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NOTE

A MODEST PROPOSAL: TOWARD IMPROVED ACCESS TO BIOTECHNOLOGY RESEARCH TOOLS BY IMPLEMENTING A BROAD EXPERIMENTAL USE EXCEPTION

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Private property, including intellectual property, is essential to our way of life. It provides an incentive for investment and innovation; it stimulates the flourishing of our culture; it protects the moral entitlements of people to the fruits of their labors. But reducing too much to private property can be bad medicine. Private land, for instance, is far more useful if separated from other private land by public streets, roads and highways. Public parks, utility rights-of-way and sewers reduce the amount of land in private hands, but vastly enhance the value of the property that remains.

So too it is with intellectual property. Overprotecting intellectual property is as harmful as underprotecting it. Creativity is impossible without a rich public domain. . . . Culture, like science and technology, grows by accretion, each new creator building on the works of those who came before. Overprotection stifles the very creative forces it's supposed to nurture.

—Judge Kozinski, *White v. Samsung Electronics America, Inc.*[1]

INTRODUCTION

In the half century since James Watson and Francis Crick used X-ray crystallography to solve the double helical structure of DNA,[2] the biotechnology revolution triggered by their discovery has fundamentally transformed modern biology.[3] Scientists continue to develop

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1 989 F.2d 1512, 1513 (9th Cir. 1993) (Kozinski, J., dissenting).

2 J. D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953); *see infra* note 145 and accompanying text. Watson and Crick based their work in large part on X-ray diffraction studies by Rosalind Franklin and Maurice Wilkins. *See, e.g.*, Rosalind E. Franklin & R.G. Gosling, *Molecular Configuration in Sodium Thymonucleate*, 171 NATURE 740 (1953); M.H.F. Wilkins et al., *Molecular Structure of Deoxypentose Nucleic Acids*, 171 NATURE 738 (1953).

3 Greater understanding of the physical mechanisms by which genes and genetic defects affect human metabolism, growth, and development has enabled medical advances akin to the development of antibiotics in the first half of the twentieth century. *See* Alessandro Aiuti et al., *Gene Therapy for Adenosine Deaminase Deficiency*, 3 CURRENT OP. ALLERGY & CLINICAL IMMUNOLOGY 461 (2003) (describing treatment of a genetic deficiency in an essential enzyme using gene therapy to insert a working copy of a gene encoding the enzyme into a patient's genome); Donald A. Berry et al., *BRCAPRO Validation, Sensitivity of Genetic Testing of BRCA1/BRCA2, and Prevalence of Other Breast Cancer Susceptibility Genes*, 20 J. CLIN-

new drugs, laboratory methods, and research tools at a staggering pace.[4] The attendant accumulation of scientific knowledge has at times outstripped the ability of government agencies responsible for setting research, technology, and patent policies to assimilate and understand these new technologies.[5] Consequently, the National Institutes of Health (NIH), the U.S. Patent and Trademark Office (PTO), and the Court of Appeals for the Federal Circuit (CAFC) have stitched together an ad hoc collection of policy directives, examination guidelines, and case law in an effort to address a variety of economic, ethical, and practical concerns about the patentability of biotechnological inventions.[6] Unfortunately, failure to systematically address the ques-

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CAL ONCOLOGY 2701 (2002) (demonstrating the utility of mutations in the BRCA1/BRCA2 genes as indicators of susceptibility to heritable forms of breast and ovarian cancer). As biotechnology companies continue to sprout up around large research universities, conventional pharmaceutical companies have radically altered their approach to research and drug development. *See generally* NAT'L RES. COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY: SUMMARY OF A WORKSHOP HELD AT THE NATIONAL ACADEMY OF SCIENCES, FEBRUARY 15–16, 1996, at 50 (1997), *available at* http://books.nap.edu/books/0309057485/html/50.html [hereinafter WORKSHOP SUMMARY] (describing the research strategy of the biotechnology industry); Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 813–18 (2001) (describing the dramatic increase in research partnerships between biotechnology "start-ups" and established pharmaceutical companies to develop novel drugs from proteins or nucleic acids to treat a variety of disorders, in contrast to the traditional "big-pharma" approach of developing small molecule drug therapies from existing drugs to treat relatively few diseases); John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 289 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

4 These tools include, among other things, recombinant DNA technology, *see* Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids* In Vitro, 70 PROC. NAT'L ACAD. SCI. USA 3240 (1973), monoclonal antibodies, *see* G. Köhler & C. Milstein, *Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity*, 256 NATURE 495 (1975), the polymerase chain reaction, *see* Kary B. Mullis & Fred A. Faloona, *Specific Synthesis of DNA* in Vitro *via a Polymerase-Catalyzed Chain Reaction*, 155 METHODS ENZYMOLOGY 335 (Ray Wu ed., 1987); Randall K. Saiki et al., *Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase*, 239 SCI. 487 (1988), and DNA micro-arrays, *see* Mark Schena et al., *Quantitative Monitoring of Gene Expression Patterns with a Complementary DNA Microarray*, 270 SCI. 467 (1995).

5 *See* Kojo Yelpaala, *Owning the Secret of Life: Biotechnology and Property Rights Revisited*, 32 MCGEORGE L. REV. 111, 188 (2000) ("[A] system designed for mechanical devices would be most unsuited to the new era of inventions and discoveries involving new life forms, living organisms, gene sequences, intra-species, and transgenic cloning of living organisms including human beings. The fundamental policy issues . . . challenge the core premises of the patent system itself."); S. Benjamin Pleune, Note, *Trouble with the Guidelines: On Urging the PTO To Properly Evolve With Novel Technologies*, U. ILL. J.L. TECH. & POL'Y 365, 365–67 (2001) (discussing difficulties that the PTO encountered in evaluating new technologies according to statutory requirements designed for different purposes).

6 *See, e.g.*, Kevin C. Hooper, *Utility and Non-Operability Standards in Biotechnology Patent Prosecution: CAFC Precedent Versus PTO Practice*, 36 IDEA 203, 210–39 (1996) (comparing the approaches of the Court of Appeals for the Federal Circuit and the PTO toward assessing utility and nonoperability in biotechnology patent prosecution); Daniel J. Kevles & Ari Berkowitz, *The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics*, 67 BROOK. L. REV. 233, 245–48 (2001) (discussing the controversy over new gene patents,

tions raised by the application of conventional patent law doctrine to the new field of biotechnology has further confused the issues.[7]

The American patent system seeks to promote scientific progress and technological development by providing financial incentives to inventors and entrepreneurs.[8] It strikes the "patent bargain" with inventors, giving them a private right (exclusive ownership of their inventions for twenty years) in exchange for a public good (full disclosure of their discoveries via publication of patent applications within one year of filing).[9] Granting exclusive rights to inventors addresses the problems inherent in the public goods nature of many inventions, which are often expensive to produce but easy to appropriate.[10] Although the patent monopoly allows inventors to restrict output and increase prices, the public ultimately benefits from the utility of inventions that might not have been produced otherwise.[11]

For many years, American patent policy has assumed that companies in "high technology" industries require the financial incentive provided by a comprehensive system of intellectual property protec-

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including ethical objections and the economic interests at stake); Sara Dastgheib-Vinarov, Comment, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 144 (2000) (suggesting that a heightened standard of nonobviousness be applied to new gene patents to ensure that other researchers have ready access to potential research tools); Matthew D. Kellam, Note, *Making Sense out of Antisense: The Enablement Requirement in Biotechnology After* Enzo Biochem v. Calgene, 76 IND. L.J. 221, 238–41 (2001) (analyzing the requirement that an inventor provide a full and enabling disclosure with a patent application in light of the Federal Circuit's holding in *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362 (Fed. Cir. 1999)).

7 Dan Burk and Mark Lemley argue that conventional, "one-size-fits-all" patent statutes designed "to meet the simpler needs of an industrial era" simply cannot accommodate the variety and complexity of new technologies. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1155 (2002) (internal quotation marks omitted). They suggest instead that the patent statutes be applied in a technology-specific way to reflect differences between various technologies, such as computer programming and biotechnology. *See id.* at 1157; *see also* Sara B. Blanchard, Comment, *The Muddled Law of Biotechnology: Frustrating Agricultural and Biomedical Progress*, 5 SAN JOAQUIN AGRIC. L. REV. 179, 180 (1995) (arguing that biotechnology quickly outgrew the existing patent system and attempts to update the patent laws produced "a fickle and inadequate structure of protection"); Pleune, *supra* note 5, at 365 (arguing that the PTO's attempts to keep up with changes in biotechnology have produced only "confusing court decisions and ineffective PTO guidelines").

8 *See* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 12–13 (2d ed. 2001); ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 126–27 (2d ed. 2000).

9 David B. Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?*, 3 J. PHIL., SCI. & L. 1 (2003), *at* http://www.psljournal.com/archives/papers/biotechPatent.cfm.

10 Creative activities often suffer from the "public goods" problem: they tend to be "costly to produce but . . . virtually costless to reproduce or to appropriate once they have been created." Burk & Lemley, *supra* note 7, at 1158. By granting the creator legal rights over the products of creative activity, the patent system allows inventors to profit from the goods they produce. *See id.*

11 *See* Resnik, *supra* note 9, at 1.

tion to invest in risky, expensive research and product development.[12] The little available empirical evidence does not clearly support this assumption.[13] Nevertheless, the policy persists despite the fact that the federally funded research enterprise successfully operated as a common resource for the public good for most of the twentieth century.[14] Under the "commons" model, the federal government sponsored basic research and encouraged its widespread publication in the public domain without regard for potential commercial applications.[15] Not until passage of the Bayh-Dole Act in 1980[16] were scientists allowed to retain patent rights to inventions created with federal research funding.[17] Since then, however, researchers and biotechnology companies have patented countless useful research methods and materials.[18] As the number of such patents increases, so too will the costs of subsequent experimentation, first because all researchers wishing to use patented research tools must first obtain a license, and secondly because patent licensing agreements frequently contain provisions restricting permissible uses of the proprietary technology.[19]

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12 The "high technology" sector encompasses the computer, semiconductor, and pharmaceutical industries, among others. Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL'Y 273, 274 (1998). Some evidence suggests that the pharmaceutical industry may, more than others, require exclusive patent rights in order to invest in research and development. *See id.* at 276. *See generally id.* at 274–80 (discussing theories advanced in support of the proposition that strong patent protection provides incentives essential to promote innovation and reporting that "knowledgeable economists" have concluded that patent protection is not an important part of the incentives driving research and development in most industries).

13 *See, e.g., id. But see* Mazer v. Stein, 347 U.S. 201, 219 (1954) ("The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in 'Science and useful Arts.'" (quoting U.S. CONST. art. 1, § 8, cl. 8)).

14 *Compare* Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243 (1968) (arguing that unrestricted sharing of limited resources results in overutilization and depletion), *with* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) (stating that scarce resources are prone to underutilization "when multiple owners each have a right to exclude others from" using them).

15 *See* Heller & Eisenberg, *supra* note 14, at 698.

16 Pub. L. No. 96–517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200–12 (2000)).

17 Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1689–92 (1996) [hereinafter Eisenberg, *Government-Sponsored Research*]; *see also infra* notes 101–15 and accompanying text (discussing the Bayh-Dole Act in more detail).

18 Walsh et al., *supra* note 3, at 296.

19 *See* Resnik, *supra* note 9, at 1. Examples of these restrictions include: (1) the patent holder's right to review manuscripts before publication; (2) delays in the publication of research results so that patent applications may be filed; (3) the patent holder's "legal claims to ownership of future scientific discoveries"; (4) "the right to refuse to license" downstream discoveries ("follow-on" innovation) to other researchers; and (5) the right to

The higher transaction costs may in turn prevent researchers from making new discoveries or commercializing new technologies.[20]

Enforcing property rights in scientific discoveries to the exclusion of other researchers conflicts with traditional scientific norms.[21] Academic scientists typically expect that data, research tools, and other scholarly resources will be widely shared and openly examined by the scientific community.[22] In fact, for much of the twentieth century, scientists rarely sought protection for their inventions.[23] After Congress passed the Bayh-Dole Act, the debate over the costs and benefits of intellectual property protection intensified. Advocates of strong patent protection[24] applauded the resulting rise in patent applications

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prevent licensees from sharing research materials and methods with competing researchers. David Bollier, *The Enclosure of the Academic Commons*, 88 ACADEME 18, 20 (2002); *see* Eugene Russo, *Regulating Researchers' "Picks and Shovels": Scientists Continue To Review NIH Research Tool Guidelines*, 14 SCIENTIST 8, 8 (2000); Ian R. Walpole et al., *Human Gene Patents: The Possible Impacts on Genetic Services Healthcare*, 179 MED. J. AUSTL. 203, 203–04 (2003), *available at* http://www.mja.com.au/public/issues/179_04_180803/wal10811_fm.pdf (citing the breast cancer gene as an example of the restrictive provisions placed on patent licensing agreements).

20 *See* Resnik, *supra* note 9, at 1.

21 *See* ROBERT K. MERTON, *The Normative Structure of Science*, *in* THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 267, 273 (Norman W. Storer ed., 1973); *see also* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 177 (1987) [hereinafter Eisenberg, *Biotechnology Research*] (evaluating the contention that "commercial incentives [that liberal patent policies provide] will weaken or . . . undermine the norms that have traditionally governed scientific research"); Michele Svatos, *Biotechnology and the Utilitarian Argument for Patents*, *in* SCIENTIFIC INNOVATION, PHILOSOPHY, AND PUBLIC POLICY 113, 117–18 (Ellen Frankel Paul et al. eds., 1996) (suggesting that the utilitarian arguments advanced in favor of granting strong patent protection to biotechnological inventions have not been carefully examined and noting that patent holders are not obligated to license their patents to competitors).

22 *See, e.g.*, MERTON, *supra* note 21, at 273; Bollier, *supra* note 19, at 1. Free access to prior discoveries allows scientists to scrutinize their peers' research (thereby guarding against fraud and error) and to use previous findings in subsequent research (thereby promoting scientific progress). *See, e.g.*, MERTON, *supra* note 21, at 270. The latter is particularly important given the cumulative nature of biotechnology research, in which new discoveries build upon previous work. *See id.*; Walsh et al., *supra* note 3, at 289–90.

23 Bollier, *supra* note 19, at 1. For example, neither Jonas Salk nor Cesar Milstein patented their work, despite its enormous commercial potential. *Id.* Salk pioneered research that led to the first polio vaccine. *Id.* Milstein "shared a Nobel Prize for helping develop monoclonal antibody technology in 1975." *Id.* Nor did Stanley Cohen and Herbert Boyer, co-inventors of recombinant DNA technology, consider filing a patent application until an attorney for Stanford University suggested that they do so. *Id.* Cohen's initial reaction to the suggestion that his work be patented "was to question whether basic research of this type could or should be patented and to point out that our work had been dependent on a number of earlier discoveries by others." *Id.* (internal quotation marks omitted). "Cohen later agreed to file for a patent, but only" on the condition that Stanford be named the exclusive beneficiary. *Id.* According to Robert Merton, "[t]he substantive findings of science are a product of social collaboration and are assigned to the community. . . . [so a] scientist's claim to 'his' intellectual 'property' is limited to that of recognition and esteem . . . . " MERTON, *supra* note 21, at 273.

24 This Note uses the term "strong patent protection" to refer to the two most important factors favoring patent holders upon a challenge to patent validity: the broad scope

and private investment in research and development.[25] Opponents charged that the increased propensity to patent would raise research costs and stifle potentially lifesaving innovations in the course of downstream research and product development.[26] These conflicting positions echo the essential dilemma at the core of American patent policy: how to balance the need for unfettered access to scientific information and essential research tools with the desire to provide sufficient economic incentives to fuel scientific innovation.[27] By passing legislation that encourages inventors to patent government-sponsored inventions, Congress may have too quickly abandoned the successful "commons" approach to publicly funded research.[28] Granting exclusive patent rights in government-funded discoveries frequently undermines incentives to develop and market products based upon new technologies.[29] Indeed, strong patent protection may in some cases actually impede scientific progress.[30]

This Note argues that a broad experimental use exception to the otherwise exclusive patent grant may diminish the problems caused by patenting research tools in biotechnology: namely, greater research

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common to biotechnology patents and the CAFC's strongly pro-patent stance. *See* ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 1136 (5th ed. 2001); Edward T. Lentz, *Adequacy of Disclosures of Biotechnology Inventions*, 16 AM. INTELL. PROP. L. ASS'N 314, 318 (1998–99).

25 Heller & Eisenberg, *supra* note 14, at 698; *see also* ANDREW J. HACKING, ECONOMIC ASPECTS OF BIOTECHNOLOGY 43 (1986) (claiming that patents are an "indispensable element" in biotechnology).

26 *See* Heller & Eisenberg, *supra* note 14, at 698; *see also* Eliot Marshall, *A Deluge of Patents Creates Legal Hassles for Research*, 288 SCI. 255, 255–56 (2000) (explaining how patenting transgenic mice has slowed down progress in some areas of molecular genetics).

27 In the words of Arti Rai and Rebecca Eisenberg, "[t]he challenge lies in distinguishing discoveries that are better developed and disseminated through open access from discoveries that are better developed and disseminated under the protection of intellectual property rights." Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 291 (2003); *see also* John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 107–08 (2001) (asking whether patent law can achieve an "ideal balance between the incentives for invention and dissemination"); Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15, 26–28 (1999) (discussing the scientific and social consequences of commodifying scientific knowledge and stating that patent policy must balance the notion that biological and genetic information "is part of the common human heritage" with the fact that such "knowledge . . . possess[es] economic value that should be realized"); Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1234 (2000) (arguing that the CAFC and the PTO must balance "the interests of inventors and scientists to create an environment that encourages innovation by adequately protecting inventions without granting overly broad patent rights").

