not publish (or at least not in this journal) if such a requirement were enforced? Thus, would we be hindering, rather than helping, communication by such a policy?

If all the journals don't have the same policy, would the JBC be losing papers in some of the most active and exciting fields? [As for those authors who do publish in the JBC,] [t]he journal cannot act as a policeman.

Id.

118. *Id.*

modified or deleted in the light of recent advances in molecular biology[?]" Each of the scientists responded by letter.¹¹⁹ These eight letters, written as the effects of proprietary rights in biotechnology inventions were just beginning to be felt, illustrate a range of views within the biomedical research community itself as to what the norms of science are, what purposes they serve, and how they actually function in practice.¹²⁰

The six academic scientists represented three distinct viewpoints. Two favored retaining the policy without modification.¹²¹ Another two favored continuing the policy as a statement of the views of the JBC, rather than as a condition of publication.¹²² The remaining two favored modifying the policy to limit it to those materials that are strictly necessary in order to permit replication of the published work.¹²³ The two industry scientists were the most hostile toward the policy, questioning even the need for publication in replicable form.¹²⁴

1. *Retention of the Policy*

The two scientists who favored retaining the policy without modification¹²⁵ came closest to embracing Merton's traditional norms of communism and universalism, emphasizing "the best interest of science," "the freedom of science,"¹²⁶ and "the general ethic of bacterial and phage geneticists."¹²⁷ Both rejected the argument raised at the editorial board meeting that, in treating organisms differently from new chemical compounds, the policy is inconsistent.¹²⁸ They pointed out that organisms are relatively easy to reproduce, whereas chemicals can be difficult to synthesize and supply.¹²⁹ One of the two expressly opposed a different rule for

119. At the time their views were solicited, the eight scientists were briefed on the issue with a written summary of arguments raised for and against the policy at the editorial board meeting. *See supra* notes 115-17 and accompanying text. The scientists referred to these arguments in their individual letters.

120. I am grateful to the editors of the *Journal of Biological Chemistry* and to Paul Berg, Donald Brown, William Harrington, Nathan Kaplan, Philip Leder, Daniel Nathans, Jesse Rabinowitz, Orrie Friedman, and I.S. Johnson for permission to use their letters.

121. *See infra* notes 125-31 and accompanying text.

122. *See infra* notes 132-36 and accompanying text.

123. *See infra* notes 137-39 and accompanying text.

124. *See infra* notes 140-45 and accompanying text.

125. These two scientists were Dr. Nathan O. Kaplan, *see supra* note 115, and Dr. Philip Leder, who was then with the Public Health Service of the National Institutes of Health and is now Chairman of the Department of Genetics at Harvard Medical School. *See* Letter from Nathan O. Kaplan to William F. Harrington (Aug. 5, 1980) [hereinafter Kaplan letter] (on file at *Yale Law Journal*); Letter from Philip Leder to William F. Harrington (July 25, 1980) [hereinafter Leder letter] (on file at *Yale Law Journal*).

126. Kaplan letter, *supra* note 125.

127. Leder letter, *supra* note 125.

128. *See supra* note 117.

129. Dr. Kaplan explains: "[O]ne cell is enough for any investigator to regrow the organism and thereby have the organism available for his studies. Living systems can be kept and maintained but chemicals can be utilized and not replaced unless someone redoes the synthesis or preparation." Kaplan letter, *supra* note 125. Dr. Leder simply noted that the two situations involved "clearly different . . . logistics . . ." Leder letter, *supra* note 125.

recombinant organisms, reasoning that such a rule would lead to different standards for academic and commercial scientists.¹³⁰ The other acknowledged the existence of competing incentives both to protect intellectual property and to earn scientific recognition, but nonetheless opposed compromising scientific norms to accommodate either "proprietary interests" or "the all-too-human foibles of individual scientists."¹³¹

2. Policy as Statement of Principle

The two scientists who favored retaining the policy as a statement of principle rather than as a binding contractual term¹³² conceded the importance of the traditional norms¹³³ but nonetheless felt that the JBC was unable to enforce the policy.¹³⁴ Both recognized that the policy is sometimes violated in practice,¹³⁵ and suggested that it be reformulated as an exhortation, rather than a requirement for publication.¹³⁶

3. Modification of the Policy

The remaining two academic scientists favored a narrower policy requiring availability only to the extent necessary for replication of published experiments.¹³⁷ Both drew a distinction in this regard between or-

130. See Kaplan letter, *supra* note 125. Dr. Kaplan objected to scientists earning recognition without observing scientific norms: "[S]ome of the people involved in commercial laboratories would like to . . . receive recognition for their research yet not follow the general ethics of scientists. . . . One cannot have it two ways." *Id.*

131. Leder letter, *supra* note 125.

132. These two scientists were Dr. Paul Berg, Department of Biochemistry, Stanford University Medical School, and Dr. Donald Brown, Department of Embryology, Carnegie Institution of Washington. See Letter from Paul Berg to William F. Harrington (July 31, 1980) [hereinafter Berg letter] (on file at *Yale Law Journal*); Letter from Donald D. Brown to William F. Harrington (July 28, 1980) [hereinafter Brown letter] (on file at *Yale Law Journal*).

133. Dr. Berg praised the objective embodied in the policy as "the ideal we should be striving towards" and "a principle that is nearly as defensible as motherhood." Berg letter, *supra* note 132.

134. Dr. Berg thought that "without comparable admonitions by the other journals . . . it would be a useless gesture." *Id.* Dr. Brown concurred that the idea behind the availability policy was sound, but thought that "to make it a law is a little like Prohibition, it is unrealistic and unenforceable." Brown letter, *supra* note 132.

135. Dr. Berg noted that the policy "reaches for a kind of openness and sharing in science that many of us would [sic] like to see practiced universally." Berg letter, *supra* note 132. Dr. Brown felt sure that previous JBC authors had "refused or delayed sending [organisms] . . . to their competitors," and added that "[t]he problem is not made new by recombinant DNA proliferation, nor by its increasing popularity with industry." Rather, he attributed the reluctance of scientists to share strains to the fact that they "want time to explore their discoveries." Brown letter, *supra* note 132.

136. Dr. Berg proposed that the JBC "construct a statement that sets forth clearly and forcefully the JBC's belief on [sic] the responsibilities of researchers and authors to make available, along with the data of their investigations and experiments, the biological material used in acquiring that information" and urge other journals to do the same. Berg letter, *supra* note 132. Dr. Brown favored reframing the policy to state that authors are "encouraged" rather than required to make their strains available. Brown letter, *supra* note 132.

137. These two scientists were Dr. Daniel Nathans, Department of Microbiology, The Johns Hopkins University School of Medicine, and Dr. Jesse C. Rabinowitz, Department of Biochemistry, University of California, Berkeley. See Letter from Daniel Nathans to William F. Harrington (Aug. 7, 1980) [hereinafter Nathans letter] (on file at *Yale Law Journal*); Letter from Jesse C. Rabinowitz to William F. Harrington (Aug. 28, 1980) [hereinafter Rabinowitz letter] (on file at *Yale Law*

ganisms isolated from nature and organisms synthesized by the authors, arguing that authors should be required to make only the former available. They justified this distinction primarily on the basis of the replicability standard.¹³⁸ Both also noted that departures from the policy were not uncommon in the case of newly-synthesized organisms, even among noncommercial scientists.¹³⁹

4. *Nonenforcement*

The two industry scientists both asserted that if the policy were enforced, the JBC would lose manuscripts from scientists in commercial laboratories.¹⁴⁰ One of them noted that enforcement of the policy could ultimately undermine the goal of disseminating new knowledge by deterring scientists in commercial laboratories from publishing,¹⁴¹ and added that the problem is not confined to commercial scientists.¹⁴² He added that

Journal).

138. Dr. Nathans thought that the JBC should also *encourage* authors to make available new mutants or recombinants described in published reports, as well as new isolates from nature, in order to facilitate research. But although it would be "desirable" to have such mutants or recombinants freely available once they have been reported in the literature, he felt that it is neither desirable nor possible "to coerce people into giving out their materials." Dr. Nathans nonetheless favored retaining the policy as a binding condition of publication for "new isolates from nature of microbes or tissue culture cells" where "the principle of verifiability of research results operates." Nathans letter, *supra* note 137.

Dr. Rabinowitz felt that both mutants and new isolates from nature should be made available because "it is not possible to characterize such organisms exactly or completely or to be certain that two organisms isolated by identical experimental procedures are, in fact, genetically identical unless they can be compared by genetic analysis." Rabinowitz letter, *supra* note 137. He noted, however, that where the manuscript provided a description of the experiment sufficient to permit replication, as would be the case for products of chemical synthesis and some recombinant organisms, it would not violate scientific norms to withhold the materials. *Id.*

139. Dr. Nathans noted that scientists who have constructed a new organism "may want to limit distribution of strains that were difficult to construct or especially important for their future work." He added that commercial incentives were compounding the problem: "Add to this an increasing number of recombinants with potential commercial value and you have a widespread interest in controlling the availability of new strains." Nathans letter, *supra* note 137.

Dr. Rabinowitz observed that investigators often avoid making available organisms that they have derived themselves, yet these transgressions have generally been overlooked. He attributed the reluctance of authors to share their strains not to competing commercial interests, but to the interests of the authors in retaining exclusive access to a new research tool: "[M]ost investigators recognize that when mutants or organisms isolated by enrichment techniques are involved, . . . free exchange of these materials has frequently not occurred. The usual reason for this has probably been to protect the advantage that the original investigator possesses having isolated an organism." Rabinowitz letter, *supra* note 137.

140. These two scientists were Dr. Orrie M. Friedman, then President and Scientific Director and now Chairman of the Board of Collaborative Research, Inc., and Dr. I.S. Johnson, Vice President, Lilly Research Laboratories, A Division of Eli Lilly and Company. See Letter from Orrie M. Friedman to William F. Harrington (Aug. 4, 1980) [hereinafter Friedman letter] (on file at *Yale Law Journal*); Letter from I.S. Johnson to William F. Harrington (Aug. 18, 1980) [hereinafter Johnson letter] (on file at *Yale Law Journal*).

141. I can say that under some circumstances commercial labs such as ours clearly would not be able to make certain of such strains available publicly. If as a result we would be barred from publication it would be regrettable from the point of view of both the individual scientist who did the work and of the others who would be deprived of the results of the work. Friedman letter, *supra* note 140.

142. Dr. Friedman asserted that "[t]he fact is that . . . organisms . . . referred to in published

availability of strains may not be necessary to ensure replicability of results.¹⁴³ The other industry scientist, going a step further, questioned whether the JBC should even require that authors make available those materials necessary for replication.¹⁴⁴ He noted that a policy requiring authors to enable readers to reproduce their work would "reduce publication incentive," citing competing incentives to preserve intellectual property.¹⁴⁵

Ultimately, the JBC decided to retain the wording of the policy "as a statement of principle, rather than as a contractual agreement between the Journal and an author." The chairman of the ad hoc committee concluded that a weakening of the statement,

such as changing the word "understood" to "urged" or "encouraged," would be interpreted as a compromise in values set by the Journal, which most agree should not occur. Moreover, since the statement seems to have worked satisfactorily in the past, we see no need to alter it at this time as long as the Journal makes no attempt to enforce the statement by requiring an oral or written pledge or otherwise policing the ethics of authors.¹⁴⁶

A superficial view of this episode suggests a straightforward conflict between scientific norms and competing incentives arising from the desire to preserve intellectual property rights. The ultimate decision of the JBC to keep the wording of the policy the same but not to enforce it lends support to the view that while the traditional norms continue to hold some moral appeal for scientists, the research science community may be losing its ability to enforce its own norms against competing commercial incentives.

papers often are not generally available upon request, often even from academic investigators." He defended this practice on the ground that "in particular instances this [complete access] would place an intolerable burden upon the investigator." *Id.*

143. Dr. Friedman used the language of patent law to make this point: "Moreover it may not be essential that they be available, provided the publication contains sufficient information so that one truly skilled in the art (as opposed to a casual practitioner) is able to reproduce the organism etc. on his own." *Id.*; cf. 35 U.S.C. § 112 (1982) (patent specification must enable any person "skilled in the art to which it pertains" to make and use invention).

