Patents and Cumulative Innovation

Clarisa Long*

Proprietary rights to the products of biomedical research have repeatedly been a source of controversy for over twenty years. Patents on biomedical innovations[1] have allowed scientists, academics, and research institutions to raise research funds and have contributed to the growth of the biotechnology industry.[2] But "one firm's research tool may be another firm's end product."[3] Patents have been a source of great concern for academic and basic researchers, who fear that proprietary rights to basic research results will hamper the progress of science, stifle the free flow of new knowledge and the dissemination of research results, and chill the research efforts of scientists who fear infringement liability.[4] The tension between a patentholder's interest of maximizing the revenue stream from a patented invention and the public and private interests of allowing downstream research to be conducted on the patented

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* Associate Professor of Law, University of Virginia School of Law. I would like to thank the organizers of, and participants in, the conference at which I presented this paper.

1. Economist Joseph A. Schumpeter argued that a fundamental difference existed between invention and innovation: invention alone "produce[s] no economic effect, while patent-based innovation has a positive impact on the economic system as new industries and new goods displace the old." Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1529 n.1 (Fed. Cir. 1995) (Newman, J., concurring) (citing JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY (3d ed. 1950)).

2. *See* LYNN G. ZUCKER ET AL., INTELLECTUAL CAPITAL AND THE BIRTH OF THE U.S. BIOTECHNOLOGY ENTERPRISES 15 (National Bureau of Econ. Research Working Paper No. 4653, 1994) ("the existence of the venture capital industry in America has had a significant effect on the development of the biotech industry"). One commentator has even said that "[b]iotechnology has emerged as an industry largely because of one economic institution: venture capital." MARTIN KENNEY, BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX 133 (1986).

3. Rebecca S. Eisenberg, *A Technology Policy Perspective On The NIH Gene Patenting Controversy*, 55 U. PITT. L. REV. 633, 647 n.51 (1994).

4. *See* Rebecca S. Eisenberg & Robert P. Merges, *Reply to Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 61 (1995); *see, e.g.*, American College of Medical Genetics, *Position Statement on Gene Patents and Accessibility of Gene Testing* (visited Feb. 12, 2000) <http://www.faseb.org/genetics/acmg/pol-34.htm>.

product is particularly acute when the invention has both basic and applied uses.

I suggest that the patent system should seek to balance incentives at all stages of the research process. Discussion of the proper role of proprietary rights in general, and patents in particular, has long been dominated by models that apply a linear approach to the process of scientific discovery and innovation.[5] Such models implicitly assume that a patented product is the final consumer end product. In fact, scientific research is not linear; reality is much more complicated. Today biomedical research proceeds not by placing one brick upon the other within a single discipline, but by solving complex multidisciplinary problems. This process is leading to new models of innovation and research, which in turn influence how researchers, whether in the public or private sector, use patent rights.

In part I of this Article, I explore the traditional conception of proprietary rights regimes as an attempt to balance information creation and dissemination. In part II, I highlight a number of fundamental shifts in the evolution of markets for biomedical information and products. In part III, I suggest that these factors affect the appropriate role for proprietary rights and conclude that we need to construct dynamic, rather than static, models of proprietary rights.

I.

The entire edifice of intellectual property rights is built around a simple dilemma: without proprietary rights, insufficient innovation will occur, but with proprietary rights, innovations will be inadequately distributed. One horn of the dilemma arises because information is expensive to create, but cheap to copy. Making an invention public reveals the information it contains to competitors, who can then copy the information and appropriate the value of the property at a price lower than the costs incurred by the original producers. If inventors cannot receive protection for their creations,

5. *See, e.g.*, Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Inventions*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609-24 (Richard Nelson ed., 1962).

the price that inventors will be able to charge for access to them will diminish, their revenues will drop, and, consequently, their incentives to invent will diminish.[6] Therefore, private actors will underproduce innovations because they cannot appropriate the full value of the innovation in the absence of proprietary rights.[7]

This aspect of the dilemma is exacerbated when the value of the invention stems predominantly from the information it contains, rather than from its physical structure. Innovators face the same costs of producing a unit of information regardless of the number of people who will use it, but once revealed, the information can be used endlessly. As a result, information is the classic example of a public good. True public goods are characterized by two conditions: 1) they are nonrivalrous, which means that one person's use does not diminish the amount of the good available for use by others, and 2) they are nonexcludable, which means that users cannot exclude others.[8] The public goods aspects of scientific research create the problem of nonappropriability: when innovators do not expect to recover the costs of invention because they cannot appropriate the full value of the resulting information, then society should expect a lower, suboptimal level of innovation.[9] Thus, it becomes necessary to supply incentives for innovators to create scientific information through research.