28 *See* Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, 5 RISK 163, 165–66 (1994) [hereinafter Eisenberg, *Patenting Problems*].

29 *See id.*

30 *See id.*

costs, misallocation of limited resources, duplication of effort, and diminution in follow-on innovation. Part I describes the nature of the patent grant, surveys the origin and evolution of the American patent system, and discusses the allocation of patent rights to inventions resulting from federally funded research. Part II explains the concepts and methods underpinning modern biotechnology and goes on to describe what constitutes patentable subject matter under 35 U.S.C. § 101. Part III explores the economics of innovation and the impact of strong patent protection on downstream applications of new technology. Finally, Part IV analyzes several proposed modifications to the existing patent system and concludes that an expansive experimental use exemption from patent infringement for noncommercial research offers the most promising antidote to problems associated with the propertization of biotechnology.

I
ORIGIN AND DEVELOPMENT OF THE AMERICAN PATENT SYSTEM

A. Nature of the Patent Grant

A patent confers upon an inventor "the right to exclude others from making, using, offering for sale, or selling the invention" claimed in the patent application for a period of twenty years.[31] Anyone may apply for a patent, regardless of "age, nationality, mental competency, incarceration, or any other characteristic," provided that he or she is the true inventor of the device in question.[32] "A patent is a form of personal property" and as such is fully alienable.[33] Accordingly, a patent owner may sell it outright or may give another person permission to use the invention in exchange for royalty payments.[34]

There are three types of patents: utility, design, and plant.[35] Utility patents cover inventions that function in a novel way to produce a useful result.[36] They include Velcro fasteners, automatic transmissions, and virtually "anything under the sun that is made by man."[37] Design patents encompass "the unique, ornamental, or visible shape

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31 35 U.S.C. § 154(a)(1), (2) (2000); *see* DAVID PRESSMAN, PATENT IT YOURSELF 1/3 (9th ed. 2002).

32 *See* PRESSMAN, *supra* note 31, at 1/3. Interestingly, neither death nor insanity provides an obstacle to obtaining a patent; deceased or mentally infirm inventors may apply for a patent through a personal representative. *Id.*

33 *Id.*

34 *Id.* Such licensing agreements are increasingly common in biotechnology-related research. *Id.*

35 *See id.* at 1/3–1/5.

36 *Id.* at 1/3.

37 Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting the Committee Reports accompanying the Patent Act of 1952, S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

or design" of a manmade object.[38] A design patent will be issued provided that the unique shape or design of an object is purely ornamental or aesthetic.[39] If the unique feature serves a functional purpose, however, the inventor should file a utility patent instead.[40] Federal law also allows inventors to patent plants.[41]

The patent monopoly extends for twenty years from the date of filing, but the inventor has no right to enforce his monopoly before then.[42] The PTO may extend the statutory period when regulatory review delays commercial marketing of the product.[43]

B. Early History

The nascent U.S. federal government initially modeled the American system of patent protection after that of England.[44] The English system consisted of "a largely informal administrative apparatus"[45] that evaluated applications describing new inventions and granted successful inventors a fourteen-year monopoly on the manufacture, sale, and use of their invention.[46] The English government intended to encourage technological innovation by granting inventors exclusive rights in their creations.[47] This approach replaced an older system

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38 PRESSMAN, *supra* note 31, at 1/4.

39 *Id.*

40 *Id.* Design and utility patents may be distinguished by asking whether eliminating the unique features of a particular object will substantially impair its intended function. *Id.* If so, then filing a utility patent is proper; if not, then filing a design patent will suffice. *Id.*

41 *See* 7 U.S.C. § 2321 (2000); PRESSMAN, *supra* note 31, at 1/4. Plant patents generally encompass plants reproduced asexually, through grafts or cuttings. *See* PRESSMAN, *supra* note 31, at 1/4. In addition, the Plant Variety Protection Act regulates patents regarding sexually reproduced plants. *Id.* Both types of plants may now be the subject of utility patent applications as well. *See* 35 U.S.C. § 101 (2000).

42 *See* PRESSMAN, *supra* note 31, at 1/7. The duration of the pendency period from filing a patent application to allowance of a patent has increased steadily since passage of the Bayh-Dole Act in 1980. *See generally* U.S. PAT.& TRADEMARK OFF., CENTURY OF AMERICAN INVENTION: A PATENT AND TRADEMARK OFFICE REVIEW, FISCAL YEAR 1999, *available at* http://www.uspto.gov/web/offices/com/annual/1999/99tbs1-10.pdf (last visited Jan. 19, 2004) [hereinafter PTO SUMMARY, FY 1999] (collecting a wide range of data on filed patent applications and allowed patents for fiscal year 1999). If and when the patent issues, the inventor obtains the legal right to stop any infringement that began during the pendency period. *See* PRESSMAN, *supra* note 31, at 1/7.

43 *See* PRESSMAN, *supra* note 31, at 1/7. Examples of such products include new drugs, medications, and food additives. *Id.*

44 *See* CHISUM ET AL., *supra* note 8, at 15; MERGES ET AL., *supra* note 8, at 126–28.

45 MERGES ET AL., *supra* note 8, at 126.

46 *See* CHISUM ET AL., *supra* note 8, at 14. With the advent of the Industrial Revolution and the accompanying advances in manufacturing technology, however, requirements for obtaining a patent grant became increasingly stringent. In particular, an applicant was required to "describe his . . . invention clearly and completely," foreshadowing the written description and enablement requirements of 35 U.S.C. § 112 (2000). MERGES ET AL., *supra* note 8, at 126.

47 *See* CHISUM ET AL., *supra* note 8, at 12–13.

that had gradually become a mechanism for dispensing royal largesse to favored courtiers.[48]

Some of the original thirteen colonies granted patents, beginning with the first recorded in Massachusetts in 1641[49] for a method of producing salt used by the fishing industry.[50] Massachusetts, Connecticut, and South Carolina were the most active colonies in granting patents.[51] New York, Maryland, Rhode Island, and Virginia together issued a total of ten, while Delaware, Georgia, New Hampshire, New Jersey, and North Carolina issued no patents during the Colonial era.[52] Boycotts of English goods during the Revolutionary War, coupled with colonial notions of self-sufficiency, stimulated industrial development both during and after the war.[53] Under the Articles of Confederation, states retained the power to issue patents after the war.[54] But industrialization sparked a series of patent conflicts between inventors from different states, and the growing frequency of such conflicts hastened calls for establishment of a uniform national patent system.[55]

Government officials rarely questioned the utility of a nationwide patent system because patent disputes affected technologies essential to the American economy.[56] In fact, James Madison suggested that the power to grant patents be vested in the federal government because "[t]he right to useful inventions . . . [should] belong to the inventors."[57] Similar sentiments prompted participants in the Constitutional Convention of 1787 to include the power to grant patents in Article I, Section 8 of the Constitution.[58] The Intellectual Property Clause of the Constitution thus granted Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective

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48 *See id.* at 13; MERGES ET AL., *supra* note 8, at 125–27.

49 *See* CHISUM ET AL., *supra* note 8, at 15; MERGES ET AL., *supra* note 8, at 127.

50 *See* BRUCE W. BUGBEE, GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 60 (1967).

51 *See* Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (5 Part I)*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 615, 630–31 (1996).

52 *Id.*

53 *See* CHISUM ET AL., *supra* note 8, at 15–16; MERGES ET AL., *supra* note 8, at 126–27.

54 *See* Edward C. Walterscheid, *To Promote the Progress of Useful Arts: American Patent Law and Administration, 1787-1836 (Part I)*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 61, 66 (1997).

55 *See* CHISUM ET AL., *supra* note 8, at 16; MERGES ET AL., *supra* note 8, at 127.

56 *See* CHISUM ET AL., *supra* note 8, at 16–18. Affected technologies included devices for calculating longitude and engines designed to propel boats with steam. *See* Edward C. Walterscheid, *Charting a Novel Course: The Creation of the Patent Act of 1790*, 25 AM. INTELL. PROP. L. ASS'N Q.J. 445, 459–60 (1997) (quoting THE FIRST FEDERAL CONGRESS PROJECT, 3 THE DOCUMENTARY HISTORY OF THE FIRST FEDERAL CONGRESS OF THE UNITED STATES OF AMERICA, MARCH 4, 1789–MARCH 3, 1791, at 49, 59–60 (Linda Grant DePauw et al. eds., 1977–1995)).

57 THE FEDERALIST NO. 43 (James Madison).

58 *See* U.S. CONST. art. I, § 8, cl. 8.

Writings and Discoveries."[59] Clearly, Congress hoped that the "productive effort thereby fostered [would] have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens."[60]

C. From the Patent Board to the PTO: Evolution of the Patent Act

Congress adopted the first American patent statute in 1790.[61] The legislation fashioned an informal registration procedure in which a patent board composed of three government officials reviewed every patent application filed.[62] In the Patent Act of 1793, a less cumbersome clerical registration requirement replaced review by the patent board,[63] and the patent system remained largely pro forma until Congress revised it again with the Patent Act of 1836.[64] Because lack of a formal examination requirement encouraged inventors to file fraudulent or duplicative patents, the 1836 Act implemented a formal review system, in which professional patent examiners evaluated each application for novelty and utility.[65] The next legislative revision of the Patent Act passed in 1870 but retained all the key provisions of the 1836 Act.[66] Since then, Congress has periodically amended the Patent Act to address issues raised by the development of new technologies.[67] In addition, the PTO frequently develops new rules to accommodate novel technologies[68] or to limit the number of patents being

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59 *Id.*

60 Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974)).

61 *See* MERGES ET AL., *supra* note 8, at 128.

62 *See id.* "[A] significant contributor to the original statute" was Thomas Jefferson, then serving as Secretary of State. *Id.* The first American patent was granted shortly thereafter, covering a process for manufacturing potash from wood ashes. *Id.*

63 *See* CHISUM ET AL., *supra* note 8, at 19.

64 *See id.*

65 *See id.* at 20.

66 *Id.* at 21.

67 Congress passed a significant revision to the Patent Act in 1952. *Id.* at 21.

68 *See, e.g.*, Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 *passim* (1998) (discussing the evolution of CAFC jurisprudence regarding the written description requirement of 35 U.S.C. § 112); Sampson, *supra* note 27, at 1265–71 (discussing the "Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. § 112(1) 'Written Description' Requirement" that the PTO issued in December 1999); Timothy A. Worrall, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 123–24 (2001) (internal footnotes omitted) (stating that because "the PTO [initially] granted proprietary rights to biotechnology too liberally," it repeatedly revised the Utility Examination Guidelines, "promulgat[ing] Interim Utility Guidelines in December 1999 and January 2000, and then final Utility Guidelines in January 2001").

issued.[69] These changes in the federal government's approach to patent protection were adopted in response to three movements that together significantly influenced the pace of technological progress in the late nineteenth and early twentieth centuries.

1. *The Industrial Revolution*

The Industrial Revolution dramatically increased the scale of industrial research and development throughout the United States.[70] With the issuance of patents for a variety of important technologies—including the incandescent light bulb, the telephone, early automobile designs, and the first airplanes—patents became a significant measure of economic productivity.[71] This change heralded a trend toward greater patent protection that lasted until the 1920s and 1930s,[72] when a series of abuses committed by large companies in several different industries made courts more reluctant to enforce patent rights.[73] The abuses invariably involved the formation of "patent pools" among competing manufacturers.[74] A patent pool is a private contractual agreement in which the contracting parties transfer their patent rights into a common company "for the purpose of jointly licensing their patent portfolios."[75] The pool consolidates formerly competing patent rights into a single entity and allows the company formed by the joint venture to license rights "to the portfolio of pooled rights, often as a single package."[76]

During the 1930s and early 1940s, federal courts greatly weakened the protections conferred by an issued patent, citing a variety of social costs incurred by the grant of limited monopolies.[77] The Supreme Court upheld a number of early cases involving large cross-

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69 *See* MERGES ET AL., *supra* note 8, at 128. For example, the "inventive step" requirement now codified at 35 U.S.C. § 103(a) (2000) originated in the mid-nineteenth century as a means to limit the number of issued patents. *See* Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248, 266 (1850).

70 *See* MERGES ET AL., *supra* note 8, at 129 (citing THOMAS P. HUGHES, AMERICAN GENESIS: A CENTURY OF INVENTION AND TECHNOLOGICAL ENTHUSIASM 1870–1970, at 150–80 (1989)).

71 *Id.*

72 *See id.*

73 *See* CHISUM ET AL., *supra* note 8, at 21; MERGES ET AL., *supra* note 8, at 129.

74 *See* Steven P. Reynolds, *Antitrust and Patent Licensing: Cycles of Enforcement and Current Policy*, 37 JURIMETRICS J. 129, 133–34 (1997) (describing the trend toward use of patent pools and cross-licensing after passage of the Sherman Act early in the twentieth century); Steven C. Carlson, Note, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359, 367–72 (1999) (offering examples of patent pools and cross-licensing agreements).

75 Carlson, *supra* note 74, at 367.

76 *Id.* at 368.

77 *See* CHISUM ET AL., *supra* note 8, at 21; MERGES ET AL., *supra* note 8, at 129.

licensing agreements[78] but overturned several others on the grounds that they imposed an unreasonable restraint on interstate commerce.[79] In general, the Court proved reluctant to enforce patent rights based upon such agreements.[80] Given the immense contributions of American inventors during World War II, however, the federal government once again came to view technological innovation as an important catalyst for economic growth and progress.[81]

2. *The War Effort*

Following World War II, "there was broad consensus" that the fruits of federally funded research should remain in the public domain or be subject only to nonexclusive licenses.[82] Only then, the argument ran, could Americans reap the full value of "their collective investment[ ]" in research and development.[83] Methods and research tools invented with federal funding were rarely patented; instead, most were published in the scientific literature.[84] As a result, they were freely used or incorporated into commercial products or processes.[85] The extraordinary levels of federal spending on research and development in support of the war effort yielded remarkable ad-

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78 For example, the Supreme Court upheld an agreement organized by the Standard Oil Company that covered a process for "cracking" petroleum. *See* Standard Oil Co. v. United States, 283 U.S. 163, 178–79 (1931).

79 For example, the Supreme Court dismantled a glass manufacturing cartel created by successive patent pooling and cross-licensing agreements among all major glassware manufacturers. *See* Hartford-Empire Co. v. United States, 323 U.S. 386, 386, 392, 432 (1945). During the first half of the twentieth century, the two main glassblowing techniques were the suction method and the suspended gob-feeding method. *Id.* at 393–94. Owens-Illinois Glass Co. (which controlled patents covering the suction method) and Hartford-Empire Co. (which controlled patents covering the suspended gob-feeding method) first cross-licensed their patent portfolios. *See id.* at 395. After the cartel acquired these two dominant patents, it obtained rights to virtually all patents covering the commercial manufacture of glass. At its peak, the cartel controlled more than 600 patents, and ninety-four percent of all glass manufactured in the United States was produced under license from Hartford-Empire. *See id.* at 400. In finding the cartel's activities anticompetitive, Justice Black asserted that "this country [had] perhaps never witnessed a more completely successful economic tyranny over any field of industry than that accomplished by these appellants." *Id.* at 436–37 (Black, J., dissenting in part); *see* Carlson, *supra* note 74, at 374–75 (citing FLOYD L. VAUGHAN, THE UNITED STATES PATENT SYSTEM: LEGAL AND ECONOMIC CONFLICTS IN AMERICAN PATENT HISTORY 78–84 (1956)).

80 *See* CHISUM ET AL., *supra* note 8, at 21; MERGES ET AL., *supra* note 8, at 130.

81 *See* Reynolds, *supra* note 74, at 138 n.63.

82 Bollier, *supra* note 19, at 2.

83 *Id.*

84 *See* Steve L. Bertha, *Intellectual Property Activities in U.S. Research Universities*, 36 IDEA 513, 514 (1996). The commons approach assumes that the unrestricted availability of research tools does not diminish the incentive to conduct research that produces such inventions in the first place.

85 *See id.* at 514.

vances in a wide range of technologies.[86] The number and variety of new commercial applications "focused the attention of the federal government on the issue" of patent policy.[87] Congress then began to address the question of who should retain title and the right to exploit technology resulting from government-sponsored research.[88]

Supporters of government-funded research argued that title to patents covering such inventions should vest in the federal government.[89] According to this argument, leaving patent rights to government contractors would concentrate market power in a handful of large corporations and enable the contractors to eliminate smaller competitors, to the detriment of both consumers and society.[90] Advocates of privately funded research countered that title to these patents should vest in the inventors.[91] Otherwise, the firms best able to transfer new technologies from the lab to the market would not accept public research funds because they would not retain title to patents on any resulting inventions.[92] After a variety of conflicting reports commissioned between 1945 and 1965, the government finally concluded that granting inventors exclusive rights to inventions produced with federal funds would better promote commercial use of new technologies.[93]

3. *Government Intervention*

Congress strengthened the protection available to inventors in the 1952 Patent Act, the first major revision of the patent statutes since 1870.[94] The 1952 Act remains largely unchanged in the more than fifty years since its passage.[95] Congress twice passed related stat-

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86 *See* Eisenberg, *Government-Sponsored Research*, *supra* note 17, at 1671. Advances in mass production techniques, metallurgy, weapons, and aviation technology helped propel the Allies to victory. *See* MERGES ET AL., *supra* note 8, at 129.

87 Eisenberg, *Government-Sponsored Research*, *supra* note 17, at 1671.

88 *Id.*

89 *See id.* at 1671–73.

90 *See id.*

91 *See id.* at 1673–74.