144. I cannot accept the position, expressed by some, that a manuscript that is not wholly enabling is valueless. Many such manuscripts add to the fund of information, sometimes in a highly significant manner. . . .

As a matter of fact, many manuscripts are readily accepted for publication even though they report work that, for one reason or another, cannot or will not be verified by others.

Johnson letter, *supra* note 140.

Dr. Johnson illustrated his point with the following example: "[A]n investigator collects thousands of sheep pituitaries and, by an arduous and lengthy procedure, succeeds in isolating a few milligrams of a previously unreported hormone. It is doubtful that the work will be verified independently. Nevertheless, a manuscript reporting it would be unconditionally accepted for publication." *Id.*

145. Dr. Johnson noted that such a policy would leave an author "with the options of disclosing the trade secret or not publishing. His decision, all too often, will be to not publish." *Id.*

146. Letter from William F. Harrington to Nathan O. Kaplan (Feb. 3, 1981) (on file at *Yale Law Journal*) (discussing suggestions of ad hoc committee).

But a closer reading of the record and a broader view of the context changes the picture somewhat. First, the letters illustrate that even where the norms are relatively clear, scientists often violate them for reasons unrelated to commercial incentives. The most widely shared norm seems to be that publishing scientists should enable subsequent investigators to replicate their research results. All of the scientists invoked this replicability norm in their analysis of the functions served by the policy. Even the scientists who favored modifying or eliminating the availability requirement nonetheless felt that the Journal should at least encourage availability of strains to promote replicability of results. Strikingly, however, most of the committee members observed that academic scientists as well as commercial scientists often depart from the norms—including even the widely-shared replicability norm—in practice.¹⁴⁷ This suggests that the problem does not originate with commercial interests or intellectual property incentives.

Indeed, the arguments raised against the policy focused on tensions within the scientific community rather than conflicting incentives from the outside. No one adopted the argument raised at the editorial board meeting that the policy unfairly benefited “free riders” at the expense of publishing scientists,¹⁴⁸ perhaps because of a sense that “free riding” on the published work of other scientists is an integral feature of scientific research.¹⁴⁹ Nonetheless, several of the scientists cited the desire of individuals to retain the exclusive benefits of a discovery for themselves as an explanation, if not a justification, for departures from the norms and for the consequent difficulty of enforcing the policy.¹⁵⁰

If the financial rewards of intellectual property protection tempt scien-

147. See, e.g., Brown letter, *supra* note 132; Friedman letter, *supra* note 140; Nathans letter, *supra* note 137; Rabinowitz letter, *supra* note 137. Even Dr. Kaplan, who came closest to claiming that the replicability norm is in fact descriptive of the behavior of academic scientists, went only so far as to state that “the academic people . . . are, from my experience, *usually* willing to give up the organism.” Kaplan letter, *supra* note 125 (emphasis added). In a personal interview, Dr. Kaplan conceded that academic scientists sometimes fail to observe this norm in practice. He gave me a copy of a facetious form letter, then circulating as a joke among scientists, declining a request for a sample of a strain and setting forth a list of possible excuses to be selected or deleted as appropriate. The letter reads in part as follows:

I regret to inform you that we are unable to send the strains you wish because* we have a graduate student who is studying this particular strain and it would be unfair to distribute it at this time/the problem you outline does not seem very significant/we have just concluded your particular study/we suspect you are lying about the purpose for which you want the strains/we suspect you are the referee with whom we had considerable trouble recently.

I might add that I, personally, am not in favour of withholding mutant strains.

*Delete as appropriate

The joke itself shows tension within the academic community over adherence to the norms. (This letter is on file at *The Yale Law Journal*.)

148. See *supra* note 117.

149. R. MERTON, *supra* note 18.

150. See, e.g., Brown letter, *supra* note 132; Johnson letter, *supra* note 140; Nathans letter, *supra* note 137; Rabinowitz letter, *supra* note 137. No one took up the suggestion raised at the editorial board meeting that it was particularly unfair to compel academic scientists to make their materials available to profit-making organizations. See *supra* note 117.

tists to depart from scientific norms, the records of the JBC controversy suggest that the temptation may simply reinforce conflicting incentives within the reward structure of science itself. Even among purely academic scientists, the norms may never have had the force that the community would like them to have. Given that professional recognition rewards only the first researcher to arrive at a particular result, it is not surprising that scientists are reluctant to give their materials to their research competitors.¹⁵¹

Moreover, when the JBC episode is considered in light of subsequent responses to the same problem by other scientific journals, it is not at all clear that scientific norms are losing ground. In the seven years since the JBC first confronted this issue, a number of prominent scientific journals have adopted policies similar to the JBC's.¹⁵² This spate of new policies addressing the issue may signify a number of things. It may indicate that the scientific community believes its norms are threatened and in need of fortification. Perhaps increasing violations of these norms have led journals to respond with express policy statements. Another possibility is that there was no need for specialized policies for biological materials until the recent increase in recombinant DNA research. Thus, the biotechnology boom may have made it necessary to clarify the implications of longstanding norms where biological materials are involved.¹⁵³

Whatever the explanation, the recent record hardly suggests that traditional scientific norms are crumbling in the face of intellectual property incentives as commercial interest in biotechnology research becomes more pervasive.¹⁵⁴ Although there are signs of tension over adherence to the norms, commercial pressures appear to be only a new aggravation of a familiar problem.

151. See *supra* text accompanying note 111.

152. The following journals now have express editorial policies requiring or encouraging the availability of biological materials referred to in manuscripts: 46 CELL No. 6 (Sept. 12, 1986) ("Information for Contributors"); 117 DEV. BIOLOGY No. 1 (Sept. 1986) ("Information for Authors"); 165 J. BACTERIOLOGY ii (Jan. 1986) ("Instructions to Authors"); 132 J. GEN. MICROBIOLOGY No. 7 (July 1986) ("Instructions to Authors"); 57 J. VIROLOGY ii (Jan. 1986) ("Instructions to Authors"); 153 VIROLOGY No. 2 (Sept. 1986) ("Notice to Authors").

153. In fact, several journals have more general policies requiring authors to give sufficient information about their materials and methods to permit reproduction of their experiments, although they make no specific reference to biological materials. Such policies are set forth in, e.g., 156 ANALYTICAL BIOCHEMISTRY ix (1986) ("Instructions to Authors"); 56 BIOLOGY OF THE CELL 93 (1986) ("Instructions to Authors"); 32 CLINICAL CHEMISTRY 2 (Jan. 1986) ("Information for Authors"); 97 J. BIOCHEMISTRY iii (1985) ("Instructions to Authors"); 23 J. CLINICAL MICROBIOLOGY iii (Jan. 1986) ("Instructions to Authors"); 137 J. IMMUNOLOGY No. 6 (Sept. 15, 1986) ("Information for Contributors"); 187 J. MOLECULAR BIOLOGY No. 2 (Jan. 20, 1986) ("Instructions to Authors"); 232 SCIENCE xi (1986) ("Information for Contributors").

154. See generally OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS (1984). Indeed, a recent survey of over 1200 faculty members at 40 major universities in the United States found that biotechnology researchers with industrial support both publish at higher rates and patent more frequently than colleagues without such support. Blumenthal, Gluck, Louis, Stoto & Wise, *supra* note 3, at 1361.

C. *Patent Rights in Biotechnology Inventions*

Without patent protection, scientists who wanted to preserve intellectual property rights in their discoveries would have to resort to either actual secrecy or trade secrecy. As we have seen, these two strategies conflict with scientific norms and rewards in that they preclude disclosure of the discoveries for which protection is sought.¹⁵⁵ Patent law interferes with scientific communication less than either actual secrecy or trade secrecy because it is premised on disclosure rather than secrecy. Patent law promotes disclosure in two ways. First, in order to obtain a patent, an inventor must include in the patent application a full description of the invention and how to make and use it.¹⁵⁶ Although this application is confidential while pending,¹⁵⁷ it becomes freely available to the public once a patent issues. Second, by granting a property right that survives disclosure, patent law removes an obstacle to disclosure of inventions that would otherwise have to be kept secret in order to preserve their commercial value.¹⁵⁸

On the other hand, patent law may be less consistent with scientific norms than secrecy protection in a different respect. Patent law grants a much more extensive right to exclude others from the use of a discovery,¹⁵⁹ thus potentially foreclosing further research to a greater degree than secrecy. A patent provides a remedy against all who make, use, or sell the invention without permission, however innocently,¹⁶⁰ whereas trade secret law provides a remedy only against wrongdoers.¹⁶¹ For example, independent discovery is not a defense to a patent infringement suit, although it is a defense to a claim for misappropriation of trade secrets. Because of the broad scope of the exclusive rights granted by a patent, patent law may offer considerably stronger protection than trade secrecy—as well as greater potential disruption of ongoing research—in competitive research fields.

By providing such broad exclusive rights, patent law may aggravate preexisting conflict between scientific norms and the reward structure of science. Scientific norms call for the dedication of discoveries to the research community without restrictions on subsequent use. But the reward structure of science grants recognition to the first scientist to make a discovery, creating an incentive to foreclose other scientists from doing competitive research. Ordinarily, the need to publish in order to gain recogni-

155. See *supra* text accompanying notes 89–92.

156. See 35 U.S.C. §§ 111, 112 (1982).

157. See 35 U.S.C. § 122 (1982).

158. Indeed, once they are assured of an enforceable property right, patent owners may have an incentive to disseminate information about their inventions in order to attract potential licensees. See Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 278 (1977).

159. See *infra* notes 207–42 and accompanying text.

160. See *infra* notes 211–13 and accompanying text.

161. See *supra* notes 86–88 and accompanying text.

tion constrains the incentive to keep discoveries out of the hands of research competitors. Although publication may help competitors to make future discoveries, the reward structure impels scientists to make this contribution to the scientific community in order to gain current recognition for discoveries already made. But if patent law gives inventors the right to exclude others from using their discoveries in competitive research even after publication, it could potentially upset this balance of incentives. A system of exclusive rights that survives disclosure could thus undermine the mechanisms of the scientific community for gaining free access to new knowledge for use in subsequent research.

I now turn to a more detailed consideration of the disclosure obligations and exclusive rights provided under the patent laws.