If the market will underproduce information because innovators will have inadequate incentives to invent and make their inventions public, then the state can attempt to overcome market failure with several strategies.[10] First, it can produce the information itself. In the field of biomedical research, the U.S. government has done just that

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6. *See, e.g.*, Subcomm. on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee, 85th Cong., 2d Sess., An Economic Review of the Patent System, Study No. 15 (1958) (prepared by Fritz Machlup); Arrow, *supra* note 5, at 615; WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE 70-90 (1969); F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 379-99 (1970); Richard R. Nelson, *The Economics of Invention: A Survey of the Literature*, 32 J. BUS. 101 (1959).

7. *See* ROBERT COOTER & THOMAS ULEN, LAW AND ECONOMICS 126 (3d ed. 2000).

8. *Id.*

9. *See* Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247 (1994).

10. Paul David, *Knowledge, Property, and the System Dynamics of Technological Change*, *in* PROCEEDINGS OF THE WORLD BANK ANNUAL CONFERENCE ON DEVELOPMENT ECONOMICS 215, 225-28 (1992).

in the form of the National Human Genome Research Institute (NHGRI), and more generally, the National Institutes of Health (NIH). Second, the state can subsidize the private production of the information it believes is socially optimal. The Orphan Drug Act and direct funding of biomedical research are examples.[11] Direct intervention, whether through active or passive state funding and participation, has been the institutional vehicle for stimulating production of information (such as basic research) when the social returns of such information are higher than the costs. As a result, universities and the government have traditionally performed much of the basic research while private entities have done much of the development. Third, the state can create enforcement measures that allow innovators to appropriate the value of the information. The patent system is an example of this approach.

The second horn of the dilemma arises because when inventors *can* get proprietary rights to their innovations, the number of people who can use the innovation will diminish, even if it could be disseminated to additional people at no cost. Under some circumstances it may be more beneficial to have fewer innovations, but have them distributed broadly, than to have many innovations that are accessible to a few people.[12] The difficulty of assuring the socially optimal diffusion or distribution of scientific information manifests itself most acutely in determining the optimum scope of protection that creators of basic research or pre-commercial inventions should receive, while assuring that downstream innovators have access to basic research results in order to build on them.[13] Although important, this problem is often overshadowed in the literature by the problem of producing enough scientific knowledge.[14]

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11. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (codified as amended at 21 U.S.C. § 360aa-360ee (1994); 26 U.S.C. § 45C (1994); 42 U.S.C. § 236 (1994)).

12. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989).

13. Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research & the Patent Law*, 5 J. ECON. PERSP. 29, 31, 34 (1991).

14. *See, e.g.*, Arrow, *supra* note 5.

II.

A number of broad trends occurring in biomedical research affects how the information creation/dissemination tradeoff plays out. The process of discovery, invention, and information diffusion is undergoing a paradigmatic shift as biomedical research has become increasingly information-based, as basic research and product development increasingly depend on continuous and nonlinear interactions with each other, and as scientific practices and industry business models are evolving to blur the traditional boundaries between public and private goods.

The amount of biomedical information available to researchers is estimated to have increased logarithmically every five years, which means that today scientists have approximately one-thousand times the quantity of information available to them that they did in 1985.[15] An entire industry has sprung up surrounding the creation of genomic information.[16] The creation of massive quantities of raw data and information about genes and protein sequences, on an almost daily basis, has created information bottlenecks in the lab and in the market.[17] No single lab or firm can absorb even a small part of this expanding information. Having compiled masses of genomic information, scientists now find themselves asking the next question: exactly what do the products of these genes do? The answer, at least as far as investors are concerned, is that it may not matter: genomic information has become a key strategic and competitive asset independent of applied products.[18] This explosion of genomics data and the proliferation of new information-based research approaches call into question many long-held beliefs and assumptions about the role of intellectual property rights as incentives for research discovery, incentives for technology innovation, and incentives for

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15. Jon Cohen, *The Genomics Gamble*, 275 SCI. 767, 768 (Feb. 7, 1997).