92 *See id.*

93 *See, e.g.*, NAT'L PAT. PLAN. COMM'N, GOVERNMENT-OWNED PATENTS AND INVENTIONS OF GOVERNMENT EMPLOYEES AND CONTRACTORS 14 (1945) (suggesting that the government make patents "available for commercial and industrial exploitation by anyone" and arguing that the government "should . . . grant exclusive licenses" only when "necessary to assure the commercial development of an invention"); U.S. DEP'T OF JUST., 1 INVESTIGATION OF GOVERNMENT PATENT PRACTICES AND POLICIES: REPORT AND RECOMMENDATIONS OF THE ATTORNEY GENERAL TO THE PRESIDENT 2–8 (1947) (advocating adoption of a uniform federal patent policy and arguing that only by retaining title to inventions made at public expense can the government ensure that the public will benefit).

94 15 U.S.C. § 1071 (2000); 35 U.S.C. §§ 1–293 (2000); MERGES ET AL., *supra* note 8, at 129; *see* CHISUM ET AL., *supra* note 8, at 21–22; Stephen McKenna, Comment, *Patentable Discovery?*, 33 SAN DIEGO L. REV. 1241, 1248 (1996).

95 *See* CHISUM ET AL., *supra* note 8, at 21–22; MERGES ET AL., *supra* note 8, at 128–30.

utes following the 1978 Domestic Policy Review on Industrial Innovation, an initative that President Carter commissioned in an effort to increase "industrial productivity and innovation."[96] The policy review "recommended that commercial rights to government-supported research be transferred to the private sector."[97] Congress implemented that recommendation in 1980 by passing the Bayh-Dole Act[98] and the Stevenson-Wydler Technology Innovation Act.[99] Both Acts sought to stimulate the commercial development of inventions[100] resulting from federally funded research.[101]

a. *The Bayh-Dole Act and the Stevenson-Wydler Technology Innovation Act*

The Bayh-Dole Act reflected a renewed governmental commitment to encouraging technological innovation,[102] addressing widespread "concern that American industry was losing its technological edge over foreign competitors."[103] The Act allowed small entities[104] "(1) [to] retain title to the inventions they created while working on a government-sponsored program, (2) [to] apply for and receive patents on those inventions, and (3) [to] pursue options to commercial-

96 Eisenberg, *Government-Sponsored Research*, *supra* note 17, at 1689–90. The Carter initiative was prompted by a study that the Committee on Government Patent Policy had commissioned to determine (1) the effects of federal patent policy on industry participation in government-sponsored research and (2) the frequency with which the resulting inventions were successfully commercialized. *Id.* at 1679–80. The study demonstrated that only 12.4% of government-sponsored inventions patented between 1957 and 1962 had been put to commercial use, *id.* at 1680 (quoting 4 HARBRIDGE HOUSE, *Government Patent Policy Study: Final Report* ii, 3–4 (1968) [hereinafter HARBRIDGE HOUSE REPORT]), and indicated that granting inventors exclusive rights to their inventions would most effectively promote commercial utilization of new technologies, particularly for inventions with obvious commercial applications that required significant additional research and development to get a product to market. *Id.* at 1681–82 (quoting 1 HARBRIDGE HOUSE REPORT, *supra*, at vii).

97 4 HARBRIDGE HOUSE REPORT, *supra* note 96, at 1689.

98 Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200–12 (2000)).

99 Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701–15 (2000)).

100 For purposes of these Acts, an "invention" is "any . . . discovery which is or may be patentable or otherwise protectable under this title," and an invention resulting from federally funded research is one "conceived or first actually reduced to practice in the performance of work under a [government] funding agreement." 35 U.S.C. § 201(d), (e).

101 *See* H.R. REP. NO. 96-1199, at 7–8 (1980), *reprinted in* 1980 U.S.C.C.A.N. 4892, 4896–98.

102 *See* David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 103 (2001).

103 Jack E. Kerrigan & Christopher J. Brasco, *The Technology Transfer Revolution: Legislative History and Future Proposals*, 31 PUB. CONT. L.J. 277, 279–80 (2002).

104 For purposes of the Bayh-Dole Act, small entities are "businesses employing less than 500 employees, non-profit organizations, and universities." Mary Eberle, Comment, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155, 155 (1999).

ize those discoveries."[105] Thus, universities and small businesses who accepted federal funding could retain patent rights to their inventions and license them to companies interested in performing additional research or willing to develop commercial applications of the novel technology.[106] In the presumably infrequent cases in which "a licensee fail[ed] . . . to commercialize [a] technology," the Act allowed a third party to petition the government for the right to license it for commercial purposes.[107] Legislators included this "march-in" provision primarily to address situations in which an original licensee was unable to meet a pressing public health care need.[108] Unsurprisingly, the federal government has never exercised its "march-in" rights.[109]

The Stevenson-Wydler Technology Innovation Act addressed Congress's concern that continuing to isolate federal research facilities from the private sector would impede U.S. leadership in technological innovation and long-term economic competitiveness.[110] This Act enabled federal research laboratories to transfer technology developed in-house to a nongovernmental entity, such as a university or biotechnology company.[111] By allowing inventors to patent inventions

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105 Diane M. Sidebottom, *Updating the Bayh-Dole Act: Keeping the Federal Government on the Cutting Edge*, 30 PUB. CONT. L.J. 225, 227–28 (2001) (citing 35 U.S.C. § 206 (2000)).

106 *See* Eberle, *supra* note 104, at 155–56.

107 *Id.* at 156; *see* Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342 (Fed. Cir. 1998). Johns Hopkins University sued CellPro alleging that CellPro had willfully infringed a university researcher's patent on an antibody used in purifying hemapoietic stem cells from bone marrow. *See CellPro*, 152 F.3d at 1346–47. The patent was licensed to Becton Dickinson and Co. and sublicensed to Baxter Healthcare Corp. *Id.* at 1346. CellPro denied infringement and argued that the patent at issue was invalid and unenforceable. *Id.* at 1348. The court held that CellPro had infringed the patent as a matter of law and granted a new trial. *See id.* at 1368; *see also* Peter Mikhail, Note, Hopkins v. CellPro: *An Illustration That Patenting and Exclusive Licensing of Fundamental Science Is Not Always in the Public Interest*, 13 HARV. J.L. & TECH. 375, 386–87 (2000) (discussing the *CellPro* case in detail).

108 *See* 35 U.S.C. § 203(b) (2000).

109 Gregg S. Sharp, *A Layman's Guide to Intellectual Property in Defense Contracts*, 33 PUB. CONT. L.J. 99, 118 (2003) ("In fact, the Government has never exercised its 'marcb-in' rights, but there have been a few close calls.").

110 Linda A. Mabry, *Multinational Corporations and U.S. Technology Policy: Rethinking the Concept of Corporate Nationality*, 87 GEO. L.J. 563, 637 (1999) ("The statute's principal goal is to eliminate the isolation of government laboratories from universities and industry, a factor long identified as a major obstacle to technological innovation in the United States."). Congress regarded the Act "as an important first step in creating a comprehensive national policy . . . to enhance technological innovation for commercial and public purposes." *Id.* (alteration in original) (internal quotation marks omitted).

111 *See* Sidebottom, *supra* note 105, at 227. The Stevenson-Wydler Technology Innovation Act was amended in October 1986 by the Federal Technology Transfer Act (FTTA). Pub. L. No. 99-502, 100 Stat. 1785 (codified as amended at 15 U.S.C. §§ 3701–05, 3707–10(d), 3711–14 (2000); 35 U.S.C. § 210 (2000)). The FTTA was intended to promote technology transfer by authorizing government-operated laboratories to enter into cooperative research agreements and by establishing a Federal Laboratory Consortium for Technology Transfer within the National Science Foundation. *See* S. REP. NO. 99-283, at 1–3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 3442, 3442–44. The Act stimulated transfer of government-owned technology to the private sector by awarding laboratories and inventors

realized with federal funding, both 1980 amendments ostensibly supported the primary goals of the patent system: encouraging public disclosure of novel discoveries and providing economic incentives for inventors to continue exploring new technologies.[112] The legislation bestowed legal authority upon universities, small businesses, and federal research laboratories to collaborate with interested commercial organizations, to earn revenues by licensing technologies developed with federal funding, and to pursue a variety of technology-transfer opportunities.[113] Since 1980, collaboration between universities and small businesses in the biotechnology industry dramatically increased, as have the number of patent applications filed and issued patents resulting from government-sponsored university research.[114] It is not yet clear whether these increases correlate with passage of the 1980 amendments.[115]

b. *Negotiating the Patent Thicket*

Because it has been much easier to obtain a biotech patent in recent years, biotechnology companies and university researchers patented or attempted to patent an increasing number of useful methods and reagents.[116] These research tools are generally applicable in up-

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cash or a portion of licensing royalties that resulted from the transfer. *Id.* It also required government scientists to report inventions with commercial potential or possible health benefits for transfer to the private sector. *See id.*

112 *See* CHISUM ET AL., *supra* note 8, at 70–76 (discussing various economic theories underlying the U.S. patent system and the incentives to invent, disclose, commercialize, or design around existing proprietary technologies).

113 *See* Sidebottom, *supra* note 105, at 227.

114 *See The Bayh-Dole Act, a Review of Patent Issues in Federally Funded Research: Hearing on Pub. L. No. 96-517 Before the Senate Comm. on the Judiciary Subcomm. on Patents, Copyrights, and Trademarks*, 103d Cong., 2d Sess. 33–37 (1994) (statement of Howard W. Bremer on behalf of the Association of University Technology Managers and the Council on Governmental Relations). *See generally* ASS'N OF UNIV. TECH. MANAGERS, AUTM LICENSING SURVEY: FY 2000: A SURVEY SUMMARY OF TECHNOLOGY LICENSING (AND RELATED) PERFORMANCE FOR U.S. AND CANADIAN ACADEMIC AND NON-PROFIT INSTITUTIONS, AND PATENT MANAGEMENT FIRMS, *available at* http://www.autm.net/surveys/2000/summarynoe.pdf (last visited Jan. 19, 2004) (collecting statistics on patent applications filed, patents allowed, and licensing revenues earned by AUTM member institutions for fiscal year 2000).

115 *See generally* Rebecca Henderson et al., *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965–1988*, 80 REV. ECON. & STAT. 119, 119–26 (1998) ("suggest[ing] that the observed increase in university patenting may reflect an increase in their propensity to patent" rather than expanded research output (internal quotation marks omitted)); Mowery et al., *supra* note 102, at 103–16 (analyzing the impact of the Bayh-Dole Act on patent filings and licensing revenues at Columbia University, the University of California, and Stanford University).

116 *See* Walsh et al., *supra* note 3, at 289–90, 296–97. A reagent is a component of a biological or chemical reaction that is used in experimentation or production because of its chemical or biological activity. *See* WEBSTER'S NEW COLLEGIATE DICTIONARY 954 (1981). Useful reagents that companies or individual researchers routinely patent include monoclonal antibodies, genomic or cDNA libraries, plasmids, cloned cDNAs, ESTs, or thermostable DNA polymerases used in the polymerase chain reaction (PCR). *See* WORK-

stream research, "i.e., research that is relatively far removed from a commercial end product."[117] Upstream patents frequently increase basic research costs by requiring researchers to license essential research tools.[118] For example, a pharmaceutical company attempting to develop drugs for the treatment of Alzheimer's disease might want access to deoxyribonucleic acid (DNA) sequences from genes implicated in the development and progression of the disease.[119] Partial gene sequences could be used to search for a full-length copy of the same gene;[120] full-length sequences could be used to produce recombinant protein for a variety of research applications.[121] Depending on the number of genes involved, a company might have to license dozens, even hundreds of genes or gene fragments.[122] If more than one company owns patents on the genes or gene fragments, a researcher might have to negotiate many different licenses.[123] Alternatively, patent holders may choose to eliminate their competition by refusing to license rights to use the genes or by charging exorbitant license fees.[124] Even though most companies successfully negotiate licenses, the transaction costs related to this "patent thicket," whether in the form of royalty payments or legal and administrative costs, might soon be high enough to deter research.[125]

Proponents of the patent system assume that most patent holders will act rationally to maximize the economic utility of their inventions

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SHOP SUMMARY, *supra* note 3, at 40–51. Useful methods include PCR and methods for inducing expression of recombinant proteins in bacteria or the construction of cDNA micro-arrays. *See id.* at 48–55. Methods and reagents are often referred to as "research tools." *See id.* at 48. Judge Newman of the Federal Circuit has defined a research tool as "a product or method whose purpose is use in the conduct of research, whether the tool is an analytical balance, an assay kit, a laser device[,] . . . or a biochemical method such as the PCR . . . ." Integra Lifescis. I, Ltd. v. Merck KGaA, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part).

117 Rai, *supra* note 3, at 816. The farther "upstream" a patented research tool is used, the more "downstream" products and processes it affects. *Id.* at 816–23 (advocating narrow rights in upstream research and technology in order to encourage competition); *see* Heller & Eisenberg, *supra* note 14, at 698 (defining "upstream" as "premarket" and discussing how changes in patent policy have caused the gradual shift of biotechnology research "from a commons model toward a privatization model").

118 *See* Rai, *supra* note 3, at 816–17.

119 *See id.* at 816.

120 *Id.*

121 *See id.*

122 *See* Resnik, *supra* note 9, at 4.

123 *See* Rai, *supra* note 3, at 816–17.

124 *See* Resnik, *supra* note 9, at 4. For example, Myriad Genetics, a company based in Salt Lake City, Utah, holds patents on BRCA1 and BRCA2, two genes associated with predisposition to breast and ovarian cancer. *Id.* at 6. Myriad developed tests to detect BRCA1 and BRCA2 mutations and charges $2,300 per test. *Id.* The company "bas licensed only a few laboratories to conduct the test," at a fee of $1,200 per use, in addition to the cost of performing the test itself. *Id.*

125 *Id.*

by freely granting licenses.[126] Although that has been true in most industries, it may not always be the case in biotechnology, where innovations "stand on the shoulders" of previous inventions.[127] Patent holders are not obligated to license their technologies to competing researchers: they may refuse to grant licenses[128] or hold out against the tantalizing possibility of extraordinary future profits.[129] Thus, in biotechnology and other "cumulative systems technologies," granting expansive intellectual property rights may increase litigation and other transaction costs.[130] Ultimately, the rush to the PTO may hinder the free and open exchange of ideas and research materials that fueled the development of the biotechnology industry in the first place.[131]

Perhaps to thwart such economically irrational behavior, Congress allowed federally funded researchers to retain title to their inventions, but also required them to convey a nonexclusive license on the federal government to use those inventions.[132] The requirement provides other federally supported researchers with inexpensive or free access to new technologies.[133] Given the proliferation of private biotechnology companies and increasingly frequent collaborations between private companies and public sector researchers, however, this provision alone will not solve the problem.

II

BASIC CONCEPTS AND METHODS OF MODERN BIOTECHNOLOGY

The inclination to assert property rights in biotechnology inventions paralleled the growth in federal funding for basic biomedical

126 *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 278 (1977).

127 *See* Walsh et al., *supra* note 3, at 289.

128 *See, e.g.*, SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1204–05 (2d Cir. 1981) (finding that unilateral refusal to license lawfully acquired patents is permitted under the patent laws and thus cannot trigger antitrust liability); United States v. Telecs. Proprietary, Ltd., 607 F. Supp. 753, 755 (D. Colo. 1983) (noting that the unilateral right to refuse to grant a license is the essence of the patent monopoly); Resnik, *supra* note 9, at 5. However, when a patent holder has significant market power in its industry, its refusal to license technology may trigger antitrust liability. *See* Hartford-Empire Co. v. United States, 323 U.S. 386, 436–37 (1945) (Black, J., dissenting in part).

129 *See* Heller & Eisenberg, *supra* note 14, at 698.

130 *See* Kitch, *supra* note 126, at 276–78 (providing examples of transaction costs that might accrue).

131 *See* Amy Ligler, *Egregious Error or Admirable Advance: The Memorandum of Understanding That Enables Federally Funded Basic Human Embryonic Stem Cell Research*, 2001 DUKE L. & TECH. REV. 37 (2001), *available at* http://www.law.duke.edu/journals/dltr/articles/2001dltr0037.html (discussing the impact of a ban on federal funding for stem cell research, the reliance of stem cell researchers on private funding, and the consequences of allowing some stem cell patents to rest entirely in the private sector).

132 *See* 35 U.S.C. § 202(c)(4) (2000).

133 *See id.*

research that began in the late 1960s.[134] Three factors encouraged this tendency: (1) a series of court rulings that greatly expanded the acceptable range of patentable subject matter for biotechnological inventions;[135] (2) efforts to strengthen international protection for intellectual property rights;[136] and (3) implementation of progressively more liberal PTO examination guidelines, which made it considerably easier to obtain patents on biotech inventions.[137] Taken together, these changes in federal policy stimulated biotechnology research and triggered a feverish race to the patent office for academic and industrial researchers alike.[138]

Part I suggested that neither the traditional approach of leaving all government-sponsored inventions in the public domain nor the modern approach of granting exclusive rights to private parties

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134 *See* Mowery et al., *supra* note 102, at 100.

135 *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 305, 308–09 (1980) (holding that a new strain of bacteria produced by artificial bacterial recombination was a patentable invention and concluding that patentable subject matter includes "anything under the sun that is made by man" (internal quotation marks omitted)); *In re* Bergy, 563 F.2d 1031, 1038 (C.C.P.A. 1977), *vacated sub nom.* Parker v. Bergy, 438 U.S. 902 (1978) (holding that a biologically pure culture of a naturally occurring bacterium is patentable); *Ex parte* Allen, 2 U.S.P.Q.2d 1425, 1427–28 (Bd. Pat. App. & Interf. 1987) (stating that the PTO considers nonnaturally occurring, nonhuman multicellular organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101); *Ex parte* Hibberd, 227 U.S.P.Q. 443, 447 (Bd. App. & Interf. 1985) (extending *Chakrabarty* to hold that manmade multicellular plants not found in nature are patentable).