1. *Disclosure*

A comparison of the patent disclosure requirements for microorganism-related inventions with the scientists' analysis of the functions of the JBC's availability policy shows considerable congruence between patent law policy and scientific norms concerning disclosure. If anything, patent law appears more rigorous than the scientific community with respect to the substance of its disclosure requirement. The two systems differ significantly, however, regarding the timing of disclosure. Patent disclosure is unlikely to occur until after a patent issues,¹⁶² which is often years later than disclosure to the scientific community would otherwise occur.

a. *Enablement*

Sections 111 and 112 of the Patent Act require an inventor to set forth in her patent application a written description of the invention, an explanation that will "enable" a skilled practitioner to "make and use" the invention, and the "best mode" contemplated by the inventor of "carrying out" her invention.¹⁶³ This disclosure requirement serves two functions. First, it ensures that the public will inherit the full benefit of the invention upon expiration of the patent term. Second, it permits the PTO to determine that the applicant has in fact developed an operative, useful embodiment of the invention. The first function parallels scientific norms by calling upon patent applicants, like publishing scientists, to dedicate

162. The statement in text assumes that the inventor has filed only a United States patent application. If the applicant also seeks foreign patent protection under the patent laws of other nations or international patent protection under the Patent Cooperation Treaty or the European Patent Convention, the application will be published 18 months after the date of first filing. Patent Cooperation Treaty, *done* June 19, 1970, art. 21, 28 U.S.T. 7647, 7666-67, T.I.A.S. No. 8733, at 7666-67; European Patent Convention, October 5, 1973, art. 93, *translated in* K. HAERTEL, EUROPEAN PATENT CONVENTION 19, 62-63 (1980), *reprinted in* 78 PAT. & TRADEMARK REV. 31, 39 (1980). See generally R. SALIWANCHIK, *supra* note 67, at 139-46.

163. 35 U.S.C. §§ 111, 112 (1982).

their inventions to the public.¹⁶⁴ The second function parallels the scientists' replicability standard by calling upon patent applicants, like publishing scientists, to supply sufficient information and materials to demonstrate to a knowledgeable audience that they have in fact achieved what they claim.¹⁶⁵

When an invention involves unique biological materials, the patent disclosure obligation extends to the materials themselves if the written description called for expressly in the statute is insufficient to enable replication of the applicant's invention. Although microorganisms were not commonly considered patentable subject matter until the Supreme Court decided *Diamond v. Chakrabarty*,¹⁶⁶ patent protection has long been available for processes *using* microorganisms and for the products of such processes.¹⁶⁷ With the commercial development of antibiotics produced by bacterial strains, inventors sought a way to make enabling disclosures of such inventions. Where the bacteria involved were generally available, the disclosure could be made by explaining how to procure the necessary materials.¹⁶⁸ But where a new or rare strain was involved, the only way to enable others to make or use (in patent law parlance, to "practice") the invention was to supply the strain. For these cases, patent attorneys devised the procedure of depositing samples of bacterial strains with recognized depositories from which the strains would become available to the public upon issuance of the patent.¹⁶⁹

164. See *infra* notes 172-75 and accompanying text.

165. See *infra* note 175 and accompanying text.

166. 447 U.S. 303 (1980). The majority in *Chakrabarty* cited three prior instances in which patents had issued on microorganisms. The first was a patent issued to Louis Pasteur on yeast in 1873, and the second and third were patents issued on microorganisms in 1967 and 1968. *Id.* at 314 n.9.

167. Note, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That Is the Question*, 52 *FORDHAM L. REV.* 592, 595-96 (1984).

168. See, e.g., *Merck & Co. v. Chase Chem. Co.*, 273 F. Supp. 68 (D.N.J. 1967).

169. See, e.g., *Ex parte Kropp*, 143 U.S.P.Q. (BNA) 148 (P.T.O. Bd. App. 1959); *Ex parte Davisson*, 118 U.S.P.Q. (BNA) 520, 521 (P.T.O. Bd. App. 1957); Levy & Wendt, *Microbiology and a Standard Format for Infra-Red Absorption Spectra in Antibiotic Patent Applications*, 37 *J. PAT. OFF. SOC'Y* 855, 855-59 (1955).

It is interesting to compare the statutory disclosure requirements under the Plant Patent Act, 35 U.S.C. §§ 161-164 (1982), and the Plant Variety Protection Act, 7 U.S.C. §§ 2321-2583 (1982), with those under the Patent Act. The Plant Patent Act, first promulgated in 1930, ch. 312, 46 Stat. 376, extends patent protection to new varieties of asexually reproduced plants. The disclosure requirement is the same as that in 35 U.S.C. § 112, except for the following qualification: "No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible." 35 U.S.C. § 162. This provision has been construed to permit disclosures failing to satisfy the section 112 requirement of a description of the manner and process of making the invention. See *In re Greer*, 484 F.2d 488, 490-91 (C.C.P.A. 1973); cf. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 133-35 (1948) (Frankfurter, J., concurring) (arguing that patent for mixed culture of bacterial inoculants should be denied not because combination of bacterial strains was "work of nature," but because, *inter alia*, description of invention was inadequate for failure to identify particular strains used). The Plant Patent Act allows patent protection for some inventions that it might not be possible to describe in accordance with section 112.

The Plant Variety Protection Act, enacted in 1970, Pub. L. No. 91-577, 84 Stat. 1542, provides patent-like protection administered by the Department of Agriculture for novel varieties of sexually reproduced plants. The disclosure provisions expressly call for both a written description and a

The Court of Customs and Patent Appeals first addressed the adequacy of microorganism deposits under section 112 in *In re Argoudelis*.¹⁷⁰ The discussion of the function of deposits in this and subsequent cases parallels the analysis of the JBC's availability policy by the scientists.

In re Argoudelis predates the JBC controversy by ten years. It involved a patent application on new antibiotic compounds and a process for preparing the compounds from microorganisms. The applicants deposited samples of their microorganisms in the permanent culture collection of the United States Department of Agriculture before the filing date of their patent application and referred to this deposit in the specification. At the request of the applicants, the depository agreed not to release the organism without their written permission until a patent issued.

Reversing the PTO, the Court of Customs and Patent Appeals approved the use of a deposit to "disclose" a microorganism obtained from nature. The court held that section 112 did not require that the general public have access to the culture before the patent issued, reasoning that as long as the materials are available to the PTO during the pendency of the patent application, the disclosure is sufficient to demonstrate completion of the invention as of the filing date. Since patent applicants in other fields need not make their patent disclosures public unless and until a patent issues, the court felt that no earlier public disclosure should be required for microorganism-related inventions.¹⁷¹

In a concurring opinion, Judge Baldwin emphasized the dual role played by enablement in patent law. First, enablement ensures that the public will receive its *quid pro quo* for the patent monopoly.¹⁷² Second, it demonstrates that as of the filing date the applicant is entitled to a patent.¹⁷³ The first function does not call for public disclosure until the pat-

deposit:

An application for a certificate recognizing plant variety rights shall contain:

. . . .

(2) A description of the variety setting forth its novelty and a description of the genealogy and breeding procedure, when known

(3) A declaration that a viable sample of basic seed necessary for propagation of the variety will be deposited and replenished periodically in a public repository

7 U.S.C. § 2422. In requiring a deposit in addition to a written description, this more recent statute follows the approach of the courts in interpreting section 112 of the Patent Act.

170. 434 F.2d 1390 (C.C.P.A. 1970).

171. *Id.* at 1393.

172. The first aspect of that role is to provide the assurance that the public will, in fact, receive something in return for the patent grant. This consideration is, of course, the full and complete disclosure of how to make and use the claimed invention. Thus, the patent adds a measure of worthwhile knowledge to the public storehouse

Id. at 1394.

173. Most, if not all, of the determinations involving the patentable merits of a claimed invention vis-a-vis the prior art require that the application filing date be regarded as the *prima facie* date of invention Because the filing date is so important in determining patent rights, it is essential that there be no question that, *at the time an application for patent is filed*, the invention claimed therein is fully capable of being reduced to practice (i.e., that no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remain in order to obtain an operative, useful embodiment).

ent issues.¹⁷⁴ It does, however, require that the patent application contain enough information for the PTO to determine whether the public will receive an enabling disclosure as of the issue date. The second function requires only that the disclosure demonstrate successful invention as of the filing date. Since *Argoudelis*' specification, including the deposited organisms, was sufficient to show successful invention by the filing date, and the disclosure would become available to the public upon issuance of a patent, the specification satisfied section 112.¹⁷⁵

Id. at 1395 (emphasis in original).

174. It should be apparent, however, that this first aspect of the enabling disclosure requirement of section 112, requires only that the adequacy of the teaching disclosure be measured as of the issue date of the patent. There is no sense in making an applicant publicly disclose any part of his invention, much less its very essence, before he has been assured that he will obtain the protection he is seeking in return for that disclosure.

Id. at 1394-95 (footnote omitted).

175. Judge Baldwin later reiterated this analysis in a majority opinion in *In re Hawkins*, 486 F.2d 569 (C.C.P.A. 1973), a case that did not involve microorganisms. The same approach has been followed in subsequent cases analyzing the use of microorganism deposits to satisfy the enablement requirement.

In *Feldman v. Aunstrup*, 517 F.2d 1351 (C.C.P.A. 1975), the court extended the reasoning of *In re Argoudelis* to a case involving the deposit of a microorganism in a foreign depository. At the time the patent application was filed, the deposit was subject to a restriction that the organism could not be released without the depositor's consent. This restriction was removed after the filing date and before issuance of a patent. *Id.* at 1352-53. The Court held that the specification was sufficient to determine whether the inventor was entitled to a patent as of the filing date, and that release of the restrictions ensured that the specification would be fully enabling to the public upon issuance of a patent. *Id.* at 1355.

The court also held that deposit in a foreign country could satisfy the enablement requirement. *Id.* at 1356. This issue is now moot because the United States has become a signatory to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1241, T.I.A.S. No. 9768. See 961 Official Gazette Pat. Off. 21-36 (Aug. 23, 1977). The Budapest Treaty establishes minimum requirements for maintaining an international depository for microorganisms and authorizes such depositories to receive and store deposits and dispense samples in accordance with the Treaty and the patent laws of the signatory nations. 999 Official Gazette Pat. Off. 2 (Oct. 7, 1980). See generally Meyer, *Problems and Issues in Depositing Microorganisms for Patent Purposes*, 65 J. PAT. OFF. SOC'Y 455 (1983) (discussing depository requirements under international treaties and section 112).

The PTO responded to the *Argoudelis* decision by promulgating an administrative rule concerning the deposit of microorganisms. See MANUAL OF PATENT EXAMINING PROCEDURE, § 608.01f(c) (5th ed. 1983, rev. 1985). Under this rule, whenever an invention requires the use of a microorganism that is not known and readily available to the public, the applicant must deposit the organism not later than the filing date "in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted." *Id.* The conditions of deposit must assure access to the deposit by the PTO during pendency of the patent application and unrestricted availability of the culture to the public upon issuance of the patent. The PTO has construed this rule strictly. For example, the PTO invoked the rule to invalidate an agreement by a depository to require that persons requesting samples of a microorganism identify the party making the request and undertake not to transmit the organism to third parties. *Restrictions Voided on Availability of Deposited Yeast Strains to Public*, 30 Pat. Trademark & Copyright J. (BNA) No. 732, at 104 (1985).

