WHY IT MIGHT BE TIME TO ELIMINATE GENOMIC PATENTS, TOGETHER WITH THE *NATURAL EXTRACTS DOCTRINE* SUPPORTING SUCH PATENTS

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ABSTRACT

The purpose of recognizing enforceable rights in intellectual property in the United States is to "promote the progress of science and useful arts." Given the changing landscapes of technologies, it is critical that policies and laws be continually adjusted to reflect the needs of new technologies. When the law tries to shield from—rather than confront—new technological realities, patents subvert rather than promote technological progress. This paper explores how the *natural extracts doctrine*, established over a century ago to allow purified compounds to be patented at a time when biochemistry was more alchemy than science, subverts rather than promotes progress in the modern biotechnological context. This paper argues that the *natural extracts doctrine*, together with the various isolation-based product patents—including gene product patents—that it has spawned, must be promptly abandoned or at least radically reduced in scope. Such patents not only violate the prohibition against the patenting of nature, but are also not commensurate with the underlying contributions made to the arts. In a proper patent regime, incentives given for today's innovation should be appropriate for today's innovations, and not be given at the expense of tomorrow's incentives. The paper concludes by offering a glimpse of what a patent system without the *natural extracts doctrine* might look like. It shows

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how a reinvigorated subject matter requirement and enablement requirement can properly incentivize innovations in biotechnology—sustainably and for the long term—without impeding the future.

I. INTRODUCTION

Many pundits have penned the 21st century as the century of biotechnology.[1] As science and technology play increasingly vital roles in society, laws and policies designed to promote their advancement have come under ever increasing scrutiny. The ever-rising stakes have also spurred increasingly heated debates over how best to incentivize innovations in biotechnology.[2] U.S. patent law features a property-based system for incentivizing innovation.[3] Property based intellectual property (IP) systems, however, present a double-edged sword.[4] Even as patents spur innovations, they can also cause underutilization

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1 John Carey et al., *The Biotech Century*, BUSINESSWEEK, Mar. 10, 1997, at 97, *available at* http://www.businessweek.com/1997/10/ b35171.htm (Nobel Prize winning chemist Robert F. Curl proclaiming that the twentieth century was "the century of physics and chemistry. But it is clear that the next century will be the century of biology."); Kenneth I. Shine, *Welcome*, NAT'L RESEARCH COUNCIL, U.S. DEP'T OF ENERGY, SERVING SCI. AND SOC'Y IN THE NEW MILLENNIUM 1 (1998) (proclaiming that, whereas "the 20th century will be known as the century of physics and astronomy," "the 21st century will be the century of the life sciences in all their ramifications"); JEREMY RIFKIN, THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD 8, 15 (New York, 1998) (describing the 21st century as the "biotech century").

2 *See generally*, *e.g.*, Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL'Y 273 (1998).

3 The right to exclude others from using one's innovation is embedded in statute. According to 35 U.S.C. § 154(a)(1), "Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." According to 35 U.S.C. § 271(a), "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." The American patent and copyright system is traced to England's Statute of Monopolies of 1624 and the intellectual property system of the Venetian Republic in the late fifteenth century. *See* BRUCE W. BUGBEE, THE GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 22–23, 39 (1967).

4 *See*, *e.g.*, FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5–6 (2003), *available at* http://www.ftc.gov/os/ 2003/10/innovationrpt.pdf (noting that despite the ability to incentivize innovations, overly broad patents also "deter market entry and follow-on innovation by competitors and increase the potential for the holder of a questionable patent to suppress competition").

of those innovations and even potentially discourage related follow-on innovations.[5]

The impressive rise of the American biotechnology sector has been nothing short of astonishing.[6] The revolution began in 1953 with the discovery of the DNA,[7] creating a new biological paradigm wherein discrete units of inheritance making up the genome of an organism[8] collectively direct and regulate all biological processes of the organism.[9] Since the creation of the first genetically engineered organisms in 1973,[10] the industry has exploded into a critical and strategic multi-billion dollar industry.[11] Many have cited the availability of

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5 *See infra* notes 230–239 and accompanying text.

6 In 2004, U.S. biotech companies marketed approximately 230 drugs, including 13 therapeutic antibodies; filed fifty-five FDA New Drug Applications (NDA), treating a wide variety of conditions including cancer, congestive heart failure, pain and diabetes; and raised $16.9 billion in capital in the U.S. alone. *Product Success and Strong Financials Drive Biotech Industry's Maturation According to Ernst & Young's 2005 Global Biotechnology Report*, (2005), http://www.ey.com/global/content.nsf/US/Media_-_Release_-_06-01-05DC.

7 J. D. Watson & F. H. C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737, 737 (1953). Equally important to the success of the industry was Stanley Cohen and Herbert Boyer's invention of recombinant DNA technologies which allowed genes to be manipulated at the genetic level for the first time. *See* Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids in Vitro*, 70 PROC. NATL. ACAD. SCI. 3240 (1973); RIFKIN, *supra* note 1, at 10–15. Further advancements including the discovery in 1983 of a generally applicable method for cloning genes for polypeptides, the development of computer controlled DNA sequencing machines in 1986, and the invention of polymerase chain reaction technology in the same year brings us to the age of modern high-throughput genetics era. *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, 306 (2002). For an overview of recent advances in DNA sequencing, *see* J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCI. 1304 (2001).

8 A genome is the total genetic information carried by a cell or organism. HARVEY LODISH ET AL., MOLECULAR CELL BIOLOGY G-9 (5th ed. 2003). Genomic patents include patents over DNA, cDNA, RNA, mRNA, SNPs, ESTs, and other genetic fragments derived from the genome of an organism.

9 Despite the discovery of DNA a half a century ago, new exciting discoveries about the fundamental roles genes play in directing biological processes continue to be made. *See*, *e.g.*, Trisha Guru, *A Silence That Speaks Volumes*, 404 NATURE 804 (2000); R.A. Waterland & R.L. Jirtle, *Transposable elements: Targets for Early Nutritional Effects on Epigenetic Gene Regulation*, 23 MOL. CELL. BIOL. 5293 (2003).

10 Cohen et al., *supra* note 7, at 3240.

11 There are about 1500 biotech companies in the U.S. in 2002. Debbie Strickland, *The Guide to Biotechnology*, (Biotechnology Industry Organization, Washington, D.C.), 2007, at 2-3. The American biotech industry has a market capitalization of about $US 225 billion in 2002 on revenues of $33 billion. *Id.*

strong patents as key to U.S. success,[12] allowing and incentivizing the private sector to carry out more and more of the industry's R&D.[13] Despite the impressive rise of the industry, there is also a general unease[14] at the current explosion of patenting activity.[15] As the number of applications skyrocket and the scope of

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12 *See* Reid G. Adler, *Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization*, 257 SCI. 908, 908 (1992); Luke Foster et al., *Patenting in the Biopharmaceutical Industry—Comparing the US with Europe*, 1 DRUG PLUS INT'L 1 (Aug. 2002), *available at* http://scientific.thomson.com/free/ipmatters/pii/8180019/ (describing patents as "the lynchpins of the biopharmaceutical industry."); Brian A. Jackson, *Innovation and Intellectual Property: The Case of Genomic Patenting*, 22 J. POL'Y ANALYSIS & MGMT. 5, 13 (2003); Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 ACAD. MED. 1348, 1351 (2002) (citing a Carnegie-Mellon survey which placed R&D mangers of medical equipment and drugs related product organizations from among 34 industry groups as the most enthusiastic about patents as mechanisms for appropriating intellectual property value); Lila Feisee, Dir., Fed. Gov't Relations and Intellectual Property of Biotechnology Ind. Org., Speech: Anything Under the Sun Made by Man (Apr. 11, 2001), *available at* http://www.bio.org/speeches/speeches/041101.asp; Michael J. Malinowski, Center for the Study of Law, Science and Technology, Arizona State University, *The Secret to US Success in Biotechnology* (Aug. 20, 1999), *available at* http://www.cid.harvard.edu/cidbiotech/comments/comments14.htm (last visited Apr. 13, 2007) (pointing out that "[b]iotechnology's extraordinary evolution in the US is largely attributable to supportive federal policy . . . which provides incentives for academic-industry research alliances (AIRS) . . . [and] intellectual property policy, beginning with recognition of the potential patentability of inventions involving living matter in the early 1980s."). Consider also the Bayh-Dole Act (Patent and Trademark Amendments Act), Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–212, 301–307), which encourages research grantees to take out patents and make exclusive licenses on innovations derived from public funded research. Publicly funded innovations developed in U.S. Universities are now routinely patented to attract interests from the private industry to commercialize University created innovations. Andrew Dervan, *Can Yale Help End the AIDS Plague?* YALE DAILY NEWS, Oct. 18, 2001, *at* http://www.yaledailynews.com/articles/view/1931.

13 Intellectual property assets form an increasingly important business asset for all corporations and universities. *See* Mark G. Edwards et al., *Value Creation and Sharing Among Universities, Biotechnology and Pharma*, 21 NATURE BIOTECHNOLOGY 618 (2003); STEPHEN M. MAURER, PROMOTING AND DISSEMINATING KNOWLEDGE: THE PUBLIC/PRIVATE INTERFACE (Sept. 5, 2002), http://www7.nationalacademies.org/biso/PD_Maurer_pdf.pdf.

14 *See*, *e.g.*, John H. Barton, *Reforming the Patent System*, 287 SCI. 1933–34 (2000) (lamenting that "[t]he number of intellectual property lawyers in the United States is growing faster than the amount of research" and noting a 70% increase between 1986 and 1994 in the number of intellectual property lawyers employed per dollar spent on research and development).

15 *See* Scherer, *supra* note 12, at 1364 (proposing research exception as a mechanism to control the negative impacts of genetic patents); *Gene Patents and the Public Good*, 423 Nature 207 (2003) (observing that there is a "growing concern among biomedical researchers that broad patents on genetic sequences may, in some cases, have a stifling effect on research and negative consequences for public health" and that "something seems to be out of balance," and also urging studies and reforms "to ensure that the patent system continues to do its job of sti-

subject matter expands, some question whether the issuance of broad fundamental biotech patents might be a herring, incentivizing current activities at the expense of future progress[16] (or perhaps even only incentivizing legal activities without research activities[17]).

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mulating innovation for the public good . . . ."); Robert Barr, Vice President, Cisco Inc., Statement to the 2002 FTC Hearings on the Anti-Competitive Effects of Patents (Jan. 6, 2005), http://swpat.ffii.org/papers/ftc02/cisco/ftc020228-cisco.en.pdf, at 3–4 ("So obtaining patents has become for many people and companies an end in itself, not to protect an investment in research and development, but to generate revenue through licensing ('holding up') other companies that actually make and sell products . . . . They try to patent things that other people or companies will unintentionally infringe and then they wait for those companies to successfully bring products to the marketplace. They place mines in the minefield. [They] . . . play the patent system like a lottery . . . . They benefit from the high cost of litigation . . . hoping that people will pay even if they don't infringe . . . . [C]onsulting firms [form] . . . to help people 'mine' their patent portfolios for patents that even they didn't know they had. It's hard to see how this contributes to the progress of science and the useful arts."); Scott A. Chambers, *Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 53 (1995); Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter As To The Patentability Of Certain Inventions Associated With The Identification Of Partial cDNA Sequences*, 23 AIPLA Q.J. 1 (1995); Andrew T. Kight, *Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of Brenner*, 73 IND. L.J. 997, 1015 (1998).

16 *See*, *e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) (warning that "[a] proliferation of intellectual property rights upstream may be stifling life-saving innovation downstream."); Jackson, *supra* note 12, at 10–11 (noting that "[t]he same gene could be relevant as a drug target, a pharmaceutical itself, part of a diagnostic test, a subject of bioengineering, a gene therapy target, and other applications. Knowledge of gene sequences and their functions can be as powerful and far reaching as any basic piece of scientific knowledge that might serve as the basis for many later discoveries and innovations."); FED. TRADE COMM'N, *supra* note 4, at 5 ("[M]any participants in and observers of the patent system expressed significant concerns that, in some ways, the patent system is out of balance with competition policy. Poor patent quality and legal standards and procedures that inadvertently may have anticompetitive effects can cause unwarranted market power and can unjustifiably increase costs."); Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 RESEARCH POLICY 531, 555 (2000) (concluding that there is "widespread unease that the costs of stronger patent protection may exceed the benefits. Both theoretical and, to a lesser extent, empirical research suggest this possibility."); Jackson, *supra* note 12, at 23; WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 316 (2003); Janice M. Mueller, *No Dilletante Affair': Rethinking the Experimental Use Exception to Patent Infringemnet for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001). *But see* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 1001–1005 (2005) (arguing that the targets of biomedical research are so diverse and numerous that the adverse effects of patenting is actually quite subdued and has been overblown).

17 *See, e.g., supra* note 14; infra note 30 and accompanying text.

Biotechnology is a field where innovations take place in multiple rounds, with important knowledge and technologies acquired throughout all stages. Genetic knowledge enables the study of biochemical pathways rationally, at a molecular level, and holds the key to new ways of studying, diagnosing, treating, and improving the human condition.[18] The discovery of a gene is but a first step to a whole series of inventions and discoveries that will hopefully one day lead to important lifesaving diagnostic and therapeutic applications.[19] Thus, while it is important to incentivize innovations today, enough incentives must also be preserved to drive the innovations of tomorrow.[20] The *Scripps* and *Amgen*[21] cases—featuring disputes involving traditional extraction and modern recombinant technologies—showcased how patents that incentivize innovations in one era may end up blocking important innovations in a later era.[22] If the genomic patenting floodgate is left unchecked, the *Scripps* and *Amgen* cases may merely foreshadow the cost of blocking genomic patents still to come.

This paper addresses the problems of overly broad patents in biotechnology, specifically of genomic patents, using an economics-based framework.[23]

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18 *See also* discussions surrounding *infra* note 391.

19 *See*, *e.g.*, Roger Brent, *Genomic Biology*, 100 Cell 169 (2000); Kevin Davies, After the Genome: DNA and Human Disease, 104 Cell 465 (2001). *See also* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1616 (2003); Scherer, *supra* note 12, at 1349; Jackson, *supra* note 12, at 18. While this paper will focus on the consequence of gene in the biomedical setting, it is noted that the study of genes has great ramification in many other fields, from military to agriculture. *See*, *e.g.*, RIFKIN, *supra* note 1, at 2.

20 *See*, *e.g.*, SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 46 (MIT Press, Cambridge, Massachusetts, 2005); Graham Dutfield, *Intellectual Property and Basic Research: Discovery vs Invention*, SCI. DEV. NETWORK, Dec. 2002, *available at* http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&policy=15&section=144& dossier=8 (noting that because of concerns of effects on follow-on innovations, "some NGOs have been campaigning to abolish the patenting not only of genes but also of all life-forms and their structural and functional components.").

21 Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991); Amgen, Inc. v. Chugai Pharmaceutical Co., No. 87-2617-Y, 1989 WL 169006 (D. Mass. Dec. 11, 1989); Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94 (D. Mass. 1989).

22 *See infra* notes 66–77 and accompanying text. Further, just as analog innovations of the past can block recombinant innovations of today when products rather than methods are patented, so can recombinant patents of today block biochemical based innovations of tomorrow synthesis proteins. *See* Aaron Xavier Fellmeth, *The Challenge to Patent Law of Pure Chemical Protein Synthesis*, 23 NAT. BIOTECH. 547, 547 (2005).

23 For a non-economic perspective, see Wendy J. Gordon, *A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property*, 102 YALE L.J. 1533 (1993) (presenting philosophical, non-economic perspectives, including those drawn from natural rights, in support of protecting intellectual property); James Boyle, *Enclosing the Genome: What Squabbles over Genetic Patents Could Teach Us* 100–04 (2003),

By genomic patents, this paper explicitly refers to product patents over a genetic fragment isolated or derived[24] from the genome of an organism.[25] This paper begins by tracing the legal foundation of gene and pharmaceutical product patents to an obscure legal doctrine heretofore referred to as the *natural extracts doctrine*. This doctrine deems any product extracted from nature to be patentable so long as the extraction process requires human intervention and the extracted product provides some novel properties to society. Then, the paper discusses the ineffective legal patchworks created by the U.S. Patent and Trademark Office ("USPTO") and courts with respect to stemming the uncomfortable tide of biotech patents. These efforts have been largely ineffective because they fail to deal directly with the fundamental problems created by the *natural extracts doctrine*. Further, the paper presents an economic framework for understanding patent scope and the economics of innovations and a discussion of the implications these insights hold for genomic patents. The paper argues that to promote long-term growth in biotechnology, the *natural extracts doctrine*, together with the broad product patents it has spawned, must be promptly and decisively abandoned or drastically reduced in scope. The subject matter eligibility requirement, specifically the prohibition against the patenting of laws of nature, must be reinvigorated. Enablement must be more strictly enforced where patent scopes are made more coincident with the contribution made to the arts by the patented invention. In concluding, the paper presents a simple vision of how a patent regime without the *natural extracts* doctrine might look like.

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http://www.law.duke.edu/boylesite/low/genome.pdf (arguing against genomics patents from a bioethics perspective); NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA 35–36 (2002), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf (presenting a bioethics perspective against the patenting of genes).

[24] An example of a derived fragment is a cDNA (complementary DNA). As Kane has noted, "[t]he typical DNA gene sequence claim is actually a claim to a complementary DNA (cDNA), which is reverse-transcribed from the mRNA encoded by the genomic DNA. . . . A patent on the corresponding cDNA will [thus] effectively provide patent protection for the gene itself despite its lack of identity to the genomic DNA." Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 741 (2004). This is an example of an "effective occlusion [of the unpatentable] . . . through the patenting of products or methods which are the only means of accessing the unpatentable." *Id.* at 765.

[25] The terms gene patent and genomic patent are used interchangeably in this paper.

II. GENERAL SENSE OF UNEASE

A. The Genetic Patent Floodgate

As of 1999, the USPTO has awarded nearly 3,000 patents related to human genes, about ten percent of the estimated 30,000 to 40,000 genes[26] in the entire human genome.[27] Craig Venter made news when he filed 6,500 provisional patent applications over human genes in October 1999.[28] To some, the increase in patent applications merely reflects increased innovations in the area;[29] to others, the increase reflects legal gamesmanship to maneuver and corner an important field.[30]

Gene product patents are especially problematic because of their broad scopes.[31] In covering the actual genomic product—i.e., the nucleotide structure and amino acid sequences of genes—today's gene patents potentially chill subsequent innovations such as discovering the functions and uses of genes. Furthermore, many of today's gene patents claim not just the genetic products, but

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26 David J. Galas, *Making Sense of the Sequence*, 291 SCI. 1257, 1257 (2001).

27 Scherer, *supra* note 12, at 1348. This does not mean that the debate over the patentability of gene is moot. Opponents of the current status quo should take heart that the eligibility of software as patentable subject matter was the subject of continual judicial review and critical scholarship over the span of several decades even as the USPTO was issuing patents over software. *See* Kane, *supra* note 24, at 766.

28 *See* Richard F. Harris, *Patenting Genes: Is it Necessary and is it Evil?*, 10 CURRENT BIOLOGY R174, R174 (2000).

29 *See*, *e.g.*, OECD Science, Technology and Industry Scoreboard, http://www.oecd.org/publications/e-book/92-2003-04-1-7294/execsumm.htm (last visited Jan. 29, 2007) (presuming that patenting is a measure of innovation).

30 *See* NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 62–64 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006), *available at* http://newton.nap.edu/ openbook/0309100674/html/62.html (noting that "[i]n many cases patenting activity has departed from its traditional role and has become strategic. Some firms are building large patent portfolios to gain access to others' technologies and reduce their vulnerability to infringement litigation."); *id.* at 37 (noting that "[p]atenting can be an important strategic tool for firms without being either a significant direct stimulus to R&D or a source of technical information on the direction of R&D or other activities of competitors."); *see also infra* note 342 and accompanying text.

31 *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1204 (2002) (noting that "the real problem in both biotechnology and software lies in the number and scope of patents that are issued"); *see also infra* notes 169–171 and accompanying text (discussing the nature and scope of product patents).

also potential derived products and uses.[32] For example, today's EST[33] applications may claim not just the isolated sequences, but also the use of the isolated fragments for diagnostic purposes, as tools for research, in gene regulation applications such as antisense and triple helix applications, and as probes to discover other genes. It is not uncommon for such an application to claim

> not only the specific ESTs . . . but also complementary sequences, allelic variations and portions thereof, full genes corresponding or hybridizing to any of the foregoing sequences, fragments of such full genes, vectors containing any such sequences or genes, panels of ESTs or sequence fragments, and antisense oligonucleotides or triple helix probes capable of blocking expression of the products of the full genes.[34]

Some go as far as to claim all gene sequences found by the use of the EST as a probe.[35] The family of patents deriving from U.S. Patent Application No. 08/724,643 is a typical example of the broad patenting practice associated with genomic patents.[36] The family of patent applications arising from an original

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32 *See* Kane, *supra* note 24, at 712 (noting that the subject of gene related patents today may encompass "subcellular and subgenetic entities such as cell lines, plasmids, vectors, genes, promoters, enhancers, single-nucleotide polymorphisms, . . . markers . . . transgenic animals and plants and recombinant DNA viruses (vectors) and microorganisms").