136 *See, e.g.*, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 1197 [hereinafter TRIPs]. The TRIPs agreement was part of the Final Act of the 1994 Uruguay Round of multilateral negotiations under the General Agreement on Tariffs and Trade, Apr. 15, 1994, 33 I.L.M. 1154 [hereinafter GATT]. The agreement is founded on the notion that "the failure to protect intellectual property rights distorts the flow of free trade and undermines the . . . benefits flowing from the GATT system." JULIE E. COHEN ET AL., COPYRIGHT IN A GLOBAL INFORMATION ECONOMY 53 (2002).

137 *See, e.g.*, Mazzoleni & Nelson, *supra* note 12, at 274 (describing changes in U.S. patent policy designed to encourage scientists to seek patent protection, including establishment of the pro-patent CAFC in 1982, passage of the Bayh-Dole Act of 1980, and "a trend toward broadening the definition of patentable subject matter"); Worrall, *supra* note 68, at 131–133 (discussing the changing approach of the PTO toward evaluating the utility of biotechnological inventions). *But see* Mary Breen Smith, Comment, *An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines*, 73 U. COLO. L. REV. 747, 770–84 (2002) (suggesting that application of the PTO's new Utility Guidelines to new gene patents will make it considerably more difficult to patent genes).

138 *See, e.g.*, PTO SUMMARY, FY 1999, *supra* note 42 (collecting a wide range of data on filed patent applications and allowed patents for fiscal year 1999); Mowery et al., *supra* note 102, at 103–04 (discussing the increase in patent applications, patents allowed, and licensing royalties that American universities have collected since 1980). Several commentators have observed that the landmark case *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), opened the floodgates to biotechnology research and development. *See, e.g.*, L. Christopher Plein, *Biotechnology: Issue Development and Evolution*, *in* BIOTECHNOLOGY: ASSESSING SOCIAL IMPACTS AND POLICY IMPLICATIONS 147, 156, 158–59 (David J. Webber ed., 1990) (internal quotation marks omitted). One scholar even characterized *Chakrabarty* "as the driving force behind the commercial development of biotechnology." *Id.* at 158.

should extend to all inventions.[139] The process of scientific discovery and commercialization of new technologies is complex, variable, and unpredictable. Thus, allowing government-sponsored inventions to remain in private hands might accelerate the development of commercial applications for some new technologies, while others might never yield a commercially viable product unless they are left in the public domain.[140] This Part reviews the basic concepts of modern biotechnology and the courts' handling of biotechnological inventions while arguing that a different approach is required.

A. The Building Blocks of Biotechnology

Modern genetics and molecular biology originated with Frederick Miescher's discovery of DNA in 1869.[141] At about the same time, Gregor Mendel proposed that genes were the unit of information that governed the inheritance of particular physical traits.[142] Following the discovery that DNA molecules contained the universal determinants of genetic behavior,[143] scientists proceeded to investigate precisely how a living organism used the information contained in that genetic blueprint to guide growth and development.[144]

In 1953, James Watson and Francis Crick published a paper describing the physical structure of a DNA molecule.[145] Subsequent experimentation revealed that information is stored in DNA as spe-

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139 *See* Eisenberg, *Patenting Problems*, *supra* note 28, at 165–66.

140 *See id.* at 165. For example, compare the semiconductor industry, in which patents played a critical role in technological development, with the software industry, in which leaving Linux computer code in the public domain provided the impetus for a wide variety of improvements. *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1693–95 (2003); Jon M. Garon, *Normative Copyright: A Conceptual Framework for Copyright Philosophy and Ethics*, 88 CORNELL L. REV. 1278, 1345 (2003); *see also* Burk & Lemley, *supra* note 7, at 1156 (arguing that patent law is unified only in theory because application of conventional patent law doctrine is technology-specific).

141 *See* MAXINE SINGER & PAUL BERG, GENES & GENOMES: A CHANGING PERSPECTIVE 23 (1991). Miescher recognized that DNA was chemically distinct from proteins based on its comparatively high phosphate content and resistance to chemical treatments that easily destroyed protein. *Id.*

142 *See* JAMES D. WATSON ET AL., MOLECULAR BIOLOGY OF THE GENE 8–11 (4th ed. 1987) (describing Mendel's experiments and the rules of genetic inheritance derived therefrom). Although Mendel's discovery came in the 1860s, his findings were not disseminated until 1900, 16 years after his death. *See id.* at 8.

143 *See* SINGER & BERG, *supra* note 141, at 23. Oswald Avery and his colleagues, along with Alfred Hershey and Margaret Chase, performed the experiments demonstrating that DNA alone carries genetic information. *Id.*

144 *See id.* at 23–34 (reviewing a series of groundbreaking experiments that determined how DNA replicated, mutated, and passed from one generation to the next and how genetic characteristics were physically expressed).

145 *See* Watson & Crick, *supra* note 2, at 737. James Watson, Francis Crick, and Maurice Wilkins shared the 1962 Nobel Prize in Physiology/Medicine for their pioneering work. *See* Nobel e-Museum, *at* http://www.nobel.se/medicine/laureates/1962/index.html (last visited Jan. 20, 2004).

cific base sequences called genes.[146] Genes contain the "instructions" for initiating and regulating various biochemical processes that comprise the biological phenomenon of life.[147] A complex series of biochemical manipulations eventually transform genetic instructions into active molecules of ribonucleic acid (RNA)[148] or protein,[149] which initiate or regulate the metabolic activities essential to life.[150] Scientists refer to these various biochemical manipulations as the process of "gene expression."[151]

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146 *See, e.g.*, SINGER & BERG, *supra* note 141, at 29–34 (describing the work uncovering the relationship between specific DNA sequences and particular physical characteristics or phenotypes that led to discovery of the genetic code).

147 *See id.*

148 *See id.* at 54–59.

149 *See id.* at 59–71. Proteins are biopolymers, much like DNA or RNA, but they are composed of twenty monomer units called amino acids, not just four nucleotide bases. *See id.* Because proteins assume a much greater range of physical structures than nucleic acids, they are more structurally diverse and biochemically versatile than either DNA or RNA. *See id.* Thus, "[p]roteins are the principal determinants of an organism's" physical characteristics. *Id.* at 29. Because nucleic acids contain only four different bases while proteins contain twenty different amino acids, mRNA is "read" in base triplets (called codons) during translation. There are 4^3=64 possible base triplets in DNA and mRNA: sixty-one specify particular amino acids, and three tell the protein synthesis machinery to stop making protein. *See id.* at 29–40, 131–32. The sixty-one codons specify only twenty different amino acids, so "several codons can specify the same amino acid," *id.* at 132 (e.g., the amino acid glycine is encoded by four codons: G-G-A, G-G-C, G-G-G, and G-G-U, *id.* at 155). Thus, because of the possibility for redundancy, the genetic code is often called "degenerate." *See id.* at 131–32. This degeneracy often poses problems for satisfying the written description requirement imposed by 35 U.S.C. § 112. *See, e.g.*, Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).

150 *See* SINGER & BERG, supra note 141, at 54–59.

151 *See id.* at 35. Gene expression involves the transfer of genetic information from DNA to RNA and from RNA to protein. *See id.* at 54. Through a process called transcription, an RNA molecule is copied using a single DNA strand as a template. *See* WATSON ET AL., *supra* note 142, at 363–64. The resulting RNA molecule, called message RNA (mRNA), then guides the synthesis of a protein through a process called translation. Sometimes RNA transcripts and not proteins are the final products of gene expression; this is the case with transfer RNA (tRNA) and ribosomal RNA (rRNA), both of which play essential roles in protein synthesis. *See id.* at 400. Most of the time, mRNA transcripts undergo extensive processing during which base sequences that do not specify protein sequences (called introns, for intervening sequences) are removed from the RNA molecule. The remaining mRNA sequences specifying the particular protein sequence of the gene product (called exons, for expressed sequences) are spliced together to produce a functional mRNA transcript that can then undergo translation to produce its protein product. *See id.* at 626–37. Processed mRNA transcripts may be fully or partially copied back into DNA using a viral enzyme called a reverse transcriptase. A full-length DNA copy of a processed mRNA transcript is called a cDNA (for complementary DNA), while a partial copy is called an EST (for expressed sequence tag). *See id.* at 609–11. The question of whether cDNA and EST sequences derived from genes of unknown function constitute patentable subject matter has been extremely controversial in recent years, in large part because so many biotechnology companies have attempted to patent such sequences. In 1997, there were "at least 350 patent applications, covering at least 500,000 gene sequence tags, pending before the" PTO. Courtney J. Miller, Comment, *Patent Law and Human Genomics*, 26 CAP. U. L. REV. 893, 894 n.3 (1997) (citing Eliot Marshall, *Companies Rush To Patent DNA*, 275 SCI. 780, 781 (1997)); *see also* Byron V. Olsen, *The Biotechnology Balancing Act: Patents for Gene Fragments,*

In 1970, scientists discovered that many kinds of bacteria possess DNA sequence-specific enzymes called restriction enzymes.[152] Researchers soon began to develop laboratory methods using the purified and active enzymes.[153] At about this time, Arthur Kornberg and his colleagues identified and characterized a variety of other enzymes involved in DNA synthesis.[154] With the help of restriction enzymes, scientists isolated an enzyme—DNA ligase—that joins the ends of DNA molecules. This finding suggested that pieces of DNA from different sources could be linked to produce a single hybrid DNA molecule.[155] In 1972, Paul Berg produced the first so-called recombinant DNA molecule, using restriction enzymes and DNA ligase.[156] Shortly thereafter, researchers in Stanley Cohen's lab demonstrated that a recombinant DNA molecule containing pieces of DNA from two different species could be inserted and maintained within individual cells of *Escherichia coli* ("*E. coli*") bacteria.[157]

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and Licensing the "Useful Arts", 7 ALB. L.J. SCI. & TECH. 295, 306–307 (1997) (discussing the National Institutes of Health (NIH)'s unsuccessful attempts to patent hundreds of gene fragments); John Murray, Note, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHI.-KENT L. REV. 231, 236–37 (1999) (discussing the race to patent ESTs and other gene fragments).

152 *See* WATSON ET AL., *supra* note 142, at 88 (citing Hamilton O. Smith & K.W. Wilcox, *A Restriction Enzyme from* Hemophilus influenzae*: I. Purification and General Properties*, 51 J. MOLECULAR BIOLOGY 379 (1970)). Members of this class of enzymes recognize a specific sequence of DNA bases from four to eight bases in length and cut DNA molecules at that sequence. For example, one such enzyme isolated from the commonly used bacterium *Escherichia coli* ("*E. coli*"), called *Eco* RI (for *E. coli* restriction enzyme I), recognizes and cuts the target sequence of bases G-A-A-T-T-C. Similarly, the enzyme isolated from *H. influenzae* by Hamilton Smith, called *Hin* dIII (for *H. influenzae* Rd enzyme III), recognizes and cuts the target sequence A-A-G-C-T-T. *Id.* at 88–89.

153 *See id.*

154 *See* Arthur Kornberg, *Mechanisms of Replication of the* Escherichia coli *Chromosome*, 137 EUR. J. BIOCHEMISTRY 377 (1983); *see also* WATSON ET AL., *supra* note 142, at 282–301 (reviewing the various enzymes required to synthesize complete DNA molecules during the process of DNA replication); Martin Gellert, *DNA Topoisomerases*, 50 ANN. REV. BIOCHEMISTRY 879, 880 (1981) (addressing "new insights into the influence of topoisomerases and DNA supercoiling on biological functions"); I. R. Lehman, *DNA Ligase: Structure, Mechanism, and Function*, 186 SCI. 790, 797 (1974) (concluding that "DNA ligase is . . . an essential enzyme required for normal DNA replication and repair in *E. coli*").

155 WATSON ET AL., *supra* note 142, at 88–89. DNA molecules containing sequences from different organisms are called recombinant DNA molecules. *Id.*

156 *See* David A. Jackson, Robert H. Symons & Paul Berg, *Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40: Circular SV40 DNA Molecules Containing Lambda Phage Genes and the Galactose Operon of* Escherichia Coli, 69 PROC. NAT'L ACAD. SCI. USA 2904 (1972).

157 *See* Cohen et al., supra note 4, at 3240. The recombinant DNA molecule used in that experiment was called a plasmid. *Id.* A plasmid typically contains: 1) a short sequence (called an origin of replication) that confers the ability to be copied by the host cell; 2) a selectable marker (usually a gene that confers resistance to an antibiotic such as ampicillin); and 3) a series of recognition sequences for a variety of different restriction enzymes at which the desired piece of DNA may be inserted. *See* BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 320–21 (3d ed. 1994) (describing different kinds of plasmids used in manipulating recombinant DNA).

These trailblazing experiments unleashed a torrent of new laboratory methods[158] that transformed the study of biology and advanced both biological research and drug development.[159] Recombinant DNA technology quickly developed more complex and sophisticated plasmids that enabled the expression of protein molecules either in living bacterial cells or *in vitro* using isolated translation machinery.[160] Consequently, the pharmaceutical industry shifted its drug development strategy from isolating and characterizing the active ingredients of traditional folk remedies[161] to exploiting new high-throughput screening and combinatorial chemistry technologies and taking advantage of recombinant DNA technology.[162] In the past, "much of the difficulty in using recombinant DNA techniques" lay in identifying, cloning, sequencing, and expressing the genes that encoded particular proteins.[163] Recent technological advances in laboratory methods and automation have simplified much of this process, turning a variety of tasks that previously required considerable effort and ingenuity into matters of routine.[164]

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158 *See* ALBERTS ET AL., *supra* note 157, at 291–331; David J. Galas & Albert Schmitz, *DNAse Footprinting: A Simple Method for the Detection of Protein-DNA Binding Specificity*, 5 NUCLEIC ACIDS RES. 3157 (1978) (DNA footprinting); Keiichi Itakura et al., *Synthesis and Use of Synthetic Oligonucleotides*, 53 ANN. REV. BIOCHEMISTRY 323 (1984) (chemical synthesis of DNA oligonucleotides); Köhler & Milstein, *supra* note 4, at 495; Tom Maniatis et al., *The Isolation of Structural Genes from Libraries of Eucaryotic DNA*, 15 CELL 687 (1978) (genomic and cDNA libraries); Mullis & Faloona, *supra* note 4, at 335; Schena et al., *supra* note 4, at 467; E. M. Southern, *Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis*, 98 J. MOLECULAR BIOLOGY 503 (1975) (gel-transfer hybridization).

159 *See generally* WORKSHOP SUMMARY, *supra* note 3, at 50 (describing the research strategy of the biotechnology industry as attempting to isolate a single useful protein, to clone and patent the gene that encoded it, and finally to produce a pure, therapeutically active recombinant version of the protein, examples of which include insulin and erythropoietin).

160 *See, e.g.*, Paulina Balbas & Francisco Bolivar, *Design and Construction of Expression Plasmid Vectors in* Escherichia coli, 185 METHODS ENZYMOLOGY 14 (1990). *In vitro* is Latin for "in glass" and has become shorthand for "in the lab," in contrast to work done *in vivo* ("in one that is living"), which describes experimentation performed in a living cell or organism. WEBSTER'S NEW WORLD COLLEGE DICTIONARY 711 (3d ed. 1997) (defining *in vitro* as "isolated from the living organism and artificially maintained, as in a test tube").

161 *See* Lawrence M. Gelbert & Richard E. Gregg, *Will Genetics Really Revolutionize the Drug Discovery Process?* 8 CURRENT OP. BIOTECH. 669, 669 (1997). Many drugs now on the market are pharmaceutically active molecules isolated from naturally occurring plants. *See id.* Before the advent of recombinant DNA technology, pharmaceutical researchers typically began searching for new drugs by synthesizing a library of chemically related derivatives of a successful drug. The library of candidate compounds would then be screened for the desired biological activity. This time-consuming and expensive process rarely yields promising drug candidates. *See id.*

162 *See, e.g.*, Mariana Vaschetto et al., *Enabling High-Throughput Discovery*, 6 CURRENT OP. DRUG DISC. & DEV. 377, 377 (2003).

163 Golden, *supra* note 27, at 114–15; *see, e.g.*, ALBERTS ET AL., *supra* note 157, at 308–18 (summarizing the advantages and disadvantages of commonly used cloning methods).

164 *See* Anita Varma & David Abraham, *DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J.L. & TECH. 53, 65 (1996) (describing how

B. Patentable Subject Matter in Biotechnology

The Patent Act traditionally limited the subject matter of patents to "invention[s] or discover[ies]."[165] The U.S. Code defines a patentable invention or discovery as "any *new and useful* process, machine, manufacture, or composition of matter, or any *new and useful* improvement thereof."[166] The term "process" encompasses any "process, art or method, [including] a new use of a known process, machine, manufacture, composition of matter, or material."[167]

While the statute ostensibly limits the breadth of patentable subject matter, its expansive language suggests that Congress "plainly contemplated that the patent laws would be given wide scope."[168] Under traditional patent doctrine, "[t]he laws of nature, physical phenomena, and abstract ideas" are generally not patentable.[169] For example, neither Einstein's theory of relativity nor Newton's laws of motion could have been patented because they are "manifestations of . . . nature, free to all men and reserved exclusively to none."[170] Similarly, a newly discovered plant or chemical element cannot be patented, despite the statutory definition of an invention as an "invention or discovery."[171] This is known as the "product of nature" doctrine:[172] an inventor cannot patent a product that occurs in nature "in essentially the same form."[173]

DNA-related biotechnology has progressed significantly in recent years, allowing a biotechnologist to simply sit down at a computer, enter a data bank, and predict a protein's entire sequence).