16. The genome is the full complement of DNA that an organism or cell possesses. *See* BENJAMIN LEWIN, GENES 657 (1994); The National Human Genome Research Institute, *Glossary of Genetic Terms* (visited Feb. 14, 2000) <http://www.nhgri.nih.gov/DIR/VIP/Glossary>. Genomics is the field of scientific research pertaining to the study of genomes.

17. *See* Cohen, *supra* note 15, at 767.

18. Justin Gillis, *California Firm Joins Race to Map Genes*, WASH. POST, Aug. 18, 1998, at C1; LEHMAN BROTHERS, GENOMICS (1996).

the diffusion of both.

As Walter Gilbert first predicted in 1991, burgeoning genetic knowledge was destined to change the paradigm of biomedical research—and he easily could have included the accepted paths for pharmaceutical industry innovation.[19] Traditionally, rapid imitation of new products in the pharmaceutical industry was difficult because patents provided solid protection, for the most part, against imitation.[20] Because pharmaceutical products are very specific, small variations in molecular structure can have disproportionate effects on the drug's pharmacological properties. With a few exceptions, this made it difficult for a competitor to invent around a patent on a molecular compound or class of compounds by making small changes to the drug's structure. Thus, although pharmaceutical innovation was a capital-intensive, high-risk process, relatively strong patent protection on the product that finally emerged at the end of the research pipeline allowed firms to recoup their investment.[21]

Biomedical research, particularly that pertaining to genomics, departs from this model. Most significantly, genomic information and research tools based on information technologies—not only the products derived from their use—have themselves become marketable. The core business of an increasing number of new market entrants is information about the genetic codes of various organisms, not the sale of drugs or diagnostics. For example, Celera, a private sector firm, announced that it derives its revenues primarily from subscription fees from database customers, rather than from licensing intellectual property rights or selling products.[22]

Biomedical research requires ongoing access to the state of the art.[23] Drug discovery, diagnostic discovery, and innovation have

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19. Walter Gilbert, *Toward a Paradigm Shift in Biology*, 349 NATURE 99 (1991).

20. Richard C. Levin et al., *Appropriating the Returns From Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECONOMICS ACTIVITY 783-831 (1987).

21. *See* Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 213-15 (1999).

22. Celera, *Celera Up Close* (visited Feb. 15, 2000) <http://www.celera.com>.

23. *See* ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, PRODUCTION AND DISTRIBUTION OF KNOWLEDGE IN THE NEW SYSTEMS OF INNOVATION: THE ROLE OF INTELLECTUAL PROPERTY RIGHTS (1996); Eliot Marshall, *Is Data Hoarding Slowing the Assault on Pathogens?*, 275 SCI. 777 (1997) (one scientist opines that "new DNA data should

become progressively more dependent on access to a common pool of accumulated scientific knowledge. Continued product discoveries and innovations also rely increasingly on the knowledge gleaned from preceding ones and on generally available techniques that have made the process of innovation more predictable. The process of innovation and invention for new drugs and diagnostics is beginning to reflect the thrust of entirely new conceptual approaches, a broad range of new market entrants in new niche markets, product life-cycles that are shortening dramatically, and the growing importance of basic research and its results to the trajectory of new product innovation.

New investment in basic biomedical research is frequently oriented "to securing ownership of research and developing it toward markets."[24] New entrants in the upstream market for genomic information are less capital intensive, exhibit much faster time to market, and offer different risk-reward models for investors than the traditional pharmaceutical companies. The marked trend to strategic alliances reflects the importance of preemptively acquiring ownership of research. Genomic database networks have stimulated the formation of strategic alliances among pharmaceutical, biotech, genomic, and information technology companies in an attempt to gain control of a package of genomic information and data to sell or license to users.[25]

Even if the information generated by new market entrants is not always patentable, the question of who owns it is becoming more porous. New biomedical research approaches and the increasing value of genomic information are creating a new "food chain" or "discovery pipeline" that undermines the traditional market structure in which nonprofit institutions, first generation biotechnology firms, and integrated drug companies play clearly defined roles shepherding research from the basic to the applied end of the discovery pipeline.[26]

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be released immediately, even daily").