In *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985), the Court of Appeals for the Federal Circuit rejected the PTO's deposit rule insofar as it requires deposit before the filing date. That case involved a patent application on biological materials useful for producing immunoglobulins. The inventor apparently filed a patent application in the mistaken belief that the materials had already been placed in a depository. In fact, the materials were not deposited until one week after the filing date. The PTO rejected the application for failure to meet the enablement requirement of section 112. The Federal Circuit reversed. Following the reasoning of *In re Argoudelis*, the court noted that the materials were available from the inventor during the pendency of the patent application under a provision of the patent statute giving the PTO the right to request "specimens or ingredients" from the applicant. See

This analysis appears congruent with scientific norms. Issuance of a patent brings about publication of the disclosure in the specification.¹⁷⁶ In patent law, as in science, a researcher may keep her discoveries secret until publication. Thereafter, she must surrender to the public an enabling disclosure that permits replication of her claims.¹⁷⁷ Indeed, in requiring access to materials through a source other than the inventor, patent law goes beyond the requirements of the scientific community.¹⁷⁸

Two further respects in which patent law may impose tougher disclosure requirements than the scientific community deserve mention. The first concerns disclosures that permit replication only after further experimentation. The second concerns disclosures that, while fully enabling, conceal from the public the "best mode" contemplated by the inventor of practicing the invention.

b. *Undue Experimentation*

Recall that a number of the scientists consulted by the JBC thought that authors should not be required to supply newly-engineered organisms described in their publications, as long as the authors give enough information about the method of synthesis to permit other investigators to re-

35 U.S.C. § 114 (1982). The court deemed recourse to this statutory provision sufficient to satisfy any need for access by the PTO to verify successful invention.

Although availability of materials from the inventor may be sufficient to allow the PTO to determine constructive reduction to practice, it is plainly not a substitute for deposit in satisfying the enablement requirement once a patent issues. Otherwise, an inventor could effectively prolong the patent monopoly by restricting access to the materials after the patent expires. *Cf. White Consol. Indus. v. Vega Servo-Control*, 713 F.2d 788 (Fed. Cir. 1983) (disclosure that incorporates trade secret available only by license from patentee fails to satisfy enablement requirement). Inventors could thereby circumvent the terms of the bargain offered by the patent system: a monopoly on the invention for a limited term in exchange for dedicating the invention to the public thereafter. *See Brulotte v. Thys Co.*, 379 U.S. 29, 31 (1964).

The PTO recently issued an advance notice of proposed rulemaking relating to the deposit of biological materials for patent purposes. 52 Fed. Reg. 34,080 (1987), *reprinted in* 34 Pat. Trademark & Copyright J. (BNA) No. 846, at 485 (Sept. 10, 1987). The proposed rule would update PTO practice in light of the decision of the Federal Circuit in *In re Lundak*; the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Protection, *see supra*; and the PTO's decision to extend patent protection to plants outside the Plant Patent Act in *In re Hibberd*, 227 U.S.P.Q. (BNA) 443, 444 (P.T.O. Bd. App. & Int. 1985).

176. In some countries, patent applications are published before a patent issues. *See supra* note 162 and sources cited therein; *see also* Meyer, *supra* note 175.

177. The timing of disclosure may nonetheless be quite different under the two systems. *See infra* notes 201-06 and accompanying text.

178. Recall that a promise of availability from the author was an acceptable substitute for deposit under the JBC policy. *See supra* note 113 and accompanying text. Under some circumstances, scientists may be reluctant to make their organisms available through a depository. For example, scientists may not trust the depository to maintain and distribute viable culture samples that will continue to show the characteristics described in prior publications. *See Hampar, Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. PAT. OFF. SOC'Y 569, 605-07 (1985). Of course, patent law does not prohibit patent holders from maintaining their own cultures in addition to those maintained by the depository and making samples from their own laboratories available to corroborate their research claims. Thus, although patent law may go beyond scientific norms in requiring that organisms be made available through a depository, it should not deter scientists who are willing to make their organisms available from seeking patent protection.

peat what was done.¹⁷⁹ Patent law also permits a disclosure that demands some further effort in order to replicate the invention, as long as replication does not require "undue experimentation."¹⁸⁰ The specification is, however, defective if replication requires "more than the skill of the art" to which the invention pertains or "an inordinate amount of work."¹⁸¹ The courts and the PTO have analyzed the "undue experimentation" standard in the context of microorganism-related inventions in *Tabuchi v. Nubel*¹⁸² and *Ex Parte Jackson*.¹⁸³

Tabuchi v. Nubel involved a priority contest between two inventors of a fermentation method for making citric acid and isocitric acid using yeasts of the genus *Candida*. The case turned on whether a specification that failed to supply a depository accession number for the particular *Candida* strain used by the applicant satisfied the enabling disclosure requirement of section 112.¹⁸⁴ The applicant argued that it would have been possible to select a citric-acid-producing strain from publicly available *Candida* strains without undue experimentation by following the process disclosed in the specification. To prove his point, the applicant hired an expert in the field who read the application, selected a strain from *Candida* strains available to the public in depositories, and made citric acid according to the process described in the specification, all in a matter of fifteen working days. The court concluded that the disclosure "would not compel those of ordinary skill in the art to perform undue experimentation in selecting a suitable strain"¹⁸⁵ and that the enablement requirement was therefore satisfied.

Ex Parte Jackson involved the discovery of three distinct microorganism strains, each of which produced the same new antibiotic. The patent applicant classified the strains as belonging to a new species and deposited each of the three strains in a recognized depository. The application included claims to the process of producing the antibiotic from any microorganisms belonging to the same species as the deposited strains,¹⁸⁶ and to the same process employing the deposited strains or any mutations

179. See, e.g., Friedman letter, *supra* note 140; Nathans letter, *supra* note 137; Rabinowitz letter, *supra* note 137; *supra* notes 137-45 and accompanying text.

180. *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 791 (Fed. Cir. 1983).

181. 2 D. CHISUM, *supra* note 7, § 7.03[4][a], [b].

182. 559 F.2d 1183 (C.C.P.A. 1977).

183. 217 U.S.P.Q. (BNA) 804 (P.T.O. Bd. App. 1982).

184. Tabuchi claimed priority on the basis of a Japanese patent application. The issue before the court was whether this application met the enablement requirement of section 112 of the Patent Act, 35 U.S.C. § 112 (1982). Section 119 of the Patent Act, 35 U.S.C. § 119 (1982), allows inventors to claim United States patent priority on the basis of a filing date in a foreign country, provided that the foreign application satisfies the disclosure requirements of section 112. *Kawai v. Metlesics*, 480 F.2d 880 (C.C.P.A. 1973).

185. *Tabuchi*, 559 F.2d at 1189.

186. See 217 U.S.P.Q. at 805.

thereof.¹⁸⁷ A divided Board of Appeals affirmed the rejection of the former claim, but reversed the rejection of the latter claim. The majority reasoned that the specification did not enable one skilled in the art to isolate other antibiotic-producing strains of the same species from nature without undue experimentation—indeed, it was possible that the deposited strains were the only strains in existence suitable for the process.¹⁸⁸ On the other hand, mutations of microorganisms are a common occurrence and “can be intentionally produced by a variety of known procedures.”¹⁸⁹ By depositing the three strains, the patent applicant enabled skilled practitioners to derive mutant strains, and he was therefore entitled to extend his process claims to the use of such mutants.

Here again patent law parallels and reinforces the scientific community’s replicability norm. The “undue experimentation” cases on one hand reinforce the disclosure obligation and on the other hand limit the scope of what may be claimed as a patentable invention. A patent applicant may not, by withholding materials, leave too much work to be done by those who would use the specification to practice the invention. Conversely, the patent applicant is limited to claiming as her invention such advances as her disclosure has fairly put within reach of the public. Patent applicants who limit their disclosures so as to require inordinate effort to achieve replication thereby limit the scope of their monopoly.

c. *Best Mode*

Section 112 of the Patent Act further requires that the specification “set forth the best mode contemplated by the inventor” of carrying out the invention.¹⁹⁰ Unlike the enablement requirement, which is an objective standard focusing on the quality of the inventor’s disclosure, the “best mode” requirement is a subjective standard focusing on the inventor’s own knowledge and belief at the time the patent application is filed.¹⁹¹ The “best mode” requirement goes beyond the scientific community’s replicability norm. An inventor who makes an enabling disclosure of an operative version of her invention will not receive a valid patent if she knows of and conceals a better way to practice the invention at the time the application is filed.¹⁹²

Once again, patent law gives teeth to scientific norms through its tougher enforcement mechanisms. An applicant’s failure to disclose the

187. *See id.* at 805–06.

188. *Id.* at 807–08.

189. *Id.* at 806.

190. 35 U.S.C. § 112 (1982).

191. 2 D. CHISUM, *supra* note 7, § 7.05[1], [2].

192. *See, e.g., In re Gay*, 309 F.2d 769, 772 (C.C.P.A. 1962) (“Manifestly, the sole purpose of [the best mode requirement] is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived.”).

"best mode" of practicing the invention is unlikely to come to the attention of the PTO in the course of the *ex parte* patent examination procedure. But it may well surface in the course of discovery in a subsequent patent infringement suit.¹⁹³ Should it appear at that time that the inventor concealed her "best mode" when she filed her patent application, the patent will be held invalid.¹⁹⁴

d. *Patent Disclosure and Scientific Norms*

Aside from considerations of timing to be examined below,¹⁹⁵ the disclosure requirements of patent law seem to fortify scientific norms to a degree that surpasses the willingness of the scientific community to enforce its own norms. Patent law reinforces the scientific community's interest in the replicability of claimed discoveries by requiring that a patent applicant make a disclosure of her invention that will enable persons skilled in the art to which the invention pertains to make and use the invention without undue experimentation. Patent law reinforces the scientific community's interest in having new discoveries dedicated to the public by requiring that the patent application set forth the best mode contemplated by the inventor of practicing the invention. Publication of the specification upon issuance of the patent and dedication of the claimed invention to the public upon expiration of the patent term further promote these interests. Scientists who protect their discoveries under the patent laws should therefore be at least as likely as scientists influenced solely by the rewards of science to disclose their inventions to the scientific community in a form that satisfies scientific norms.

In some circumstances, scientists may choose to forgo patent protection in order to circumvent enforcement of these norms. For example, scientists might want to restrict access to their organisms in order to keep the organisms out of the hands of their research or commercial competitors. If the scientific community is willing to publish the research of these scientists while allowing them to keep their organisms to themselves, it may be possible for scientists to earn recognition in the scientific community while undermining the community's interest in replicability and public dedication of research claims. Even if the publication is enough to forfeit legal trade secrecy protection, a strategy of publishing research results while maintaining the materials as actual secrets might permit scientists to bypass the strictures of both patent law and scientific norms. They could thus earn scientific rewards and preserve the benefits of exclusivity without ever giving an enabling disclosure of their inventions.

193. See Biggart, *supra* note 52, at 2-73.

194. *E.g.*, *Engelhard Indus. v. Sel-Rex Corp.*, 253 F. Supp. 832, 836-37 (D.N.J. 1966), *aff'd*, 384 F.2d 877 (3d Cir. 1967).

195. See *infra* text accompanying notes 201-06.

It might seem that the protection of a patent would be adequate to persuade inventors to forgo the narrower and more fragile protection of secrecy, since a patentee has the right to enjoin others from making, using, or selling the invention during the term of the patent even after disclosure.¹⁹⁶ But the patent law exchange of disclosure for a right to exclude is not always attractive where secrecy is a feasible alternative.¹⁹⁷ For one thing, an invention that can be exploited in secrecy by the inventor can often also be exploited in secret by a patent infringer. The unrestricted deposit of an organism necessary for replicating such an invention may "enable" infringements that cannot be detected.¹⁹⁸ Cell lines and microorganisms can be propagated so easily that it is difficult under the best of circumstances to keep track of who has access to samples.¹⁹⁹ An inventor may choose instead to keep the organism to herself.