165 35 U.S.C. § 100(a) (2000).

166 *Id.* § 101 (emphasis added). Novelty and utility are evaluated separately according to 35 U.S.C. §§ 102 and 103, respectively.

167 *Id.* § 100(b). A process is simply a method to produce a desired result as, for example, by mixing an aqueous solution of DNA with sodium acetate and ethyl alcohol to precipitate the DNA from solution as a sodium salt. *See* Bruce A. Roe, *Concentration of DNA by Ethanol Precipitation, at* http://iprotocol.mit.edu/protocol/64.htm (last visited Jan. 20, 2004). For purposes of this Note, "[a] machine is an assemblage of parts that transmit forces, motion, and energy to one another in a predetermined manner." HERBERT F. SCHWARTZ, PATENT LAW AND PRACTICE 63 (3d ed. 2001). Further, "[a] composition of matter is a new substance resulting from the combination of two or more different ingredients." *Id.* (citing Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980)). Finally, "[a] manufacture . . . is anything man-made that is not a machine or a composition of matter." *Id.* (citing Riter-Conley Mfg. Co. v. Aiken, 203 F. 699 (3d Cir. 1913)).

168 *Chakrabarty*, 447 U.S. at 308.

169 *Id.* at 309.

170 Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

171 35 U.S.C. § 100(a); *see Chakrabarty*, 447 U.S. at 309–14 (noting the exception that genetically modified plants may now be the subject of utility patent applications under 35 U.S.C. § 101).

172 DONALD S. CHISUM, 1 CHISUM ON PATENTS § 1.02(7), at 7–20 (2003).

173 John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 371, 373 (2003).

In the landmark case *Diamond v. Chakrabarty*, the Supreme Court held that a product of biotechnology will comprise patentable subject matter only if it is a "product of human ingenuity" in the form of "a non[-]naturally occurring manufacture or composition of matter."[174] Federal courts consistently refuse to grant patents for newly discovered natural phenomena.[175] However, the *Chakrabarty* Court interpreted the language of the 1952 Patent Act and its amendments broadly to mean that "anything under the sun . . . made by man" was patentable.[176] To obtain a patent on any naturally occurring matter, therefore, an inventor need only "appl[y] . . . the law[s] of nature to a new and useful end."[177] Likewise, in order to patent a gene, the inventor must isolate the gene from nature, purify it, and determine its sequence.[178] The PTO has applied this rationale in granting patents for a variety of biotechnological inventions, such as cloned DNA sequences, stem cell lines, purified recombinant proteins, and trans-

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174 *Chakrabarty*, 447 U.S. at 309.

175 *See* Am. Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566, 596–99 (1874) (suggesting that purification of a preexisting natural substance does not render it patentable subject matter unless the product is significantly altered). In evaluating a patent claiming, *inter alia*, a purified form of cellulose isolated from wood and straw, Justice Strong noted:

> There are many things well known and valuable in medicine or in the arts which may be extracted from divers[e] substances. But the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.

Id. at 593–94.

176 *Chakrabarty*, 447 U.S. at 309 (internal quotation marks omitted). One author of the 1952 Patent Act used virtually identical language to describe the intended breadth of 35 U.S.C. § 101. *Id.* at 309 n.6 (quoting *Hearings on H.R. 3760 Before Subcomm. No. 3 of the House Comm. on the Judiciary*, 82d Cong., 1st Sess. 37 (1951) (testimony of P.J. Federico, a principal draftsman of the 1952 Patent Act)).

177 Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948). This requirement dates to the first quarter of the twentieth century and applied to biological materials well before the advent of recombinant DNA technology. *See In re* Bergstrom, 427 F.2d 1394, 1395, 1401–02 (C.C.P.A. 1970) (reversing the patent examiner's rejection of claims for purified prostaglandins, molecules involved in regulating the inflammatory response); Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 103–04 (S.D.N.Y. 1911) (upholding a patent for purified adrenaline).

178 *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991). The court reasoned that, because naturally occurring chemicals are patentable once a researcher has isolated one from nature and determined its chemical structure and because DNA is a chemical compound, DNA sequences are also patentable once they have been sequenced. *See id.* Accordingly, DNA that has been isolated from an organism and sequenced constitutes patentable subject matter under 35 U.S.C. § 101 (2000) and according to the CAFC. *See* Smith, *supra* note 137, at 760. This pragmatic approach echoes John Locke's opinion that "[t]he *labour* of [a man's] body, and the *work* of his hands . . . are properly his[,]" so that "[w]hatsoever . . . he removes out of the state that nature hath provided, and left it in, he hath mixed his *labour* with, and joined to it something that is his own, and thereby makes it his *property*." JOHN LOCKE, TWO TREATISES ON GOVERNMENT § 27, at 209 (John Bumpus 1821) (1680).

genic animals.[179] *Chakrabarty's* progeny further expanded the scope of patentable subject matter in biotechnology to cover biologically pure cultures of naturally occurring bacteria;[180] manmade multicellular plants not found in nature;[181] and non-naturally occurring, nonhuman multicellular organisms, including animals.[182]

This increasingly expansive definition of patentable subject matter has sparked controversy. For example, attempts by the NIH to patent thousands of "expressed sequence tags" (ESTs), partial gene cDNA sequences identified during the human genome project, triggered public outrage.[183] In 1992, research scientist Craig Venter—then working for the NIH—filed three applications seeking patent protection for more than 6,800 ESTs, mostly of unknown function.[184] Although Venter and the NIH ultimately dropped their requests for patent protection,[185] their actions spurred intense debate[186] that has continued as ever-growing numbers of private biotechnology companies undertake basic research on DNA sequences and then seek to patent them.[187]

III

THE ECONOMICS OF PATENT PROTECTION IN BIOTECHNOLOGY

The PTO issues patents to inventors as an incentive to develop and commercialize new technologies, thereby securing for the public

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179 *See* Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 307–08 (2002).

180 *See In re* Bergy, 563 F.2d 1031, 1038 (C.C.P.A. 1977), *vacated sub nom.* Parker v. Bergy, 438 U.S. 902 (1978).

181 *See Ex parte* Hibberd, 227 U.S.P.Q. 443, 447 (Bd. App. & Interf. 1985).

182 *See, e.g.*, Allen Archery, Inc. v. Browning Mfg. Co., 819 F.2d 1087 (Fed. Cir. 1987).

183 *See, e.g.*, Christopher Anderson, *U.S. Patent Application Stirs up Gene Hunters*, 353 NATURE 485, 485–86 (1991); Olsen, *supra* note 151, at 306–07; Leslie Roberts, *Genome Patent Fight Erupts*, 254 SCI. 184, 184–85 (1991). An EST is a piece of cDNA that encodes a partial gene sequence—of known or unknown function—that is transcribed into mRNA. NAT'L CTR. FOR BIOTECH. INFO., A SCIENCE PRIMER, ESTs: GENE DISCOVERY MADE EASIER 2, *available at* http://www.ncbi.nlm.nih.gov/About/primer/est.html (last accessed Jan. 20, 2004). ESTs are usually obtained by random sampling of cDNA libraries and typically contain 200 to 500 base pairs. *Id.* Because they are comparatively inexpensive to produce and relatively quick to obtain, ESTs are useful research tools in the preliminary steps of isolating genes, identifying coding regions of genomic DNA, and analyzing patterns of gene expression in living tissue. *See* Tyra G. Wolfsberg & David Landsman, *A Comparison of Expressed Sequence Tags* (ESTs) to Human Genomic Sequences, 25 NUCLEIC ACIDS RES. 1626, 1626–31 (1997). These methods use the cDNA fragments as tags to "fish" desirable genes out of chromosomal DNA or from a cDNA library by hybridization. *See id.* at 1631–32.

184 Jonathan Kahn, *What's the Use? Law and Authority in Patenting Human Genetic Material*, 14 STAN. L. & POL'Y REV. 417, 420 (2003).

185 *See* Christopher Anderson, *NIH Drops Bid for Gene Patents*, 263 SCI. 909, 909–10 (1994).

186 Kahn, *supra* note 184, at 420.

187 Murray, *supra* note 151, at 237–39.

the myriad benefits of scientific progress.[188] Although policymakers generally accept this utilitarian justification,[189] it is not clear that the existing patent system actually "promote[s] the Progress of Science and useful Arts"[190] as intended, or that the current system is the most efficient way to do so.[191] Nevertheless, the federal government amended the Patent Act of 1952[192] and relaxed the PTO examination guidelines to encourage the development and commercialization of the fledgling biotechnology industry.[193] In addition, federal courts have construed the statutory requirements of patentability expansively,[194] causing the number of biotechnology patents granted since 1980 to soar.[195] With the increase in such patents, however, experi-

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188 *See* MERGES ET AL., *supra* note 8, at 12; Svatos, *supra* note 21, at 113–14 (quoting HACKING, *supra* note 25, at 46).

189 A number of commentators have asserted that a strong regime of intellectual property protection is essential to the survival of the emerging biotechnology industry, but few as emphatically as Andrew Hacking:

> Patenting is necessary to ensure that producers of new inventions or innovations receive a return on their investment in research and development. It is justified as being essential to induce innovation and to support research. Information may be expensive to produce but relatively cheap to copy. In biotechnology as elsewhere patents are an indispensable element in research and development, and much effort must be directed to ensure that work is patentable, otherwise it may have little commercial value.

HACKING, *supra* note 25, at 43–44.

190 U.S. CONST. art. I, § 8, cl. 8; Svatos, *supra* note 21, at 116–17.

191 This Note takes the position that stimulation of technological progress in general, and biotechnology in particular, is justified on utilitarian grounds.

192 *See* Federal Technology Transfer Act, Pub. L. No. 99-502, 100 Stat. 1785 (codified as amended at 15 U.S.C. §§ 3701–05, 3707–10(d), 3711–14 (2000); 35 U.S.C. § 210 (2000)); Stevenson-Wydler Technology Innovation Act, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701–15 (2000)); Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200–12 (2000)).

193 *See* Worrall, *supra* note 68, at 123; Smith, *supra* note 137, at 748–51 (discussing application of the 1999 PTO Utility Guidelines to new gene patents). Relaxing the examination guidelines has resulted in the PTO allowing extremely broad claims on biotechnology inventions, particularly compared with typical chemical cases. *See* Lentz, *supra* note 24, at 318.

194 *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980); *In re* Bergy, 563 F.2d 1031, 1038 (C.C.P.A. 1977), *vacated sub nom.* Parker v. Bergy, 438 U.S. 902 (1978); *Ex parte* Hibberd, 227 U.S.P.Q. 443, 447 (Bd. App. & Interf. 1985). Statistical analysis of decisions by the CAFC led one leading commentator to conclude "that the enforcement climate [in the context of infringement litigation] in the United States . . . strongly favors" patent holders. HARMON, *supra* note 24, at 1136.

195 For example, 2,160 biotechnology patents issued in 1989, compared with 7,005 in 2000. Biotechnology Industry Organization Survey, *available at* http://www.bio.org/er/statistics.asp (last visited Jan. 22, 2004). The number of individual biotechnology firms receiving more than fifty patents in the previous six years also increased from zero in 1990 to thirteen in 1999. *See* Walsh et al., *supra* note 3, at 295 (citing Diana Hicks et al., *The Changing Composition of Innovative Activity in the U.S.—A Portrait Based on Patent Analysis*, 30 RES. POL'Y 681, 682 (2001)). This increase paralleled an overall growth in patenting activity across all technologies. For example, 104,219 utility applications were filed with the PTO in 1980, compared to 270,646 in 1999. Similarly, 56,618 utility patents issued in 1980, compared to 142,856 in 1999. *See* PTO SUMMARY, FY 1999, *supra* note 42, at tbl. 2.

mentation has become more expensive, time-consuming, and difficult—in large part because biotechnology developments frequently depend upon access to previously invented (and often patented) research tools, methods, and reagents.[196] This Part discusses the economics of innovation and the potential impact of strong patent protection coupled with ever-growing numbers of patents for biotechnological inventions upon follow-on research.[197]

A. Biotechnology As a Commercial Enterprise

Unlike the pharmaceutical industry, which several well-established multinational companies dominate, the emerging biotechnology industry in the United States consists of several hundred small, privately held companies that depend heavily on private funding to survive.[198] While venture capital firms commonly provide most of the industry's startup funds and initial operating capital in exchange for stock and some degree of management control, virtually all new biotechnology companies require significant additional funding before they can market a product derived from their research.[199] Companies typically obtain such funding by one of three means: 1) "enter[ing] into a research collaboration agreement with . . . [another] company";[200] 2) "mak[ing] an initial public offering (IPO) of stock";[201] or 3) licensing their intellectual property to other companies.[202] Because of the lengthy, expensive research and development process and the extensive testing required to obtain Food and Drug Administration (FDA) approval of a new drug, few biotechnology startups ever

196 *See* Eisenberg, *Biotechnology Research*, *supra* note 21, at 177; Heller & Eisenberg, *supra* note 14, at 698–99; Marshall, *supra* note 26, at 255–56 (reporting that the growing propensity of biotechnology researchers to patent their research tools and methods has produced legal problems for both biotechnology companies and public sector scientific researchers as the interests of patent holders and licensees increasingly conflict); Rai, *supra* note 3, at 816–17.

197 Follow-on research refers to research based upon an earlier, patented discovery.

198 PHILIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY: FUNDAMENTALS OF GLOBAL LAW, PRACTICE AND STRATEGY 370 (1999).

199 *Id.*

200 *Id.* Startups that develop particularly promising technology may be able to initiate a research collaboration agreement with a larger pharmaceutical company. *See id.* Typically, the pharmaceutical company then provides research funding and technical support in exchange for licensing rights or royalty payments on sales of future products. *Id.*

201 *Id.* Although some companies have performed spectacularly well after such offerings, they are an extremely risky business. Once a company's stock is publicly traded, its value will rise (or fall) with the success (or failure) "of every . . . clinical trial or unsubstantiated rumour." *Id.* at 370–71. *See also* Amgen, Inc. v. Hoechst Marion Rousel, Inc., 126 F. Supp. 2d 69, 79 n.5 (D. Mass. 2001) (stating that "the publicly traded stocks of the litigants would bob or dip in response to some random comment by the Court, the trial lawyers, or a particular witness," thereby illustrating "the utterly speculative nature of the stock market" at the time).

202 *See id.* at 370.

get a product onto the market.[203] For many companies, a patent portfolio is the only potentially lucrative asset available for exploitation.[204] These companies rely upon patent licensing revenues for much of their operating capital until they can develop a steady revenue stream.[205] Thus, by granting expansive patent protection to biotechnological inventions, the government arguably subsidizes the biotechnology industry.

B. Patents As Incentive To Innovate

American patent policy has long assumed that rewarding inventors with the limited monopoly conferred by a patent grant will encourage innovation.[206] A patent gives companies the opportunity to recover research and development costs, thereby providing an incentive to invest in further research.[207] Some commentators argue that the PTO's tendency to grant biotechnology patents of extremely broad scope dramatically altered the balance between providing incentives to the inventor and encouraging follow-on innovation, resulting in underutilization of many inventions.[208] Because some follow-

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203 *Id.* at 371. Surveys estimate the total development time and cost required to get a single drug from the laboratory to the pharmacy at ten years and several hundred million dollars. *See* Golden, *supra* note 27, at 118. Because few startups have that amount of cash and time, for many companies the best possible result is to be purchased by a larger company. *See, e.g.*, John Cook, *Venture Capital: Seattle Biotech Shakeout Under Way, Some Fear*, SEATTLE POST INTELLIGENCER, Aug. 30, 2002, at D1, *available at* http://seattlepi.nwsource.com/venture/84865_vc30.shtml (last visited Jan. 22, 2004).

204 *See* GRUBB, *supra* note 198, at 373–76.

205 *Id.* at 370. With the recent wave of consolidation in the pharmaceutical industry and the ever-rising cost of research and development, many startups have recognized the long odds of getting a genetically engineered drug onto market. Consequently, some companies have shifted their focus from producing drugs to "developing platform technologies such as genomics or high-throughput screening[,] which can be used in collaboration with large companies having the resources needed for drug development." *Id.*

206 *See* Svatos, *supra* note 21, at 114. Patents share some important features with monopolies but do not inherently create them. *See, e.g.*, Seymour v. Osborne, 78 U.S.(11 Wall.) 516, 533 (1871) ("Letters patent are not to be regarded as monopolies . . . but as public franchises granted . . . to promote the progress of science and the useful arts.").

207 *See* Svatos, *supra* note 21, at 114. The exclusive nature of the patent grant allows inventors to recoup their investment in research and development in exchange for compulsory public disclosure of technical details. This exchange is thought to maximize social welfare by simultaneously encouraging inventors to increase the stock of beneficial technical knowledge and discouraging inefficient duplication of inventive effort. *See* John S. Leibovitz, Note, *Inventing a Nonexclusive Patent System*, 111 YALE L.J. 2251, 2256 (2002). The required public disclosure of inventions also provides an important stimulus for downstream research. *Id.* at 2257.