33 EST stands for Expressed Sequence Tag. "ESTs: Gene Discovery Made Easier, http://www.ncbi.nih.gov/About/primer/est.html (last visited Jan. 29, 2007). According to the Genbank science primer, "ESTs are small pieces of DNA sequence (usually 200 to 500 nucleotides long) that are generated by sequencing either one or both ends of an expressed gene. *Id.* The idea is to sequence bits of DNA that represent genes expressed in certain cells, tissues, or organs from different organisms and use these 'tags' to fish a gene out of a portion of chromosomal DNA by matching base pairs." *Id.* "ESTs provide researchers with a quick and inexpensive route for discovering new genes, for obtaining data on gene expression and regulation, and for constructing genome maps." *Id.*

34 *See id.* at 13–14, 38; *see also* S.M. Thomas et al., *Ownership of the Human Genome*, 380 NATURE 387, 387–88 (1996).

35 *See* Eisenberg & Merges, *supra* note 15, at 3, 13–14, 16–17.

36 The issued patents currently include: U.S. Patent Nos. 6,093,809 (filed May 6, 1997), 6,261,836 (filed May 9, 1997), 6,475,789 (filed Aug. 14, 1997), 6,166,178 (filed Nov. 19, 1997), 6,444,650 (filed Mar. 31, 1998), 6,309,867 (filed Oct. 29, 1999), 6,617,110 (filed Nov. 24, 2000), 6,808,880 (filed Jan. 19, 2001), and 6,627,619 (filed Sept. 14, 2001). For up-to-date information patent status regarding the immediate patent family and their claims, use the USPTO's Patent Application Information Retrieval (PAIR), http://portal.uspto.gov/external/portal/home. Note that it is not unusual for a gene patent applications to provide a broad disclosure that are subsequently subdivided into several continuing patent applications each focused on (i.e. "restricted" to) a narrow set of claims. As can be also seen in this family of patents, besides claiming a nucleic acid (DNA), a family will also typically claim

> the protein encoded by the DNA sequence, a recombinant vector containing the inserted DNA sequence, a cell line producing the protein encoded by the

single U.S. application aim to cover not just a specific gene, but also the telomerase amino acids, proteins imputed in the aging and cancer mechanisms associated with the gene; drugs derived from the protein coded by the gene; the use of the gene in biological studies; and pharmacological compositions that could be derived from the gene.[37]

At the heart of the controversy over gene patents is a debate over the nature and scope of genetic related innovation.[38] Does the discovery of a gene constitute the creation or invention of the gene? Does the patenting of genes constitute patenting of nature?[39] Should genes be patentable when sequencing is becoming increasingly routine and should such patents be allowed when scientists continue to show interest to work in the area irrespective of the existence of patent incentives?[40] Today, the status of gene patents remains uncertain.[41] The Supreme Court of the United States ("Supreme Court") has side-stepped the

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> DNA sequence, a method for producing the protein from the DNA sequence, a method for producing the cell line, a method for producing the protein from the cell line, diagnostic and therapeutic methods using the DNA sequence, and other permutations of the basic invention.

Kane, *supra* note 24, at 712 n.21.

37 Jackson, *supra* note 12, at 12 (referring to U.S. Patent No. 6,093,809, but observations referring more generally to the entire family of patents deriving from U.S. Patent Application No. 08/724,643).

38 *See* Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 434–35 (1988); Rebecca S. Eisenberg, *Why the Gene Patenting Controversy Persists*, 77 ACAD. MED. 1381, 1381 (2002).

39 *See* RIFKIN, *supra* note 1, at 45 (arguing that "[a]t the very heart of the issue of patentability is the question of whether engineered genes, cells, tissues, organs, and whole organisms are truly human inventions or merely discoveries of nature. . . . No molecular biologist has ever created a gene, cell, tissue, organ, or organism *de nove*. . . . No reasonable person would dare suggest that a scientist who isolated, classified, and described the properties of hydrogen, helium, or oxygen ought to be granted the exclusive right, for twenty years, to claim the substance as a human invention.").

40 *See* Jackson, *supra* note 12, at 15 (questioning "whether the simple act of disclosing a sequence is of sufficient value to merit the societal reward of monopoly rights"); *id.* at 16 ("[S]ince research groups are willing to perform these tasks and disclose their results without the reward of patent rights, society should pay no premium to other firms or individuals to do so."); Harris, *supra* note 28, at R175 (describing how "intellectual property can now be manufactured by the bushel barrel. Mostly what it requires is some DNA sequencers, a cadre of PhDs and a computer algorithm that can spot homologies between novel stretches of DNA and sequences of known function. Presto, a gene patent is born . . . ."). James Watson, one of the discoverers of the helical nature structure of DNA, has characterized today's mass-structural sequencing effort as work too routine ("monkey work") to merit patent protection. *Who owns your genes?*, THE ECONOMIST, July 1, 2000.

41 *See* SCOTCHMER, *supra* note 20, at 242.

issue of subject matter eligibility in the biomedical context numerous times,[42] and while the USPTO has officially pronounced genes to be patentable subject matter, it has also allowed a very long backlog of patent applications to build up.[43] In 2004, the European Patent Office revoked controversial[44] patents related to cancer-causing genes BRCA1 and BRCA2, sending perhaps a signal that it will now be much more difficult to obtain gene patents in Europe.[45] The concern among many scientists and the changing attitude in Europe toward gene patents is adding pressure the U.S. to reform its practices of gene patenting.[46] Fearful of the harm that gene patents can cause to future research, some in the private sector have taken the problem into their own hands. For example, the charity group Cancer Research UK has taken out several BRCA1 and BRCA2 related patents so they can be freely licensed.[47] Ten prominent pharmaceutical companies have joined with the Welcome Trust, another private charity, to pat-

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42 *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2921 (2006) (per curiam) ("dismiss[ing] as improvidently granted" a writ of certiorari that the Court had earlier granted); Kane, *supra* note 24, at 727 (noting that "to date, no judicial review of DNA gene sequences as patentable subject matter has occurred"). The issue raised in *Metabolite* concerned whether "a method for detecting a form of vitamin B deficiency . . . [involving measurements of] elevated levels of certain amino acids and deficient levels of vitamin B . . . using any device, whether the device is, or is not, patented[,] . . . [is] invalid because one cannot patent 'laws of nature, natural phenomena, and abstract ideas.'" Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 543 U.S. 1185, 1185 (2005). *Cf.* infra note 396.

43 Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 784 (2000). Even for those opposing genomic patents, the gene patent backlog is not necessarily good news. If all 30,000 to 40,000 human genes are decidedly patented today, at least the patent term will start ticking and we will have the certainty that in twenty or so years, the gene patent issues will all be behind us. With the backlog, we get uncertainty instead, producing the ironic result that we are looking to be dealing with the issues and effects of gene patents for much further than twenty years into the future.

44 There were many opponents of the patent, including the European Parliament, which issued a resolution calling for the EPO to rescind all gene patents. *See* European Parliament Resolution on the Patenting of BRCA1 and BRCA2 ('Breast Caner') Genes (Apr. 10, 2001), http://www.cptech.org/ip/health/biotech/eu-brca.html.

45 *See* Andy Coghlan, *Europe Revokes Controversial Gene Patent*, NEW SCIENTIST, May 19, 2004, http://www.newscientist.com/article.ns?id=dn5016.

46 *See id.* (stating that "[o]n 19 April, a report on patents by the US National Academies of Science urged the USPTO to be more careful in handing out patents for gene sequences"); *id.* ("Aside from the economic implications for breast cancer screening in Europe, the decision could increase pressure on the US Patent and Trademark Office to reject or revoke 'obvious' gene patents. 'It has demonstrated the difference between patent protection in Europe and the US[.] . . . So it might be an important precedent-setter.'").

47 *See* Grit Kienzlen, *Concern Over BRCA2 Patent*, THE SCIENTIST, May 16, 2004, http://www.the-scientist.com/news/20050516/01/.

ent a collection of SNPs[48] only to disavow them and legally prevent others from patenting a similar library of SNPs.[49] Public interest foundations have been formed to challenge undeserving patents in courts.[50]

B. Concerns from Scientists' Perspectives

The controversy over genetic patents is reminiscent of recent controversies over other recent expansions of patentable subject matter, such as those

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48 SNPs are Single Nucleotide Polymorphisms. SNPs: Variations on a Theme, http://www.ncbi.nih.gov/About/primer/snps.html (last visited Jan. 29, 2007). SNPs constitute "a small genetic change, or variation, that can occur within a person's DNA sequence. . . . By studying stretches of DNA that have been found to harbor a SNP associated with a disease trait, researchers may begin to reveal relevant genes associated with a disease." *Id.*

49 Harris, *supra* note 28, at R175. There are other efforts aimed at countering the trend toward the privatization of basic knowledge. For example, easily accessible major databases are increasingly coming online for genes (e.g., GenBank, Celera), proteins (e.g., Blueprint Worldwide and Protein Data Bank), and genetic probes (e.g., the quasi-public Merck Gene Index and SNPs Consortium). *See* John P. Walsh et. al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 329 (Wesley M. Cohen & Stephen A. Merrell eds., 2003); Andrew Pollack, *Celera to Quit Selling Genome Information*, N.Y. TIMES, Apr. 27, 2005, at C2. Most biomedical journals now routinely require authors to deposit gene and protein sequences associated with their research in public databases as a condition for publication. Walsh, *supra* at 329. The NIH has negotiated generic license agreements on behalf of academic researchers for important privately-owned research tools, has publicly funded the development of new research tools (e.g., transgenic lab animals), and has required researchers not to patent certain inventions derive from NIH-supported research. *Id.* Even Merck, a for-profit pharmaceutical company, has promised to provide to the research community the use of 150 patent-free transgenic mice at cost without use restrictions. *Id.*

50 For example, The Public Patent Foundation has been founded on the basis that:

> Most people still do not realize how significantly undeserved patents and unsound patent policy are assailing their health, their freedoms, and their wallets. The pharmaceutical and information technology industries are full of markets hampered by undeserved patents. Similarly, free speech, privacy, and other individual liberties are increasingly being threatened by undeserved patents, especially as daily life becomes more technologically dependent. Unfortunately, the interests of the public to be free from undeserved patents and unsound patent policy are not adequately represented. As such, there is great need for a public service organization to represent those interests. PUBPAT is that organization.

The Public Patent Foundation, About PUBPAT, http://www.pubpat.org/About.htm (last visited Apr. 21, 2007).

over software and business methods.[51] On closer examination, however, the gene patent controversy is also very different. A primary concern among opponents of software and business methods patents related to patent quality.[52] The USPTO, which bases most of its prior art research on the patent literature, issued many patents of questionable quality when it did not possess a comprehensive library of patents that adequately reflected the prior art. As the USPTO database has built up and certain examination procedures tightened, however, the uproar over software and business patents has apparently also receded.[53] On

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[51] *See* Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 7–11 (2001); Douglas L. Price, *Assessing the Patentability of Financial Services and Products*, 3 J. HIGH TECH. L. 141, 155–56 (2004); *see also supra* notes 42 and *infra* notes 52–53 and accompanying text (discussing the controversy surrounding software patents); *infra* notes 52–53, and 221 and accompanying text (discussing the controversy surrounding business method patents).

[52] John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 BERKELEY TECH. L.J. 987, 989–90 (2003); Carl Shapiro, *Patent System Reform: Economic Analysis and Critique*, 19 BERKELEY TECH. L.J. 1017, 1018 (2004); John A. Squires & Thomas S. Biemer, *Patent Law 101: Does a Grudging* Lundgren *Panel Decision Mean that the USPTO is Finally Getting the Statutory Subject Matter Question Right?*, 46 IDEA 561, 582 (2006); *see also* Pamela Samuelson, Benson *Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025 *passim* (1990) (arguing against the patenting of software); Matthew G. Wells, *Internet Business Method Patent Policy*, 87 VA. L. REV. 729, 770–73 (2001) (outlining the arguments for and against business method patents for use on the internet).

[53] *See* Burk & Lemley, *supra* note 19, at 1618–19, 1622 (acknowledging that while "[t]he early history of the software industry is one in which innovators developed impressive new products at very little cost in the absence of patent protection," recent economic changes in the industry (i.e. software have become more complex and more expensive to build) rendered arguments against software patents "unlikely to prevail"); Cohen & Lemley, *supra* note 51, at 56–57 (acknowledging that software patents constitute clearly patentable subject matter and recommending only "minor doctrinal adjustments" to the system). Regarding Burk, Cohen, and Lemley's comments about software patents, the fact that software has become more complex and expensive to build does not necessarily support the contention that patents, which were not needed before, have now become necessary. Software and business patents are proper if they are used to compensate for innovation risks but not when they are used to compensate for other risks such as implementation risks, where related investments which may not be nonexclusive. For example, while an innovative idea may be easily copied, an innovative business model may not be. Business assets can often be protected and made exclusive through trademark, execution, branding, quality and/or first mover's advantage. *See also* Burk & Lemley, *supra* note 19, at 1618 (discussing that "companies have ample incentives to [innovate] even without patent protection, because the competitive marketplace rewards companies that use more efficient business methods. Even if competitors copy these methods, first mover advantages and branding can provide rewards to the innovator."). Software assets (e.g. designs and codes) can be made exclusive through encryption and/or copyright. Businesses should not be allowed to rely on patents instead of competitive execu-

the other hand, it seems the controversy over gene patents has not only not subsided, but perhaps even increased.[54] Proponents argue that genes should be patentable because such protection would incentivize progress.[55] Opponents—including professional medical organizations,[56] Nobel Prize winners,[57] government officials,[58] religious leaders,[59] bioethics councils,[60] and even respected sci-

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tion in creating compelling value propositions. *See also infra* note 226 (discussing the extent to which innovations constitute public goods).

54 Eisenberg, *supra* note 38, at 1381 (observing that one unique feature of the controversy over gene patenting is that instead of subsiding, the controversy has grown and even evolved). The quality problem also seems to persist. *See*, *e.g.*, Jordan Paradise et al., *Patents on Human Genes: An Analysis of Scope and Claims*, 307 SCI. 1566, 1566–67 (reporting typical problems encountered while briefly surveying a number of genomic patents).

55 *See*, *e.g.*, Phyllida Brown & Kurt Kleiner, *Patent Row Splits Breast Cancer Researchers*, NEW SCIENTIST, Sept. 24, 1994, at 44 (Mark Skolnick (founder of Myriad Genetics), whose company planned to file for patents over cancer-causing genes BRCA1 and BRCA2, arguing for the patenting of the genes by noting that "[i]f it's not patented, you won't get some group to spend money to develop it, and you won't get a high-quality, inexpensive test. . . . The question is, does the world deserve a high-quality, inexpensive test?"). For an overview of the BRCA story, including the recent invalidation of the gene patent by the European Patent Office, for example see NAT'L RESEARCH COUNCIL, *supra* note 30, at 35; NUFFIELD COUNCIL ON BIOETHICS, *supra* note 23, at 39–40.

56 For official policy positions opposing the granting of gene patents, for example see Genes Patents Detrimental to Care, Training, Research, http://www.cap.org/apps/docs/advocacy/advocacy_issues/Issue_Genepat.html (last visited Jan. 29, 2007); Am. Coll. of Med. Genetics, Position Statement on Gene Patents and Accessibility of Gene Testing (Aug. 2, 1999), http://genetics.faseb.org/genetics/acmg/pol-34.htm.

57 *See*, *e.g.*, JOHN SULSTON & GEORGINA FERRY, THE COMMON THREAD: A STORY OF SCIENCE, POLITICS, ETHICS AND THE HUMAN GENOME 266 (2002) (quoting Dr. John Sulston, Director of the Sanger Institute, a research organization belonging to the Human Genome Project International Consortium, and 2002 Winner of the Nobel Prize in Medicine or Physiology, to say: "[t]he genome sequence is a discovery, not an invention."). The distinction between "discovery" and "invention," as a matter of law, is not always easy to delimit though. *See infra* note 326 and accompanying text.

58 *See*, *e.g.*, Eliot Marshall, *Clinton and Blair Back Rapid Release of Data*, 287 SCI. 1903, 1903 (2000) (reporting the British Prime Minister and the American President exhorting private companies to make raw genetic data publicly available and to use patents responsibly); European Parliament Resolution, *supra* note 44; Ken Ernhofer, *Ownership of Genes at Stake in Potential Lawsuit*, CHRISTIAN SCI. MONITOR, Feb. 27, 2003, *available at* http://www.csmonitor.com/2003/0227/p07s03-woam.html (reporting that the Canadian province of Ontario had publicly declared that it would offer its own, less expensive breast cancer diagnostic tests using the genes patented by Myriad Genetics of Utah despite notices from the company to cease and desist; also quoting Tony Clement, Ontario's health minister, to call gene patenting "abhorrent" and pronounce that the government "do[es] not accept their claim and [is] disregarding that claim.").

59 *See* RIFKIN, *supra* note 1, at 65.

ence fiction writers[61]—however have argued against such patents. If there is ever a law of biology, the genome, constituting the blueprint of all biological processes, would be it.[62] The genome represents the sort of basic knowledge that is traditionally not incentivized by the patent system.[63] As will be discussed throughout the paper, while patents do probably have a role to play in promoting gene related innovations, broad genomic patents—designed to broadly cover gene products and sequences—probably hinder rather than foster innovations.[64]

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60 *See* NUFFIELD COUNCIL ON BIOETHICS, *supra* note 23, at 47–48 (advocating against the allowance of gene product patents and calling for limiting the scope of gene patents to specifically cited uses, disavowing assertions of later identified uses).

61 Michael Crichton, *Patenting Life*, NEW YORK TIMES, Feb. 13, 2007, *available at* http://www.nytimes.com/2007/02/13/opinion/13crichton.html.

62 Marshall Nirenberg, *The Genetic Code (Dec. 12, 1968)*, NOBEL LECTURES, PHYSIOLOGY OR MEDICINE 1963–70 (1972), at 372, 390 (noting that "most, perhaps all, forms of life on this planet use essentially the same genetic language, and that language is translated according to universal rules"). Dr. Nirenberg, along with Dr. Robert W. Holley and Dr. Har Gobind Khorana, won the 1968 Nobel Prize in Physiology for Medicine for the elucidation of the genetic code. *See* NobelPrize.org, The Nobel Prize in Physiology or Medicine 1968, http://nobelprize.org/nobel_prizes/medicine/laureates/1968/ (last visited Apr. 21, 2007).

63 *See* Kane, *supra* note 24, at 713 (arguing that "[t]he patenting of genes results in a constructive preemption of the genetic code, a result that is contrary to the Supreme Court's dictate that the laws of nature are not patentable"); Kevin Davies, Perspective on the Human Genome Project, http://www.csu.edu.au/learning/eubios/MURSE/MURSKD.html (last visited Jan. 29, 2007) (Mike Stratton, head of the team at the Institute of Cancer Research, arguing against the patenting of cancer causing genes BRCA1 and BRCA2 by noting that "[w]e do not believe pieces of the human genome are inventions; we feel it is a form of colonization to patent them. I don't think it is appropriate for [a disease gene] to be owned by a commercial company . . . ."); Jon Henley, *Cancer Unit Fights US Gene Patent*, THE GUARDIAN, Sept. 8, 2001), http://education.guardian.co.uk/businessofresearch/story/0,,549499,00.html (Jean-Francois Mattei, a prominent geneticist, opining the state of affairs of gene patenting: "Under the guise of providing legal protection for biotechnological discoveries, we are preventing possibly vital research and therapeutic advances being made by anyone other than the patent-holder."); James Meek, *US Firm May Double Cost of UK Cancer Checks*, THE GUARDIAN, Jan. 17, 2000, http://www.guardian.co.uk/genes/article/0,,191861,00.html (Neva Haites, professor of genetics at Aberdeen university and chairman-elect of the British Society of Human Genetics in 2001 and 2002, observing: "In the US, Myriad has managed to convince all the labs that used to test for this gene to shut down. . . . Some countries in Europe are coming out with very strong statements about the patenting of genes . . . saying they will not let their countries have their patient care inhibited.").