Another reason why biotechnology inventors may be unwilling to deposit their organisms in exchange for patent protection is that a patent may not be broad enough to protect inventors from research competition. For reasons more fully explored below,²⁰⁰ the use of patented inventions in competitive research may not constitute patent infringement. Scientists who make an enabling disclosure of their inventions for patent purposes may find that they have enabled their research competitors to gain scientific credit for subsequent discoveries to which the originator of the materials might otherwise have eventually claimed priority. If the patenting scientist does not gain a corresponding right to exclude research competitors from using the materials, she might prefer to keep her materials to herself and forego patent protection. Of course, withholding research materials after publication to avoid being forestalled by research competitors violates scientific norms. But the reward structure of science sets up an incentive to maximize claims to priority of discovery that conflicts with these norms. And if patent law enforces its enablement requirement more zealously than the scientific community enforces its own norms, scientists may find

196. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489-90 (1974).

197. Of course, not all inventions may be exploited in secret. If an invention may be readily reverse-engineered, patent protection will be more attractive than futile efforts at secrecy. See R. SALIWANCHIK, *supra* note 67, at 10-11.

198. For example, suppose a company has created a new recombinant organism producing a protein that is indistinguishable from human insulin. The recombinant product differs from previously-sold insulin solely in its lower cost of production. The company has a choice of either patent protection or trade secrecy. If the company chooses patent protection, competitors will gain access to the organism once the patent issues. Since the recombinant insulin is identical to insulin produced by other means, it will be impossible to detect whether competitors are infringing the patent. The PTO's prohibition against agreements between inventors and depositories permitting inventors to monitor who gets access to deposits, see *supra* note 175, can only increase the likelihood of undetectable infringement.

199. The ease of propagation can also make it difficult to keep microorganisms as trade secrets or actual secrets. See *supra* notes 84-85 and accompanying text.

200. See *infra* notes 226-42 and accompanying text.

that secrecy provides a more congenial strategy for maximizing their professional and commercial rewards.

e. Timing of Disclosure

There is one important respect in which the incentives arising from scientific rewards and those arising from the patent laws diverge: The timing of disclosure may be quite different for scientists seeking patent protection than for scientists seeking scientific recognition alone. Both the patent laws and the scientific community reward priority of invention,²⁰¹ thus placing a premium on prompt disclosure of new claims. Nonetheless, patent applicants are likely to publish later than scientists motivated solely by scientific norms and rewards. One reason for this difference is that basic research discoveries might be ripe for recognition in the scientific community before they are ripe for patent protection.²⁰² But if a scientist, guided by scientific norms and rewards, publishes results of research that has not yet yielded a patentable invention, she may be unable to obtain a patent for inventions developing out of this research at a later date.²⁰³ Pursuit of patent protection may therefore lead scientists to defer publication until their research has yielded patentable inventions, prolonging the period of secrecy until after they have filed patent applications and thereby slowing down scientific communication and progress.

Once an inventor has a patent application on file, she may publish her research results without impairing her prospects for patent protection on those inventions already claimed.²⁰⁴ Even then, however, patent applicants who are uncertain whether their inventions are patentable may choose to defer publication until a patent actually issues.²⁰⁵ Publication prior to that time is a risky proposition because the inventor thereby forfeits secrecy protection²⁰⁶ without any assurance of obtaining patent rights. A patent

201. R. MERTON, *supra* note 24, at 286-324; see 35 U.S.C. §§ 101, 102 (1982).

202. This disparity in timing is in part a consequence of patent law mechanisms for limiting patent protection to applied technology. See *supra* notes 38-47 and accompanying text.

203. There are two ways in which early publication could jeopardize the scientist's eligibility for patent protection. First, a publication that discloses a subsequently claimed invention bars United States patent protection unless the application is filed within one year of the publication date. 35 U.S.C. § 102. Foreign patent protection may be forfeited immediately upon publication. Second, publication could have untoward consequences for subsequent patentability because of the nonobviousness requirement of 35 U.S.C. § 103. An invention is generally deemed to have been made on the date the inventor files a patent application, and the patentability of the invention turns on whether the invention is obvious in light of the "prior art" as of that date. The prior art includes the applicant's own publication. See, e.g., *Mass. Inst. of Technology v. AB Fortia*, 227 U.S.P.Q. (BNA) 428, 431-32 (Fed. Cir. 1985). If the inventor's own prior publication discloses enough information to make the later-claimed invention obvious, the inventor will not be able to obtain a patent. See Chisum, *Sources of Prior Art in Patent Law*, 52 WASH. L. REV. 1 (1976).

204. But such publication may impair the inventor's prospects for obtaining patent protection on broader claims at a later date. See *In re Ruscetta*, 255 F.2d 687 (C.C.P.A. 1958).

205. If the inventor also applies for foreign patent protection, publication may occur 18 months after the application is first filed. See *supra* note 162.

206. In the United States patent system, secrecy may be preserved prior to the issuance of a patent. 35 U.S.C. § 122 (1982).

application may languish in the PTO for several years before a patent ultimately issues. Thus, the combination of uncertainty as to the patentable status of research discoveries and time lags in the PTO is likely to slow down the dissemination of information in the scientific community.

In sum, notwithstanding the congruence between the substantive disclosure requirement of the patent laws and scientific norms, patent disclosure may occur considerably later than disclosure motivated solely by scientific norms and rewards.

2. *Exclusive Rights*

Disclosure, of course, is only one side of the patent law bargain. Even if patent applicants make broader disclosures of their inventions than scientists motivated only by scientific norms and rewards, they do so in exchange for a seventeen-year monopoly. Publication traditionally marks the end of exclusivity in science, but public disclosure through issuance of a patent marks the beginning of exclusive rights in the patent system. An "enabling" disclosure may be small consolation to a scientific community that is disabled from using it.

Although the patent statute permits patent holders to exclude others from using their inventions, they do not always choose to do so. Depending on the nature of the invention and its market, a patentee may find it advantageous to exploit the invention directly as a monopolist, to suppress the invention entirely, or to license others to exploit the invention on an exclusive or non-exclusive basis in exchange for royalties.²⁰⁷

Licensing of patented inventions may pose special problems where the inventions are useful primarily for subsequent research rather than for commercial applications. The serendipitous nature of research discoveries may make it difficult to place a value on the right to use a patented invention before the outcome of a research project is known. Moreover, most scientific research relies on many prior discoveries. If researchers needed to obtain licenses from each of the prior inventors on whose work they build, the royalties and transaction costs could mount quickly.²⁰⁸

There are several reasons why a patentee might elect not to extend licenses to research competitors. The patentee might want to suppress the

207. For an economic analysis of the exploitation of patent monopolies, see F. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 379-99 (1970); see also Machlup, *An Economic Review of the Patent System*, Study No. 15 of the Subcomm. on Patents, Trademarks, and Copyrights of the Senate Comm. on the Judiciary, 85th Cong., 2d Sess. (1958) (economic overview of patent system as whole).

Nonexclusive licensing of patented inventions minimizes interference with subsequent research. Patent rights on the basic process for recombinant DNA, owned jointly by Stanford and the University of California, are licensed on a nonexclusive basis to all interested companies. See M. KENNEY, *supra* note 1, at 257-59.

208. See generally Gordon, *Fair Use as Market Failure: A Structural and Economic Analysis of the Betamax Case and Its Predecessors*, 82 COLUM. L. REV. 1600 (1982).

invention in order to bolster its position in a related market, as happens when corporations build up extensive patent portfolios to prevent potential licensees from using competitive technologies.²⁰⁹ Or the patentee might fear that licensed use of the patented invention in further research will facilitate inventing around the patent, thereby undermining the future value of the patent.²¹⁰ Finally, the patentee might wish to preserve exclusivity in subsequent research in order to maximize future claims to priority of discovery for purposes of both intellectual property and scientific credit.

The extent to which patent law actually permits patent holders to enjoin the use of their inventions by others in subsequent research is unclear. On its face, the statute seems to forbid *any* unauthorized use of the patented invention. Section 154 of the Patent Act by its express terms grants to patentees "the right to exclude others from making, using, or selling the invention throughout the United States" during the patent term.²¹¹ Section 271 of the Patent Act supplies a corresponding definition of patent infringement: "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent."²¹² According to the cases, this seventeen-year period of exclusive use is the consideration paid by the public for the disclosure of an invention which it will be free to use once the patent expires.²¹³ The enabling disclosure in the patent specification assures that the public will receive its end of the bargain upon expiration of the patent.²¹⁴

This commonplace formulation of the patent law bargain is indeed at odds with the traditional mechanisms of the scientific community for building upon prior research. Scientific research promotes the dissemination of new knowledge to research competitors by awarding recognition to those who make their claims freely available to the community.²¹⁵ Patent law, in contrast, promotes investment in innovation by providing exclusive rights in inventions.²¹⁶

But other features of the patent statute indicate that this exclusivity is

209. F. SCHERER, *supra* note 207, at 392. Patents for inventions made by universities and small businesses in the course of federally-sponsored research cannot be held back from exploitation in this way. See *supra* notes 102-08 and accompanying text.

210. For an example of how this might occur, see *infra* note 242.

211. 35 U.S.C. § 154.

212. 35 U.S.C. § 271(a). A patentee may obtain an injunction against infringement "in accordance with the principles of equity," as well as damages "in no event less than a reasonable royalty" and up to three times the amount of actual damages in the discretion of the court. 35 U.S.C. §§ 283, 284. Reasonable attorney fees are also available to the prevailing party "in exceptional cases." 35 U.S.C. § 285.

213. See, e.g., *Brulotte v. Thys Co.*, 379 U.S. 29 (1964); *United States v. Dubilier Condenser Corp.*, 289 U.S. 178 (1933).

214. E.g., *In re Argoudelis*, 434 F.2d 1390, 1394-95 (C.C.P.A. 1970) (Baldwin, J., concurring).

215. See *supra* notes 17-28 and accompanying text.

216. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974).

not absolute. If the public had absolutely no right to make, use, or sell the patented invention until the *end* of the patent term, it would be somewhat puzzling to require that the patentee give the public an enabling disclosure of the invention at the *beginning* of the patent term. The requirement of early disclosure suggests that certain uses of patented inventions during the patent term do not constitute patent infringement.

Perhaps the most important function of early disclosure is to facilitate improvement of the patented invention or invention around the patent.²¹⁷ Disclosure during the patent term also permits verification of the sufficiency of the disclosure.²¹⁸ Other practitioners in the field of the invention may be in a better position than the patent examiner to determine whether a disclosure is enabling.²¹⁹ Since an insufficient disclosure makes the patent invalid and unenforceable, those who have a use for the patented technology will be motivated to uncover defects in the specification in order to avoid liability to the patentee.²²⁰ If an insufficient disclosure were not made public until the expiration of the patent term, the public would already have tolerated "the embarrassment of an exclusive patent"²²¹ without receiving its *quid pro quo*.²²² Disclosure at the outset of the patent term also reveals the scope of the patent claims, thereby giving notice to potential infringers (and to potential licensees) of the metes and bounds of the patent monopoly.²²³ Finally, early disclosure may facilitate "the Progress of Science and the useful Arts"²²⁴ by giving the public access to those parts of the specification that the patentee does not claim.²²⁵

At least the first two of these functions—inventing around the patent and checking the sufficiency of the disclosure—seem to contemplate some

217. See generally *Yarway Corp. v. Eur-Control USA*, 775 F.2d 268, 277 (Fed. Cir. 1985) ("negative incentive" to "design around" other patented products is benefit of patent system); *State Indus. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) (same).