208 *See, e.g.*, Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 868 (1990). This tendency is particularly acute with respect to pioneering technologies widely used in downstream research. *See, e.g.*, Hybritech Inc. v. Monoclonal Antibodies, Inc., 623 F. Supp. 1344, 1345–46 (N.D. Cal. 1985), *rev'd*, 802 F.2d 1367 (Fed. Cir. 1986); *Genentech Inc. Receives Broad Patent for Basic Gene-Splicing Techniques*, WALL ST. J., Nov. 4, 1987, at 8. Note that Köhler and Milstein, who invented monoclonal antibody technology, won a Nobel prize for their discovery and yet did not file a patent

on inventions might result in products that are "significantly better than the patented technology, broad patents could discourage useful research.[209]

Patent proponents maintain that the benefits of the patent system outweigh the potential problems of granting inventors a temporary monopoly.[210] The current patent system nevertheless encourages wasteful duplication of effort, provides "an arbitrary incentive to focus" research on only those areas likely to yield patentable inventions, and incurs "substantial legal and administrative costs."[211] Patents encourage "excessive duplication of effort"[212] in at least two ways. First, they encourage the development of "work-around" inventions that "differ only slightly from the original patented invention."[213] Limited funding for research and development should be devoted "to build[ing] a better mousetrap rather than another variation on an old one."[214] The problem is even more severe when a researcher attempts to duplicate technologies for which a substitute may not be available.[215] Second, they frequently launch "a race to invent."[216] The resulting inefficiencies may be especially acute in the biotechnology industry, in which many companies are simultaneously attempting to develop drugs to treat the same range of diseases.[217] Such competi-

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application, despite almost immediate recognition that their trailblazing research had tremendous commercial potential. *See* Merges & Nelson, *supra*, at 905.

209 *See* Merges & Nelson, *supra* note 208, at 870.

210 *See* Svatos, *supra* note 21, at 117. Inventors have frequently taken advantage of their monopoly to reap excessive profits. Consider the case of Milton Reynolds, the inventor of the ballpoint pen. In 1945, Mr. Reynolds charged $12.50 for a pen that cost about $.80 to manufacture and reaped profits of up to $500,000 a month on his initial investment of $26,000. *See* WILLIAM P. ALBRECHT, JR., ECONOMICS 467–68 (4th ed. 1986). In other cases, inventors may refuse to license their proprietary technology, and instead zealously protect it against infringement, thereby stifling "follow-on" development of new technologies. This kind of strategic, or at least economically irrational, behavior eliminates the societal benefit of full disclosure so often cited as a significant public benefit of the patent system. *See* Svatos, *supra* note 21, at 114.

211 Svatos, *supra* note 21, at 117.

212 *Id.* at 120.

213 *Id.*

214 *Id.*

215 *Id.*

216 *Id.*; *see* 3 FRITZ MACHLUP, THE ECONOMICS OF INFORMATION AND HUMAN CAPITAL 176 (1984).

217 *See* MACHLUP, *supra* note 216, at 176. The consequences may be especially dire for biotechnology startups because their limited financial resources often force them to concentrate on one or a few related products in the early stages of product development. As a result, the consequences of losing the race to the PTO (or of having a drug fail during the FDA approval process) may be more than simply wasting limited research capital. *See* Anne G. Evans & Nikhil P. Varaiya, *Anne Evans: Assessment of a Biotechnology Market Opportunity*, 28 ENTREPRENEURSHIP: THEORY & PRAC. 87, 89 (2003) (asserting that, during the 1990's and into early 2000 "biotech after biotech burned through their cash, experienced product failures well into clinical development, fell out of favor with the investment community,

tion not only encourages wasteful duplication of effort,[218] but also tends to increase research costs by imposing more time pressure on researchers: in the race to the PTO, there is no prize for second place.[219]

The complexity of the patent landscape has grown along with the propensity to patent research tools and other increments of innovation.[220] Thus, when deciding whether to undertake a particular research project, researchers now must spend considerable time identifying relevant third party patents and attempting to negotiate license agreements for the necessary technology.[221] Public and private sector researchers have found a variety of working solutions to minimize transaction costs associated with the potentially limited access to intellectual property rights for biotechnology research tools. The NIH, the courts, and the PTO have encouraged these provisional solutions, which include defensive patenting, a "do-it-yourself" approach to obtaining proprietary tools, and informal recognition of an "academic use" exception to infringement.[222]

Companies that opt for defensive patenting decide to patent every component of their proprietary technology.[223] This strategy minimizes the chances of an expensive, time-consuming, acrimonious infringement dispute because each side has a substantial patent portfolio and thus retains some leverage in negotiations.[224] The increase in defensive patenting may minimize patent stacking problems for the biotechnology industry.[225] The resulting patent thicket, however, will

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laid off double digit percentages of their personnel, and ultimately failed as going concerns").

218 *See* Merges & Nelson, *supra* note 208, at 871–74; Svatos, *supra* note 21, at 121. Edmund Kitch has suggested that granting broad patents after invention but before commercialization allows inventors to invest in further development without fear of preemption and to coordinate future research with competing firms, thereby reducing duplication of effort. *See* Kitch, *supra* note 126, at 276–77. Other economists argue that coordinated development of new technologies is considerably less effective than competitive development, in part because the former fails to consider strategic behavior and instead assumes that patent holders will act rationally to maximize utility. *See* Merges & Nelson, *supra* note 208, at 872.

219 *See* GEOFFREY WYATT, THE ECONOMICS OF INVENTION: A STUDY OF THE DETERMINANTS OF INVENTIVE ACTIVITY 126 (1986).

220 *See, e.g.*, Henderson et al., *supra* note 115, at 119–26; Walsh et al., *supra* note 3, at 293–96. The phrase "increments of innovation" refers to intermediate or diagnostic molecules, research tools, and methods essential to conducting a course of experimentation. Heller & Eisenberg, *supra* note 14, at 698.

221 *See* Walsh et al., *supra* note 3, at 293–96.

222 *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

223 *See* Walsh et al., *supra* note 3, at 293–94.

224 *See id.* This is common in the new field of genomics and has been employed for years in the Japanese electronics industry. *See id.* at 295, 300.

225 Empirical data suggests that few public or private sector research projects have been discontinued for failing to negotiate access to all needed intellectual property, but the risk remains. *Id.* at 298–99.

probably continue to make public sector research more difficult and expensive, in part because many academic researchers are unable to pay high licensing fees for access to proprietary information or technology.[226] Some universities have solved this problem by initiating research collaborations with industry or establishing core facilities to share expensive resources like automated sequencing and high-throughput screening.[227]

Other academic researchers adopt a "do-it-yourself" approach, making patented research tools without obtaining a license or purchasing research tools from an unlicensed manufacturer.[228] Consequently, university researchers "have a reputation for routinely ignoring IP rights" arising in the course of their work because many research tools are quite easy to duplicate in the lab.[229] Despite the CAFC's recent narrowing of the experimental use exception,[230] many academic scientists justify infringement of research tool patents by reference to an analogous "academic use" exception.[231] Limited empirical data suggests that infringement of research tool patents also is widespread within the biotechnology industry.[232] Some firms have argued that such infringement should be permitted because research projects rarely yield commercial products.[233] For those that do, licenses may be negotiated after completion of research but before the resulting product reaches the market.[234] Companies have little incentive to license research tools because patent holders cannot easily detect their unlicensed use.[235] Even if patent holders do identify infringers, the statute of limitations on claims of patent infringement may have expired during the lengthy drug discovery process.[236]

As the biotechnology industry has diversified and become economically viable, the financial incentive provided by patents has motivated many academic scientists to shift their emphasis from basic to applied research.[237] Concomitantly, academic researchers and gradu-

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226 *See id.* at 300–02. Licensing fees for access to genomic databases can cost tens of millions of dollars, though some companies offer significant discounts to university researchers. *See id.*

227 *Id.* at 302. Of course, in negotiating research collaboration agreements, academic labs frequently must relinquish intellectual property rights or accept a variety of onerous conditions, often including publication restrictions. *See id.*

228 *See id.* at 302, 324.

229 *Id.* at 324.

230 *See infra* notes 302–07 and accompanying text.

231 *See* Walsh et al., *supra* note 3, at 327.

232 *Id.*

233 *See id.* at 327–28.

234 *Id.* at 327 n.58.

235 *Id.* at 327.

236 *Id.* at 327–28.

237 *See* Svatos, *supra* note 21, at 122–24. Basic research is directed at answering a scientific question of general interest without concern for specific applications of new technol-

ate students in particular, may find their research options limited to those subjects thought to have significant commercial potential.[238] As public sector scientific research becomes more commercially oriented, the reallocation of research dollars from nonpatentable subjects to patentable ones may guide research and development into projects "without regard for maximizing utility," thereby generating additional inefficiencies.[239] This change may ultimately result in a "brain drain" of researchers leaving academic research for industrial positions.[240] As industry demand for inventors continues to increase, the movement of scientists from academia to industry will dilute the training available for the next generation of researchers, with potentially dire consequences for the American research enterprise.[241]

Finally, the biotechnology industry must devote an ever-increasing amount of its comparatively limited financial resources to patent prosecution and infringement litigation.[242] Filing a relatively straightforward application with the PTO typically costs $10,000 to $15,000 in attorney, filing, issue, and maintenance fees; foreign filing costs are often significantly more.[243] Coverage in ten European countries, including maintenance fees over the life of the patent, routinely costs well over $95,000.[244] According to one estimate, worldwide spending in 1992 on biotechnology patent costs exceeded $100 million.[245] The amount is certainly much larger today.[246]

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ogy, whereas applied research is that directed at solving a specific problem with new technology. CAMBRIDGE HEALTHTECH INST., RESEARCH GLOSSARY: EVOLVING TERMINOLOGY FOR EMERGING TECHNOLOGIES, *at* http://www.genomicglossaries.com/content/research_genomics.asp (last visited Feb. 12, 2004).

238 *See* Svatos, *supra* note 21, at 123 (quoting DOROTHY NELKIN, SCIENCE AS INTELLECTUAL PROPERTY 26 (1984)).

239 *Id.* at 124 (citing Martha Crouch, *The Very Structure of Scientific Research Mitigates Against Developing Products to Help the Environment, the Poor, and the Hungry*, 4 J. AGRIC. & ENVTL. ETHICS 151, 154–56 (1991)). For example, biotechnology companies have genetically engineered rice so that it contains high levels of several amino acids commonly lacking in the diets of chronically malnourished children in developing countries. Unfortunately, subsistence farmers in developing countries cannot readily afford the genetically engineered seed required to grow the rice. Martha Crouch suggests that our resources might be more productively applied to improving traditional farming practices, control of pests, and crop rotation cycles. *See* Crouch, *supra*, at 156–58.

240 Svatos, *supra* note 21, at 123.

241 *Id.* Thus, the patent system and the biotech industry "may well be slowly killing the goose that laid the golden egg." *Id.*

242 *Id.* at 124–27; *see* Demaine & Fellmeth, *supra* note 179, at 421–24. Patent prosecution is the process of patenting an invention with the PTO, beginning with the filing of a patent application and continuing until the patent is granted or the application rejected under 35 U.S.C. §§ 101-103, or 112.

243 *See* Erwin F. Berrier, *Global Patent Costs Must Be Reduced*, Address Before the International Patent Club (Sept. 12, 1995), *in* 36 IDEA 350, 351 (1996).

244 *Id.*

245 *See* Clive Cookson & Julie Clayton, *Of Mice, Men and Money: Legal Action over Patent Disputes Threatens to Stifle Investment in Biotechnology*, FIN. TIMES, June 3, 1992, at 18.

246 *See id.*

While patent fees alone may have a chilling effect on research, litigation costs present an even more significant burden to companies.[247] For many underfunded startups, the mere threat of patent-related litigation is often enough to make their researchers pursue new and different directions.[248] Consequently, one unanticipated result of the race to the patent office is that

> [f]irms are often forced to take out patents of uncertain validity and fight off challenges to them in the courts because their competitors are doing the same. . . . However, patent battles are usually won by the company with the greatest financial resources for legal costs. The necessity of litigation and the uncertainty about biotechnology firms' ability to enforce proprietary rights has added to the uncertainty faced by investors, making the biotechnology industry less attractive, at least in the short run. Industry analysts expect the patent scramble to contribute to a trend over the next few years of great consolidation in the biotechnology industry.[249]

Thus, rather than fueling innovation, the patent system has triggered an "arms race" that has dramatically increased the costs of innovation in biotechnology, in the form of legal fees and researchers' time spent away from the lab talking to patent attorneys.[250] As biomedical re-

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247 *See* Svatos, *supra* note 21, at 124–25. Consider the case of research groups from the Hospital for Sick Children in Toronto and Children's Hospital in Boston, both working on different parts of the gene responsible for causing Duchenne's muscular dystrophy. Each group filed for a patent on its portion of the gene, but "[t]he Toronto group . . . dropp[ed] its application because it could not afford the $20,000-plus cost of pursuing the patent." Bernice Wuethrich, *All Rights Reserved: How the Gene-Patenting Race Is Affecting Science*, 144 SCI. NEWS 154, 154 (1993). The Toronto group nevertheless continued working on the gene, only to be threatened with a lawsuit by Genica Pharmaceuticals Corp., a biotechnology firm to which the Boston group had licensed its patent. Genica alleged that the Toronto group's use of antibodies corresponding to patented portions of the dystrophin gene constituted commercial use. "The Toronto doctors had three choices: stop their work, pay royalties, or await a lawsuit" for patent infringement. *Id.* Royalty stacking costs also may strongly influence the direction of future research. *See* Demaine & Fellmeth, *supra* note 179, at 415–19.

248 *See* FRED WARSHOFSKY, THE PATENT WARS: THE BATTLE TO OWN THE WORLD'S TECHNOLOGY 247 (1994). From 1980 to 1990, patent litigation increased by fifty-two percent. *Id.* According to one author, "legal briefs outweigh scientific papers by orders of magnitude, and lawyers are as eagerly sought as Ph.D.'s." *Id.* This trend will likely continue, because biomedical patents are more likely to be litigated than patents on other technologies. *See* Walsh et al., *supra* note 3, at 315 (citing O.J. LANJOUW & M. SCHANKERMAN, ENFORCING INTELLECTUAL PROPERTY RIGHTS 35 (Nat'l Bureau of Econ. Research, Working Paper No. 8656, 2001)).

249 Beverly Fleisher, *Who Will Benefit from Agricultural Biotechnology: An Analysis of Economic and Legal Influences*, *in* BIOTECHNOLOGY: ASSESSING SOCIAL IMPACTS AND POLICY IMPLICATIONS 101, 104–05 (David J. Webber ed., 1990).

250 *See* Cecil D. Quillen, Jr., *Innovation and the United States Patent System Today*, Paper presented to the Antitrust and Patent Sections of the American Bar Association Meeting 5–6 (Oct. 19, 1992), *reprinted in* WARSHOFSKY, *supra* note 248, at 246. Moreover, as with the bursting of the "dot-com" bubble, an industry-wide wave of consolidation and reorganization may have a significant economic impact outside the industry. *See, e.g.*, Anatole Kalet-

search continues to move "from a commons model toward a privatization model,"[251] these costs will hamper the progress of research and development, and eventually will be passed to consumers in the form of higher prices and diminished access to biotechnology products.[252]

C. Patenting Biotechnology Research Tools May Deter Innovation

The rapid proliferation of patents covering biotechnological inventions may ultimately impede rather than accelerate scientific progress and downstream innovation.[253] The PTO's issuance of broad patents covering basic research methods and reagents[254] has allowed patent holders to slow the progress of public and private research by charging prohibitively high licensing fees, subjecting would-be users of licensed materials to onerous restrictions, or simply refusing to license their patents at all.[255]

Concerns that the tendency to patent each new discovery would drive up research costs and impede scientific progress motivated a 1992–93 revolt led by several academic scientists which the NIH joined several years later.[256] The conflict initially centered upon the policies of GenPharm, a company that supplied researchers with a strain of transgenic mice that lacked a tumor suppressor protein called p53.[257] GenPharm charged researchers between $80 and $150 per mouse and forbade purchasers to breed the animals.[258] In response, some 300 disgruntled researchers attended a meeting held

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sky, *What Happened to the Day of Reckoning?*, TIMES ONLINE, Sept. 2, 2003, at 24, *available at* http://www.timesonline.co.uk/article/0,,630-800787,00.html (last visited Jan. 22, 2004).

251 Heller & Eisenberg, *supra* note 14, at 698.

252 Demaine & Fellmeth, *supra* note 179, at 416.

253 *See, e.g., id.* at 415–21 (discussing the costs of patent stacking as well as conflicting and blocking patents); Heller & Eisenberg, *supra* note 14, at 698–99 (discussing the gradual shift of biotechnology research "from a commons model toward a privatization model"); Marshall, *supra* note 26, at 256–57 (describing a revolt led by the NIH then-Director in which academic scientists who were using a proprietary technology controlled by the DuPont Corporation to create transgenic mice strains refused to solicit the company's approval before sharing the technology among themselves); Merges & Nelson, *supra* note 208, at 904–08 (discussing the impact of broad patents that cover pioneering technology on future innovation in science-based industries).

254 These include patents not only for methods of producing monoclonal antibodies and expressing recombinant proteins in bacteria but also for an array of single nucleotide polymorphisms and cDNAs. *See* Demaine & Fellmeth, *supra* note 179, at 415–16.

255 *See id.* at 414; Heller & Eisenberg, *supra* note 14, at 698–99.

256 Marshall, *supra* note 26, at 256.

257 *Id.* The p53 protein helps regulate the progression of cell division. Mutations in the p53 gene have been implicated in a wide variety of human cancers. *See* David G. Kirsch & Michael B. Kastan, *Tumor-Suppressor p53: Implications for Tumor Development and Prognosis*, 16 J. CLINICAL ONCOLOGY 3158 (1998). This mouse strain was thus extremely useful in studies of the process by which a normal cell is transformed into a cancer cell. *See id.* at 3165.