24. John Hodgson, *Biotechnology in a Year of Living Prosperously*, 15 NATURE BIOTECHNOLOGY 227-30 (1997).

25. *See, e.g.*, LEHMAN BROTHERS, *supra* note 18, at 15-16; HERMAN SAFTLAS, STANDARD & POOR'S INDUSTRY SURVEYS: BIOTECHNOLOGY 17 (1999).

26. As one blunt genomics information CEO concluded: "The more genomics companies we link ourselves with, the more we migrate up the food chain and the less and less we'll be

Instead, both ends of the spectrum are coming together as pharmaceutical producers enter into strategic alliances with, or acquire outright, small firms specializing in the production of genetic information.[27] New risk-sharing collaborative arrangements such as strategic alliances consortia, and mergers and acquisitions also introduce significant changes in the status quo.

The enhanced role of ideas and discoveries in value and wealth creation means larger firms must become research portfolio managers, both internally and externally. Once a research finding or technology appears promising, there are incentives to acquire rights to it. Once it shows sufficient value in enabling product development, integrated firms often buy the owner. For the bulk of research, however, there is a growing need to broker uncertainty and risk, including the ownership of rights, which creates an environment in which strategic alliances and brokerage functions dominate.

The link between scientific breakthroughs and marketable innovations continues to shorten and tighten. The compression of the time involved in this research and innovation makes the linkage even stronger as new complementary relationships must be forged to meet the competitive pressures of basic biomedical research in universities and in the marketplace. The initial evidence suggests that, as occurred in the electronics industry when product life-cycles shortened dramatically, innovation rewards increasingly will come from so-called "first mover" advantages in being the first to market rather than from patent rights alone.[28] For example, Celera has announced that its competitive strategy is to "promote use of [its] information by a wide variety of users . . . to ensure access to valuable sequencing data by the entire biomedical and agricultural research community."[29]

The sheer quantities of information created by the Human Genome Project and other genomics research ventures have focused attention away from defining information possession, the raison d'être of the intellectual property system, to optimizing information

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butting heads with academics." Cohen, *supra* note 15, at 772.

27. *See, e.g.*, Glenn A. Friedrich, *Moving Beyond the Genome Projects*, 14 NATURE BIOTECHNOLOGY 1234 (1996).

28. *Patently Outdated*, ECONOMIST, July 18, 1987, at 18; *Testing, Testing*, ECONOMIST, Feb. 1, 1997, at 82.

29. Celera, *supra* note 22.

management—an area in which the intellectual property system is decidedly deficient. While the scientific community is faced with the fundamental questions of how to cope with this information explosion, and how to apply it to key areas, the intellectual property system is challenged by the fact that it simply was not designed to handle the realities of information production and management that are occurring in the field of genetic research today. This is creating a number of cross-currents that are forcing a reexamination of the scope and nature of rights needed to maintain discovery and innovation.

III.

The characteristics of basic biomedical research and of markets for biomedical information suggest that the dissemination/creation tradeoff I discussed in part I may be particularly acute when applied to the products of biomedical research. As I argued in part II, biomedical research is cumulative and characterized by information-intensive inputs. Current models of intellectual property protection fail to account for the nuances of a research and development process in which patents can be granted at multiple stages. The information-intensive qualities of scientific innovations, combined with the cumulative nature of scientific research, suggest that current models of proprietary rights protection are insufficient. Neither a model that grants broad rights to all initial inventors nor a model that reserves excessive protection for subsequent innovators should be applied across the entire range of basic research results. The full implications of this problem cannot possibly be discussed here, but I would like to highlight a few issues that need further research.