The prevalence and social value of inventing around patented technologies are subject to dispute. Compare Turner, *The Patent System and Competitive Policy*, 44 N.Y.U. L. REV. 449, 455 (1969) (patent forces competitors to invest resources in finding noninfringing ways of achieving same result as patented invention, which may in many instances be wasteful if it diverts resources from other unsolved problems) with Adelman, *The Supreme Court, Market Structure and Innovation: Chakrabarty, Rohm and Haas*, 27 ANTITRUST BULL. 457, 464 (1982) (efforts to invent around patent are unlikely to occur unless competitor and patentee have different views of cost of developing alternative technology and will not result in net loss to society because patented invention might never have been made without patent system).

218. See *infra* notes 232–34 and accompanying text.

219. Cf. generally *Loom Co. v. Higgins*, 105 U.S. 580, 586 (1882) (patent specifications should be addressed to those skilled in art); *Mowry v. Whitney*, 81 U.S. (14 Wall.) 620, 644 (1871) (same).

220. See, e.g., *Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 239 (1832).

221. *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1965) (quoting Thomas Jefferson).

222. *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186–87 (1933); *Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 247 (1832).

223. See *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 434 (1822) (specification warns innocent user of patented invention against infringement and permits public to check whether patentee is entitled to patent).

224. U.S. CONST. art. I, § 8, cl. 2; see *supra* text accompanying notes 38–39.

225. See generally *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (1926) (disclosure of unclaimed invention in specification of issued patent puts such invention in public domain).

"use" of the disclosed invention during the term of the patent, if only in the laboratory. And while the statute itself does not expressly permit any use of patented technology during the term of the patent, the cases have recognized an exception to patent infringement for "experimental use" of an invention.²²⁶

It is difficult to discern the scope of this exception with any degree of precision. Since experimental use becomes an issue only in infringement actions, judicial pronouncements on its reach address situations where patentees have found a defendant's activities sufficiently annoying to be worth the trouble of pursuing a lawsuit. This factor has undoubtedly skewed the universe of experimental use decisions toward cases that implicate commercial interests. Within this universe, the experimental use defense is frequently raised and rarely sustained.²²⁷

The experimental use doctrine was first expounded by Justice Story in dictum in an 1813 decision, *Whittemore v. Cutter*.²²⁸ In that case, the trial court had entered judgment on a verdict for the plaintiff in a patent infringement suit. On appeal, the defendant argued that the jury had been erroneously instructed "that the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right."²²⁹ Justice Story noted that the instruction was actually favorable to the defendant because it limited infringement liability to the making of a machine with an intent to use it for profit. He supposed that this limitation "was adopted by the court from the consideration, that it could never have been the intention of the legislature to punish a man, who constructed such a machine *merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects*."²³⁰

226. *Roche Prods. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 862-63 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984); *Pfizer, Inc. v. International Rectifier Corp.*, 217 U.S.P.Q. (BNA) 157, 160-61 (C.D. Cal. 1982). See generally 4 D. CHISUM, *supra* note 7, at § 16.03(1); Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957); Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. OFF. SOC'Y 617 (1985).

227. The Court of Appeals for the Federal Circuit has called the defense "truly narrow," *Roche Products v. Bolar Pharmaceutical Co.*, 733 F.2d at 863, and one commentator has argued that the defense is inconsistent with the language of the statute and the policies of patent law. See Bee, *supra* note 226, at 359, 377.

228. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600); see also *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391). The doctrine continued to appear solely in dicta for the next 45 years. See, e.g., *Jones v. Pearce*, Webster's Pat. Case 122, 124-25 (K.B. 1832); *Byam v. Bullard*, 4 F. Cas. 934, 935 (C.C.D. Mass. 1852) (No. 2,262). It finally found its way into a published holding in 1858, when the Circuit Court for the Southern District of New York approved a jury instruction that the use of a patented invention "merely for experiment, and not with a view to profit" would not give rise to infringement liability. *Poppenhusen v. New York Gutta Percha Comb Co.*, 19 F. Cas. 1059, 1063 (C.C.S.D.N.Y. 1858) (No. 11,283).

229. 29 F. Cas. at 1121. The defendant objected to this instruction on two grounds: first, that as a matter of statutory construction the making of a machine without using it could not constitute patent infringement; and, second, that the mere making of a patented machine without actually using it causes no damage and thus could not be the basis for infringement liability. Justice Story rejected both of these arguments.

230. *Id.* at 1121 (emphasis added).

Although subsequent cases elaborated the doctrine in confounding ways,²³¹ Justice Story's original articulation seems, at least in theory, to meet the needs of the research science community. The first exemption from liability for making a patented device—"philosophical experiments"—appears to protect "pure" research from patent infringement liability, while the second—"ascertaining the sufficiency of the machine to produce its described effects"—appears to permit replication of research claims.

Elsewhere in the opinion Justice Story elaborates a patent law correlative to the scientific community's interest in replicability. In objecting to a jury instruction that omissions from the patent specification rendering it nonenabling would not invalidate the patent unless the omissions were deliberate, the defendant argued that a materially defective specification should provide a defense to an infringement action even without proof of intentional deception. Story felt compelled to reject the argument under the language of the 1793 Patent Act,²³² but was clearly sympathetic nonetheless to the defendant's position:

[T]he monopoly is granted upon the express condition, that the party shall make a full and explicit disclosure, so as to enable the public, at the expiration of his patent, to make and use the invention or improvement in as ample and beneficial a manner as the patentee himself. If therefore it be so obscure, loose, and imperfect, that this cannot be done, it is defrauding the public of all the consideration, upon which the monopoly is granted

It was probably with a view to guard the public against the injury arising from defective specifications, that the statute requires the let-

Later that year Justice Story reiterated his conception of the experimental use doctrine in the case of *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391), as follows:

[T]he making of a patented machine to be an offence . . . must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

Id. at 555 (citation omitted).

231. For example, some later decisions suggest that the rationale for the experimental use defense is that experimental use causes no harm. *See, e.g.,* *Byam v. Bullard*, 4 F. Cas. 934, 935 (C.C.D. Mass. 1852) (No. 2,262); *Albright v. Celluloid Harness-Trimming Co.*, 1 F. Cas. 320, 323 (C.C.D.N.J. 1877) (No. 147). Since Justice Story rejected the argument that making a patented machine without causing harm cannot give rise to liability in *Whittemore*, *see supra* note 229, this cannot have been his rationale for the defense.

232. Section 6 of that Act reads in part as follows:

Provided always, . . . That the defendant in such action shall be permitted to plead . . . that the specification, filed by the plaintiff, does not contain the whole truth relative to his discovery, or that it contains more than is necessary to produce the described effect, which concealment or addition shall fully appear to have been made, for the purpose of deceiving the public.

Patent Act of 1793, ch. 11, 1 Stat. 318 (1793), *quoted in* 6 D. CHISUM, *supra* note 7, at app. 10-3 (emphasis in original). Despite the language of the statute, the Supreme Court subsequently held in *Grant v. Raymond*, 31 U.S. (6 Pet.) 218 (1832), that a defendant in an infringement suit could avoid liability by showing that the specification was defective even without any intent on the part of the patentee to deceive the public.

ters patent to be examined by the attorney general, and certified to be in conformity to the law, before the great seal is affixed to them. In point of practice, this must unavoidably be a very insufficient security, and the policy of the provision, that has changed the common law, may be very doubtful.²³³

In recognizing an exception to patent infringement for use of the invention "for the purpose of ascertaining the sufficiency of the machine to produce its described effects," Justice Story may have been trying to correct for this deficiency in the 1793 statute. If, as Justice Story thought, examination by the attorney general prior to patent issuance is "a very insufficient security" against defective disclosures, giving the public a right to check the adequacy of the disclosure without liability for infringement provides additional assurance that the public has received its *quid pro quo* for the patent monopoly. The most effective scrutinizers of the patent disclosure are likely to be potential infringers—or at least potential users of the patented invention. These people have the greatest knowledge of the relevant field and care the most whether the claimed invention works as described. The experimental use doctrine thus gives the patentee's competitors a right during the patent term to vindicate the public's interest in having an enabling disclosure.

Although a few decisions have allowed the experimental use defense where the defendant simply wanted to see if the claimed invention worked,²³⁴ hardly any cases have allowed the defense to excuse otherwise infringing activities that were conducted "merely for the purpose of philosophical experiments."²³⁵ When commercial companies have claimed that their uses of patented inventions were for "philosophical experiments," the defense has generally been denied.²³⁶

233. 29 F. Cas. at 1122.

234. See, e.g., *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 229 (S.D.N.Y. 1944); *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 333 (N.D.W. Va. 1937). But cf. *National Meter Co. v. Thomson Meter Co.*, 106 F. 531 (C.C.S.D.N.Y. 1900) (use of patented invention to see if it works constitutes threatened infringement by business competitor sufficient to support injunction).

235. These cases have recently been reviewed in Hantman, *supra* note 226.

236. See, e.g., *United States Mitis Co. v. Carnegie Steel Co.*, 89 F. 343, 351 (C.C.W.D. Pa. 1898) (noting that defendant's use of patented invention "was a commercial use, extending over a period of several months, and involved a very large product"); *Bonsack Machine Co. v. Underwood*, 73 F. 206, 211 (C.C.E.D.N.C. 1896) (noting that machine "has not been made simply as an experiment, but has been used for profit, that is, for the purpose of selling the [defendant's] patent"); *Albright v. Celluloid Harness-Trimming Co.*, 1 F. Cas. 320, 323 (1877) (No. 147) (holding use of patented invention in trial manufacture "is a technical infringement, and is sufficient to authorize an injunction restraining . . . future use" but not sufficient for award of damages); *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279) (noting that defendants "are rivals of the complainant in the very business to which his patents relate").

The Robinson patent treatise, published in 1890, took the position that an experimental use of a patented invention in order to use or sell the products of the experiment or with a view to adapting the invention to the experimenter's business is "hostile to the interests of the patentee" and thus constitutes infringement. W. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898 (1890). Consistent with this view, defendants who used patented inventions in the course of producing products for sale or performing services for customers have met with little success. E.g., *Spray Refrig-*

A rare case allowing the experimental use defense for the use of a patented invention in research is *Ruth v. Stearns-Roger Manufacturing Co.*²³⁷ In that case, the defendant made unauthorized sales of patented machines and replacement parts to several customers, including the Colorado School of Mines. In awarding damages, the court adopted the recommendations of a special master, who had distinguished between direct infringement for the sale of whole machines and contributory infringement for the sale of parts.²³⁸ The special master had calculated damages for direct infringement on all sales of infringing machines, including those sold to the Colorado School of Mines. In calculating damages for contributory infringement, however, the special master had excluded sales of replacement parts to the Colorado School of Mines on the ground that these parts "were for use in laboratory machines used for experimental purposes, and consequently did not contribute to an infringing use."²³⁹ Be-

eration Co. v. Sea Spray Fishing, Inc., 322 F.2d 34, 36-37 (9th Cir. 1963) (use of patented apparatus and method for freezing fish "for the purpose of experimentation as to the desirability of using this method" constituted patent infringement where use occurred in course of commercial fishing operation of kind which patent was designed to serve); Imperial Chem. Indus., PLC v. Henkel Corp., 545 F. Supp. 635, 656 (D. Del. 1982) (defendant's manufacture of 1200 pounds of patented chemicals for "pilot plant use" infringed patent where defendant supplied samples to potential customers and made it known in market that chemicals were commercially available); Northill Co. v. Danforth, 51 F. Supp. 928, 929 (N.D. Cal. 1942) ("Defendant's experiments were evidently not made for philosophical or amusement purposes but were made in connection with his business as a manufacturer and salesman of anchors."); Sprout, Waldron & Co. v. Bauer Bros., 26 F. Supp. 162, 169 (S.D. Ohio 1938) ("The defendant cannot escape on the ground of experimental use where the machines were used to operate upon customers' products in the ordinary course of business."); Radio Corp. of Am. v. Andrea, 15 F. Supp. 685, 687 (E.D.N.Y. 1936), *modified on other grounds*, 90 F.2d 612 (2d Cir. 1937) (assembling parts of patented combination to test them was infringement where assembly was "not a scientific research or an engineering inquiry" but rather "a step which the defendants apparently deemed necessary in the manufacture and sale of their product"); Pairpearl Prods., Inc. v. Joseph H. Meyer Bros., 58 F.2d 802, 804 (D. Me. 1932) (use of patented process for extracting pearl essence infringed patent notwithstanding defendant's claim that use was experimental as incident to search for new agent, where pearl essence extracted through patented process was sold to customers); Cimiotti Unhairing Co. v. Derboklow, 87 F. 997, 999 (C.C.E.D.N.Y. 1898) (use of patented machine for customers "in the ordinary course of business" was patent infringement, notwithstanding defendant's claim that he was "experimenting" with machines in order to see if he could improve them).