258 *See* Marshall, *supra* note 26, at 256.

during a scientific conference at the Cold Spring Harbor Laboratory in 1992 and suggested that the National Academy of Sciences "review . . . restrictions on the sharing of research tools."[259] The NIH then funded the creation of a repository of genetically altered mice strains, in order to provide all researchers with equal access to transgenic mice.[260]

The repository temporarily solved the access problem, but the staff had difficulty keeping track of and complying with the conditions for use of the deposited strains.[261] In the mid-1990s, the lab stopped accepting mice created with a proprietary gene-insertion method called Cre-loxP, which enables a researcher to select particular conditions under which expression of a transgene may be induced or repressed.[262] The DuPont Pharmaceutical Company ("DuPont") licensed the patent covering the Cre-loxP technology from Harvard University in 1990 and promptly demanded that scientists using transgenic mice created with that method not share the technology among themselves without the company's prior approval.[263] DuPont later asked scientists who had published data obtained with Cre-loxP mice to sign an agreement allowing company officials to review any future scientific journal articles before publication.[264] Finally, the company sought to obtain "reach-through" rights to downstream inventions arising from the use of transgenic animals created by the Cre-loxP method.[265] A concerned group of scientists—led by Nobel Prize winner and NIH director Harold Varmus—revolted once again.[266] On behalf of the NIH, Varmus refused to sign an agreement covering use of Cre-loxP mice, inconveniencing thousands of research staff and,

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259 *Id.*; *see also* WORKSHOP SUMMARY, *supra* note 3, at vii (summarizing a workshop held at the National Academy of Sciences in February 1996 that built on the findings of an earlier meeting about "how the scientific community should respond to various constraints on the use of research tools and, in particular, to the terms set by Human Genome Sciences for access to its private EST database").

260 The Induced Mutant Resource is located at The Jackson Laboratory in Bar Harbor, Maine. *See* Marshall, *supra* note 26, at 256; *The Induced Mutant Resource*, *at* http://www.jax.org/imr/index.btml (last visited Jan. 18, 2004).

261 *See* Marshall, *supra* note 26, at 257.

262 A transgene is a foreign gene used to transform a mouse (or other animal) to make a transgenic strain. It is generally a gene from another organism implicated in the etiology or progression of a particular disease of interest, expression of which causes the animal to contract the disease. *See* SINGER & BERG, *supra* note 141, at 890–92.

263 Researchers were allowed to exchange neither transgenic strains nor the technology to engineer them. *See* Marshall, *supra* note 26, at 257.

264 *Id.*

265 *Id.* Though "reach-through" rights and royalties are often regarded as abuse of the leverage granted by a patent monopoly, granting sucb rights does not necessarily constitute patent misuse. Nor is the grant of "reach-through" royalties inherently bad, provided the parties involved are of equal bargaining power and negotiate at arm's length. *See* Marina Lao, *Unilateral Refusals to Sell or License Intellectual Property and the Antitrust Duty to Deal*, 9 CORNELL J.L. & PUB. POL'Y 193, 207 (1999).

266 *See* Marshall, *supra* note 26, at 257.

perhaps more importantly, publicly embarrassing DuPont officials.[267] He told DuPont that its restrictive terms "could seriously impede further basic research and thwart the development of future technologies that will benefit the public."[268] After intensive negotiations, DuPont stopped demanding pre-publication review of research, relaxed its animal sharing policies, and stopped pursuing its reach-through claims.[269]

Michael Heller and Rebecca Eisenberg have argued that the proliferation of patents covering upstream technology is creating an "anticommons" in biotechnology research.[270] "Responding to a shift in U.S. government policy" since 1980, the NIH and major public research universities "have created technology transfer offices to patent and license their discoveries."[271] In addition, a growing number of commercial biotechnology firms increasingly rely on licensing revenues from their patent portfolios to finance their research.[272] Consequently, upstream biomedical research "is increasingly likely to be private," whether "supported by private funds, carried out in a private institution, or privately appropriated through patents, trade secrecy, or [licensing] agreements that restrict the use of materials and data."[273] While the patent system does occasionally induce researchers to undertake risky research projects, the proliferation of patents on ever smaller increments of innovation has produced "a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream."[274] Therefore, a "tragedy of the anticommons" may arise when a researcher requires access to several patented materials in order to conduct a single experiment.[275] As Heller and Eisenberg note, "[e]ach upstream patent allows its owner to set up another

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267 *Id.*

268 *Id.* (internal quotation marks omitted).

269 *Id.*; *see* Eliot Marshall, *NIH, DuPont Declare Truce in Mouse War*, 281 SCI. 1261, 1261–62 (1998). DuPont eventually agreed to let NIH scientists and all other federally funded researchers at nonprofit institutions exchange animals without directly obtaining DuPont's approval, though the company did retain commercial rights to the technology. *See* Eliot Marshall, *NIH Cuts Deal on Use of OncoMouse*, 287 SCI. 567, 567 (2000).

270 *See* Heller & Eisenberg, *supra* note 14, at 698. "Anticommons" property refers to a "mirror image of [the] commons property," first described by Garrett Hardin in 1968. *Id.*; *see* Hardin, *supra* note 14, at 1244. According to the anticommons theory, "a resource is prone to underuse . . . when multiple owners each have a right to exclude others from [using] a scarce resource." Heller & Eisenberg, *supra* note 14, at 698.

271 Heller & Eisenberg, *supra* note 14, at 698; *see* Eisenberg, *Government-Sponsored Research*, *supra* note 17, at 1691–92; Mowery et al., *supra* note 102, at 100.

272 *See* GRUBB, *supra* note 198, at 373–76 (discussing royalty income from patents); MARTIN KENNEY, BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX 255–56 (1986).

273 Heller & Eisenberg, *supra* note 14, at 698 (internal quotation marks omitted).

274 *Id.*

275 *Id.* at 698–99.

tollbooth on the road to product development, adding to the cost and slowing the pace of downstream . . . innovation."[276]

IV
ALLEVIATING THE IMPACT OF STRONG PATENT PROTECTION ON FUTURE INNOVATION

Proponents of the patent system generally assume that the market will induce patent holders to act rationally in their economic interest. Accordingly, they should attempt to maximize economic utility by licensing their inventions to others working in the same field and continuing to improve their technology.[277] With increasing frequency, however, patent holders refuse to license their inventions, license them subject to burdensome restrictions, or use their patents to leverage their way into secondary markets. This decreases or eliminates the putative economic benefits of the patent system.[278] Faced with mounting evidence that the continued privatization of scientific knowledge will produce additional market failures,[279] increase research costs, and inhibit technological progress, several commentators have proposed ways to address the problem by modifying the existing patent system.[280] This Part first discusses several possible modifications of the Patent Act. It then reviews the origin and application of the common law experimental use exception. Finally, it argues that implementing a reformulated and broadly applied experimental use

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276 *Id.*

277 *See* Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1179 (2000).

278 *See id.*

279 Recall the prolonged battle between DuPont and the NIH regarding the use of transgenic mice created with DuPont's proprietary Cre-loxP technology. *See supra* notes 261–269 and accompanying text.

280 *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1078 (1989) [hereinafter Eisenberg, *Progress of Science*] (recommending "an experimental use exemption from patent infringement liability" to verify the accuracy of a specification or the validity of patent claims, but not for "[r]esearch use of a patented invention with a primary . . . market among research users," and suggesting that when exempt experimental use leads to significant improvement in the patented technology, the patent holder "might be . . . award[ed] a reasonable royalty"); Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1679, 1684 (2001) (suggesting a compulsory licensing regime for gene patents in return for a royalty keyed to the financial success of the product developed by the licensee and proposing an experimental use exemption for government and nonprofit researchers); Leibovitz, *supra* note 207, at 2268 (proposing a nonexclusive "patent system that, instead of granting exclusive property rights to the first inventor of a new technology, protects him from free-riding competitors, but not against competitors who independently develop the same technology"); O'Rourke, *supra* note 277, at 1180–81 (arguing that patent law should implement a fair use defense to infringement in order to address increasingly common instances of market failure in technology-based industries).

exception to patent infringement will most effectively remedy the effects of privatizing scientific knowledge.

A. Nonexclusive Patents, Compulsory Licensing, or Fair Use?

John Leibovitz suggested the adoption of a system of nonexclusive patent protection.[281] According to this proposal, a patent grant would protect the inventor from free-riding competitors, but not from other inventors who independently develop the same technology.[282] Thus, the first person to invent a new technology would not necessarily obtain exclusive property rights in it.[283] A nonexclusive patent grant would allow rivals to compete with the original inventor "based on legitimate investments in research and development" and an objective assessment of the costs and benefits of each research project, rather than on the possibility of winning or losing a technological monopoly.[284]

Other scholars have suggested either a compulsory licensing regime or an experimental use defense to patent infringement.[285] Donna Gitter proposed a two-part reform. First, a compulsory licensing regime would require holders of patents for DNA sequences to license their inventions to commercial researchers in return for a variable royalty payment based on the financial success of any products the licensees develop.[286] Second, an experimental use exception from compulsory licensing would allow government and nonprofit researchers to use the inventions free of charge.[287] While Professor Gitter's approach would enable researchers to access patented DNA sequences, opponents of issuing gene patents continue to argue that individuals or companies should not be allowed to control access to

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281 *See* Leibovitz, *supra* note 207, at 2268.

282 *Id.* According to Leibovitz, agreeing that "the law must protect inventors so they can appropriate returns from their inventions . . . does not necessarily imply that only the *first* inventor should be able to appropriate those returns." *Id.*

283 *See id.*

284 *Id.* at 2269. Leibovitz argues that a nonexclusive patent system would also "reduce the possibility of anticompetitive behavior" during downstream technological development because when "the monopoly threat is high"—as with pioneering inventions for which substitutes are not readily available—"inventors would face potential competition from" other inventors attempting to develop the same technology. *Id.* Thus, the incentive driving the competition would depend on the potential profits derived from the invention. *See id.* Despite the theoretical appeal of this approach, it would require a radical reformulation of our current system of intellectual property protection, and so may be most useful as a starting point for discussion.

285 *See, e.g.*, Eisenberg, *Progress of Science*, *supra* note 280, at 1078 (suggesting an experimental use exception); Gitter, *supra* note 280, at 1679 (recommending a compulsory licensing system); O'Rourke, *supra* note 277, at 1180 (proposing a fair use defense).

286 Gitter, *supra* note 280, at 1679–84.

287 *Id.* at 1679, 1684–90.

our genetic information because the human genome embodies the collective heritage of the human race.[288]

Maureen O'Rourke described a fair use doctrine modeled on provisions of American copyright law.[289] Determining what constitutes fair use of a patented invention would require evaluation of five factors:

(i) the nature of the advance represented by the infringement;
(ii) the purpose of the infringing use;
(iii) the nature and strength of the market failure that prevents a license from being concluded;
(iv) the impact of the use on the patentee's incentives and overall social welfare; and
(v) the nature of the patented work.[290]

O'Rourke further argued that a fair use doctrine must be formally adopted[291] because current patent law doctrines provide an incentive to license for patent holders who might otherwise refuse[292] but do not

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288 *See, e.g.*, David Ewing Duncan, *Tracking Genes in Iceland: Sifting Viking Records Yields a Marker for Stroke*, S.F. CHRON., Oct. 19, 2003, at I1, *available at* http://ginasmith.typepad.com/biotech_news_digest_/2003/10/tracking_genes_.html (last visited Feb. 5, 2004) (mentioning the importance of privacy issues in the context of genetic screening and the creation of a genetic database in Iceland); Catherine Goldwater, *Iceland Exploits Its Genetic History* (BBC television broadcast, Feb. 4, 2000), *available at* http://news.bbc.co.uk/2/hi/science/nature/630961.stm (last visited Feb. 5, 2004) (discussing the controversy surrounding scientists' attempt to create a genetic database of Iceland's citizens, due to the implication of privacy issues and the possible adverse use of the information by drug companies).

289 *See* O'Rourke, *supra* note 277, at 1198–1211. The analogy between permissible use of patented inventions and fair use in copyright law is gaining some prominent supporters, most notably Judge Newman of the Federal Circuit. *See* Integra Lifescis. I, Ltd. v. Merck KgaA, 331 F.3d 860 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part). When the CAFC was asked to determine the scope of the safe harbor provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(1)(2000), a statutory exemption from infringement for uses "reasonably related" to securing regulatory approval for generic drugs—Judge Newman argued that the "[s]tudy of patented information is essential to the creation of new knowledge, thereby achieving further scientific and technological progress." *Integra*, 331 F.3d at 864–65, 876 (Newman, J., concurring in part and dissenting in part). In her view, although the safe harbor provision does not "reach back down the chain of experimentation to embrace development and identification of new drugs," the fact that research is conducted with the goal of commercialization should not automatically eliminate the exception. *Id.* at 877 (Newman, J., concurring in part and dissenting in part).

290 O'Rourke, *supra* note 277, at 1205.

291 *See id.* at 1198–1211.

292 *Id.* at 1198. In particular, O'Rourke is concerned with the reverse doctrine of equivalents and the doctrine of blocking patents. *See id.* at 1193–94. The doctrine of equivalents allows a court to interpret the scope of a patent's claims expansively to find infringement even when the accused infringing device does not read directly onto the patented claims. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29–30 (1997). The reverse doctrine of equivalents excuses an infringement when the infringer has radically improved a device to the point that it "is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim." Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608–09 (1950). The doctrine of blocking patents refers

permit infringement that is socially beneficial.[293]

Finally, Rebecca Eisenberg recommended allowing the experimental "use of a patented invention to check the adequacy of the [patent] specification and the validity of the patent holder's claims about the invention."[294] Eisenberg maintains that a patent holder should not be permitted "to enjoin the use of a patented invention in subsequent research in the field of the invention, which could potentially lead to improvements in the patented technology or to the development of alternative means of achieving the same purpose."[295] Despite her willingness to permit some infringing uses, Eisenberg opposes exemption from infringement liability for experimental use of a patented invention that is useful only to other researchers "when the research user is an ordinary consumer of the patented invention."[296]

B. The Common Law Experimental Use Exception

The common law has recognized a narrow experimental use exception to patent infringement since the nineteenth century. Justice Story first articulated the defense in *Whittemore v. Cutter*,[297] arguing in dicta that the legislature could not have intended to punish a man who built "a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[298] Later that year, Justice Story revisited the notion in *Sawin v. Guild*, distinguishing "the making with an intent to use for profit" (an infringing use) from making "for the mere purpose of [scientific] experiment, or to ascertain the verity and exactness of the specification" (a noninfringing use).[299] To support a charge of infringement, he continued, "the making [of a

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to a situation in which one inventor patents an improvement on a previously patented invention. The improver infringes the earlier patent, but the original patentee has no rights to the patented improvement. *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1009–1010 (1997). By giving the infringer some bargaining power in licensing negotiations, the doctrine of blocking patents may help overcome market defects like strategic behavior during negotiations and high transaction costs. *See id.* at 1065.

293 *See* O'Rourke, *supra* note 277, at 1196–98. According to O'Rourke, socially desirable types of infringement include those committed in order to verify that a patented invention functions as claimed and those committed during the course of not-for-profit research or teaching. *See id.*

294 Eisenberg, *Progress of Science*, *supra* note 280, at 1078.

295 *Id.* Eisenberg acknowledges that "it might be appropriate in some cases to award a reasonable royalty after the fact to be sure that the patent holder receives an adequate return on the initial investment in" research and development. *Id.*

296 *Id.*

297 *See* 29 F.Cas. 1120 (C.C.D. Mass. 1813) (Story, J., sitting as Circuit Judge).

298 *Id.* at 1121.

299 21 F. Cas 554, 555 (C.C.D. Mass. 1813).

patented device] must be [done] with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery."[300]

Later cases established the boundaries of the exception,[301] which resulted in a strictly construed exemption for experiments conducted "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[302] *Roche Products, Inc. v. Bolar Pharmaceutical Co.* further restricted the reach of the experimental use exception by characterizing it as "truly narrow," such that it did not extend to the use of a patented invention "in keeping with the legitimate business of" an alleged infringer.[303] In the court's view, "argument[s] that the experimental use rule deserve[d] a broad construction [were] not justified."[304] Any infringing activity with "definite, cognizable, and . . . [ ]substantial commercial purposes"—however "experimental"—fell short of the experimental use exception.[305] Several years later, the court in *Deuterium Corp. v. United States* applied a "purpose test" to determine whether the defendant's actions fell within the exception.[306] Under that test, the experimental use exception applies if "the accused devices [are] used for amusement, to satisfy idle curiosity, or for philosophical inquiry[,]"[307] but not if a use is "in keeping with the legitimate business of the using agency" or "has [a] definite, cognizable, and not insubstantial commercial purpose[ ]."[308]

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300 *Id.*

301 *See* Dugan v. Lear Avia, Inc., 55 F. Supp. 223, 229 (S.D.N.Y. 1944) ("[The allegedly infringing device] can be eliminated from consideration [under the experimental use exception] for it affirmatively appeared, without contradiction by plaintiff, that defendant built that device only experimentally and that it has neither manufactured it for sale nor sold any."); Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697, 713 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1935) ("The making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement." (citation omitted)); Bonsack Mach. Co. v. Underwood, 73 F. 206, 211 (C.C. E.D.N.C. 1896) ("It is true that . . . [a] machine . . . made or used [only] as an experiment . . . do[es] not . . . constitute an infringement.").

302 Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (addressing the scope of the experimental use exception in the context of infringing experimentation by a generic drug manufacturer). In response to the Federal Circuit's decision in *Roche*, Congress later passed legislation implementing a broad experimental use exemption solely applicable to the generic drug industry. *See* 35 U.S.C. § 271(e) (2000).

303 *Roche*, 733 F.2d at 863 (quoting Pitcairn v. United States, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976)).

304 *Id.*

305 *Id.*; *see* 35 U.S.C. § 271(e) (allowing uses reasonably related to the development and submission of information related to the seeking of FDA approval for generic drugs).