64 *See* Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 577 (2002) (providing anecdotal evidence suggesting that aggressive assertion of gene patents has impeded the application and use of medical diagnostic innovations); Stuart M. MacLeod & Donald J. Willison, *Patenting of Genetic Material: Are the Benefits to Society Being Realized?*, 167 CAN. MED. ASS'N J. 259, 261 (2002) (observing that some thirty percent of laboratories testing for hemochromatosis stopped developing or providing for the test after the patent holder

C. Scripps's and Amgen's Recombinant DNA Cases

Two high profile biotechnology cases in the late 1980s illustrate the type of problems broad product patents in biotechnology can cause to long-term technological progress.[65] In *Scripps Clinic and Research Foundation v. Genentech, Inc.* ("*Scripps I*"),[66] patentee Scripps sued Genentech over Genentech's effort to commercialize recombinant Factor VIII:C.[67] Factor VIII:C is a naturally occurring protein found in the human body essential to blood clotting, and the purified form was a leading drug candidate to treat hereditary bleeding disorders such as hemophilia.[68] Scripps had previously isolated Factor VIII:C from human blood plasma using large sources of blood and, even though its innova-

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began to enforce its patent over the associated target gene); Dutfield, *supra* note 20 (arguing that the patenting of genes constitutes "anti-innovation, since it potentially hinders opportunities for follow-on researchers to carry out further investigations on genes that had previously patented for one out of possibly numerous functions"); Heller & Eisenberg, *supra* note 16, at 698 (warning of "an unintended and paradoxical consequence of biomedical privatization: A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development"); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 301–02 (2003) (raising the concern that genetic patents can impede advancements in diagnostic tests such genechips); NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 26–27 (Stephen A. Merrill et al. eds., 2004) (raising the concern that patents over targets such as receptors and mutated genes can restrict access to critical drug targets).

65 Under the patent system, a patent can issue even if an earlier broad patent cover the same subject area. Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1379 n.2 (Fed. Cir. 2000). An inventor may thus obtain a so-called improvement patent over a subsequent invention but may not have the right to practice that invention without a license from the original pioneer. *Id.* For example, a first inventor obtains a patent over a vessel to hold liquid; a second inventor improves the invention by inventing a cup by attaching a handle to a vessel designed to hold liquid and similarly obtains a patent. Under such circumstances, neither the subsequent nor original inventor will be able to practice the cup invention without a license from the other. *See id.*; Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1325 (Fed. Cir. 2002); LANDES & POSNER, *supra* note 16, at 317. Carl Shapiro has coined the term "patent thicket" to describe the phenomenon of overlapping patent claims resulting sometimes from the natural workings of the patent system (as discussed above) and sometimes because patents scope is systematically too broad (as in the cases of *Amgen* and *Scripps*, discussed below). Carl Shapiro, *Navigating the Patent Thicket: Cross Licensing, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 121 (Adam B. Jaffe et al. eds., 2001); *accord* Burk & Lemley, *supra* note 19, at 1614.

66 666 F. Supp. 1379 (N.D. Cal. 1987).

67 *Id.* at 1393.

68 *See*, *e.g.*, Michael S. Greenfield, Note, *Recombinant DNA Technology: A Science Struggling with the Patent Law*, 44 STAN. L. REV. 1051, 1052 (1992).

tion was in the processes needed to isolate Factor VIII:C, was able to successfully obtain a product patent broadly over purified Factor VIII:C.[69] Because of the inefficiencies involved in Scripp's analog purification techniques, however, it was not until Genentech successfully synthesized purified Factor VIII:C through recombinant DNA techniques that Factor VIII:C began to hold out real commercial promise.[70] To the dismay of Genentech and many others, the courts held that Genentech's recombinant-produced Factor VIII:C infringed Scripp's patent over monoclonal-derived Factor VIII:C because Scripp's original patent covered not just the monoclonal processes but also *all purified Factor VIII:C, however derived*.[71]

In *Amgen, Inc. v. Chugai Pharmaceutical Co.* ("*Amgen I*"),[72] Amgen sued, among other reasons, to declare that its efforts to commercialize recombinant erythropoietin ("EPO")[73] did not infringe U.S. Patent No. 4,677,195 (the '195 patent), to which Chugai was a licensee.[74] EPO is a naturally occurring substance found in the human body essential to red blood cell production, and the purified form was among the leading drug candidates to treat disorders such as anemia and renal anemia.[75] The '195 patent disclosed a method to isolate and purify EPO from urine.[76] Because of the large quantities of urine required, however, this analog-derived EPO did not offer commercial viability until Amgen finally succeeded in manufacturing EPO through recombinant techniques.[77]

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69 *Scripps I*, 666 F. Supp. at 1383.

70 *Id.* at 1384.

71 *Id.* at 1394. For the history of the case, see Scripps Clinic & Research Found. v. Genentech, Inc. (*Scripps III*), 927 F.2d 1565, 1571–74 (Fed. Cir. 1991) (reversing invalidity rulings and remanding for further proceedings); Scripps Clinic & Research Found. v. Genentech, Inc. (*Scripps II*), 707 F. Supp. 1547, 1554–55, 1557 (N.D. Cal. 1989) (setting aside infringement rulings on the ground that the '011 patent was invalid for failing to disclose the "best mode" and on grounds of inequitable conduct). The parties eventually settled, apparently in terms favorable to Genentech. *See* Press Release, Genentech, Inc., Settlement Reached in Factor VIII Litigation Involving Genentech, Miles, The Scripps Research Institute and Rhone-Poulenc Rorer (Jan. 19, 1994), http://www.gene.com/gene/news/press-releases/display.do?method=detail&id=4397&categoryid=1.

72 706 F. Supp. 94 (D. Mass. 1989).

73 Recombinant erythropoietin is erythropoietin produced by recombinant DNA techniques.

74 *Amgen I*, 706 F. Supp. at 97.

75 *Id.* at 96.

76 *See id.* at 96.

77 *See*, *e.g.*, Greenfield, *supra* note 68, at 1053 n.14. The court also seemed to recognize the value of Amgen's unique contributions. For example, partly in recognition that "recombinant EPO is an extraordinarily valuable medicine that promises marked relief from renal failure," the court refused on public policy grounds to enter a preliminary injunction against

Again, to the dismay of many, the court held that Amgen's recombinant-produced EPO infringed Chugai's analog-derived EPO because the original patent covered not just the analog-derived EPO, but also *all purified EPO, however derived*.[78]

The disputes in *Scripps* and *Amgen* raised serious concerns about the impact that overly broad product patents have on long-term progress in the biotech industry.[79] Through a doctrine that this paper will refer to as the *natural extracts doctrine*, a pioneering inventor of a novel process—by virtue of being first to isolate a compound from nature—obtains a patent on not just the isolation process or use of the isolated product, but also on the isolated product itself.[80] Such product patents, however, in general go beyond what is really contributed by the underlying innovation. These patents impede subsequent innovations, such as the invention of other extraction methods or discovery of other uses associated with the isolated product. As discussed in more detail *infra*, method patents could have protected pioneering innovation such as those in *Scripps* and *Amgen* without unnecessarily impeding subsequent innovations. If the goal of patents is to promote progress, the patent system must get the contribution to the art right so the proper advancements can be incentivized at every

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Amgen. Amgen, Inc. v. Chugai Pharm. Co. (*Amgen II*), No. 87-2617-Y, 1989 WL 169006, at *4 (D. Mass. Dec. 11, 1989).

78 *Amgen I*, 706 F. Supp. at 103–04. For the subsequent case history, *see Amgen II*, 1989 WL 169006, at *86 (magistrate upholding ruling that rEPO infringed the patent '195's product claims), and *see* Amgen, Inc. v. Chugai Pharm. Co. (*Amgen III*), 927 F.2d 1200, 1219 (Fed. Cir. 1991) (reversing in part by ruling that the '195 patent was invalid but without reversing prior holding that a recombinant protein would infringe a patented isolate derived from natural sources.).

79 *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 884 (1990) (warning of "a real danger that allowing patent scope to be overbroad may enable the individual or firm who first came up with a particular practical application to control a broad array of improvements and applications . . . ."); Dutfield, *supra* note 20 (describing how negotiating for the licensing of some 70 patents is inextricably delaying the development of the "Golden Rice."); Jackson, *supra* note 12, at 17 (reporting that "[p]hysicians and academic medical centers have asserted that high fees and strict licensing terms are already making it difficult to do diagnostic genetic tests for patented genes . . . ."); *id.* (noting that "firms that hold the patents on genes involved in breast cancer and Alzheimer's disease have reportedly exercised their patent-given right to be the sole performer of tests for those defects . . . .").

80 A product patent confers right to the patentee over all uses of a product, including undiscovered uses. The USPTO has rejected the notion "that DNA patent claim scope should be limited to uses that are disclosed in the patent application," explaining that "[a] patent on a composition gives exclusive rights to the composition . . . even if the inventor disclosed only a single use for the composition." Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001).

stage of the innovation process. In industries where innovations are built on top of other innovations, it is critical for patents to incentivize not just one particular link of innovation, but also entire chains of innovations.

III. HOW WE GOT INTO THIS MESS: THE LONG ARMS OF THE *NATURAL EXTRACTS DOCTRINE*

A. Carving out an exception to the prohibition against the patenting of nature

Section 101 of the Patent Act defines four categories of subject matter that is eligible for patenting.[81] Despite *Chakrabarty's* expansive interpretation of patentable subject matters, U.S. case law has also long prohibited (and continues to prohibit) the patenting of a *product of nature*—or more broadly, laws of nature, natural phenomena, and abstract ideas.[82] Thus, neither a new mineral discovered in nature, a new plant found in the wild, natural laws such as Einstein's celebrated equation, $E = mc^2$, nor Newton's law of gravity constitute patentable subject matter.[83] Nor can one claim "a novel and useful mathematical formula,"[84] electromagnetism or steam power,[85] "[t]he qualities of . . . bacteria, . . . the heat of the sun, electricity, or the qualities of metals."[86] Prior to *Chakrabarty*, life forms and genes were generally considered a product of nature and ineligible subject matter.[87]

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81 35 U.S.C. § 101 (2006) grants patent protection for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."

82 Diamond v. Diehr, 450 U.S. 175, 185 (1981); *accord* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980); Parker v. Flook, 437 U.S. 584, 589 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); O'Reilly v. Morse, 56 U.S. (15 How.) 62, 113 (1854); Le Roy v. Tatham, 55 U.S. (14 How.) 156, 174–75 (1853); *In re* Bergy, 596 F.2d 952, 965 (C.C.P.A. 1979).

83 *Chakrabarty*, 447 U.S. at 309; *Flook*, 437 U.S. at 593 n.15.

84 *Flook*, 437 U.S. at 585.

85 *O'Reilly*, 56 U.S. at 113.

86 *Funk*, 333 U.S. at 130. Other examples of prohibited subject matter include: the Pythagorean theorem ($a^2 = b^2 + c^2$), *In re* Bergy, 596 F. 2d at 965, earth's acceleration constant ($a = 32$ ft/sec^2), In re Meyer, 688 F.2d 789, 794 (C.C.P.A. 1982), formulas to compute a circle's circumference ($C = 2 \cdot \pi \cdot r$), *Flook*, 437 U.S. at 595, the Arrhenius equation, *Diehr*, 450 U.S. at 188, and the multiplication tables, *Flook*, 437 U.S. at 598 (Stewart, J., dissenting).

87 *See* Kane, *supra* note 24, at 735.

A prominent exception to the prohibition against the patenting of nature relates to the patentability of purified biological or chemical products.[88] Under the *natural extracts doctrine*, so long as a biological or chemical product requires human activity to obtain and confers novel properties not found in the natural version of the product, the product would be considered patentable subject matter.[89] For example, Pasteur was allowed in 1873 to patent his famous yeasts even though he never "created" any new species of organisms.[90]

The modern genesis of the *natural extracts doctrine* is Learned Hand's seminal *Parke-Davis* decision.[91] In *Parke-Davis*, Learned Hand held that purified adrenaline was patentable subject matter because adrenaline, once purified and extracted, became a product that differed "not in degree, but in kind" from that of the naturally occurring form.[92] In *Parke-Davis*, Hand suggested that an analysis of the underlying molecule to ascertain whether a new compound was really created was not important.[93] Nor did it seem in general important to evaluate the essence of the contribution to the art. Instead, Hand took a more pragmatic approach, focusing on the benefits offered by the alleged new product from a *layman's* perspective, constructively proclaiming that an artificial compound would be created as long as some novel properties were offered.[94] As

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88 *See* Kane, *supra* note 24, at 746 (noting that "even natural products can be rendered patentable"). Kane also explains that

> [t]he development of the judicially created product of nature doctrine has been a formidable obstacle for patent applicants presenting inventions derived from the natural world. . . . If the product itself is not altered, an argument can be advanced that removal of the product from its natural context constitutes an inventive act which facilitates use. . . . [Subsequent case law, however, has created] the practice of denoting a natural product as 'isolated' to distinguish it from the naturally occurring product [where the distinction is made not on basis of actual molecular alterations but on the grounds of utility conferred by purified compounds].

Id. at 732–33, 739–41.

89 *See* Kane, *supra* note 24, at 738–41.

90 *See* U.S. Patent No. 141,072 (granted July 15, 1873) (claiming, among others, "[y]east, free from organic germs of disease, as an article of manufacture").

91 Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

92 *Id.* at 103.

93 *Id.* (asserting that "even if [the adrenaline] were merely an extracted product without change . . . [and thus, merely] a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.'').

94 *See id.* at 115 (stating "[t]he line [between the natural and the artificial] . . . is to be drawn . . . from the common usages of men [rather] than from nice considerations of dialectic."). How-

later case law would also affirm,[95] since purified adrenaline "for every practical purpose [is] a new thing commercially and therapeutically," it constituted a new artificial and hence patentable product.[96]

Modern courts have widely adopted Hand's approach. In the *Amgen* and *Genentech* cases, the courts upheld product patents for purified EPO and purified Factor VIII:C because both purified products required human intervention to isolate and offered novel therapeutic properties that their natural counterparts allegedly did not.[97] In *In re Bergy*, the United States Court of Customs and Patent Appeals ("CCPA") held a "biologically pure culture of the microorganism Streptomyces vellosus" to be patentable subject matter because such cultures "can be produced only under carefully controlled laboratory conditions"

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ever, as Learned Hand noted in his conclusion, while an understanding of the underlying technology was not critical, even Hand acknowledged that it should be relevant. *Id.*

> I cannot stop without calling attention to the extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon such questions as these. . . . The court summons technical judges to whom technical questions are submitted and who can intelligently pass upon the issues without blindly groping among testimony upon matters wholly out of their ken. How long we shall continue to blunder along without the aid of unpartisan and authoritative scientific assistance in the administration of justice, no one knows; but all fair persons not conventionalized by provincial legal habits of mind ought, I should think, unite to effect some such advance.

Id.

95 *See* Kane, *supra* note 24, at 739–41 (discussing some of the case law); *see also In re* Bergy, 563 F.2d 1031, 1032, 1035 (C.C.P.A. 1977); Scripps Clinic & Research Found. v. Genentech, Inc. (*Scripps I*), 666 F. Supp. 1379, 1394 (N.D. Cal. 1987); Amgen, Inc. v. Chugai Pharm. Co. (*Amgen I*), 706 F. Supp. 94 (D. Mass. 1989). For a detailed and nuanced discussion of the evolution of the natural extracts case law, *see* Demaine & Fellmeth, *supra* note 7, at 331–60.

96 *Amgen I*, 706 F. Supp. at 103. Note that while Judge Hand did seem to conclude that there was structural dissimilarity, he chose, as a matter of law, a convenient level of granularity for comparison. *See* Parke-Davis, 189 F. at 98 (observing that "The chemical distinction between 'substances' depends, not upon the presence of the same atoms, but upon their definite structural association in known proportion into molecules . . . ."). (As following discussion will show, the boundary between natural and man-made is often dependent upon the level of granularity under which the innovation is examined. *See infra* note 178 and accompanying text.) The real justification and motivation for deeming the isolated and purified adrenaline to be novel in Parke-Davis was a rationale based on utility—the extracted compounds were novel because of the novel therapeutic functions offered by the extracts. *See* Demaine & Fellmeth, *supra* note 7, at 338. For a critique of basing patentability on utility, *see id.* at 351–52.

97 *See Scripps I*, 666 F. Supp. at 1394; *Amgen I*, 706 F. Supp. at 103–04.

and enabled antibiotic lincomycin to be collected in sizable quantities for the first time.[98]

The seminal decision in *Diamond v. Chakrabarty*[99] set the stage for dramatically broadening the application of the *natural extracts doctrine*. In *Chakrabarty*, the Supreme Court held that microorganisms were not ineligible subject matter since patentable subject matter "include[s] anything under the sun that is made by man."[100] In deciding whether genetically engineered bacterium constituted a new manmade bacterium (rather than say a mere reshuffling of naturally occurring genes), the Court followed a logic similar to that set out in *Parke-Davis*. Instead of looking to see what was really being contributed to advance the art, the Court instead simply looked to the benefits offered by the transgenic bacterium for proof that a new product had been created. The Court pronounced that a genetically engineered bacterium constituted a new manmade product because it possessed "markedly different characteristics from any found in nature" with its capabilities to break down multiple components of crude oil, rendering the transgenic bacterium "a product of human ingenuity."[101]

While the Court did not deal directly with the issue of whether genes constituted patentable subject matter, the decision nevertheless profoundly affected the legal status of gene subject matter eligibility.[102] Even though the

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98 *In re* Bergy, 563 F.2d 1031, 1032, 1035 (C.C.P.A. 1977).

99 447 U.S. 303 (1980).

100 *Id.* at 309 (holding that microorganisms should not be disqualified as patentable subject matter merely by fact of being living organisms since Congress had intended "anything under the sun that is *made* by man" to be patentable). While the Court did deal with the issue of whether life forms constitute eligibility subject matter, the Court mainly held on the ground of whether recombinant organisms constituted natural discoveries or man-made inventions. *See id.* at 306 (arguing that "the fact that microorganisms . . . are alive [is] without legal significance" and thus that "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."). *But see id.* at 322 (Brennan, J., dissenting) (arguing that "[i]t is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern."). The USPTO would announce in 1987 that non-naturally occurring nonhuman multi-cellular living organisms were patentable subject matter under 35 U.S.C. § 101. Patent & Trademark Office: Nonnaturally Occurring Non-Human Animals Are Patentable Under 101, 33 Pat., Trademark & Copyright J. (BNA) 664 (1986).

101 *Chakrabarty*, 447 U.S. at 309–10.

102 *See* Kane, *supra* note 24, at 736 (noting that "[the *Chakrabarty*] decision is frequently characterized and cited for its effect on opening the gates of the patent system to biotechnology . . . [even though ironically it] did not specifically address the patent eligibility of . . . genes, a fact that is often overlooked . . . ."); GARY ZWEIGER, TRANSDUCING THE GENOME: INFORMATION, ANARCHY, AND REVOLUTION IN THE BIOMEDICAL SCIENCES 161 (McGraw-Hill

Court made it clear that its decision should not be taken as any statement of policy, the gene floodgate broke.[103] In 1995, the United States Court of Appeals for the Federal Circuit ("CAFC" or "Federal Circuit") affirmed that partially published sequences were patentable.[104] In October 1998, the USPTO issued the first patent for a gene fragment (an EST) to InCyte Pharmaceuticals Inc.[105] Today a large number of genes are patented—from genes with little understood functions to genes with well understood functions, and from small sequences constituting gene fragments (such as ESTs and SNPS) to full sequences representing complete genes.[106]

B. Ineffective legal patchwork to stem the uncomfortable tide of biotech patents

As discussed *supra*, the proliferation of genomic patents has attracted much attention and concern. The USPTO has attempted to reinvigorate the utility requirement while the Federal Circuit, in one of the more interesting twists of modern intellectual property law, has tried to create a new independent quid pro quo written description disclosure requirement. As will be discussed *infra*, these legal patchworks have however been ineffective in stemming the uncomfortable tide of biotech patents.

A more effective way to reform the patent system might be through modifying the so-called "patent levers" of the patent regime.[107] The current controversy over the patentability of genes ultimately involves a debate over whether genes constitute the type of subject matter that ought to be incentivized by patents and the scope of product protection is commensurate with gene related

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2001) (detailing the floodgate of biotechnological patenting activities following the *Chakrabarty* decision).

103 *See Chakrabarty*, 447 U.S. at 317.

104 *In re* Deuel, 51 F.3d 1552, 1553, 1555 (Fed. Cir. 1995).

105 NAT'L SCI. BOARD, SCIENCE & ENGINEERING INDICATORS—2002, *Industry, Technology and the Global Marketplace* 6-25–6-32 (Nat'l Sci. Found. 2002), *available at* http://www.nsf.gov/statistics/seind02/pdf/volume1.pdf (last visited Apr. 21, 2007).