Two recent decisions have denied the experimental use defense to generic drug manufacturers who performed clinical tests of patented drugs prior to expiration of the patents, reasoning that such testing relates to a commercial activity or the operation of a business. *Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 862 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984); *Pfizer, Inc. v. International Rectifier Corp.*, 217 U.S.P.Q. (BNA) 157, 160-62 (C.D. Cal. 1982).

Congress responded to the decision in *Roche v. Bolar* by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585. That Act amends § 271 of the Patent Act to exempt from infringement liability the use of a patented drug solely to develop the information that must be submitted under federal law in order to obtain permission to sell the drug. See 35 U.S.C.A. § 271(e) (West Supp. 1987).

237. 13 F. Supp. 697 (D. Colo. 1935).

238. The unlicensed sale of a patented machine directly infringes the patent regardless of the use to which the machine is put by the buyer, but the sale of parts does not constitute direct infringement unless the parts are themselves the subject of patent claims. Selling unpatented parts with the intention that they be used in a patented machine might nonetheless constitute contributory infringement, but only if the buyer's use of the parts itself constitutes direct infringement. See 35 U.S.C. § 271(a), (c) (1982); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341-42 (1961); 4 D. CHISUM, *supra* note 7, § 17.03.

239. 13 F. Supp. at 703.

yond this conclusory statement, the only information offered in the opinion as to the nature of the use is that "[t]hese machines were all used in the laboratory and were cut up and changed from day to day."²⁴⁰ The case offers no guidance for distinguishing a philosophical experiment from an infringing use.²⁴¹

The scope of the experimental use defense remains unclear, making it difficult to assess the degree to which the exclusive rights of patent holders might impede the progress of science. Justice Story's original formulation of the experimental use doctrine seems in principle to accommodate the interests of the scientific community in replicating and building upon new knowledge in basic research. The first prong of Justice Story's experimental use privilege, permitting "philosophical experiments," is not well defined in the cases, but it seems to permit subsequent researchers to use the patented invention at least in traditional basic research with no commercial implications. The second prong, allowing the defense where the use is for the purpose of testing the adequacy of the specification, parallels the scientific community's interest in replication of published claims.

The difficulty arises in trying to apply these principles when basic research has commercial value. As patent protection for basic research discoveries becomes more commonplace, and as the use of patented inventions in research becomes more of a threat to the interests of patent holders, the experimental use defense is likely to be litigated in new contexts requiring careful analysis of its purposes and scope.

The optimal extent of the experimental use defense cannot be determined without attention to its likely effects on the scientific community. Too narrow a defense could stifle basic research and impair the community's mechanisms for validating and building upon new knowledge. Too broad a defense could cause industrial sponsors to lose interest in biotechnology research or to rely on secrecy in lieu of patent protection. There may be no way to avoid both of these potential problems completely.

The case for allowing the defense appears strongest where the subsequent user is attempting to devise alternatives to the patented invention.²⁴²

240. *Id.*

241. In a recent review of experimental use cases, Ronald Hantman approved the *Ruth* decision while questioning its precedential value:

This case is unlike any other experimental use case because it is the only one in which the exception is claimed for use at a university. Few would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function. Because of the limited scope of the research in *Ruth*, the case probably has little precedential value for experimental use cases not involving university research.

Hantman, *supra* note 226, at 633.

242. The facts of a pending lawsuit, *Scripps Clinic & Research Found. v. Genentech, Inc.*, 3 U.S.P.Q.2d (BNA) 1481 (N.D. Cal. 1987), illustrate how the issue might arise. The lawsuit concerns technology for producing Factor VIII:C, a protein used in treating hemophilia. Plaintiffs hold patents on methods for recovering Factor VIII:C from human blood plasma in purified and concentrated form and on the purified and concentrated protein itself. The patented methods are costly, however, and involve a risk of transmitting disease. These difficulties make the protein a likely candidate for pro-

In such a case, the interests of the research user are congruent with the interests of the public and the scientific community in advancing the state of human knowledge. The patent holder, by contrast, has an interest in prolonging the period in which the public is dependent on the patented technology. If the patentee sees the research user as a competitor rather than a customer, she may refuse to license the invention. Without an experimental use defense, it is possible that no one would be able to build on the inventor's discovery until the patent expired.

At the other end of the spectrum, the case for allowing the defense appears weakest where the research user is essentially consuming a patented invention in an unrelated research effort—for example, by using a patented laboratory machine. To allow such a user to avoid infringement liability on the ground that the machine was used in research would eviscerate patent protection for technologies used primarily in research laboratories. The user falls squarely within the patentee's market, and there is no reason to suppose that the patentee would refuse to negotiate a license.

If patent protection permits scientists to exclude the scientific community from making use of published research discoveries, it could undermine a critical mechanism of the scientific community for facilitating the progress of science. Without the exclusive rights granted by the patent system, the reward structure of science encourages scientists to dedicate their results to the scientific community by requiring that they publish in order to gain recognition. This system promotes the interests of the community in the validation and extension of new knowledge by overriding the individual scientist's contradictory incentive to hoard her findings. Dedication of new discoveries to the community necessarily entails facilitating the work of one's competitors, but this is the price individual scientists must pay for current recognition. As the records of the JBC controversy show, the norms of dedication and replicability cease to be self-enforcing when it is possible for scientists to earn recognition without fully dedicating their results to the community—for example, when scientists can publish their research claims without supplying otherwise unavailable materials to their competitors. By granting exclusive rights after publication, patent law may offer scientists another mechanism for earn-

duction through recombinant DNA technology.

Genentech is charged with infringing plaintiffs' patents in the course of cloning the gene for Factor VIII:C. Genentech used purified Factor VIII:C made by the plaintiffs' process to determine the sequence of amino acids in the protein, and used this information to identify and clone in a recombinant organism the human gene responsible for manufacturing Factor VIII:C.

The district court held that Genentech's use of the patented invention in its laboratories infringed the patent. *Id.* at 1486. Since Genentech evidently never asserted the experimental use defense, the court did not reach the question of whether the "philosophical experiments" prong of the experimental use doctrine privileges research use of a patented invention by a commercial company. Had Genentech raised the issue, this might have been an appropriate case for allowing the experimental use defense (at least as to the method claims), since Genentech's goal was to invent around the patent, rather than to exploit the patented technology itself.

ing recognition while deferring payment of the price of dedication for seventeen years. It remains to be seen whether the experimental use defense will develop into a means of reconciling scientific norms with the patent monopoly.

D. *An Illustration of the Conjunction*

A recently-settled dispute illustrates some of the problems that arise when scientists influenced by scientific norms and rewards seek to preserve intellectual property rights. The dispute erupted between competing teams of scientists at the National Cancer Institute (NCI) in Bethesda, Maryland, and the Pasteur Institute in Paris. Both teams of scientists had been doing research related to acquired immune deficiency syndrome (AIDS), separately and collaboratively, for several years. Their competitive efforts to secure intellectual property rights and scientific credit for invention of a test to detect the presence of antibodies to the AIDS virus in human blood became the subject of two legal proceedings: a breach of contract action in the United States Claims Court²⁴³ and a patent interference proceeding in the PTO.²⁴⁴

NCI scientists, under the direction of Dr. Robert Gallo, began studying human retroviruses²⁴⁵ before the onslaught of the AIDS epidemic. In 1978, the scientists isolated the first human retrovirus, which they called human T-cell lymphotropic virus because of its affinity for T-lymphocytes. The same group discovered a second human retrovirus, associated with leukemia, in 1982. They renamed the first human retrovirus HTLV-I and called the new retrovirus HTLV-II.²⁴⁶ This early research laid the groundwork for the subsequent discovery that AIDS is caused by yet another retrovirus.²⁴⁷

Scientists at the Pasteur Institute began studying AIDS under the direction of Dr. Luc Montagnier in late 1982. In February of 1983, they isolated a virus from the lymph nodes of a patient suffering from persistent lymphadenopathy. They called their virus lymphadenopathy-associated virus or LAV. This virus ultimately proved to be associated with AIDS. During this period, the NCI and Pasteur Institute scientists

243. *Institut Pasteur v. United States*, No. 730-85 (Cl. Ct. Dec. 12, 1985) (complaint reprinted as attachment C to Lipsey, Brezner & Majofis, *Protecting Trade Secrets in Biotechnology*, in *PROTECTING TRADE SECRETS*, *supra* note 83, at 807, 861); see *Institut Pasteur v. United States*, 10 Cl. Ct. 304 (1986), *rev'd*, 2 U.S.P.Q.2d (BNA) 1048 (Fed. Cir. 1987).

244. See Norman, *AIDS Patent Negotiations Break Down*, 232 *SCIENCE* 819 (1986); Altman, *Ruling May Settle AIDS Test Dispute*, N.Y. Times, Apr. 30, 1986, at 10 col. 3.

245. A retrovirus is a virus that carries its genetic information in the form of ribonucleic acid (RNA) rather than deoxyribonucleic acid (DNA) and reproduces itself by using an enzyme called reverse transcriptase to make a DNA strand corresponding to its own viral RNA. This DNA then integrates itself into the chromosomes of the host cell and uses the biological mechanisms of the host to replicate the virus. See Gallo, *The First Human Retrovirus*, *SCI. AM.*, Dec. 1986, at 88.

246. *Id.*

247. See Gallo, *The AIDS Virus*, *SCI. AM.*, Jan. 1987, at 47.

began communicating with each other and sharing biological materials.²⁴⁸ The NCI scientists supplied materials from their prior work with retroviruses, which allowed the Pasteur Institute scientists to identify LAV as a retrovirus distinct from either HTLV-I or HTLV-II. The Pasteur Institute published this finding in May of 1983.²⁴⁹

Despite the propensity of the LAV virus to kill the cells in which it was grown, the Pasteur Institute scientists were able to propagate the virus in small quantities. By August of 1983, they had developed a test that detected antibodies to LAV in twenty percent of serum samples taken from AIDS patients.²⁵⁰ They filed patent applications for their test in London in September of 1983 and in the United States in December of 1983, claiming the date of the European filing for purposes of priority.²⁵¹

In the meantime, the NCI scientists were also attempting to isolate a virus from AIDS patients. While they found evidence of retrovirus in AIDS patients, they were having difficulty growing the virus in culture.²⁵² The Pasteur group twice sent samples of their virus to NCI,²⁵³ but the NCI scientists assert that they were unable to propagate the Pasteur virus.²⁵⁴ Finally, in November of 1983, the NCI group found a cell line that could survive infection with the AIDS virus, making it possible to grow the virus in significant quantities. Now the NCI group was able to characterize the virus, which they called HTLV-III, and to develop a more sensitive test to detect antibodies to the virus in blood samples. NCI published its findings in May of 1984.²⁵⁵ A patent was issued on NCI's test kit in May of 1985.²⁵⁶

248. The terms under which these materials were shared, and the actual use made of the shared materials, are disputed. *Institut Pasteur v. United States*, No. 730-85 (Cl. Ct. Dec. 12, 1985).