One concern is that biomedical research is an area in which overbroad patents to initial innovators will enervate the incentives for downstream research. One commentator has argued that "[e]xcessive protection for first generation innovation can impede later stages, thereby undermining some of the salutary effects of strong intellectual property protection."[30] Under some circumstances, strong

30. Peter Menell, *The Challenges of Reforming Intellectual Property Protection for Computer Software*, 97 COLUM. L. REV. 2644, 2646 (1994).

protection for certain discoveries too early in their evolution will retard further development or redirect research in less beneficial directions. For example, the semiconductor industry in its formative years was marked by rapid, multidirectional progress in both the underlying basic research and the cumulative technology that grew out of it.[31] This highly beneficial burst of scientific, technological, and economic advancement had broad social consequences, only partially glimpsed at the time, that would not have been possible in a legal regime that strongly protected intellectual property rights in many of the early innovations.[32]

Other industries, however, rely heavily on strong patent protection. One study shows that eighty percent of firms surveyed in the chemical, transportation equipment, electrical equipment, food, metals, and machinery industries indicated that the strength of intellectual property protection had a "major effect" in their willingness to invest in research and development facilities abroad.[33] There are significant differences, however, between sectors in research and development, investment, and innovative performance.[34] The impact of patent protection on market behavior depends on the character of technology in a field, the nature of the industry involved, and the way in which research is conducted.[35] It is unclear whether conclusions gleaned from industries characterized by tangible commercial products can be extrapolated to biomedical research generally. It is certain that such conclusions cannot be extended to patents on biomedical research results that are so far upstream that no commercial product currently exists.

Strong protection for upstream innovation can significantly affect the incentive to conduct follow-on research, but commentators disagree on precisely how. While one model of intellectual property

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31. Richard C. Levin, *The Semiconductor Industry*, *in* GOVERNMENT AND TECHNICAL PROGRESS: A CROSS-INDUSTRY ANALYSIS 9-100 (Richard Nelson ed., 1982).

32. *Id.*

33. Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer*, International Finance Corporation, Discussion Paper Number 19 (The World Bank: Washington, D.C., 1994), p. 1.

34. Levin et al., *supra* note 20.

35. Renato Mazzoleni & Richard R. Nelson, *Economic Theories About the Benefits and Costs of Patents*, IIEE PAPERS 20 (June 20, 1996).

protection argues that early allocation of patent rights can make downstream research allocations more efficient,[36] other models suggest that upstream protection steers research away from incremental improvements over existing inventions.[37] When innovation in a field of scientific endeavor, such as biomedical research, is cumulative and characterized by information-intensive inputs, I do not presume that granting a broad scope of protection induces efficient downstream innovation. Instead, I regard this as an unsettled issue in need of more research. If biomedical research is an area in which proprietary rights at early stages of innovation determine the outcomes of later stages, it would be helpful to know what factors cause proprietary rights at early stages to hinder or help downstream research.

Analysis is complicated by the fact that patentability standards have proven to be very dynamic over the past twenty years. Over time, patentable subject matter has crept ever closer to the basic end of the biomedical research spectrum. Today, the scope of protection for biomedical inventions can be very broad and may cover very basic research.[38] For example, patents have issued on such inventions as any "non-human mammal" all of the cells of which contain an introduced cancer-inducing DNA sequence,[39] stem cells,[40] and partial gene fragments so small that they comprised, on average, less than 0.000005% of the human genome.[41] Each of these inventions has

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36. *See* Edmund W. Kitch, *The Nature & Functions of the Patent System*, 20 J.L. & ECON. 265 (1977).

37. *See, e.g.*, Arrow, *supra* note 5; Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839-916 (1990).

38. The Organization for Economic Cooperation and Development (OECD) defines basic research as "experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts." OECD DIRECTORATE FOR SCIENTIFIC AFFAIRS, THE MEASUREMENT OF SCIENTIFIC AND TECHNOLOGICAL ACTIVITIES: PROPOSED STANDARD PRACTICE FOR SURVEYS OF RESEARCH AND EXPERIMENTAL DEVELOPMENT: FRASCATI MANUAL 1993 29 (1994).