106 For a sample of the types of gene fragments that can be patented, see NUFFIELD COUNCIL ON BIOETHICS, *supra note* 23; *see also supra* notes 31–37 and discussions therein (discussing the scope and nature of genomic patents).

107 Burk & Lemley, *supra* note 19, at 1641 (identifying subject matter eligibility, utility, experimental use, level of skill in the art, secondary considerations for obviousness, written description, reasonable interchangeability, pioneer patents, reverse doctrine of equivalents, presumption of validity, new secondary considerations, patent misuse, and injunctions as potential "patent levers" by which an otherwise monolithic patent system can be tailored to industry specific conditions).

inventions or discoveries. In the patent lever framework, this translates into a focus over subject matter eligibility and quid pro quo disclosure enablement.

1. The utility requirement as gateway to patentability of genes

The USPTO currently deems genes—more specifically "excised genes"[108]—to be patentable subject matter as long as the patentee has characterized some gene functions.[109] According to the USPTO, the disclosed invention must have some "specific, substantial, and credible utility."[110] The USPTO's emphasis on utility is, ironically, reminiscent of the Supreme Court's failed attempts to rein in speculative patents on grounds of utility in *Brenner v. Manson*.[111] In *Brenner*, the Supreme Court declared that the purpose of patents is to protect inventions with "substantial utility"—i.e. inventions where "specific

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[108] *See, e.g.*, *Ex parte* DNA Sequence Coding for Human Tissue Plasminogen Activator Originating from Human Normal Cells, 27 U.S.P.Q.2d 1067, 1068 (B.P.A.I. 1993) (disallowing a patent over a DNA sequence because the claims "contain no indication that the DNA sequence is either purified or isolated. Therefore, it appears that the DNA sequence to which these claims are directed does not distinguish from the naturally occurring substance.").

[109] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092–97 (Jan. 5, 2001) (comments 1, 4, 7, 8, 10, 16, and 19). Many businesses have argued that genes should be patented because the patent is directed toward the excised gene not the naturally occurring genes, where the extractions require sophisticated biotechnological techniques to isolate. *See* RIFKIN, *supra* note 1, at 37.

[110] Utility Examination Guidelines, 66 Fed. Reg. at 1093. The USPTO explains,

> [i]f a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. . . . [However,] where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

Id. at 1095. Utility can arise from an observation as simple as the ability of a gene fragment to hybridize near a disease-associated gene. *Id.*

[111] Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (holding that "'[A] patent system must be related to the world of commerce rather than to the realm of philosophy . . . .'"). Interestingly, note also that if the goal is to incentivize discoveries of gene functions, as it would appear from the USPTO's emphasis on the disclosure of utility, the award of a product patent would be too broad. If a gene possesses multiple functions, the award of one broad product patent would disincentivize the discoveries of other functions yet to be discovered. A method patent over the use of a gene's function might be more appropriate. *Cf. infra* notes 193–197 and accompanying texts for an analogous discussion of product versus method patents for the protection of drug/chemical extracts.

benefit exists in currently available form."[112] The Court struck down a patent for a tumor-fighting drug candidate where the only indication of utility was that the compound's structure was similar to that of a compound that had previously been proven to inhibit tumors in mice.[113] Concerned that such early, speculative patents would impede subsequent innovations,[114] the Court famously pronounced, "a patent is not a hunting license"[115] and that a patent is "not a reward for the search, but compensation for its successful conclusion."[116]

Subsequent case law considerably downplayed *Brenner's* specific utility approach.[117] Determining whether an invention has "substantial utility" has proven to be much more difficult than anticipated.[118] Given the compressed

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112 *See id*. at 536.

113 *Id*. at 521–22, 531–32.

114 *Id.* at 534 (expressing concerns that patents over early stage technologies would "confer power to block off whole areas of scientific development, without compensating benefit to the public.").

115 *Id.* at 536.

116 *Id.*

117 *See In re* Brana, 51 F.3d 1560, 1567–68 (Fed. Cir. 1995); Mueller, *supra* note 16, at 161 (discussing how the Federal Circuit has given little attention to *Manson* and has in fact lowered the bar back toward the more lenient pre-Manson "practical utility" standards); *see also In re* Brana, 51 F.3d at 1567–68 (clashing with the USPTO over whether the threshold of utility for compounds required FDA approval for clinical trials).

118 Eisenberg and Nelson describing the blurring boundary between basic science and applied research for researchers working under Donald Stokes' so-called "Pasteur's Quadrant":

> the objective [of such researchers] is to achieve the fundamental understanding necessary to solve practical problems. . . . This hybrid motivation characterizes most research in the biomedical sciences as well as in material science, computer science, and theoretical work in engineering . . . posing a serious challenge to a taxonomy that draws a sharp distinction between basic science and applied technology. In recent years private industry has been a growing source of funds for academic research in these areas, and universities have been increasingly inclined to patent their discoveries. . . . The other side of the coin is that corporate research and development (R&D) often involves the pursuit of fundamental knowledge . . . [where s]ome private firms perform basic research, and many of their researchers publish scientific papers, although for-profit firms are less inclined than universities to place their findings in the public domain without restrictions.

Rebecca S Eisenberg & Richard R Nelson, *Public vs. Proprietary Science: A Fruitful Tension?* 131 DAEDALUS 89, 91 (2002); *see also* Geoffrey Duyk et al., *Attrition and Translation*, 302 SCI. 603, 605 (2003) (discussing the need for the public and private sectors to "develop a consensus on the boundary between precompetitive and competitive research activities (as well as licensing and intellectual property policies) that preserves the necessary exclusivity required for commercialization and rewards innovation"); Malcolm R Parks & Mary L Disis,

timelines of innovations today, that proposition has only become even more difficult.[119] In fact, the isolation of any gene fragment may be argued to inherently possess "substantial utility" since purified and isolated sequences of genetic materials are the raw materials needed to enable almost any biotechnological techniques used to study or manipulate the genetic material. [120] "Substantial utility" has in practice ceased to be a useful doctrine,[121] except apparently, at the USPTO.[122]

Conflicts of Interest in Translational Research, 2 J. TRANSLATIONAL MED. 28 (2004), *available at* http://www.translational-medicine.com/content/pdf/1479-5876-2-28.pdf (discussing the conflict of interests between basic and applied research that can arise in the translational research setting).

119 *See*, *e.g*, Dutfield, *supra* note 20 (noting that "the dividing line between invention and discovery has become increasingly difficult to determine").

120 According to the USPTO rules,

> an inventor's discovery of a gene can be the basis for a patent [so long as it has been] isolated from its natural state and processed through purifying steps. . . . An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because . . . an excised gene . . . [purified] DNA molecule does not occur in that isolated form in nature . . . . Patenting compositions or compounds isolated from nature follows well-established principles . . . .

Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001). As Dr. Michael Gillen, a member of Canada's Patent Appeals Board, added with respect to his company's successful patenting of BRCA1, "the BRCA1 cancer gene—as an isolated gene— . . . can [be] put . . . into a kit and use[d] . . . in a test to test for cancer. The gene as it occurs in nature doesn't have that same utility. That's where the value-added comes, and that's the intellectual part of the equation and that's why patents are granted." Ken Ernhofer, *Ownership of Genes at Stake in Potential Lawsuit*, CHRISTIAN SCIENCE MONITOR Feb. 27, 2003, *available at* http://www.csmonitor.com/2003/0227/p07s03-woam.html.

121 JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 160–61 (Apen Publishers 2003).

122 According to the USPTO rules,

> If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the 'utility' requirement. That is, where the application discloses *a specific, substantial, and credible utility* for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

Utility Examination Guidelines, 66 Fed. Reg. at 1093 (emphasis added).

2. Federal Circuit's new quid pro quo written description requirement

The Federal Circuit has apparently taken an alternative tack by creating a heightened written description requirement for biotechnology-related inventions.[123] This attempt to create a new independent quid pro quo "written description" requirement has fostered an intra-Circuit controversy that the Federal Circuit Bar Association Patent and Trademark Appeals Committee has cited as one of the top conflicts in current Federal Circuit jurisprudence.[124]

35 U.S.C. § 112 is the modern statutory basis of the disclosure requirement, consisting of three requirements: enablement, written description, and best mode.[125] Traditionally the key gatekeeper of disclosure, the enablement requirement is assessed at the time of filing and requires a detailed enough disclosure that enables one of ordinary skill in the art to practice the invention.[126] The enablement requirement represents the quid pro quo of the *basic patent bargain*. In return for a grant of monopoly rights, a patentee must disclose the

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123 *See* Dan L. Burk & Mark A. Lemley, *The Law, Technology and the Arts Symposium: The Past, Present and Future of the Federal Circuit: Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 694–96 (2004) [hereinafter Uncertainty Principle]; Burk & Lemley, *supra* note 19, at 1653–54 (observing that the court's new requirement "would be inconceivable in other industries, such as software . . . [but the] effect is to narrow the scope of biotechnology patents—or at least DNA patents—rather dramatically.").

124 Fed. Circuit Bar Assoc. Patent and Trademark Appeals Comm., *Conflicts in Federal Circuit Patent Law Decisions*, 11 FED. CIR. B.J. 723, 725 (2001) [hereinafter Conflicts]; *see also* Duane M. Linstrom, *Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as It Applies to Genetic Patents*, 40 SAN DIEGO L. REV. 947, 969–70 (2003) (lamenting that "[t]he latest Enzo decision has clarified some issues, but ultimately leaves the 112 written description requirement for genetic patents in a continued state of uncertainty . . . .").

125 According to section 112, ¶1 of the Patent Act,

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶1 (2006).

126 *Id.*; *see* Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070–71 (Fed. Cir. 2005); LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005); Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1313 (Fed. Cir. 2004); Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1263 (Fed. Cir. 2004); PPG Indus. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 1654 (Fed. Cir. 1996).

invention in such sufficient detail as to *enable* the public to practice it.[127] That is, the patent must place the public "in possession"[128] of the claimed invention.[129] The written description requirement is an administratively constructed rule that is traditionally invoked in the context of "time gap" situations.[130] The rule pro-

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[127] *See* Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1372–73 (Fed. Cir. 1999) (invalidating broad claims over a biotechnology method involving "antisense" to control the expression of individual genes when even patentee had only demonstrated the technique to a few cell types, whence the "amount of experimentation required to adapt the practice . . . was quite high"); Newman v. Quigg, 877 F.2d 1575, 1581–82 (Fed. Cir. 1989) (holding that an inventor need not "correctly set forth, or even know, how or why the invention works . . . [but must teach] how to achieve the claimed result, even if the theory of operation is not correctly explained or even understood."); *see also In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (constructing an "undue experimentation" standard for assessing enablement); *In re* Fisher, 427 F.2d at 839 (holding that the "undue experimentation" standard is fact-specific and can turn on a variety of factors such as how "predictable" or "unpredictable" a technology is). For specific applications, see The Incandescent Lamp Patent, 159 U.S. 465, 474 (1895) (invaliding Sawyer and Mann's broad claim over the use of fibrous or textile materials for incandescent lighting on the ground that the claimed subject that the public was not placed "in possession" of the invention, that it would take the genius and work of an Edison to properly enable the claimed invention); *O'Reilly*, 56 U.S. at 120 (invalidating Morse's claim for all methods of communicating at a distance over electromagnetic waves on the ground that Morse had only actually demonstrated (i.e. enabled) one such methods); *In re* Angstadt, 537 F.2d 498, 502 (C.C.P.A. 1976) (stating that "the scope of enablement provided to one of ordinary skill in the art . . . is . . . to be commensurate with the scope of protection sought by the claims."); *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (holding that "the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.").

[128] *See*, *e.g.*, *In re Angstadt*, 537 F.2d at 502 ("What is of maximum concern . . . is whether that disclosure contains sufficient teaching regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and to use the claimed invention."); Eisenberg & Merges, *supra* note 15, at 38 ("The requirement of an enabling disclosure . . . is justified as a means of ensuring that the public receives its quid pro quo for the patent monopoly.").

[129] Placing the public "in possession" is important for at least two reasons. First, such disclosure promotes further dissemination of ideas and can spur further innovations. *See* FED. TRADE COMM'N, *supra* note 4, at 2 (noting that "[b]ecause the patent system requires public disclosure, it can promote a dissemination of scientific and technical information that would not occur but for the prospect of a patent."). Second, such public disclosures ensure that the invention is placed squarely in the public domain after the patent expires. *Id.*

[130] *See* ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 208 (Aspen 3d ed. 2003); MUELLER, *supra* note 121, at 83; *see also* Burk & Lemley, *supra* note 19, at 1652–53 (discussing how historically written descriptions "served the purpose now served by claims: to define the technology protected under the patent, and to put the public on notice of the boundaries that would define infringement" under "older versions of the patent statute that lacked a requirement for the inventor to provide claims" and that "[b]ecause these purposes are now served by the claims, the written description criterion has

vides a framework to date and assign priority of inventions when issues regarding priorities of inventions arise. This can occur for example when amendments are made in patent applications, when a patent claims the priority date of another patent application, or in interference proceedings.[131] Best mode, having a more modern origin, requires applicants to disclose the *best use* of their invention.[132] The theory is that to fully communicate an invention, an inventor must disclose not just the substance of the invention but also the context in which the invention is meant to be used.[133] Recent developments, however, suggest that the best mode rule may soon be discarded.[134]

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evolved to serve a new purpose . . . to ensure that at the time the patentee files a patent application, she actually has conceptual possession of the invention she is now claiming.").

131 MUELLER, *supra* note 121, at 88; *see also* Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d, 956, 978 (Fed. Cir. 2002) (Rader, J., dissenting) (quoting *In re* Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976)) ("The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him."); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991) (noting that "[t]he purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*.") (emphasis in original); Eisenberg & Merges, *supra* note 15, at 44–45 (Under the written description requirement, "the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention").

132 *See* 35 U.S.C. 112, ¶1; MUELLER, *supra* note 121, at 76–78.

133 *See* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 922 (Fed. Cir. 2004) (noting that the best mode requirement helps to prevent a situation where "otherwise only an inferior mode would be disclosed."); Christianson v. Colt Inds. Operating Corp., 870 F.2d 1292, 1303 n.8 (7th Cir. 1989) (agreeing with the observation that "the best mode requirement is intended to allow the public to compete fairly with the patentee following the expiration of the patents"); MUELLER, *supra* note 121, at 76–77 (noting that "[s]ome courts have posited that the underlying goal of the best mode requirement is that when a patent expires, members of the public should not only be able to make and use at least one embodiment of the invention, but rather, through the best mode disclosure, should be put in a commercially competitive position with the holder of the expired patent."). *Contra* 3-7 DONALD S. CHISUM, CHISUM ON PATENTS § 7.05 (2002) (disagreeing with the 7th Circuit's view on the ground that it "ignores the realities of the patent system and the commercial marketplace" where rarely will the best mode known at the time of application "be of competitive interest when the patent expires . . . .").

134 A recent House bill has been introduced to eliminate the requirement altogether. *See*, *e.g.*, *Public Knowledge*, *H.R.2795: The Patent Reform Act of 2005*, http://www.publicknowledge.org/issues/hr2795. There are other reasons to suspect why the rule might not survive long. *See*, *e.g.*, Steven B. Walmsley, *Best Mode: A Plea to Repair or Sacrifice This Broken Requirement of United States Patent Law*, 9 MICH. TELECOMM. TECH. L. REV. 125, 167 (2002). One ground for abandoning the best mode requirement is in the in-

In *Regents of University of California v. Eli Lilly &Co.*,[135] the Federal Circuit held that a patent claiming all DNA encoding vertebrate and mammalian insulin was defective for failing to disclose the actual DNA sequences even though the patent application did disclose a method that enabled one of ordinary skill in the art at the time of the application to obtain those sequences.[136] The results of *Eli Lilly & Co.* came as quite a shock for many because the Federal Circuit held for the first time that the amount of disclosure an inventor must disclose when filing an application may not be sufficient even if it is sufficient to enable one of ordinary skill in the arts to practice the invention.[137] In *Univer-*

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terest of international patent regime uniformity. The U.S. is the only country in the world with the best mode requirement. Some have argued that in the advent of the WTO agreement over Trade-Related Aspects of Intellectual Property Rights (TRIPs), increasing globalism, and the rising importance of IP in an increasingly technologically driven world, the requirement should be abandoned altogether. *See* BOARD ON SCIENCE, TECHNOLOGY, AND ECONOMIC POLICY, A PATENT SYSTEM FOR THE 21ST CENTURY 127 (Stephen A. Merrill, Richard C. Levin, and Mark B. Myers, eds. 2004), *available at* http://www.nap.edu/books/0309089107/html/127.html. Many have also argued that the requirement should be sacrificed because it is "self-enforcing." As Professor Chisum has noted, "[t]he priority rules on patent rights create ample incentives for inventors to disclose valuable 'best modes,' even if there were no best mode requirement." Donald S. Chisum, *Best Mode Concealment and Inequitable Conduct in Patent Procurement: A Nutshell, A Review of Recent Federal Circuit Cases and a Plea for Modest Reform*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 277, 318 (1997); *see also* Bayer AG v. Schein Pharm., Inc., 301 F.3d 1306, 1325 (Fed. Cir. 2002) (Rader, J., concurring) (proffering that the best mode is unnecessary because it is self-enforcing). Disclosing an invention without disclosing the best mode may not only inspire a competitor to discover the actual best mode, but also enable the competitor to file a subsequent patent that preclude the original pioneer from practicing that best mode! *Id.* Some have noted that if an inventor has qualms about disclosing an invention, they would have kept their invention as a trade secret.

135 119 F.3d 1559 (Fed. Cir. 1997).

136 *Id.* at 1567. Enablement not withstanding, the patentee must also have disclosed "information . . . pertaining to [the] cDNA's relevant structural or physical characteristics," the enabled disclosure of a "process for obtaining human insulin-encoding cDNA" notwithstanding. *Id.*

137 *See* Phillips v. AWH Corp., Nos. 03-1269, 03-1286, 2005 WL 1620331, *5 (Fed. Cir. 2005) (holding that claim terms are constructed according to "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."); Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1378 (Fed. Cir. 2000) (noting that "our precedent is well-settled that a court will typically limit its inquiry to the way one of skill in the art would interpret the claims in view of the written description portion of the specification."); Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed. Cir. 1986) (explaining that "[a] decision on whether a claim is invalid under § 112 2d para., requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.").

sity of Rochester v. G.D. Searle Inc.,[138] the Court invalidated a patent for a non-steroidal anti-inflammatory drug because it failed to disclose the actual structure of the drug.[139] The Court characterized the application as merely "a research plan"—even though the application did disclose a method that enabled one of ordinary skill in the art at the time of the application to isolate the drug.[140] In *Eli Lilly & Co.*, the panel went as far as to declare that, as a matter of law, an independent written description requirement compelled that the disclosure of all biological molecules must categorically include "a precise definition, such as by structure, formula, chemical name, or physical properties," regardless of whether a lesser disclosure would have enabled one of ordinary skill to practice the invention.[141]

Responding to criticisms, a Federal Circuit panel in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*[142] responded that times have changed to justify a change in rules.[143] Judge Lourie tried to articulate the underlying motivation that prompted the court to create a new doctrine:

> [n]ew interpretations of old statutes in light of new fact situations occur all the time. I believe these issues have arisen in recent years . . . [because of the] perceptions that patents are stronger [and are] tempt[ing] patent owners to try to assert their patents beyond the original intentions of the inventors and their attorney . . . Claims are now being asserted to cover what was not reasonably described in the patent.[144]

The Court seems to be especially concerned about the state of biotechnology patents.[145] Lourie went on,

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138 358 F.3d 916 (Fed. Cir. 2004).

139 *Id.* at ,927.

140 *Id.* The patent disclosed a method to identify certain non-steroidal anti-inflammatory compounds that did away with the gastrointestinal side effects (e.g., stomach upset, irritation, ulcers, and bleeding) commonly associated with traditional drugs such as aspirin, ibuprofen, ketoprofen, and naproxen. *Id.* at 917–18, 929–30.

141 *See Eli Lilly & Co.*, 119 F.3d at 1566 (quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed Cir 1993)) (An adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention").

142 323 F.3d 956 (Fed. Cir. 2002).

143 *See id*. at 969.

144 *Id.* at 971–72 (Lourie, J., concurring).

145 *Id.* at 974 ("Perhaps there is little difference in electrical and mechanical inventions between describing an invention and enabling one to make and use it, but that is not true of chemical and chemical-like inventions.").