249. Barré-Sinoussi, Chermann, Rey, Nugeyre, Chamaret, Gruest, Dauguet, Axler-Blin, Vézinet-Brun, Rouzioux, Rozenbaum & Montagnier, *Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)*, 220 SCIENCE 868 (1983).

250. Norman, *Patent Dispute Divides AIDS Researchers*, 230 SCIENCE 640, 642 (1985).

251. See *supra* note 184.

252. Norman, *AIDS Priority Fight Goes to Court*, 231 SCIENCE 11 (1986).

253. Complaint, *Institut Pasteur v. United States*, No. 730-85 (Cl. Ct. Dec. 12, 1985).

254. Norman, *supra* note 252, at 12.

255. Gallo, Salahuddin, Popovic, Shearer, Kaplan, Haynes, Palker, Redfield, Oleske, Safai, White, Foster & Markham, *Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV-III) From Patients With AIDS and at Risk for AIDS*, 224 SCIENCE 500 (1984); Popovic, Sarnagadharan, Read & Gallo, *Detection, Isolation, and Continuous Production of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and pre-AIDS*, 224 SCIENCE 497 (1984); Shaw, Broder, Essex & Gallo, *Human T-Cell Leukemia Virus: Its Discovery and Role in Leukemogenesis and Immunosuppression*, 30 ADV. INTERN. MED. 1 (1984); Shupbach, Popovic, Gilden, Gonda, Sarnagadharan & Gallo, *Serological Analysis of a Subgroup of Human T-Lymphotropic Retroviruses (HTLV-III) Associated with AIDS*, 224 SCIENCE 503 (1984). Almost two years later, controversy over priority of discovery was aggravated by the disclosure that electron micrograph pictures of the AIDS virus accompanying these publications depicted cells infected with LAV supplied by the Pasteur Institute rather than cells infected with HTLV-III isolated by the NCI scientists. See Gilden, Gonda, Sarnagadharan, Popovic & Gallo, *HTLV-III Legend Correction*, 232 SCIENCE 307 (1986) (letter to editor); Norman, *A New Twist in AIDS Patent Fight*, 232 SCIENCE 308 (1986).

256. U.S. Patent 4,520,113. NCI also filed a patent application, Serial No. 602,946, on a method of continuous production of HTLV-III retrovirus from patients with AIDS and pre-AIDS. This application is still pending. See *In re Gallo*, 231 U.S.P.Q. (BNA) 496 (Comm'r Pat. 1986).

The Pasteur Institute initiated legal proceedings to establish its priority of invention for purposes of both patent rights and scientific credit. In the patent interference proceeding, the Pasteur Institute asserted that its researchers were the first to isolate the AIDS virus and to develop an AIDS antibody test kit, and that it was therefore entitled to the patent rights on this invention. In the Court of Claims action, the Pasteur Institute alleged that NCI had violated express and implied contracts with Pasteur in patenting and licensing its own test kit and denying appropriate recognition to the Pasteur Institute scientists. Crucial to this latter action was the extent of NCI's actual use of the virus supplied by the Pasteur Institute in developing the NCI test kit. The Pasteur Institute asserted that it supplied the virus to NCI solely for "research purposes" and not for "industrial purposes," and that NCI's HTLV-III "is, or is identical to, the LAV strain first isolated by Pasteur."²⁵⁷ President Ronald Reagan and French Prime Minister Jacques Chirac announced the settlement of both proceedings on March 31, 1987, during a visit to Washington by Chirac.²⁵⁸ This dramatic conclusion to the conflict indicates the extraordinary degree of public interest in AIDS research.

This controversy illustrates a number of the themes developed in the foregoing analysis of the interaction of scientific norms with intellectual property law. First, apart from intellectual property concerns, it shows the dilemma confronting scientists who seek current scientific recognition in the course of a competitive research effort. Each team of scientists benefited from work done by the other, and, conversely, each team facilitated the work of the other through its own disclosures. These disclosures undoubtedly earned scientific recognition for the publishing scientists and advanced the progress of science, but they may also have given a boost to the competition.

The dispute also highlights the difference in timing between a discovery that is ripe for scientific recognition and an invention that is ripe for patent protection. The Pasteur Institute developed a more primitive test kit first; NCI developed a more sensitive test kit later. In the patent interference proceeding, NCI contended that Pasteur was not entitled to a patent because the test kit that was the basis for Pasteur's patent application was useless without a method for growing the virus in quantity, and that NCI rather than Pasteur was the first to develop such a method. This argument may encourage biotechnology inventors to defer publication and dissemination of their discoveries until they are confident that their inven-

257. Complaint, *Institut Pasteur v. United States*, No. 730-85 (Cl. Ct. Dec. 12, 1985).

258. Barnes, *AIDS Patent Dispute Settled*, 236 SCI. 17 (1987). Under the settlement agreement, the parties will share patent rights and jointly contribute 80% of their royalties on the antibody test kits to an AIDS research foundation. Both teams of scientists will be recognized as joint inventors of the test kits. As part of the settlement, Drs. Gallo and Montagnier signed a chronology of key discoveries in AIDS research.

tions are patentable. Had the Pasteur and NCI scientists followed such a strategy of interim secrecy, it might have taken additional months or years for either team to develop its AIDS screening test.

The Pasteur Institute's efforts to restrict dissemination of LAV even after publication of its discovery demonstrate that the scientific community may enforce its disclosure norms less rigorously than the patent law enforces its disclosure requirement. In this regard, it may be significant that *Science* magazine, where much of the research of both groups was published, did not at that time have a policy requiring publishing authors to make their materials available to other researchers, although it has since adopted such a policy.²⁵⁹ Without such a requirement, the Pasteur Institute was able to restrict access to LAV to its research collaborators and to prevent its use for "industrial purposes" or its dissemination to other scientists without their express permission. Restrictions on access to the virus would not have been possible if a patent had already issued on an invention requiring use of the virus.²⁶⁰

On the other hand, a patent might have given either team the right to enjoin the other from using the patented invention in subsequent research. Laboratory use of the virus by scientists seeking to develop an antibody test kit for ultimate sale in the market arguably falls outside the scope of the experimental use defense.²⁶¹ Fortunately, in this case neither team of scientists sought to enjoin the other's research. It is clear in retrospect, however, that the research of each team represented a threat to both the commercial and the professional interests of the other. Both of these interests provide an incentive to impede the research efforts of competitors. But while the scientific community does not empower inventors to enjoin the use of prior discoveries in subsequent research, patent law may.

CONCLUSION

The commercialization of basic research discoveries in biotechnology and the availability of patent protection for such discoveries have generated concern in the scientific community about the impact of intellectual

259. The *Science* policy now provides: "When a paper is accepted for publication in *Science*, it is understood by the editors that any materials necessary to verify the conclusions of the experiments reported will be made available to other investigators under appropriate conditions." 232 *SCIENCE* xi (1986) ("Information for Contributors"). The Pasteur Institute's restrictions on NCI's use of LAV might constitute "appropriate conditions" for making its materials available to other investigators within the meaning of the new *Science* policy.

260. See *supra* notes 175-78 and accompanying text. The dispute also illustrates the risk of undetectable infringement of patents involving the use of microorganisms. The Pasteur Institute contended that NCI used LAV to develop its test kit, while NCI insisted that it isolated its own virus. Subsequent studies indicated that the two viruses differ in their genetic sequences by approximately 1.5%, compared to a difference of approximately 6% relative to an AIDS virus isolated by another laboratory. Norman, *HTLV-III and LAV: Similar, or Identical?*, 230 *SCIENCE* 643 (1985). Since AIDS viruses can undergo spontaneous mutation, this genetic similarity is consistent with but does not prove use of LAV by NCI.

261. See *supra* notes 234-41 and accompanying text.

property law on the behavior of research scientists in biotechnology-related fields. Analysis of intellectual property rules in light of scientific norms and incentives reveals substantial parallels between the two systems. The disclosure requirements of patent law fortify scientific norms promoting publication of research results in replicable form. To the extent that these requirements go beyond scientific norms, mandating broader disclosure than is necessary to earn recognition in the scientific community, some inventors may choose to forgo patent protection in favor of secrecy. Trade secrecy and actual secrecy, while offering feasible strategies for protection of some biotechnology-related inventions, conflict considerably more with scientific norms and rewards than patent law in that they entail substantial nondisclosure. Even for inventors who choose patent protection over secrecy, patent disclosure is likely to occur later than disclosure motivated solely by scientific norms and rewards. Moreover, if the patent statute forbids anyone but the patentee from making or using the invention for any purpose, subsequent researchers may be prevented from building on patented inventions. Insofar as patent law permits inventors to keep research competitors from using their discoveries, it could aggravate existing conflict between scientific norms and the incentives created by scientific rewards. The experimental use doctrine offers a potential mechanism for reconciling the patent monopoly with the interest of the research community in building upon prior discoveries through subsequent research.

Of course, it is open to question whether the patent system should do anything at all to avoid aggravating existing conflict between the norms and the reward structure of science. The patent system formulates rules to advance its own agenda, which may not coincide with the aims of the scientific community. If patent rules and incentives conflict with the norms and rewards of science, perhaps the scientific community should either adjust its own norms and rewards, or do without patent protection.

There are several reasons why it might make sense for the patent system to make some adjustments as well.

First, the two systems are not far apart. Although patent law has traditionally operated in the realm of applied technology, whereas scientific norms and rewards have governed basic research, both systems promote the creation and dissemination of new knowledge by rewarding priority of discovery in exchange for disclosure. As patent law moves into areas traditionally defined as basic research, it will be able to achieve its ends more effectively if it draws from the experience of the scientific community in developing norms and incentives to achieve similar ends.

Second, harmonizing the incentives of private research sponsors with the norms and incentives of research scientists can help attract vitally-needed private dollars to basic research projects. While private sponsorship may have some undesirable side effects, such as distorting the re-

search agenda of the scientific community, it nonetheless offers some protection against the vicissitudes of political support for federal research funding.

Third, the extension of patent protection to living organisms demands a fresh look at traditional patent doctrine. As the PTO and the courts explore the special challenges posed by this new kind of intellectual property, sensitivity to the interaction of patent rules with scientific norms and rewards can facilitate the progress of science in these fields while preserving incentives for private sector funding of research.

Finally, the patent system will influence the behavior of research scientists more effectively if it takes into account the norms and incentives that guide behavior in the scientific community. Although patent law has avoided interference with basic research in the past, the two systems of rules and incentives are beginning to converge. Legal rules are more likely to succeed in influencing the behavior of scientists if they resonate with scientists' conception of appropriate behavior than if they call for counter-intuitive departures from the norms of science.