306 Deuterium Corp. v. United States, 19 Cl. Ct. 624, 631 (1990) (describing the test in *Douglas v. United States*, 181 U.S.P.Q. (BNA) 170, 177 (Ct. Cl. 1974), *aff'd*, 510 F.2d 364 (1975)).

307 *Douglas*, 181 U.S.P.Q. (BNA) at 177.

308 *Roche*, 733 F.2d at 863.

Deuterium Corp.'s extremely narrow experimental use exception survives to this day, though perhaps not for much longer.[309] Judge Rader of the CAFC would eliminate the exception[310] because "the Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement."[311] In cases of minimal or wholly noncommercial infringement, "the damage computation process . . . [allows] courts to preclude large (or perhaps any) awards for minimal infringements," making the exception unnecessary.[312] Moreover, Judge Rader argues that continued recognition of the exception effectively destroys the value of research tool patents,[313] even though it was intended to allow only minimal encroachment on the rights of patentees in pursuit of FDA approval.[314] Because "patented [research] tools often facilitate general research to identify candidate drugs, as well as downstream safety-related experiments on those new drugs," all research tools used at any stage of drug development could potentially be used without fear of infringement under the safe harbor provision.[315] Such an outcome would contravene the purpose of § 271(e), which was intended "to reverse the effects of *Roche* under limited circumstances, not to deprive entire categories of inventions of patent protection."[316]

C. Expanding the Experimental Use Exception and Subjecting Essential Research Tools to Compulsory Licensing Will Ameliorate the Problems Associated with Patent Stacking

Many of the anticommons effects of patenting biotechnology research tools may be mitigated within the existing framework of patent law. This Note proposes a three-pronged approach to the problem.

1. *The Experimental Use Exception Should Apply to Public Sector Researchers*

An expansive experimental use exception for public sector researchers would eliminate research bottlenecks and decrease transac-

309 *See* Integra Lifescis. I, Ltd. v. Merck KGaA, 331 F.3d 860, 867 (Fed. Cir. 2003) (Rader, J.) (narrowly construing § 271(e)(1) "to reverse the effects of *Roche* under limited circumstances, not to deprive entire categories of inventions of patent protection").

310 *See* Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J., concurring).

311 *Id.* (Rader, J., concurring).

312 *Id.*

313 *Integra*, 331 F.3d at 867. In trying to solve the problem of access to proprietary research tools, academic researchers and the biotechnology industry bave often caused the precise problems that Judge Rader anticipated from 35 U.S.C. § 271(e)(1) (2000) and a broad experimental use exception. *See supra* notes 220–241 and accompanying text.

314 *See Integra*, 331 F.3d at 867.

315 *Id.*

316 *Id.* Similar reasoning explains Eisenberg's formulation of an experimental use exception, wbich excludes researcbers who are "ordinary consumer[s]" of patented research tools. Eisenberg, *Progress of Science*, *supra* note 280, at 1078.

tion costs resulting from patent stacking. The exception would cover noncommercial use of any biological material, reagent, or research tool for which an equivalent substitute is not readily available.

The American patent system is designed to accomplish two goals: (1) to provide financial incentive to create new scientific knowledge and develop new products from that knowledge to benefit the public, and (2) to increase the body of published scientific and technical knowledge.[317] Requiring patent holders to disclose the details of patented inventions facilitates greater understanding of a patent holder's technological advance and, in turn, improvement upon that technology. To achieve the aims of the Constitution's Intellectual Property Clause, however, "[t]he rigbt to conduct research to achieve such knowledge need not, and should not, await expiration of the patent."[318] Nor should it depend on a patent holder's willingness to license proprietary technology. Despite the importance of research and development in today's technology-based economy, courts continue to narrow the already limited common law research exemption.[319] Yet continued recognition of an experimental use exception to the patent grant is essential to facilitate ongoing technological innovation.[320]

Proscribing all research into patented subject matter unless the patent holder gives permission—the route apparently mandated by *Integra v. Merck*—would seriously impede technological progress. Information disclosed in patents is a major source of scientific knowledge and is seldom published elsewhere. An expansive experimental use exception would allow the study of patented subject matter "in order to understand it, or to improve upon it, or to find a new use for it, or to modify or 'design around' it."[321] Without such an exception, technological innovation would slow significantly or stop entirely because the holder of a pioneering patent in a particular field of research "could bar not only patent-protected competition, but all research that might lead to such competition, as well as . . . [the] improvement or challenge or avoidance of patented technology."[322] Much of modern technology builds upon knowledge gleaned from disclosure of previously patented inventions. Therefore, a blanket

317 *See supra* notes 8–11 and accompanying text.

318 *Integra*, 331 F.3d at 873 (Newman, J., concurring in part and dissenting in part).

319 *See id.* at 872 (suggesting that the court had "essentially eliminate[d] the common law research exemption").

320 *See id.* (remarking that the court's holding "is ill-suited to today's research-founded, technology-based economy").

321 *Id.* at 875 (Newman, J., concurring in part and dissenting in part).

322 *Id.*

prohibition of research that probes this knowledge undermines the purposes of American patent law.[323]

In exchange for "the right to exclude others from making, using, . . . or selling the [claimed] invention,"[324] the Patent Act requires the patent holder to make a full and detailed disclosure of his invention.[325] The disclosure must include descriptions of enabling experiments, the best mode of implementation, preferred embodiments of the invention, schematic drawings, and other essential technical details.[326] Such comprehensive disclosure would be unnecessary and irrelevant if the information could not be used for twenty years. Similarly, the requirement that patent applications be published within one year of filing "would be [of] little value . . . if the information [was] then placed on ice and protected from further study and research investigation" for twenty years.[327] Instead, "the patent system both contemplates and facilitates research into patented subject matter, whether the purpose is scientific understanding, evaluation, comparison, or improvement," because such activities are essential to technological progress.[328]

The Patent Act does not require a patent holder to use his invention, but only to disclose and describe it in sufficiently enabling detail that it can be reproduced without undue experimentation.[329] Researchers should not be required to obtain a patent holder's permission whenever a patented device is made, modified, or otherwise investigated. Study of patented information is crucial to scientific and technological progress. An expansive experimental use exception would permit the use of patented information in research and development while preserving the patent holder's incentive to innovate. Although an effective patent law must first consider the rights of the inventor, who may freely profit from his invention or enjoin any commercial or precommercial application, the patent grant does not expressly forbid research that precedes such applications.[330]

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323 *See supra* notes 29–30 and accompanying text.

324 35 U.S.C. § 154(a)(1) (2000).

325 *See id.* § 112.

326 *See Integra*, 331 F.3d at 875 (Newman, J., concurring in part and dissenting in part).

327 *Id.*

328 *Id.*

329 According to the CAFC, a specification satisfies the written description requirement of § 112 if it enables "a person skilled in the art to make the [material] . . . needed to practice the claimed invention without undue experimentation." *In re* Wands, 858 F.2d 731, 733 (Fed. Cir. 1988).

330 *See Integra*, 331 F.3d at 875–76 (Newman, J., concurring in part and dissenting in part).

An expansive experimental use exception should, however, apply only to public sector researchers.[331] This would permit noncommercial use of any biological material, reagent, or research tool for which an equivalent substitute is not readily available.[332] For cases in which it is difficult to distinguish commercial use of patented technology from noncommercial use, courts should be guided by the words of Judge Newman, who noted "that there is a generally recognized distinction between 'research' and [product] 'development,' as a matter of scale, creativity, resource allocation, and . . . the level of scientific [or] engineering skill needed for the project."[333]

2. *A Collective Rights Organization Should Administer a Compulsory Licensing Regime*

Subjecting essential reagents and research tools used in commercial research to a compulsory licensing regime would eliminate much anticompetitive behavior in the biotechnology industry. Whereas the experimental use exception would cover noncommercial use of patented methods, reagents, and research tools, a collective rights organization (CRO)[334] would negotiate licenses for the use of proprietary technologies in commercial research. CROs include both patent pools and collective copyright licensing organizations, such as the American Society of Composers, Authors and Publishers (ASCAP) and Broadcast Music Inc. (BMI).[335] Unlike traditional compulsory licensing schemes, in which uniform licensing rates are set by statute,

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331 "Public sector" researchers work for a university, state or federal government, or other nonprofit organization whose primary mission is research or teaching and not the commercial development of biotechnology research tools or pharmaceuticals. *See* BLACK'S LAW DICTIONARY 1246 (7th ed. 1999) (defining "public sector" as "[t]he part of the economy or an industry that is controlled by the government"); *see also id.* at 1214 (defining "private sector" as "[t]he part of the economy or an industry that is free from direct governmental control").

332 Extending the experimental use exception from DNA sequences to every irreplaceable or unique biological material, reagent, or research tool will best serve the constitutionally mandated goal of "promot[ing] the Progress of Science and useful Arts." U.S. CONST. art. 1, § 8, cl. 8. This approach also acknowledges that research materials other than DNA sequence information may be essential to scientific progress.

333 *Integra*, 331 F.3d at 876 (Newman, J., concurring in part and dissenting in part). Judge Newman and other commentators have analogized experimental use to fair use in copyright law. *See id.* at 876 n.9 (Newman, J., concurring in part and dissenting in part); O'Rourke, *supra* note 277, at 1205 n.118. In both, although the question of whether a particular use comes within the experimental use exception arises in myriad situations, it is generally clear whether the exception applies. *See Integra*, 331 F.3d at 876 (Newman, J., concurring in part and dissenting in part).

334 Collective rights organizations are private agreements established "to break the transactional bottleneck" interfering with exploitation of intellectual property rights. Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1295–96 (1996).

335 *See id.* at 1295 (noting that two advantages of CROs are "expert tailoring and reduced political economy problems").

"knowledgeable industry participants set the rules of exchange" for a CRO.[336] These rules vary according to the broad features of the rights being transferred.[337] Licensing terms for specific intellectual property rights derive from members' knowledge of and experience with the given technology.[338] Consequently, the contracts "reflect[ ] not only collective industry expertise but also the need for efficiency in carrying out a high volume of transactions."[339] In addition, private CROs can adjust their rates to accommodate market fluctuations more easily than statutory compulsory licensing schemes can be amended.[340]

In order to balance the competing demands of commercial and noncommercial researchers with the public good, the CRO should contain representatives from public sector academic research institutions, the NIH, the National Science Foundation, and the Biotechnology Industry Organization.[341] This CRO would then assess the development costs and commercial potential of new methods, reagents, and research tools and set licensing fees accordingly. For broadly applicable technologies, the licensing regime could be modeled upon the approach taken by the University of California and Stanford University in licensing the Cohen-Boyer patents, which covered basic recombinant DNA technology.[342] Instead of granting the patent holder prohibitive reach-through[343] royalties based on the commercial success of any resulting products, these universities recognized the broad applications of their discovery, licensed the technology widely and nonexclusively to public sector researchers, and assessed only minimal reach-through royalties if a product made it to the market. Institutional users paid a nominal annual fee for a license covering every researcher at a particular campus or research facil-

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336 *Id.*

337 *Id.* at 1295–96.

338 *Id.* at 1296.

339 *Id.*

340 *See id.* at 1295–96.

341 The National Science Foundation dispenses research funding in the form of peer-reviewed grants, as does the NIH. Members of the Biotechnology Industry Organization include biotechnology and pharmaceutical companies as well as law firms practicing intellectual property law. *See* http://www.2.bio.org/members/members.asp (last visited Feb. 12, 2004). Such a roster of members would ensure that both public and private interests were equally represented on the CRO.

342 *See* WORKSHOP SUMMARY, *supra* note 3, at 40–42. The Cohen-Boyer technology, which covered three separate patents, was licensed on an annual basis for a flat fee of $10,000 plus a royalty on sales of any product made with the proprietary method (starting at 1% of the first $5 million in sales and decreasing to 0.5% of sales over $10 million). *See* HACKING, *supra* note 25, at 45–46. The license extended to every researcher working for the licensee. *Id.*

343 A "reach-through" royalty is typically negotiated as part of a license agreement: a licensee agrees to pay royalties on sales of future products developed with the licensed technology. *See* James Gregory Cullem, *Panning for Biotechnology Gold: Reach-Through Royalty Damage Awards for Infringing Uses of Patented Molecular Sieves*, 39 IDEA 553, 561–62 (1999).

ity.[344] This approach was extremely successful: in terms of licensing revenue, the Cohen-Boyer patents are the most lucrative ever produced by university research,[345] and their pioneering technology was successfully transferred to the commercial sector without hindering the progress of basic research.[346] For technologies with more limited research applications, the terms of the license agreement could include a higher fee or, in extreme cases, even reach-through royalties.

3. *Biotechnology Patents Should Have Limited Scope*

Finally, narrow application of the enablement and written description requirements to biotechnological inventions would limit the scope of issued patents. This would reduce conflict between patent holders who control proprietary technologies and researchers who use or improve upon those technologies.

According to 35 U.S.C. § 112, the disclosure included in a patent application must be sufficient "to enable any person skilled in the art . . . to make and use" all the embodiments of the invention claimed in the patent.[347] This requirement is often applied rather loosely during patent prosecution: sometimes an application "that describes only one working example of an invention but that supplies less guidance on the subject matter at the fringes of [the] claims" will suffice.[348] While intuitively it makes sense to limit the rights of patent holders to those embodiments enabled in the specification, such literal application of § 112 would encourage competitors to patent minor modifications of the original invention and would render patent

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344 This Note recognizes that the Cohen-Boyer technology was anomalous because it was inexpensive, of critical importance to the development of modern biotechnology, and no ready substitute was available, so there was little resistance to its widespread licensing. In fact, the terms of the licensing agreement were such that they "encouraged firms" to license rather than challenge the validity of the patents. *See* Arti K. Rai & Rebecca S. Eisenberg, *The Public and the Private in Biopharmaceutical Research*, CONF. ON THE PUB. DOMAIN (2001), *at* http://www.law.duke.edu/pd/papers/raieisen.pdf (last visited Feb. 12, 2004). While not every patented research tool will be as essential or as widely used, intellectual property rights must nevertheless be distributed so as to avoid impeding scientific research.

345 *See* Mowery et al., *supra* note 102, at 110.

346 *See id.* at 110–14. Failure to preempt the anticommons problem in biotechnology patents will leave it in the hands of Congress. *See* Dan L. Burk, *Patenting Speech*, 79 TEX. L. REV. 99, 156–58 (2000). So far, Congress has displayed a willingness to create novel statutory exceptions to the exclusive patent holder's right that are effectively "compulsory license[s] at . . . a royalty of zero." *Id.* at 158. For example, generic drug manufacturers are permitted to use a patented drug to obtain any information required to secure FDA approval before expiration of the original patent term. *Id.* at 156–57 & n.331 (citing 35 U.S.C. § 271(e)(1) (1994 & Supp. IV 1998)). In addition, healthcare professionals are allowed to use patented medical procedures without authorization if necessary. *Id.* at 159 & n.343 (citing 35 U.S.C. § 287(c) (Supp. IV 1998)).

347 35 U.S.C. § 112 (2000).

348 Merges & Nelson, *supra* note 208, at 845.

protection practically worthless.[349] In practice, a patent's specification "need not point out precisely how to make every device" that falls within its claims; rather, it should disclose an "inventive concept or principle whose precise contours are defined by the claims."[350]

On the other hand, it is equally possible to extend the requirements of § 112 too far. Although an inventor certainly should be able to claim embodiments beyond his precise disclosure, the PTO currently "seems to permit a range of claims that may stretch beyond the spirit of the enablement doctrine."[351] A narrow reading of § 112 would permit an application including relatively narrow claims in which the specification "provide[d] only a starting point, a direction for further research,"[352] but would allow the PTO and courts to reject an identical application with extremely broad claims. Because biotechnology remains an unpredictable science, "an enabling description . . . must provide those skilled in the art with a specific and useful teaching."[353] At the same time, a narrow application of § 112 would allow the PTO and the CAFC to issue patents of narrower scope.

CONCLUSION

Passage of the Bayh-Dole Act in 1980 capped a sea change in American technology policy. When the federal government allowed researchers to retain patent rights to any inventions conceived and reduced to practice with the aid of federal funding, the lure of potentially massive revenues—whether from licensing research tools or sales of a blockbuster drug—caused a race to the PTO. The resulting increase in the number of patent applications filed and patents granted has played a crucial role in the development of the biotechnology industry. With this increase, however, has come the gradual realization that something must be done to reverse the "creeping propertization"[354] of science before downstream innovation is irrevocably diminished.

This Note has argued that implementing a broad experimental use exemption from patent infringement for noncommercial research would ameliorate problems caused by the increasing propensity to

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349 *See id.*

350 *Id.* at 846; *see also* Gillette Safety Razor Co. v. Clark Blade & Razor Co., 187 F. 149, 149 (C.C.D.N.J. 1911), *aff'd*, 194 F. 421 (3d Cir. 1912) (upholding a patent for the first disposable blade safety razor despite the fact that it did not sufficiently describe all possible embodiments of the blade).

351 *See* Merges & Nelson, *supra* note 208, at 848; Walsh et al., *supra* note 3, at 297.

352 Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

353 *Id.* at 1367–68.

354 Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, *in* SCIENTIFIC INNOVATION, PHILOSOPHY, AND PUBLIC POLICY 147 (Ellen Frankel Paul et al. eds., 1996) (emphasis omitted).

patent biotechnology research tools. In addition, forming a CRO to license proprietary methods, reagents, and research tools for commercial use will accommodate the conflicting interests of public- and private-sector researchers. Finally, restricting the scope of biotechnology patents will reduce conflicts and increased transaction costs that result from patent stacking. Together, these changes will alleviate the inefficiencies and market failures resulting from the unchecked proliferation of biotechnology patents, and enable the American research enterprise to continue driving technological change well into the future.