> 'consider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described.' . . . This is surely part of the recent history of some biotechnology patents.[146]

On the previous page, Lourie reasons this:

> [A]mong the problems . . . in a biotech context is that a functional description of DNA does not indicate which DNA has been invented. And simply acknowledging the presence of a DNA that serves a particular function, whose existence has been postulated since, perhaps, Mendel, plus a general process for finding it, is not a description of the DNA. It is a research plan at best, and does not show 'possession' of any invention.[147]

Recently, the court seems to be retracting its bid to create a new independent written description requirement. In *Union Oil Co. of California v. Atlantic Richfield Co.*,[148] the court held that "[t]he written description requirement does not [necessarily] require the applicant 'to describe exactly the subject matter claimed, [but only that] the description must clearly allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed.'"[149] In *Falkner v. Inglis*,[150] the court seemed to retract even further by proclaiming that "there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure."[151] Then as if harping back on the merits of enablement, the

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146 *Id.* at 975 (quoting *In re* DiLeone, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971)). It is unclear to the author why the court is concerned about an inventor not actually reducing to practice C when he had already enabled one skilled in the art to do so. The court has never required a subject matter to be actually reduced in order to be patentable.

> To serve as constructive reduction to practice, the disclosure of the subject matter . . . must meet the requirements of 35 U.S.C. § 112, first paragraph . . . [, which stipulates that t]he specification shall contain a written description . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . . .

Bigham v. Godtfredsen, 857 F.2d 1415, 1417 (Fed. Cir. 1988); *see also* Elan Pharmaceuticals, Inc. v. Mayo Found. for Med. Educ. and Research, 346 F.3d 1051, 1055 (Fed. Cir. 2003) (holding that though the "disclosure in an assertedly anticipating reference must be adequate to enable possession of the desired subject matter . . . [by] the public . . . [i]t is not, however, necessary that an invention disclosed in a publication shall have actually been made . . . .").

147 *Gen-Probe*, 323 F.3d at 974.

148 208 F.3d 989 (Fed. Cir. 2000).

149 *Id.* at 997; *see also* Conflicts, *supra* note 124, at 732.

150 448 F.3d 1357, 1366, 1368 (Fed. Cir. 2006).

151 *Id.* at 1366, 1368. The court further explained,

Court asserted that "[a]s each field evolves, the balance also evolves between what is known and what is added by each inventive contribution."[152]

The Federal Circuit's attempt to create a new written specification requirement has drawn mixed reactions. Some have applauded the court's action as a necessary check on the explosion of biotech patents[153] while others have denounced it as an overly reactionary response that perilously distorts established patent doctrines.[154] The court's recent actions may be considered adven-

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> As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly we hold that where . . . accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here 'essential genes'), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences.

Id. at 1368.

152 *Id*.

153 *See*, *e.g.*, Scott A. Chambers, *Written Description and Patent Examination Under the US Patent and Trademark Office Guidelines*, 6 IP LITIGATOR 9, 10 (Sept.–Oct. 2000),

> Thus, the Federal Circuit's present interpretation of the written description requirement maintains the vitality of the US patent system, and provides disclosures that others can build on. By suggesting that disclosure of the structure or actual sequence of complex chemical entities may sometimes be required, the Federal Circuit may have advanced the goal of the patent system to actually put the claimed invention into the hands of the public.

Id.; 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, 1260–61 (2000),

> Without a heightened written description requirement, inventors could receive patent rights to sequences of which they have no knowledge, in organisms with which they have never worked . . . . Therefore, the Federal Circuit's approach to the written description requirement in the area of biotechnology has prevented nucleotide sequence claims from becoming a Pandora's box that the patent law is unable to control.

Id.

154 *See*, *e.g.*, Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 617 (1998) ("The *Lilly* decision establishes uniquely rigorous rules for the description of biotechnological subject matter that significantly contort written description doctrine away from its historic origins and policy grounding. The *Lilly* court elevate[s] . . . written description to an effective 'super enablement' standard. . . . [This] will likely chill development."); Mark D. Janis, *On Courts Herding Cats: Contending with the 'Written Description' Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 60, 70, 83 (2000),

turous especially since enablement has been successfully applied to a wide variety of fields for a long time.[155] By focusing on the contribution a disclosure makes to the state of the art, enablement represents the basic quid pro quo of patents. By demanding the level of disclosure to be commensurate only with what is required by one of ordinary skill the art to practice the invention, it is uniquely adapted to changing technological landscapes.[156] In comparison, the court's judicially constructed written description requirement appears almost too rigid, superficial, and formalistic.[157] The court's recent actions raise the specter of "judicial improvisation"[158] and unnecessarily unsettle judicial expectations.[159]

> [T]he written description requirement is a threat to the coherence of disclosure doctrines . . . ." "Today . . . the written description requirement enjoys a prominence wholly out of proportion to its humble origins. . . . Recent efforts to elaborate the 'possession' standard both confirm the substantial redundancy of the enablement and written description requirements and illustrate the capacity of the written description requirement to serve as a tool for judicial improvisation.

Id.

155 *See* Burk & Lemley, *supra* note 19, at 1648–51 (discussing how "calibrated" notions of enablement has been successfully applied across a wide variety of fields through notions of PHOSITA (i.e. perspective of the person having ordinary skill in the art)).

156 *See* Enzo Biochem Inc. v. Gen-Probe Inc., 323 F.3d 956, 982 (Fed. Cir. 2002) (Rader, J., dissenting),

> Beyond mere adequacy of disclosure, [enablement] serves as the line of demarcation between the visionary theorist (adds nothing to the useful arts) and the visionary pioneer (contributes to the useful arts [citations omitted] and also serves to limit claim scope thus demarking the boundary between pioneer inventions and patentable improvements. [citations omitted] The WD [written descriptions] possession test cannot perform these functions.

Id.; *Enzo Biochem, Inc. v. Calgene Inc.*, 188 F.3d 1362, 1375 n.10 (Fed. Cir. 1999) (In assessing enablement and "[i]n view of the rapid advances in science, we recognize that what may be unpredictable at one point in time may become predictable at a later time."); *In re* Vaeck, 947 F.2d 488, 495–96 (Fed. Cir. 1991) (In assessing enablement, where claims involve "pioneering," "unpredictable" technologies, "the required level of disclosure will be greater than, for example, the disclosure of an invention involving a 'predictable' factor such as a mechanical or electrical element.").

157 In response to the Federal Circuit's recent decisions, the PTO has created a new Written Description Guidelines allowing an invention to be described by its functional characteristics "when coupled with a known or disclosed correlation between function and structure." Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001); *see also* Lawrence T. Kass & Michael N. Nitabach, *A Roadmap for Biotechnology Patents? Federal Circuit Precedent and the PTO's New Examination Guidelines*, 30 AIPLA Q.J. 233, 248–61 (2002) (reviewing the revised utility and written description guidelines).

158 *See* Mueller, *supra* note 154, at 70.

The Court's willingness to undertake such adventures highlights how serious the problem the biotech patent floodtide is and how a solution is desperately needed.

C. A better tack to controlling the biotech patenting floodgate

Rather than relying on an unworkable notion of utility or inventing a new unproven doctrine to control the flood of biotech patents, this paper proposes a better way to confront the biotech patent explosion. The paper argues that the root cause of the floodgate is a misconception of science and technology created by the *natural extracts doctrine*. These misconceptions have mischaracterized the boundary between the natural and the manmade and skewed the process by which innovations are assessed. The paper argues that for these misconceptions to be corrected, the *natural extracts doctrine* must be promptly abandoned. Drawing from insights into the economics of patents and innovations, this paper argues that for patents to incentivize innovations in the biotechnological context for the long term, subject matter eligibility must be reinvigorated and patent scope must be vigilantly limited.

Subject matter and quid quo pro disclosure enablement can be thought of as two of at least six "patent levers" through which the patent system can be reformed and adapted. Generally, the six major gatekeepers to the patent system—subject matter, novelty, utility, nonobviousness, and quid pro quo disclosure (i.e. enablement)—can be considered to constitute six natural "patent levers."[160] These requirements can in turn be grouped into roughly three categories. The first, the subject matter requirement, invokes questions of general policy regarding whether a subject matter belongs to a class of inventions that ought to be incentivized through the patent system.[161] Ironically, despite the controversy surrounding broad biotechnological patents, no court has yet meaningfully

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159 "[T]he Supreme Court repeatedly cautioned against the disruption of the settled expectations of the inventing community." *Gen-Probe*, 323 F.3d at 982 (Raider, J., dissenting). "The responsibility for changing [settled law] rests with Congress. Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 739 (2002).

160 *See id.*; 35 U.S.C. §§ 101–103, 112 (2006); Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1311 (Fed. Cir. 2004).

161 *See* Kane, *supra* note 24, at 725 (noting that subject matter patentability requirement "remains as the gatekeeping provision of patent law and might be characterized as the patent law version of standing").

evaluated the role of subject matter eligibility in the biotechnological context.[162] The second category of patentability requirements—involving novelty, utility, and nonobviousness requirements—defines a minimal threshold of contribution that inventions must make for the patent system to offer patent protection.[163] The third category of patentability requirements relates to disclosure, the most important of which is the quid pro quo enablement requirement, which requires that the scope of patents awarded be commensurate with the contribution an invention makes to the art.[164] Since the current controversy over the patentability of genes involves, ultimately, a debate over whether genes constitute the type of subject matter that ought to be incentivized and what scope of protection should be awarded for gene related discoveries, concerns about the gene patent floodgate can probably best be addressed through reforms of the subject matter eligibility and the quid pro quo enablement requirements.

IV. THE PROBLEM WITH THE NATURAL EXTRACTS DOCTRINE

The *natural extracts doctrine* was originally created to carve out a narrow exception against the patenting of nature in order to allow for the patenting of certain pharmaceutical products.[165] Under the *natural extracts doctrine*, products extracted from nature constitute patentable subject matter as long as the extraction involves human intervention and the isolated product offers novel properties unavailable in the natural form. The Federal Circuit's chemical-

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[162] *See* Kane, *supra* note 24, at 763 (noting that "[i]n contrast to the lengthy judicial struggle with the patent eligibility of software inventions and algorithms, no judicial scrutiny of DNA gene sequences as patentable subject matter has occurred despite significant public controversy."); *see also supra* note 42 and accompanying text (discussing Supreme Court's reversal to grant cert for a recent case raising issues of subject matter eligibility in the biomedical context). This may seem all the more surprising since "[d]octrinally, the patentable subject matter inquiry is the locus for much of the vigorous opposition to DNA gene patents because the determination of patent eligibility governs the entry of genes into the patent system." Kane, *supra* note 24, at 727.

[163] *See infra* note 254 and accompanying text.

[164] *See supra* notes 126–129 and accompanying text.

[165] *See* Demaine & Fellmeth, *supra* note 7, at 311–12 (arguing that "[t]he traditional doctrine forbidding the patenting of naturally occurring phenomena or purified versions of preexisting products was slowly undermined by a series of misinterpretations of then-existing patent law by a few circuit courts. The resulting patent doctrine was reinforced by misreadings of the 1952 Patent Act . . . [by] the Federal Circuit . . . ."); *id.* at 460–61 (observing that "[t]he increased pressure on courts [around the turn of the century] to reward persons who had not strictly invented anything but who had found something potentially useful in the medical sciences led many to reinterpret the term "discovery" in its modern context, so as to undermine the requirement of invention.").

centric perspective of genes,[166] viewing genes as chemical extracts, paved the ground for extending the application of the *natural extracts doctrine* to the gene context, a context far beyond what was originally envisioned.

A. The level of granularity at which the boundary between the natural and manmade is evaluated is unarticulated and inaccurately presumed

The boundary between the "natural" and "artificial" as defined by the *natural extracts doctrine* depends heavily on an unstated and uninformed level of granularity at which innovations are evaluated. Contrast the cases of *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[167] and *In re Bergy*.[168] The invention ins *Funk Brothers* concerned a unique mixture of bacteria which when applied to certain leguminous plants enabled the plants to fix nitrogen directly from air.[169] The invention in *Bergy* concerned a purified culture of Streptomyces vellosus which allowed researchers to collect the antibiotic lincomycin in sizable quantities. Under *Parke-Davis*, both microorganism cultures should constitute patentable subject matter because both inventions required human effort to extract and both products exhibited novel, useful properties.[170] Yet, the courts held that the nitrogen fixing mixture in *Funk* was not patentable subject matter[171] while the purified lincomycin producing culture in *Bergy* was.[172]

These two seemingly inexplicable results can be explained by the granularity at which the courts examined the invention. In *Funk Brothers*, the Court drilled down and evaluated the bacteria at a microscopic level.[173] The Court invalidated the patent on the ground that "[t]he combination of species produces no new bacteria, no change in the [disclosed] species of bacteria . . . . Each species has the same effect it always had. The bacteria perform in their natural way."[174] Viewed at this level of granularity, "these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all

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166 *See supra* notes 186–187 and accompanying text.

167 333 U.S. 127 (1948).

168 563 F.2d 1031 (C.C.P.A. 1977).

169 *Funk Bros.*, 333 U.S. at 131.

170 *See supra* notes 92–96 and accompanying text.

171 *Funk Bros.*, 333 U.S. at 131.

172 *In re Bergy*, 563 F.2d at 1032.

173 333 U.S. at 131.

174 *Id.*.

men and reserved exclusively to none."[175] On the other hand, in *Bergy*, the United States Court of Claims and Patent Appeals ("CCPA") assessed the invention at a much higher level of granularity.[176] Focusing on the end user's perspective, the CCPA held that a "biologically pure culture of the microorganism Streptomyces vellosus" was patentable subject matter because such cultures "can be produced only under carefully controlled laboratory conditions," allowing manufacturers to collect the antibiotic lincomycin in sizable quantities for the first time.[177] It did not matter whether any new bacteria were created or whether the new bacterium functioned in unexpected ways. All that mattered was that it produced some useful new properties.

The discrepancies between *Funk* and *Bergy* illustrate the importance of the granularity at which innovations are evaluated under the *natural extracts doctrine*. Had the Supreme Court in *Funk* assessed the bacteria at a more macroscopic level as the CCPA did in *Bergy* or Learned Hand did in *Parke-Davis*, the law should have deemed the Funk bacteria a patentable "manufacture" since the Funk bacteria did offer novel characteristics (i.e. nitrogen fixing) that naturally occurring cultures do not. By the same token, had the *Bergy* court—and, for that matter, the *Parke-Davis*, *Amgen*, and *Scripps* courts also—evaluated their respective final purified products at a low enough level of granularity, the courts would not have found patent eligibility. At a low enough scale of granularity, the bacteria mixtures in *Bergy*, the adrenaline extract in *Parke-Davis*, the extracted EPO in *Amgen*, and the Factor VIII:C in *Scripps* would all have been no more than a mere restructuring of natural elements because, at a low enough scale of granularity, almost any product invention can be considered a product of—or a mere rearrangement of the products of—nature.[178]

Even the recombinant invention in the seminal *Chakrabarty* case is not immune to the level of granularity at which it is evaluated.[179] At the granularity

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175 *Id.* at 130.

176 563 F.2d at 1032, 1035.

177 *Id.*

178 *See* Arrhythmia Research Tech. Inc. v. Corazonix Corp., 958 F.2d 1053, 1063 (Fed. Cir. 1992) (observing that "[e]verything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.'")

179 *See* RIFKIN, *supra* note 1, at 46 (quoting Key Dismukes, former Study Director for the Committee on Vision of the National Academy of Sciences, to clearly and forcefully articulate the misguided logic underlying the patenting of life),

> Let us get one thing straight: Ananda Chakrabarty did not create a new form of life; he merely intervened in the normal processes by which strains of bacteria exchange genetic information to produce new strains with an altered metabolic pattern. "His" bacterium lives and reproduces itself under the forces

of the organism level, the Court probably correctly pronounced that recombinant organisms constituted a new "manufacture" since a new organism with a never before seen characteristic, the ability to break down an oil slick, was indeed created. However, had the Court evaluated recombinant organisms at a lower level of granularity, say at the genetic element level, the Court would probably have found no "manufacture."[180] Recombinant organisms would have been deemed the results of mere reshufflings of naturally occurring genes no more artificial than Funk's remixing of naturally occurring bacteria. Each fragment of recombinant genes would have been considered to work as it always did, endowing each alleged new organism with wholly predictable properties arising from the mere re-aggregation of naturally occurring elements. At the level of genes, barring modification to the actual sequence of genes, recombinant genes could not be considered "artificial" patentable "manufacture[s]."[181]

Obviously, innovations should not be evaluated at an overly high or overly low level of granularity. Part of the problem with the natural extracts doctrine is that by presuming an unarticulated level of granularity at which innovations are evaluated, the *natural extracts doctrine* prescribes *as a matter of law* an arbitrarily high level of granularity at which innovations are to be evaluated. This leads to mischaracterizations of innovations, especially when innovations are evaluated by impacts made to society rather than contributions to the arts. At a high enough level of granularity, all technologies can seem magical. Consequently, at a high enough level of granularity, all technologically derived products can be deemed artificial.

> that guide all cellular life. Recent advances in DNA techniques allow more direct biochemical manipulation of bacterial genes than Chakrabarty employed, but these too are only modulations of biological processes. We are incalculably far away from being able to create life *de novo* . . . . The argument that the bacterium is Chakrabarty's handiwork and not nature's wildly exaggerates human power and displays the same hubris and ignorance of biology that has had such devastating impact on the ecology of our planet.

Id.

180 *See* Kane, *supra* note 24, at 733 (noting the importance and difficulty of distinguishing "whether an inventor has simply manipulated naturally occurring processes (which argues against patentability) or when an inventive act has occurred to generate a non-naturally occurring organism.").

181 Note that even if no new manufacture is created, the innovation can still be valuable and be protected. A method patent could issue for example on use of a transgenic gene to confer a specific property to a specific bacteria species.

B. The high level evaluation of innovations codifies outdated science

Historically, as scientific fields mature, they steadily moved from higher to ever-lower levels of granularity in terms of understanding and ability to manipulate.[182] If legal understanding is to keep up with technological understanding, the granularity at which the law assesses innovation should evolve to conform to the current understanding of the state of the art as well.

Consider how the meaning of "manufacture" can have different meanings in the two drastically different fields of metallurgy and soil preparation. In metallurgy, alloys—the combination of two or more metals to enhance properties such as hardness and conductivity—are considered manmade (and hence patentable) even though alloys, in general, are mixtures of *known natural products* to produce novel material properties, not unlike the way that Funk's bacterial mixture was a mixture of bacterial assembled to produce novel soil properties.[183] The reason that metallurgical combinations are considered patentable "manufacture[s]" while Funk's bacterial mixtures would probably not arise from differences in the state of the art between two fields. The thrust of metallurgy is in finding novel combinations of known metallurgical components that give rise to novel bulk material properties. As such, the level of granularity at which innovations are evaluated is at bulk sample or alloy level (i.e. whether the alloy exhibits novel properties) not the level of the constituting elements. In contrast, the thrust of soil preparation technology at the time of *Funk*, unless the Supreme Court got it wrong, did not share this attribute. A person skilled in the arts would have already routinely been studying and making soil preparations based on understanding of the properties of microorganisms in the soil. Hence the exhibition of novel soil properties, even if useful, did not per se constitute a creation of a new product. What was actually achieved—what was really contributed to the arts—was a novel use of a mixture of bacteria. Thus neither science nor law (correctly) recognized the creation of a new product. Under that lens, according to the Supreme Court, "[e]ach species has the same effect it always had"; hence no new patentable "manufacture" was deemed to have been formed.[184]

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182 Physics, for example, started out as a study of macro phenomenon, but as the field matured, the thrust of it moved to ever-smaller scales. Medicine, too, has similarly moved from studying macro phenomenon to studying micro and molecular phenomena. *See* RIFKIN, *supra* note 1, at 32–36.

183 *See* Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 780–81 (Fed. Cir. 1985) (emphasizing on analyzing whether the combinations of elements are new and not whether the elements by themselves are new).

184 *See Funk Bros.*, 333 U.S. at 130-31.

Failure to appreciate the state of the art can thus dramatically distort the application of patent law.[185] To assess Funk's soil bacterial mixtures at a higher level of granularity than the microscopic granularity, deeming the bacteria mixtures to be manmade products simply because it exhibited new soil properties, or conversely to assess today's metallic alloys at a level of granularity lower than the bulk sample level, deeming all alloys to be mere remixes of natural products, would be to mischaracterize each respective innovation. Such mischaracterizations would discourage innovations and constitute codification of inaccurate science.