39. Leder & Stewart, *Transgenic Non-Human Mammals*, U.S. PATENT NO. 4,736,866, Apr. 12, 1988.

40. Tsukamoto et al., *Human Hematopoietic Stem Cell*, U.S. PATENT No. 5,061,620, Oct. 29, 1991.

41. Au-Young et al., *Human Kinase Homologs*, U.S. PATENT NO. 5,817,479, Oct. 6, 1998. For additional examples of broad patents on biotechnological inventions, see John H. Barton, *Patent Scope in Biotechnology*, 26 INT'L REV. INDUS. PROP. & COPYRIGHT L. 605 (1995).

been, or is anticipated to be, the source from which further research and discoveries will spring.

At the same time, the nature of biomedical research has changed: no longer can research results be divided neatly into "pure" basic research, which seeks to expand general understanding of the laws of a scientific field, and "pure" applied research, which is directed toward some commercial or practical use.[42] One of the most profound changes in biomedical research to occur in the last two decades has been the "commercialization" of what was traditionally considered to be basic science research.[43] One commentator has argued that scientific inquiry is "being transformed by financial considerations."[44] Cutting-edge biomedical research requires ever-increasing amounts of money that cannot be met from traditional government or nonprofit sources. Throughout most of the Cold War, government heavily subsidized the collection and distribution of basic scientific data. For both budgetary and ideological reasons, the government's role as an information provider and clearinghouse is being scaled back and this function is being privatized.[45]

Scientific fields characterized by researchers possessing the same knowledge base and perceiving the same opportunities experience more races to patent and to publish. Strong intellectual property rights for early stage innovation can result in redundant or duplicative research in the race to capture proprietary rights.[46] The ongoing race to patent gene fragments, for example, illustrates how multiple independent discoveries can result in long patent application backlogs and knotty questions about who owns what, and on what terms.[47] At

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42. *See* DONALD E. STOKES, PASTEUR'S QUADRANT: BASIC SCIENCE AND TECHNOLOGICAL INNOVATION 7 (1997) (describing the blurring of categorization of basic and applied research).

43. Tiffany Ayers ed., *Science and Technology Leaders Discuss Innovations for the Future*, 286 SCI. 1753 (1999).

44. *Id.*

45. Eric A. Benhamou, *R&D Needs Washington's Support*, WALL ST. J., June 17, 1999, at A26 ("From 1987 to 1995, federal investment in basic research shrank by 2.6% a year. As a fraction of gross domestic product, the federal investment in research and development is about half of what it was 30 years ago.").

46. Partha S. Dasgupta & Joseph E. Stiglitz, *Uncertainty: Industrial Structure and the Speed of R&D*, 11 BELL J. ECON. 1 (1980); Glenn C. Loury, *Market Structure and Innovation*, 93 Q. J. ECON. 395-410 (1979).

47. Eliot Marshall, *Companies Rush to Patent DNA*, 275 SCI. 781 (1997).

the same time, however, patent races can achieve desirable side effects when they accelerate the rate of innovation. Competition between the public and private sectors to sequence the human genome resulted in several years being shaved off the estimated completion time of the project. [48]

Tension exists between publishing research results and patenting them.[49] In the scientific arena, publication and discussion of research results is the coin of the realm.[50] Research results must be verified by repeatable experiments and cross-checked by one's peers. Several rounds of publication and feedback are considered necessary before a discovery is considered to be adequately developed. Because a single round of publication and peer review often takes more than one year, scientists are left with the choice of either publishing or patenting, but not both. Under the patent laws, a patent cannot be granted on an invention that has been in the public domain for more than one year.[51] Scientists who share their research results also run the second-order danger of precluding themselves from getting patent rights to inventions down the road if the publications are later deemed to render their inventions obvious.[52]

Strong intellectual property protection may deter research and investment if researchers determine the field to be so crowded that the costs of research outweigh the benefits.[53] Protection for scientific information may stimulate innovation, but at a high social cost when it delays access to, and dissemination of, new ideas. Enclosure of raw scientific data and basic research results could result in less timely communication among researchers in a field in which the time value of information is high. By the same token, it remains a serious

48. Ralph T. King, Jr., *Code Green: Gene Quest Will Bring Glory to Some*, WALL ST. J., Feb. 10, 2000, at A1.

49. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L. J. 177-231 (1987).

50. *See id.*; KENNEY, *supra* note 2, at 108; ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATION 267-78 (1973).