Such a miscodification, unfortunately, may be partly behind the Federal Circuit's current persistence in treating genes as nothing more than mere chemical extracts. Instead of embracing the functional roles genes play in biology—as templates and directions for life—which would presumptively not be patentable as elements of nature or natural knowledge,[186] the Federal Circuit has steadfastly persisted in viewing genes as mere chemicals, treating genetic products—including DNA's, cDNA's, RNA's, EST's, SNP's, etc.—as chemical extracts.[187] This chemical-centric view of genetics stems no doubt in part from the court's relative familiarity with chemical inventions and relative unfamiliar-

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185 The assessment of patentability under a PHOSITA framework requires innovations to be assessed by a person of ordinary skill in the arts, which can be heavily influenced by the dominant paradigms of the field. Thomas S. Kuhn, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (University of Chicago Press 3d ed. 1996). As Kuhn has noted, even though science is practiced under the banner of objectivity, scientific and technological fields in general still develop through evolution of paradigms. *Id.* at 23–34. In any one epoch, the framing of questions and assessment of advances are evaluated through perspectives of paradigms. *See id.* at 52–76 (discussing how established paradigms frame potential empirical discrepancies and how these discrepancies in turn drive future scientific advancements); *see also supra* notes 219–220 and accompanying text (discussing the use of PHOSITA). If science proceeds under paradigms, the law should not be ignorant of these paradigms in assessing innovations.

186 In *Amgen Inc. v. Chugai Pharm. Co.* ("*Amgen I*"), the district court held that the DNA claims at issue could not have been directed toward the "DNA sequence encoding human EPO since that is a nonpatentable natural phenomenon 'free to all men and reserved exclusively to none.'" No. 87-2617-Y, 1989 U.S. Dist. LEXIS 16110 at *88–*89 (D. Mass. 1990). Instead, the invention must have been directed toward underlying genetic compounds, "the 'purified and isolated' DNA sequence encoding erythropoietin." *Id.*; *see also* Examination Guidelines, 66 Fed. Reg. 1092, 1092-97 (Jan. 5, 2001) (explaining that "[a] DNA sequence is not patentable because a sequence is merely descriptive information about a molecule.").

187 The Federal Circuit views genes as "a chemical compound, albeit a complex one . . . ." Amgen, Inc. v. Chugai Pharm. Co. ("*Amgen II*"), 927 F.2d 1200, 1206 (Fed. Cir. 1991). The USPTO has pronounced that while "a DNA sequence itself is not patentable . . . [a] purified DNA molecule isolated from its natural environment, on the other hand, is a chemical compound and [may be] patentable." Utility Examination Guidelines, 66 Fed. Reg. at 1094.

ity with innovations in biotechnology, but the reduction of the genetic patentability debate into an issue of chemical patentability is inappropriate if the thrust of the field involves the study and manipulation of information contained in gene sequences. The main purpose and effect of patenting genes appears to be for control over the use of genetic information.[188] Genes are much more than the DNA in which they are encapsulated.[189] Genes contain information that not only encodes proteins that control all biochemical pathways but also regulate each other's expression. Even the so-called junk DNA has been found to serve important regulatory, if not evolutionary, roles.[190]

The high level, black box evaluation of innovations promoted by the *natural extracts doctrine*, uninformed by evolving scientific paradigms, inevitably codifies outdated or inaccurate science into the law.[191] This is unfortunate as it discourages innovations. Only by evaluating innovations at the proper level of granularity can patents effectively incentivize contributions to the art. Only by recognizing the true nature of genes and the broad ramifications gene patents

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188 *See* Eisenberg, *supra* note 43, at 786–87, 788–89 (suggesting that the primary motive to patenting genetic materials is for control over the information coded by the molecules); Heller & Eisenberg, *supra* note 16, at 699–700 (describing the use of so-called reach-through license agreements (RTLAs) that gives the patentee of a prior patent rights in subsequent downstream discoveries made using the patent); Jackson, *supra* note 12, at 11 n.13 (explaining that "genes are expressions of information, but . . . the information contained in them is essentially a work of nature (and is valuable mainly because it is broadly found in nature) . . . ."); RIFKIN, *supra* note 1, at 37 (noting that "[g]enes are the 'green gold' of the biotech century. The economic and political forces that control the genetic resources of the planet will exercise tremendous power over the future world economy, just as in the industrial age access to and control over fossil fuels and valuable metals helped determine control over world markets. . . . A battle of historic proportions has emerged between the high-technology nations of the North and the poor developing nations of the South over the ownership of the planet's genetic treasures."); *id.* at 48–60 (discussing in more detail the struggle between the first and third world nations over control of the planet's genetic resources).

189 *See* Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 836 (1999) ("Although DNA is, obviously enough, a chemical compound, it is more fundamentally a carrier of information."); Kane, *supra* note 24, at 712–13 ("The complexity of the DNA molecule requires a theory of the gene that incorporates its duality as chemical and template to properly evaluate its eligibility for patent protection."); *id.* at 765 (noting that patenting of extracted gene products constitute "effective occlusion [of the unpatentable] through the patenting of products or methods which are the only means of accessing the unpatentable.").

190 *See*, *e.g.*, BRUCE ALBERTS ET. AL., MOLECULAR BIOLOGY OF THE CELL 491 (4th ed. 2002); Barmak Modrek & Christopher Lee, *A Genomic View of Alternative Splicing*, 30 NATURE GENETICS 13, 18 (2002).

191 *Cf.* Burk & Lemley, *supra* note 31, at 1191 (arguing that "the Federal Circuit application of the PHOSITA standard in [biotechnology and software] is wrong as a matter of science.").

have on research and innovations can the law fully address the issues raised by genomic patents.[192]

C. The high level, black box evaluation of innovations confuses product for process innovations

A specific result that arises from the high level, black box evaluation of innovations promoted by the *natural extracts doctrine* is the confusion of process innovations for product innovations.[193] This doctrine awards the first to extract, by the mere fact of being the first to extract, to obtain a patent not only on the extraction techniques but on the extracted product as well even though the innovation does not involve the actual creation of a heretofore-unknown product. This is problematic because in reality product and method innovations constitute distinct inventive endeavors.[194] In law, product and method patents should thus be distinguished, not confused.[195]

Product patents confer rights over a physical product to the patentee. As such, product patents should be awarded only when a truly new material or

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192 *See* Eisenberg, *supra* note 43, at 786–87; Kane, *supra* note 24, at 764–66.

193 *See* MERGES, *supra* note 130, at 903 (concluding that arguments that equate process innovations for product innovations are "not convincing.").

194 From a utility perspective, the first isolation of a chemical and the creation of a chemical that provide a novel therapeutic effect need not be distinguished because both provide the same effect—i.e. the same impact on society. For a scientist working in the field, however, the distinction is important to make because the contributions made to the art by the two inventions are very different, and it is upon these contributions that future advancements are made.

195 As Kane noted,

> A patent on a compound grants a patent holder rights to all uses of the compound, present and future. The concern about patents granted to underdeveloped compounds is that if a compound is presented for patenting but is not fully characterized, an issued patent will allow its holder to control all uses of the compound, whenever and wherever those uses are developed. Although a later inventor could identify a new use for the compound and receive a method patent for that use, the inventor must still negotiate with the compound patent holder in order to utilize that compound.

Kane, *supra* note 24, at 718–19. Consider the case of Biocyte and a patent over umbilical derived blood cells, where "this patent was awarded simply because Biocyte was able to isolate the blood cells and deepfreeze them. The company made no changes in the blood itself." RIFKIN, *supra* note 1, at 61. Another example is a patent by Systemix to cover all human bone marrow stem cells even though Systemix had not altered the cells in any meaningful way. *Id.* at 62.

substance has been conceived and reduced to practice.[196] Because a product patent awards a right to monopolize the product itself, casually awarding overly broad product patents can impede subsequent innovations by discouraging, for example, innovations relating to alternative uses involving the product or new processes for isolating or manufacturing the product.[197] Method patents confer rights over a novel use or process to the patentee. If all that an innovation involves was the extraction of an otherwise existing product from nature or the discovery of a novel use for an extracted product, a method patent over the novel extraction technique or newly discovered use would properly compensate the inventor for such invention—and without unnecessarily impeding future innovators from making subsequent innovations.

Under the *natural extracts doctrine*, method innovations and product innovations are often confused because, at a high enough level of abstraction, innovations can come to be characterized by the benefits they confer rather than the substantive contribution they make to state of the arts.[198] When adrenaline was purified, Judge Hand did not have to have to base his opinion on whether the alleged innovation involved the creation of an extraction process or the creation of an actual new product. Instead, Hand could treat the invention as a black box, evaluating innovations by their impact on society rather than their contribution to science.[199] An extracted product could become patentable solely on the basis that the product brought about a substantial enough benefit to society.

The award of patents based on impact instead of contribution to the arts is however an ineffective way to promote the types of scientific and technologi-

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196 In today's biotechnological context, this most likely means that a novel, unique molecular structure needs to be created. *See* Fellmeth, *supra* note 22, at 547-48 (arguing that if "any [protein] product is patentable, it is a protein that has been substantially transformed by way of physical alteration so as to perform a new biological function.").

197 *See*, *e.g.*, *Parke-Davis*, 189 F. at 97.

198 Note that while patents are to incentivize technological progress, patent incentives should be based on the contribution made to the state of the art, not by their impacts to society. It is province of the law to award patentees for contributions to the state of the art while it is the province of the market to award inventors for the impact made on society. *Cf.* Graham v. John Deere Co., 383 U.S. 1, 9 (1966) (holding that evidence of commercial success (indicative of impact on society) could be considered only to be secondary, probative factors on patentability issues such as utility and obviousness (indicative of contribution to the art)).

199 *See Parke-Davis*, 189 F. at 103 (focusing on the existence of novel commercial and therapeutic utility to judicially construct a new compound); Kane, *supra* note 24, at 739 (noting that Hand's "analysis relied on the potential unleashed by purification of a natural substance-even if the act of purification does not alter the substance in any manner . . . . This finding of patentable subject matter particularly relies on the *utility* doctrine for legitimacy; a focus on usefulness is an analytic recourse also used in determinations of computer-related patentable subject matter.") (emphasis added).

cal progress.[200] It is the contribution to the science that future scientific progress will be built. Impact on society is an issue for the marketplace, not the patent system, to address. In the context of today's biotechnology, unless an invention involves the actual creation of a new product (e.g., creation of a new molecular structure or at least some novel media to stabilize an otherwise unstable purified product),[201] patents should probably be limited to cover the novel process and/or use, but not the related product as well.[202]

D. The misconstruction of science and technology creates substantive legal and policy problems

The mere codification of outdated or inaccurate science would not by itself be a problem if the law could nevertheless effectively incentivize innovation. Unfortunately, getting the science wrong does discourage innovations.[203] The *Scripps* and *Amgen* cases showcased how seriously an overly broad patent can adversely impede subsequent innovations. The concern is amplified several fold in the genetic context.[204] Even as our knowledge about biology expands

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200 For example, to a computer user, the user may be agnostic about how a computer is sped up - whether it is achieved through increased memory, faster co-processor, or improved architecture. The impact, at a high enough level of granularity, is the same. However, to a engineer working in the field, the specific type of improvements made is all important. To accurately decipher the innovation, it is necessary to isolate what has really been innovated. It is these underlying innovations that the patent ought to be concerned because it upon these innovations that progress is built.

201 *See supra* note 196.

202 Other scholars have similarly advocated similar positions. *See*, *e.g.*, 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, 394–95 (2003) (arguing for revitalization of the prohibition against the patenting of nature to the context of DNA patents); Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 392 (2002) (advocating for a more rigorous "substantial transformation test" where an extracted product should be significantly altered from its natural form before it can qualify for patenting); Rai & Eisenberg, *supra* note 64, at 299 (suggesting that a "reinvigoration" of the subject matter restriction requirement to the context of DNA and other bio-molecules would constitute good policy).

203 *See* Qin Shi, *Patent System Meets New Sciences: Is the Law Responsive to Changing Technologies and Industries?*, 61 N.Y.U. ANN. SURV. AM. L. 317, 344 (noting that "[t]o promote continued innovation and efficient commercialization in these areas, it is clear that courts and the PTO, in applying patent rules and standards, ought to make special efforts to stay informed of technology advances and their commercial implications.").

204 Adelman, *supra* note 16, at 997 (noting that there has been "a significant rise in defensive patenting, particularly in the genomic sciences."); L. B. Andrews, 803 Nature Rev. Genet. 3

geometrically, the number of genes is fixed and limited.[205] Some have suggested that there is no evidence that broad patents discourage subsequent innovations, at least in the genetic context.[206] Such arguments may be too short sighted. Evi-

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(2002) (noting that the impact of gene patents on scientific research and medical care can be especially severe because there are no alternatives to using a patented gene in making advances in diagnosis, treatment, and research); Jackson, *supra* note 12, at 20 (noting that genetic workarounds are practically impossible especially when the practice of patent portfolio and thickets are incorporated). *See* Matthew Herper, *Genome Scientists: Gene Patents Are Bad*, FORBES June 26, 2002, *available at* http://www.forbes.com/2002/06/26/0626targets.html (quoting Craig Venter, a famous biologist who has himself taken out many gene patents, admitting that "[b]locking another biotech or a pharmaceutical company from trying to come up with a cure for disease really does block research . . . and the public loses. Why should one company say that's their unique source of biology?"); Kane, *supra* note 24, at 766 (observing that the deleterious effects of gene patents would be orders of magnitude worse than that caused by pharmaceutical product patents because of the fundamental "asymmetry in the central dogma [of genetics], where DNA is a template for a protein, but not the reverse."); Paradise, *supra* note 54, at 1566 (noting that "there are no alternatives to a patented gene in diagnosis, treatment, and research"). Besides negatively impacting technological progress through exclusionary legal rights, gene patents may also be negatively impacting progress by changing research culture, such as by disincentivizing research collaboration and sharing of research and data. *See* M. K. CHO, PREPARING FOR THE MILLENNIUM: LABORATORY MEDICINE IN THE 21ST CENTURY, 47-58 (AACC Press, Orlando, FL, ed. 2, 1998); Eric. G. Campbell et al., *Data Withholding in Academic Genetics Evidence From a National Survey*, 287 JAMA 473, 477–80 (Jan. 23/30, 2002); J. F. Merz et al., 415 NATURE 577, 578–79 (Feb. 7, 2002).

205 *See* RIFKIN, *supra* note 1, at 12 (noting that "[t]he speed of the discoveries is truly phenomenal. It is estimated that biological knowledge is currently doubling every five years, and in the field of genetics, the quantity of information is doubling every twenty-four months.").

206 *See* Lee Bendekgey & Diana Hamlet-Cox, *Gene Patents and Innovation*, 77 Acad. Med. 1373, 1378 (2003) (arguing that there is very little if any evidence that gene patent has inhibited research activities); F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U.L. REV. 691, 703–04 (noting that "basic biology research process, like any process, can be viewed as one that requires inputs and generates outputs, and experience shows that patents on inputs generally do not prevent the production of outputs."); John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, 299 SCI. 1021, 1021 (2003) (observing that "IP on research tools, although sometimes impeding marginal projects, rarely precluded the pursuit of worthwhile projects" because of "working solutions" such as "licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges, and . . . infringement"); *id.* (noting that in many cases patentees have willingly allowed academic research infringement simply because in the long run "it can increase the value of the patented technology."); Adelman, *supra* note 16, at 999, 1001 (reporting that "[studies have] found that, although time consuming, negotiations over licensing agreements rarely halted projects and that royalty payments rarely threatened the commercial viability of downstream products and virtually never halted research projects. . . . [Thus while] the expanding number of patents requires more negotiations for licenses and increases

dence of discouragement may be subtle and may not manifest until further in the future.[207] As discussed above and will be discussed further below, because biotechnological innovations also typically develop cumulatively, it is important for patent scope to properly assess and incentivize contributions made at each round to ensure that entire chains of innovations, not just a targeted few phases, are incentivized.[208]

V. AN ECONOMICS FRAMEWORK FOR UNDERSTANDING PATENT SCOPE

The policy foundation underlying this country's intellectual property regime is decidedly utilitarian.[209] The patent regime constitutes an important

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the costs of biomedical research, it has not led to Heller and Eisenberg's dire anticommons predictions."); John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCI. 2002, 2002 (in a most recent study, reporting that none of a random sample of academics under study reported stopping a line of research due to third party patents, and that only about 1% of the researchers reported experiencing a delay or modified their research due to third party patents). ."). *See also* Kieff, *supra*, at 704 (observing that the "ability for patents to bring immense amounts of, and diversity in, sources of funding and other resources to the basic biological research community is recognized as a critical factor in the great success the community has enjoyed since 1980."). However, replacing government funding with private funding is not necessarily good. As Senator Birch E. Bayh noted in a keynote speech to the AUTM conference in San Francisco on 3/9/2007, when universities come to depend on private funding to sponsor some of the important basic research money can be, there is a risk that the most sensitive of our research can be outsourced to foreign countries in the future. Senator Birch E. Bayh, Keynote Speech to the AUTM Conference in San Francisco (March 9, 2007).

207 *See* Walsh, Cho & Cohen, *supra* note 206, at 2003 (concluding that while the results of the study "offer little empirical basis for claims that restricted access to IP is currently impeding biomedical research, []there is evidence that access to material research inputs is restricted . . . . [I]t is not clear whether patent policy contributes to restricted access to materials, although the commercial activities fostered by patent policy do seem to restrict sharing, as [however also] do the burden of producing the materials and scientific competition.").

208 *See supra* note 200 (discussing through an example why it is so important to assess innovations by their contribution to the arts not other metrics such as impact to society).

209 U.S. CONST. art I, § 8, cl. 8. *See* FED. TRADE COMM'N, *supra* note 4, at 14 ("The PTO functions as a steward of the public interest . . . to encourage invention, disclosure, and commercial development"); *see generally* ROBERT PATRICK MERGES, PATENT LAW AND POL'Y: CASES AND MATERIALS 1–13 (2d ed. 1997) (discussing general patent history and theory); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–44 (1989) (surveying various theories in support and critique of patents); Frank D. Prager, *A History of Intellectual Property From 1545 to 1787*, 26 J. PAT. OFF. SOC'Y 711 (1944) (tracing origins of Western patent law). For a survey of non-utilitarian arguments for and against patents, see references cited in *supra* note 23.

policy lever through which Congress promote technological progress.[210] Article I, § 8 of the Constitution provides that Congress shall have the power to "promote the Progress of Science and useful Arts."[211] The Supreme Court has stated that

> [t]he patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right . . . [is] . . . at odds with the inherent free nature of disclosed ideas. . . [o]nly inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly.[212]

Arguably, patent law, more so than most other branches of law, should be policy rather than doctrinally driven.[213] Judges should strive to be informed about the

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210 *See* NIH: Moving Research from the Bench to the Bedside: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 108 Cong. 3, 3 (2003) (statement of Sherrod Brown, Member H. Comm. on Energy and Commerce) ("Policy tools like patents, the Bayh-Dole Act, the Stevenson-Wydler Act, and incentives for commercialization, are important links in the bench to bedside chain."); Burk & Lemley, *supra* note 19, at 1576 (referring to patents as "our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge.").

211 U.S. CONST. art I, § 8, cl. 8. Historical note: the term "Science" in the Constitution actually referred only to copyrightable subject matter. It is the phrase "useful Arts" that corresponds to the modern notion of "technologies" and "industries." *See* MUELLER, *supra* note 121, at 27–28 (discussing the Constitution's so-called IP clause).

212 *Graham*, 383 U.S. at 9; *see also* Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1944) ("A patent . . . is a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts' . . . [constitutes] an exception to the general rule against monopolies and to the right to access to a free and open market.").

213 *See* U.S. CONST. art I, § 8, cl. 8; Burk & Lemley, *supra* note 31, at 1205 (observing that "the current legal rules are not expressly informed by the economics of the industries, but by an ad hoc combination of judicial anthropology and stare decisis. Not surprisingly, they do not reflect optimal patent policy . . . ."). As an aside, for a variety of reasons, Congress has decided to rely on a property-based legal rather than a "policy-actuated" regime to incentivize innovations. In theory, it might be argued that a legal patent regime unnecessarily disintermediates policy from the incentivization of innovations. A policy-actuated regime that bypasses the law (doing away with legal doctrines) and administers innovations directly as part of a country's unified industrial policy might arguably offer a more effective innovation management regime. A policy-actuated "patent regime" might manage innovations similar to the way the Board of Governors of the Federal Reserve manages the interest rate tax or the FDA manages applications for food and drug safety. When the Federal Reserve decides to raise or lower rates, the debate is never over whether the Federal Reserve is following precedent or muddling with established expectations. Instead, the debate is over whether the action will help to accomplish a set goal—effectively managing economic growth. Similarly, when the FDA approves or disapproves certain products, the issue is not over whether FDA is conforming with past behavior (unless of course when corruption or cronyism is sus-

greater technological and economic context in which patents are used.[214] While this does not mean that judges should become policy makers,[215] it probably means that judges should refrain from reasoning behind a cloak of stare decisis and established legal doctrines in applying patent law.