51. 35 U.S.C. § 102(b) (1994) ("A person shall be entitled to a patent unless—the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for in the United States").

52. 35 U.S.C. § 103 (1994).

53. Dasgupta & Stiglitz, *supra* note 46, at 19-20.

question whether the incentives created by proprietary rights are necessary for discoveries or innovations that would appear in the public domain even in the absence of proprietary rights.

As digital technologies continue to lower the costs of reproducing information, the cost of copying information drops relative to the costs of creating the information. Faced with the possibility of not being able to recoup its investment costs, an entity producing basic research information faces the incentive either to withhold information, to wait until the innovation reaches a more commercial—as opposed to basic—stage, or not to innovate. Thus, tension exists between trying to reconcile competing incentives: those needed to obtain the creation and early release of valuable first-generation inventions with those that will encourage second- and third-generation follow-on innovations. Some commentators believe that the incentives between multiple stages of innovation cannot be reconciled to eliminate this tension.[54]

Discussion about the social costs and benefits of the patent system often assumes that the maximizing invention is the only purpose served by the patent system. Many scholars, especially economists, have proposed models based on the tacit assumption that inventors work in noncompeting areas and do not produce duplicative or redundant inventions.[55] According to these models, when inventions are not redundant, stronger patent protection results in a greater number of inventions, and thus creates a net increase in overall social utility. But what happens when this assumption becomes inapplicable?

The assumption that inventors are not working in competing areas does not apply to biomedical research. In many respects government institutions and universities have become new entrants in innovation markets by design and by financial necessity.[56] Beginning with the

54. Scotchmer, *supra* note 13, at 31, 34.

55. *See, e.g.*, Arrow, *supra* note 5, at 619-22; WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (1962); F.M. Scherer, *Nordhaus's Theory of Optimal Patent Life: A Geometric Reinterpretation*, 62 AM. ECON. REV. 422 (1972).

56. Jerome Schultz, *National Science Foundation's Perspective on University-Industry Interaction*, *in* BIOTECHNOLOGY: SCIENCE, ENGINEERING AND ETHICAL CHALLENGES FOR THE TWENTY-FIRST CENTURY 131-46 (Frederick B. Rudolph & Larry V. McIntire eds., 1996).

Bayh-Dole Act in 1980, federal policy has permitted and encouraged universities to obtain intellectual property rights on government-funded research as a means to stimulate technology transfers.[57] Although many scholars consider the policy wisdom of this approach to be controversial,[58] a recent report calculated that this legislation has created $11 billion in product sales and 75,000 new jobs.[59] New university patents have grown from about 280 a year before 1980 to more than 2,600 a year.[60]

The motives of universities are not monolithic in the biomedical research arena. In part, some are taking an entrepreneurial approach towards the products of their research; they want to shore up sagging balance sheets and overcome the loss of federal funding.[61] Other institutions see intellectual property rights as the best means to transform their technology into products that benefit everyone.[62] One study of academic basic research identified "intellectual property" as the third major function of the university.[63] Regardless of motive, universities have opportunistically created a growing array of cooperative undertakings with industry and their own faculty.[64]

Interaction is not just inter-sectoral, in which industrial players compete and cooperate with academic ones. In addition, individual research teams, often within the same sector and even the same firm or institution, compete to be either the first to publish the data or the first to the patent office with an application on the results of their basic research. An example of this can be found in the ongoing race

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57. 35 U.S.C. §§ 200-11 (1994).

58. *See, e.g.*, Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, 5 RISK: HEALTH, SAFETY & ENV'T 168 (1994).

59. Schultz, *supra* note 56, at 134.

60. *Id.*

61. *See* Benhamou, *supra* note 45, at A26 (describing the drop in federal funding for basic research).

62. John T. Preston, *The Research University, in* GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 208-13 (Mitchel B. Wallerstein et al. eds., 1994).

63. Daryl E. Chubin, *How Large an R&D Enterprise, in* THE FRAGILE CONTRACT: UNIVERSITY SCIENCE AND THE ROLE OF GOVERNMENT 125 (David H. Guston & Kenneth Keniston eds., 1994).