While the application of patent law should be informed by the greater context in which patents are used, the patent system should not be abused to compensate beyond the range of risks the patent system has been designed to compensate.[216] The patent system, as is currently designed and implemented, is

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pected), but over whether consumer safety is advanced. In a policy-actuated innovation or patent regime, the scope of protection given to innovations can be adjusted in accordance with the changing innovation landscape. The focus will be on promoting technological progress instead of following or developing legal doctrines. It is beyond the scope of this paper to deal with the specific issues associated with a policy-actuated innovation regime or the question of whether a property-based legal regime or an industrial policy-actuated regime (or even a rewards-based system (*see generally* Steven Shavell, *Rewards versus Intellectual Property Rights*, 44 J.L. & ECON. 525 (2001))) might be better at promoting long-term technological innovation.

214 *See* John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 102(2001) (arguing that "Only by studying the broader context of patent law, and—in particular—only by locating patent law within a modern world of both publicly funded and privately funded research, can one hope to identify the optimal balance between motivation and constraint that patent monopolies would ideally provide."). *But see* R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341, 1359 (2003) (arguing however that there is little reason to be confident that judges will make economically sound policy based decisions).

215 This paper does not address questions regarding institutional competencies associated with suggested patent reform, leaving that topic for another day.

216 Patents have been used for many purposes unrelated to the incentivization of innovations. Such ancillary uses cannot form primary justifications for patents. In fact, some can be more accurately characterized as transaction costs associated with the existence of a patent system. Patents are often used defensively, as tools to preserve one's right to access a technology and/or increase leverage in license negotiations. *See*, *e.g.*, *supra* note 49; *infra* note 378 (several authors discussing the use of patents to preserve access) and note 251 (citing various references discussing license pools). Patents have also been used as tools to convert a company's unused technological assets into windfall licensing revenue streams. *See generally* RIVETTE & KLINE, *infra* note 371 (regarding "Rembrandts"). Patents can also be used as business valuation tools. *See generally* Richard Razgaitis, VALUATION AND PRICING OF TECHNOLOGY-BASED INTELLECTUAL PROPERTY (Wiley 2003); Jeffery H. Matsuura, *An Overview of Intellectual Property and Intangible Asset Valuation Models*, 14 RES. MGMT. REV. 33 (2004), *available at* http://www.ncura.edu/data/rmrd/pdf/v14n1.pdf; Markus Reitzig, *Improving Patent Valuation Methods for Management*, 33 RES. POL'Y 939 (2004); Robert Pitkethly, *The Valuation Of Patents : A review of patent valuation methods with consideration of option based methods and the potential for further research*, ELECTRONIC JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, *available at* http://www.oiprc.ox.ac.uk/EJWP0599.html.

not an all-encompassing industrial policy regime meant to compensate for the long litany of risks that might be encountered on the uncertain road from the invention of technologies to the commercialization of those technologies (such as marketing, regulatory, legal, implementation, operations, and manufacturing risks). Consider the six major patentability requirements: subject matter, utility, novelty, nonobviousness, and disclosure (enablement, written descriptions, and best mode).[217] These all are motivated by a need to incentivize the creation of innovations, as measured by *contribution made to a technological art*. Other potentially interesting metrics such as *impact on society* or *degree of commercialization* are not the main subject of concern for patents.[218] When the law refers to the perspective of a hypothetical person having ordinary skill in the art ("PHOSITA") in evaluating inventions, courts have almost exclusively limited such inquiries to technical literatures or experts in a technical field.[219] Inquiries revolve primarily around consultation of experts like scientists, engineers, doctors, and technicians involved in the inventive process, *but not* economists, bureaucrats, market analysts, businessmen, regulators, lawyers, psychologists, or even lay users who may be more familiar with the commercialization, marketing, and social impact of the invented technologies.[220]

The use of patents to compensate for extra-innovation risks is in general not appropriate because the returns on such are in general not necessarily nonrivalrous and nonexclusive.[221] In developing commercializations, for example,

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217 *See* 35 U.S.C. §§ 101, 102, 103 & 112.

218 *See supra* notes 198–200 and accompanying text (discussing why it is important to evaluate innovation based on contribution to the state of the art and not impact to society); *infra* notes 254–256 and accompanying text (explaining how patent scopes can be described as broad or narrow with respect to subject matter, enablement, and patentability thresholds such as novelty, utility, and nonobviousness); *infra* notes 347–390 and accompanying text (discussing why it is important to distinguish between innovations and implementation risks).

219 *See* 35 U.S.C. § 103 (mandating that obviousness is evaluated "at the time the invention was made to a *person having ordinary skill in the art* to which said subject matter pertains." (emphasis added)); 35 U.S.C. § 112 para. 1 (mandating disclosures that "enable any *person skilled in the art* . . . to make and use the same . . . ." (emphasis added)); Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950) (applying the doctrine of equivalence by referencing to PHOSITA); Burk & Lemley, *supra* note 19, at 1650 (noting that "PHOSITA-based analysis is specific to the particular art in which the invention is made.); *supra* note 123 (defining enablement by referencing to PHOSITA); Craig Allen Nard, *A Theory of Claim Interpretation*, 14 HARV. J.L. & TECH. 1, 6 (2000) (discussing how claim construction uses a PHOSITA-based analysis to understand terms used in patent claims).

220 For an example of a patent regime that encompass extra-technological factors, see *supra* note 213 and accompanying text.

221 In fact, other than concerns about quality, much of the criticisms against business method patents revolve around the question whether business methods are truly nonexclusive and re-

businesses often can protect and make exclusive its investments in business assets—including branding, product lines, and services—through extra-patent mechanisms such as better execution, trademark, marketing, quality control and/or first mover's advantage.[222] It is thus important to separate efforts to incentivize the creation of innovations and efforts to incentive commercialization of innovations.

As an innovation-centric framework focused on incentivizing creation of innovations, the patent system must accurately assess and be informed about new technological developments. The system must be adept at assessing the true state of the art, recognizing what developments have already been made and what developments still need to be incentivized. It would be tragic—if not unconstitutional—for the law to shield itself from new technological realities or to try to compensate for risks of not innovating only to subvert technological progress in the process. This section presents an appropriate economics framework for discussing patent law and policy. It is hoped that these discussions will not only shed light on the economics of innovation but also help to shape a more enlightened, policy-driven patent regime.

A. The "public goods" problem of innovations and the patent solution

The purpose of patents is to facilitate the development of useful innovations. Innovation needs a "helping hand"[223] because it is a "public good" that is *nonrivalrous* and *nonexcludable*.[224] Innovations take resources to develop but

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quire patent protection. Sufficient incentives may already exist to incentivize business method innovations without patents. *See* Burk & Lemley, *supra* note 19, at 1618 (noting that "companies have ample incentives to [innovate] even without patent protection, because the competitive marketplace rewards companies that use more efficient business methods. Even if competitors copy these methods, first mover advantages and branding can provide rewards to the innovator."); Scherer, *supra* note 12, at 1350 (discussing how non-patent incentives such as a head start could be enough to effectively incentivize innovations).

222 *See id.*

223 *See* Burk & Lemley, *supra* note 123, at 693 (observing that "[l]egal rights in inventions allow inventors to control and profit from goods that are costly to produce, but which are virtually costless to reproduce or to appropriate once they have been created."). Note that imitation by itself should not be frowned. America is built on competition and the "[f]reedom to imitate, to copy, is a cornerstone of competition." LANDES & POSNER, *supra* note 16, at 23. It is the effect of externalization of benefit specifically in the innovations context that raises concern here.

224 A public good is a good that is available to all, once it is produced. It is *nonrivalrous* because consumption by one does not decrease the ability of another to consume; it is *nonexclusive* because it is difficult to exclude others from consuming the same resource once the

are easily copied, conferring benefits to imitators at the expense of the inventor.[225] Such externalizations discourage innovations.[226] The grant of limited-term monopoly rights over inventions helps inventors to better internalize the benefits conferred by their innovations.[227] However, patents, as limited monopolies, incur social costs and present a double-edged sword. While they may help inventors to appropriate economic rents created by monopoly rights, they also incur social costs such as deadweight loss, increasing the cost society must pay for access to the patented innovation.[228] On a larger scale, patents may also discourage subsequent inventors from making follow-on innovations especially when subsequent innovators are required to obtain licenses from the pioneer in order to practice the subsequent innovations.[229]

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resource is produced. For a classical, formal articulation of public goods, see Paul A. Samuelson, *The Pure Theory of Public Expenditure*, 36 REV. ECON. AND STAT. 387 (1954).

225 *See* LANDES & POSNER, *supra* note 16, at 294 (noting that the "conventional rationale for granting [IP legal protection] is the difficulty that a producer may encounter in trying to recover his fixed costs of research and development when the product or process that embodies a new invention is readily copiable.").

226 The amount by which an innovation suffers the "public good" problem depends on a number of factors, including the ease by which inventions are copied, whether the invention is funded by private or public resources, and the ease which market conditions allow innovators to internalize benefits. *See* Burk & Lemley, *supra* note 19, at 1616–17. Innovations that are not easily copied do not pose a big "public goods" problem. Innovations that the public sponsors, such as those through the government, do not pose a major public good problem since their free availability is supposed to ensure that the benefits are all accrue back to the taxpaying public eventually, albeit potentially unevenly. (For a discussion why the Bayh-Dole Act nevertheless promotes the patenting of government-sponsored research, see *infra* notes 367–390 and accompanying text.) Finally, technologies in markets that offer high first mover advantage and barrier to entry also do not pose big problems because those conditions minimize the advantages achieve by copying alone.

227 SCOTCHMER, *supra* note 20, at 127 (noting that the key to incentivizing pioneering innovations is to introduce "incentive mechanisms . . . to make sure that earlier innovators are compensated for their contributions, while ensuring that later innovators also have an incentive to invest."). For an interesting discussion about the use of so-called reach-through licenses, where upstream innovators contractually seek a piece of the profits of downstream products through contracts, to help internalize benefits of innovations, see generally Rebecca S. Eisenberg, *Reaching Through the Genome*, *in* Proceedings of a 2002 Conference Sponsored by the Federal Reserve Bank of Dallas 105, *available at* http://www.dallasfed.org/research/pubs/science/eisenberg.pdf.

228 *See infra* note 235 and accompanying text.

229 *See id.*

B. A more comprehensive analysis that looks beyond the immediate costs and benefits of patents

Among the benefits often cited in favor of patents are that they: provide incentives to innovate; stimulate investment on patentable technologies; rationalize development of broad technology fields; enable disclosure and dissemination of technical knowledge; and provide a good yardstick for businesses to assess the value of technology startups.[230] Among the costs often cited are that they: encourage costly patent races that waste duplicative, overlapping expenditures on R&D; create monopoly profits that result in deadweight loss to society; increase transaction costs by increasing the associated licensing and litigation activities; and impede the development related and follow-on innovations through the creation of blocking patents.[231]

Cost-benefit analysis of the patent system is not new.[232] Most of the literature, however, has focused on the immediate tradeoff between the incentive and the deadweight underutilization of innovations.[233] Influential works in this area include those by Nordhaus, Kaplow, Gilbert, Shapiro, Scherer, and Klemperer.[234] A framework such as one proposed by Merges & Nelson expands the

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230 *See* Jackson, *supra* note 12, at 7; LANDES & POSNER, *supra* note 16, at 294–95 (observing that the purpose of patents is not just to monopolize, but also to disclose knowledge so that others can be spurred to make further innovations); SCOTCHMER, *supra* note 20, at 254–55 (arguing that two inventors each innovating together will lead to faster breakthroughs, where a breakthrough requires at least two sequential inventive steps). *See generally* T. O'Donoghue, *A Patentability Requirement for Sequential Innovation*, 29 RAND J. OF ECON. 654 (1998). *See also supra* note 216 (discussing ancillary uses of patents today having little to do patent regime's basic qui pro quo).

231 SCOTCHMER, *supra* note 20, at 98, 138; *see* Jackson, *supra* note 12, at 7; *see generally* V. Denicolò, *Patent Races and Optimal Patent Breath and Length*, 44 J. OF IND. ECON. 249 (2001).

232 A classic study on the economic impacts of patents is Fritz Machlup, *An Economic Review of the Patent System*, Study No. 15, Subcomm. Pat. Trademark & Copyright, Jud. Comm., 85th Cong., 2d Sess. 9 (1958). Other leading works include WARD S. BOWMAN, JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL, 15–32 (University of Chicago Press 1973), and F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 442–43 (Edward Jaffe 2d ed., Rand McNally 1980) (1970).

233 Burk & Lemley, *supra* note 19, at 1608–10; Merges & Nelson, *supra* note 79, at 869–70.

234 W. NORDHAUS, INVENTION, GROWTH, AND ECONOMIC WELFARE, 3–15 (1969). *See also* BOWMAN, *supra* note 232, at 32–34; Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 993–1000 (1997); SCHERER, *supra* note 232, at 443–50; A. Samuel Oddi, *Un-Unified Economic Theories of Patents—The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267, 273–81 (1996). *See generally* R. Gilbert & C. Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. OF ECON. 106 (1990); Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813 (1984).

scope of analysis by explicitly including both these immediate effects and the downstream costs and benefits as well.[235] In these more comprehensive cost-benefit accounting analyses, the ability of the patents to incentivize innovations and also cause underutilization of those innovations is considered along with those patents' ability to internalize follow-on benefits and impede follow-on innovations.[236]

A brief example illustrates this principle. Consider Morse's claim on telegraphy and his attempt to broadly claim all methods of telecommunications, including subsequent inventions such as the radio and television.[237] Under a traditional cost-benefit framework, the award of a telegraphy patent is justified on grounds to compensate Morse for devoting the resources and taking the risks to develop the telegraph. Society compensates the patentee, Morse, in the form of deadweight loss and reduced overall utilization of the invention that arise from a patent monopoly. An expanded framework opens up the issue to include the question of how broad the scope of a patent should be. Should Morse's invention of the telegraphy be strictly limited to the enabled invention—the telegraph—or should it also entitle him to broadly claim all subsequent telegraphy-based inventions such as the telephone and radio, which are based on Morse's telegraphy work but which still others need work on to invent? On the one hand, Morse should be allowed to broadly claim his invention since that more fully compensates pioneers like Morse whose contribution to society is not just the immediate invention (e.g., the telegraph), but also the foundation upon which many subsequent yet to be enabled inventions (e.g., the telephone and

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235 *See* LANDES & POSNER, *supra* note 16, at 325 (explaining that beyond the immediate cost benefits of patents, "[b]road patent protection has still another, and fundamental, double-edged effect: it increases the return to the first inventor, which encourages invention, but increases the cost of invention to his successors, which discourages invention."); Burk & Lemley, *supra* note 19, at 1609–10 (noting that "Although initial inventors will sometimes be entitled to patent claims that cover later improvements, the later improver also needs incentives to innovate."); Merges & Nelson, *supra* note 79, at 843. *See generally* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PER. 29 (1991).

236 *See id.*

237 The claim at issue is: "I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, signs or letters at any distances, being a new application of that power, of which I claim to be the first inventor or discoverer." O'Reilly v. Morse, 56 U.S. 62, 62 (1854).

radio) will be built.[238] On the other hand, the grant of broad patents will chill follow-on valuable innovations, especially if follow-on inventors will have to license from Morse just to sell or make use of their own inventions.[239]

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238 The dissent argued that Morse's invention lies in the use of electromagnetism to communicate over a distance. No future application of telegraphic innovations would lie outside the scope of Morse's invention since all such applications would be built upon Morse's original insights to use the electromagnetic medium for this purpose. *See Morse*, 56 U.S. at 134–35 (dissent arguing that the significance of Morse's contribution lay "in compelling this hitherto useless element.").

239 Note that doctrinally, patent law has never acknowledged the need to award an inventor for inspiring the future, no matter how high an impact his insights might prove to be. Patents are to be awarded only for enabled innovations. *See* Roger L. Beck, *The Prospect Theory of the Patent System and Unproductive Competition*, 5 RES. L. & ECON. 193 (1983). Nevertheless, telegraphy also no doubt facilitated later telecommunication innovations such as the radio and television. Morse could have even foreseen the development of subsequent innovations such as the radio and telephone and been motivated to make his pioneering contributions based on an expectation of sharing the profits arising from those innovations. *See In re* Fisher, 427 F.2d 833, 839 (CCPA 1970) (discussing that the "inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are will within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that . . . the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification . . . ."). *See also* Scherer, *supra* note 12, at 1361–62 (observing that the enablement requirement allows innovators to internalizes only part of the benefits of his innovation). *But see* Suzanne Scotchmer, *Protecting Early Innovators: Should Second-Generation Products be Patentable?*, 27 RAND J. OF ECON. 322 (1996), *available at* http://socrates.berkeley.edu/~scotch/Sc96.pdf (arguing that under some circumstances, the award of broad pioneering patents and withholding of patents for subsequent innovators might actually promote development of subsequent innovations).

In an ideal market where transaction cost[240] can be ignored, the issuance of broad patents does not per se pose a problem.[241] As Coase has posited, the initial distribution of property rights does not disturb the final optimal distribution of property—i.e. the outcome of a Pareto superior solution—provided transaction costs can be ignored.[242] That is, if transaction costs can be ignored

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240 Transaction cost is a term of art in economics that refers to more than just transaction fees such as lawyer's fees. All economic transactions carry inefficiencies, or transaction costs, which can deter otherwise value producing transactions. *See*, *e.g.*, *infra* note 242 and accompanying text (describing transaction costs in terms of information asymmetry, participant irrationality, and licensing costs). One type of transaction costs arises from information asymmetries. A patentee may use his patents to block the development of a follow-on competing technology even if the new technology will make society or even the patentee better off because the patentee fails to appreciate the new technological landscape well enough. *See generally* LANDES & POSNER, *supra* note 16, at 321–22 (discussing how monopoly leads to complacency and information asymmetry, which ultimately increases transaction costs of licensing.); SCOTCHMER, *supra* note 20, at 147–48 (discussing how entrenched innovators may wish to prolong a previous generation of technologies at the expense of new entrants even though new entrants might bring in more revenues to the original innovators in terms of license royalties). Another type of costs arises from inefficiencies in an economic system. An inventor blocks the development of a clearly superior follow-on technology because—due to a number of factors, including market, economic, and regulatory—the benefits do not efficiently accrue to the inventor. An individual's pursuit of private profits fails to produce an optimized final solution for the overall system. Yet another type of cost arises from the distributive nature of competition. An inventor may fail to cooperate with other inventors when cooperation would have clearly made everyone better off because the inventor is concerned about losing his relative competitive position vis-à-vis other inventors in the open marketplace. *See* LANDES & POSNER, *supra* note 16, at 320–21 (discussing how transaction costs may arise when parties look to game each other in a competitive landscape); Eisenberg, *supra* note 209, at 1072–73 (explaining that "[t]he risk that the parties will be unable to agree on terms for a license is greatest when . . . the research threatens to render the patented invention technologically obsolete."); Heller & Eisenberg, *supra* note 16, at 701 (observing how "people systematically overvalue their assets and disparage the claims of their opponents when in competition with others.").

241 *See* Anastasia P. Winslow, *Rapping on a Revolving Door: An Economic Analysis of Parody and Campbell v. Acuff-Rose Music, Inc.*, 69 S. CAL. L. REV. 767, 780 (1996) (arguing that in accordance with the Coase theorem, the initial assignment of property rights between original creators and improvers is irrelevant).

242 Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1 (1960). *See also* Lee G. Anderson, *Conceptual Constructs for Practical ITQ Management Policies*, *in* RIGHTS BASED FISHING 191, 196 (Philip A. Neher, Ragnar Arnason & Nina Mollett eds. 1989) (concluding that the market for randomly-allocated "Individual Transferable Quotas" in a fish stock management system would lead to efficient allocation through subsequent trading of rights among firms); THRA'INN EGGERTSSON, ECONOMIC BEHAVIOR AND INSTITUTIONS 104–05 (Cambridge University Press 1990) (recognizing that "Coase's main contribution . . . was to arouse our awareness of the implications of *positive* transaction costs."); Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the*

(e.g., if "information is perfect, all parties are rational, and licensing is costless"[243]), the parties will work out a deal that allows the most valuable technologies to be developed, regardless of original ownership of the intellectual property assets (e.g., no matter how broad Morse's patent is).[244] If a patent is overly broad (i.e. if the original intellectual property distribution was incorrect), the pioneer and subsequent innovators will simply negotiate for licenses that redistribute intellectual property rights to facilitate the most valuable subsequent uses and innovations.[245] Morse will license his broad telegraphy patent to enable the commercialization of the radio if the radio is a more valuable invention than the telegraph. Morse will do so even if radios compete with (or out-compete, as the case may be) the telegraph because if the radio is valuable enough, Morse will maximize his income precisely when radios replace telegraphs.[246] In general,

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Cathedral, 85 HARV. L. REV. 1089, 1094–95, 1128 n.12 (1972) (discussing the implication of Coase in a zero-transactional-cost setting); Wendy J. Gordon, *Asymmetric Market Failure and Prisoner's Dilemma in Intellectual Property*, 17 U. DAYTON L. REV. 853, 857–58 (1992) (discussing Coase in the context of efficient licensing); Merges & Nelson, *supra* note 79, at 876.