64. University researchers have formed alliances with industry for research funds, as well as serving in a for-profit capacity as consultants, equity holders, and directors. See David Blumenthal, *University-Industry Research Relationships in Biotechnology: Implications for the University*, 232 SCI. 1361, 1364 (1986).

between entities, such as Human Genome Science and Incyte, that are attempting to patent DNA fragments known as expressed sequence tags or ESTs, and entities, such as the National Institutes of Health, Merck, and Celera, that are attempting to get the same basic research information into the public domain. The result contains both costs and benefits: research is spurred by the race, but the research is duplicative as one set of players tries to obtain proprietary rights to what another set of entities is trying to give away.

Where proprietary rights start out often determines where they end up. Valuation problems arise when patentees attempt to determine the value of a license on a patent covering an innovation that has no current commercial uses. Although the ultimate private values of basic research results are frequently uncertain in advance, one way to attempt to maximize the public value is to make basic research results widely available to all researchers who might need them.[65]

Enclosure of research results from being a public good to being subject to proprietary rights affects innovators differently. This is because information is not only an output of basic research, but also a critical input.[66] It remains an open question as to whether broad claims on basic biomedical research will, on balance, create net incentives or disincentives for investment in biotechnology research.[67] Take, for example, the patent issued by the United States Patent and Trademark Office to Incyte on October 6, 1998, which some consider the first patent issued on a type of gene fragment known as an expressed sequence tag or EST.[68] Such patents will become increasingly important as we gain increased understanding of the mechanisms of the genome.[69]

Rebecca Eisenberg and Michael Heller have argued that, in the context of biomedical research, too many patent rights on basic research discoveries may stifle downstream research and product

65. *See* Eisenberg, *supra* note 12, at 1065.

66. Arrow, *supra* note 5, at 618.

67. *See, e.g.*, Dorothy R. Auth, *Are ESTs Patentable?*, 15 NATURE BIOTECHNOLOGY 911, 911 (1997) (expressing concern that broad claims to ESTs would create disincentives to invest in biotechnology).

68. Au-Young, *supra* note 41.

69. King, Jr., *supra* note 48, at A1.

development by greatly increasing transaction costs.[70] Whether allowing patents on basic research tools results is a net advance or deterrence of innovation is a complex empirical question that remains unanswered. If Heller and Eisenberg are right about transaction costs,[71] then the current model of allowing patenting "close to the lab bench" ironically creates one market failure (excessive transaction costs) in the attempt to overcome another (the problem of public goods).[72]

Ultimately, the argument boils down to whether, in the long run, strong patents encourage or discourage investing.[73] As the costs of doing basic research continue to rise and innovation cycles shorten, it remains essential to assure innovators that adequate incentives exist to develop follow-on innovations. It is unclear which factors, or mix of factors, determine the optimal level of protection at each stage of the research process. The number of second, third, and fourth generation innovations that can spring from an initial invention appears to be one such factor. Increasing appropriability by allowing patenting close to the research bench when no commercial product is in sight, however, does not necessarily lead to more innovation.[74] Fostering more socially beneficial innovation does not rest solely with solving the public goods problem by tinkering with the incentives to ensure additional appropriability.

CONCLUSION

Clearly, there is at present no analytical answer to the question of how to distribute the incentives between basic researchers and downstream innovators so as to optimize innovation at all stages of the research and development process. In all likelihood, the answer

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70. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

71. *Id.*

72. Cooter and Ulen define four different kinds of market failure: monopoly and market power, externalities, public goods, and severe informational asymmetries. COOTER & ULEN, *supra* note 7, at 38-41. *See also id.* at 84-89 (describing transaction costs and their impact on legal rules).

73. Mazzoleni & Nelson, *supra* note 35.

74. Levin, *supra* note 20, at 816 ("Stronger appropriability will not yield more innovation in all contexts and, where it does, innovation may come at excessive cost.").

will vary from industry to industry, from scientific field to scientific field, and from one innovation to the next. At the end of the day, one thing is clear: The path of scientific research and technological innovation is complex, nonlinear, variable, and uncertain. Economic and legal models that do not account for follow-on innovations overlook the multidimensional complexity of the inventive process. We need to revamp our models of proprietary rights to reflect the research environment accurately and to create the optimum incentives for scientific innovation.