243 Burk & Lemley, *supra* note 19, at 1602.

244 *See* Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: the Case of Blocking Patents*, 62 TENN. L. REV. 75, 78 (observing that "if a bargain would benefit both parties, they will reach one."). It is in no one's interest to block, and everyone's interest to allow a worthwhile follow-up invention that will in aggregate make everyone better off—provided, of course, that the distributive aspect of this process does not hold up the process. *See also* SCOTCHMER, *supra* note 20, at 133–34.

245 *See generally* LANDES & POSNER, *supra* note 16, at 12–14 (discussing how contractual transactions can help to attain optimal use and investment of properties); SCOTCHMER, *supra* note 20, at 162 (noting that intellectual property disclosures, facilitated by the mechanism of licensing, can promote subsequent innovations by shortening current innovation lifecycle and jump-starting future innovation cycles); H. Demsetz, *Toward a Theory of Property Rights, in* 1 ORGANIZATION OF ECONOMIC ACTIVITY 104, 112–13 (1988) (discussing how licensing and bargaining can lead to efficient redistribution of patent rights); Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?, in* INNOVATION POLICY AND THE ECONOMY 71–72 (Vol. 2, Adam Jaffe, Joshua Lerner & Scott Stern, eds., MIT Press 2001), *available at* http://socrates.berkeley.edu/~scotch/G_and_S.pdf (observing that "the optimal design of the property right should depend on whether firms contract with others for the use of their protected innovations. With fluid contracting, policies that otherwise would be inefficient may be optimal."). Note that the fact that an optimal distribution of IP assets will be reached does not mean that there is an equitable distribution of those benefits. Undeserving holders of overly broad IP in a skewed original distribution for example will be able to benefit from that initial fortune to the extent they do not become so greedy as to block the subsequent innovations from taking place.

246 *See* SCOTCHMER, *supra* note 20, at 135–37 (noting the importance of properly dividing profits in proportion to the actual costs expended by each inventor). In general, an efficient economy (i.e., one with negligible transaction costs) will both correctly value innovations,

whatever shortfall Morse may encounter in revenue shortfalls from telegraphs should be more than made up by increases in royalties from radios.

It might even be argued that if transaction costs can truly be minimized to allow for the efficient redistribution of intellectual property assets, overly broad patents should even be systematically encouraged. Broad patents not only increase blocking, but also boost the number of stakeholders participating in the redistribution process. The increased number of stakeholders increases the number of potential solutions and the chance that an optimal solution can be found through the subsequent intellectual property redistributions.[247] Unfortunately, transaction costs in general cannot be ignored. Transaction costs can arise, for example, from information asymmetry, externalities in the market system, and the distributive gamesmanship of competition.[248] Subsequent transactions in general cannot guarantee an efficient redistribution of intellectual property asset and usage.[249] Consequently, in the real world, the initial distribution

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and guarantee the more valuable innovation to be developed. An appropriation of profits between the pioneer and subsequent innovator redistributes wealth between the pioneer and subsequent innovator but does not make invention any less valuable per se. Transaction costs, in the form of rent seeking, may arise from the distributive process associated with redistributing the wealth. If any one party tries to strike a deal that is too unfair, the party risks blocking the transaction altogether. Assuming this unfair deal is unsuccessful, an "appropriate" license will be negotiated where both the pioneer and subsequent innovator will conclude that the making and using of the subsequent invention is the more profitable route to take.

247 *See* EASTERBROOK, *infra* note 355, at 411 (articulating confidence in private redistribution of property, stating, "the more complex the problem, the more the 'right' answer varies over time and the affected population; and the easier it is to address the problem by private contract, the less we should attempt to resolve it by law."); Burk & Lemley, *supra* note 19, at 1610 (summarizing the literature to argue "that granting patents to both [pioneer and follow-on inventors]—so-called blocking patents—will normally balance incentives [of innovations] correctly"); *id.* (articulating the argument that in cumulative innovations, "unfinished products, early versions, and improvements to a subset of a product should all be patentable.").

248 *See* Merges, *supra* note 244, at 82–89 (discussing scenarios where pioneering and follow-on inventors fail to come to terms).

249 *See* SCOTCHMER, *supra* note 20, at 131 (noting that "intellectual property is a blunt instrument for [this] delicate problem"); Carol Rose, *The Comedy of the Commons: Custom, Commerce, and Inherently Public Property*, 53 U. CHI. L. REV. 711, 718–719 (explaining how "[s]ince the mid-nineteenth century, economists have told us that there exist predictable instances of 'market failure,' where Adam Smith's invisible hand fails to guide privately owned resources to their socially optimal uses. These involve 'public goods,' 'natural monopolies,' 'externalities,' and the like. While some of these problems may be solved by collective agreements among the owners of the resources, such agreements are costly and, particularly where a large number of parties must be involved, private collective action is not always possible. Inefficiencies will remain."); Scherer, *supra* note 12, at 1362 (observing that the determination of "the division of rents between the original discoverer and follow-on

of property cannot be arbitrarily assigned;[250] broad patents (such as that asked for by Morse) cannot be cavalierly awarded.[251] Instead, careful attention should be paid to issuing patents with proper scopes, calibrated to ensure not only efficient incentivization of the innovations, but with an eye toward potentially deleterious effects on subsequent innovations as well.[252]

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developers requires bargaining, and solutions may materialize that either stalemate further progress or undermine incentives for additional private investment in basic discovery."); Lemley, *supra* note 234, at 1048–72 (discussing the results of Coase in the presence of moderate transaction costs); Jerry R. Green & Suzanne Scotchmer, *On the Division of Profit in Sequential Innovation*, 26 RAND 20 (1995), *available at* http://socrates.berkeley.edu/~scotch/Gr_and_Sc.pdf.

250 *See* ROBERT COOTER & THOMAS ULEN, LAW AND ECONOMICS 105 n.15 (Pearson Addison Wesley, 1988) (discussing how the initial distribution of property rights can affect the ultimate level of output despite subsequent trading of rights among bargaining parties).

251 *See* Merges & Nelson, *supra* note 79, at 876 (noting that "as elaboration of the Coase theorem has made clear, the initial distribution of property rights can make a difference in the equilibrium level of output of the bargaining parties."). The *Scripps* and *Amgen* cases discussed earlier provide two prime examples where overly broad patents threaten to impede subsequent innovations. However, patent pooling and consolidations may present potential remedies. *See* T. O'Donoghue, S. Scotchmer & J. F. Thisse, *Patent Breath, Patent Life and the Pace of Technological Progress*, 7 J. ECON. AND MGMT. STRATEGY 1 (1998). *See generally* J. Lerner & J. Tirole, *Efficient Patent Pools*, 94 AMERICAN ECONOMIC REVIEW 691 (2004). On the other hand, patent pools pose unique problems of their own. But patent pooling and consolidations also raise concerns. *See* Barton, *supra* note 14, at 1933 (explaining how patent pools can dilute incentives to innovate). *See also* SCOTCHMER, *supra* note 20, at 176–77 (noting that pools consisting generally of complementary technologies, create real overall value and should be considered generally good; while pools that consist generally of technological substitutes, create artificial market monopolies (with few values) and should be considered generally bad). *See generally* S. Graham et al., *Patent Quality Control: A Comparison of U.S. Patent Re-examinations and European Patent Oppositions, in* PATENTS IN THE KNOWLEDGE BASED ECONOMY, 74–119 (Nat'l Acads. Press 2003) (discussing how patent pools can serve as barriers to new comers in the innovation process); C. Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 119, 139 (2001) (raising various concerns regarding patent pools and joint licensing schemes, including whether pools should be allowed where less restrictive mechanisms, such as cross-licensing, exist to unlock blocking patents); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003) (discussing how patent pools can reduce competition in the market place).

252 *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989) ("The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'").

C. Assessing the proper patent scope

In order to award patents with "proper scopes," it is important to possess a proper framework for assessing such.[253] Patent scope is described in this paper as *broad* or *narrow*, with respect to the contribution to the art, or as discussed in a still later section, the subject matter over which it ought to incentivize.[254] *Contribution to the arts* is a natural yardstick because the ultimate goal of patents is, after all, to incentivize contribution to the arts.[255] The subject matter of a patent is also a relevant yardstick because only certain subject matters that would promote progress should fall under the ambit of the patent system.

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253 A few notable scholarly writings on patent scope include: John B. Shoven, *Intellectual Property Rights and Economic Growth*, *in* INTELLECTUAL PROPERTY RIGHTS AND CAPITAL FORMATION IN THE NEXT DECADE 46, 49–50 (Charles E. Walker & Mark A. Bloomfield eds., University Press of America 1988); Gilbert & Shapiro, *supra* note 234; D. G. McFetridge & M. Rafiquzzaman, *The Scope and Duration of the Patent Right and the Nature of Research Rivalry*, 8 RES. L. & ECON. 91 (1986). *See generally* F. M. Scherer, *Nordhaus's Theory of Optimal Patent Life: A Geometric Reinterpretation*, 62 AM. ECON. REV. 422 (1972).

254 Patent scope may also be described with respect to some threshold of patentability. *See supra* notes 108–116 and accompanying text. Patent thresholds represent another potential way by which the patent system can be reformed. A high threshold of patentability means that a high level of "inventiveness" is generally needed for patentability. A high threshold of patentability will tend to result in fewer patents awarded, each possessing broader claims, as only large break-through innovations would be patentable. A low threshold of patentability will tend to result in more patents awarded, each possessing narrower claims—as small, routine, incremental innovations would be generally patentable. Setting the threshold of patentability too high is not necessarily good. It may over-focus on breakthrough innovations, which may already be adequately incentivized by extra patent incentives such as science-based incentives, while leaving too little incentives for the more routine innovations that depend on patents for development. A high threshold may also heighten anticompetitive-type concerns as well, where such patents endow their owners with potentially very broad market monopoly powers. Setting the threshold of patentability too low is also not necessarily good. Too low a threshold of patentability may produce anticommons concerns, where patent rights are distributed piecemeal among too many patent owners. A low threshold may also produce "junk" patents—where patents are taken out that cover "routine innovations."

255 *See* LANDES & POSNER, *supra* note 16, at 294–95 (observing that for patents to efficiently incentivize innovations, patent scopes should be coincident with the amount that the disclosures enable a person skilled in the arts to practice the invention).

1. Why patent scope should be broader than the contribution to the arts made by the underlying innovation

Perhaps the most compelling argument for broad patents is Kitch's prospector theory of intellectual property.[256] Kitch analogized patent claiming to mining.[257] Just as a miner who discovers a coalfield is entitled to all the coal in the vicinity, not just to the few granules he actually finds, an inventor is entitled to an area of technology *opened up by* his innovation, not just the invention he actually reduces to practice.[258] According to Kitch, to justify the risks and up-front resources needed to make an invention (or to open a new field), inventors must be given "breathing room" to develop their innovations without fear that others—sitting on the sidelines conserving resources, learning and benefiting from the pioneer's initiatives—will unfairly preempt the pioneers at later opportune moments.[259]

Another justification for broad patents is Kitch's theory of coordinated developments.[260] Without broad patents, Kitch observed, intense competition would develop over (often a limited set of) follow-on, related innovations, leading to tremendous waste of resources.[261] When a new area is opened up after a pioneering discovery, it would be more efficient to have one party manage and

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256 In economic terms, prospecting is a mechanism to internalize related and follow-on benefits, as discussed earlier. *See supra* note 239 and accompanying text.

257 Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276–77 (1977).

258 *See* LANDES & POSNER, *supra* note 16, at 13 (describing how broad patent "enables people to reap where they have sown. Without that prospect the incentives to sow is diminished."); Burk & Lemley, *supra* note 19, at 1604 (noting that under "prospect theory . . . patents should be granted early in the invention process, and should have broad scope and few exceptions.").

259 Kitch, *supra* note 257, at 276–77. *See generally* Dasgupta, *Patents, Priority and Imitation or, The Economics of Races and Waiting Games*, 98 ECON. J. 66 (1988) (exploring conditions where waiting is more profitable than joining patent races).

260 Kitch, *supra* note 257, at 279.

261 *Id.*; *see also* Isabelle Brocas, *Optimal Regulation of Cooperative R&D under Incomplete Information*, 52 J. OF IND. ORG. 81 (2004) (discussing how patents promote more sharing of information than in a competitive marketplace); Neil Gandal & Suzanne Scotchmer, *Coordinating Research through Research Joint Ventures*, 51 J. OF PUB. ECON. 173 (1993) (exploring how firms can cut down the cost of innovation by delegating specific follow up research to efficient firms); Pankaj Tandon, *Rivalry and the Excessive Allocation of Resources to Research*, 14 BELL J. ECON. 152 (1983) (analogizing invention races to fishing races in a pool, where "overfishing" result when too many people seek develop the same inventions).

coordinate the subsequent developments in the field opened up by the pioneer.[262] Broad patents enable pioneering patentees to coordinate such developments.[263] Pioneers are arguably in the best position to offer such coordination given the interests, foresight, and expertise they have already exhibited in making the pioneering innovations.

A third reason to prefer broad patents relates to the problems that can arise when *narrow patents* are systematically awarded. This problem is sometimes referred to as the anticommons problem.[264] When narrow patents are awarded, intellectual property assets for a field can become fragmented into pieces, owned by multiple patentees, many of whom are competitors in the marketplace.[265] To assemble any one real-world application, the competitors would have to work together to assemble a wide diversity of intellectual property into a coherent whole. The concern is that the transaction costs involved in coordinating among competitors the fragmented assets can become so prohibitively expensive as to deter[266] the realization of many applications altogether.[267] In gen-

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262 *See* Kitch, *supra* note 257, at 271–75. *See generally* Brian D. Wright, *The Resource Allocation Problem in R & D*, *in* THE ECONOMICS OF R & D POL'Y 41, 49–55 (George S. Tolley, James H. Hodge & James F. Oehmke eds. 1985) (discussing the economic similarity between the general common pool model, which leads to competitive waste as multiple parties compete to make the same follow-on innovations, and the so-called "race" models, where multiple parties compete to make the same early pioneering innovation to attempt to corner a market).

263 *See* Kitch, *supra* note 257, at 285–87.

264 *See* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 64–68 (Princeton 2003) (discussing the problem with patenting research tools and *Madey v. Duke*). *See generally* Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998); Heller & Eisenberg, *supra* note 16, at 699 (explaining that "The tragedy of the anticommons refers to the . . . complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. [Where] [e]ach upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation."); Donald J. Willison & Stuart M. MacLeod, *Patenting of Genetic Material: Are the Benefits to Society Being Realized?*, 167 CAN. MED. ASS'N J. 259, 260 (2002) (noting that "[a]lthough the patenting of upstream discoveries has stimulated a huge influx of private investment capital, inventors of downstream applications are likely to cross the boundaries of several patents, necessitating the 'stacking' of royalties to patent holders. This could reduce the value of all patents, vastly increase legal costs and actually inhibit innovation.").

265 *See generally* Heller, *supra* note 264.

266 A notorious example concerns the experience of a research team formed to study the use of genetically engineered vitamin fortified rice to reduce the incidence of blindness arising from vitamin A deficiency. Just to license the rice, these researchers had to negotiate seventy pat-

eral, concentrating patents into the hands of a select few—either by broadening the patent scope of each patent or by promoting consolidation of the industry[268]—represents one approach to alleviate the anticommons problem. Another approach may be to increase the patentability threshold to make patents harder to get, reducing the total number of patents awarded in a field.[269]

2. Why patent scope should closely track the contribution to the arts made by the underlying innovation

One reason to limit patent scope to the contribution to the art is that it better aligns patent incentives with the goals they are meant to foster. When

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ents with over thirty-one institutions! Even if existence of so many patents does really indicate actual R&D advances, the taking out of so many patents cannot bode well for subsequent research. *See* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 997 (2005); Richard C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management; Intellectual Property Rights*, 299 SCI. 174, 174 (2003); Roger N. Beachy, *IP Policies and Serving the Public*, 299 SCI. 473, 473 (2003); Ronald L. Phillips, *Intellectual Property Rights for the Public Good: Obligations of U.S. Universities to Developing Countries*, 6 MINN. J.L. SCI. & TECH. 177, 181 (2004).

267 ROBERT P. MERGES, INSTITUTIONS FOR INTELLECTUAL PROPERTY TRANSACTIONS: THE CASE OF PATENT POOLS, IN EXPANDING THE BOUNDARIES, IN EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 129 (Rochelle Cooper Dreyfuss et al. eds., 2001) (noting that "[t]he key issue is the cost of integrating disparate rights."); Carl Shapiro, *Setting Compatibility Standards: Cooperation or Collusion?*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY 81, 97–101 (Rochelle Cooper Dreyfuss et al. eds., 2001) (discussing how the general problem of compound marginalization can occur when multiple companies are assigned complementary rights); Lloyd Cohen, *Holdouts and Free Riders*, 20 J. LEGAL STUD. 351, 356 (1991) (discussing how parties holding out can bribe up to the value of the project, increasing the ultimate cost of the project, sometimes prohibitively); Heller & Eisenberg, *supra* note 16, at 700.

268 *See* Burk & Lemley, *supra* note 19, at 1613 (observing that "Economists, by contrast, tend to assume that the solution to vertical complementarity problems [i.e. anticommons problems] is to vertically integrate—that is, to consolidate rights in a single company."); Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 833–36 (2001) (suggesting that to ameliorate the anticommons problem in the biomedical context, biotechnology companies may join with pharmaceutical companies to form large companies that own all the IP assets necessary to carry out activities from research to drug design to manufacture, but also warning that such activities might over-concentrate IP in a few companies).

269 *See* Burk & Lemley, *supra* note 19, at 1613 (observing that "Most legal scholars working in the anticommons literature have assumed that the solution is to grant fewer patents, particularly to developers of upstream products like research tools or DNA sequences."). *See also supra* notes 108–116 and accompanying text (discussing the use of utility to increase the patentability threshold).

gaps develop at the forefront of the state of the art, an effective patent system should effectively and promptly mete out incentives that foster innovations that fill those gaps. To do so, the patent system needs to accurately assess the contours of the state of the art and the contributions made by alleged innovations. This requires that the legal understanding of innovations should be coincident with the actual technological landscape. When either overly broad or overly narrow patents are awarded, gaps between legal understanding and technological reality inevitably occur, reducing the effectiveness of law to incentivize technological innovations.

In general, overly broad patents tend to over-recognize innovations,[270] prematurely recognizing innovations that are not yet made in the field.[271] Overly narrow patents on the other hand tend to under-recognize innovations,[272] refusing to recognize innovations that have already been made in the field.[273] Over-recognition can spur unproductive patent races and promote risky, ill-advised research.[274] The patent frenzy in biotechnology today may be symptomatic of

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270 Consider a broad patent that gives the right to A, B, and C in return for only the enablement of A. Normally, rational parties would spend only up to the (risk adjusted) value of A to develop A. However because of the legal generosity represented by broad patents, a rational party could now spend up to the (risk adjusted) value of A, B, and C for enabling just A. Over-incentivization thus occurs because the amount of the average monopoly rent exceed, after factoring risk-adjusted interest cost adjustments, the cost of R&D. *See* Scherer, *supra* note 12, at 1350.

271 When law over-recognizes innovations, it prematurely recognizes an invention that has really not been invented (i.e. enabled). This distincentives future innovation because when that invention finally takes place, no patent right is available to give.

272 When a patent gives the right over only A in return for the enablement of A, B, and C, the patentee would have to expend the (risk-adjusted) cost of developing A, B, and C in return for getting only the (risk-adjusted) benefit of A. This under-incentivizes the creation of A.

273 When law under-recognizes innovations, it fails to realize that a legitimately current contribution is being made to the state of the art, which in turn disincentivizes innovation.

274 *See* LANDES & POSNER, *supra* note 16, at 361 (explaining how "excessive investment by those seeking patent protection" become "most wasteful when the cost of making the invention is falling rapidly over time . . . for then . . . the making of the invention probably should be deferred."); *id.* at 17–18 (discussing how R&D races that produce premature technologies with no immediate application actually constitute a net social loss); SCOTCHMER, *supra* note 20, at 46 (discussing problems related to the over-incentivization and under-incentivization of research); Tim Hubbard and James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLOS BIOLOGY 147, 150 (describing how increased patent incentives have incentivized R&D of "diminishing returns"); Scherer, *supra* note 12, at 1360 (describing how R&D activities, like any other activities, exhibits a diminishing rate of returns). As low hanging fruits of research opportunities are picked, any additional resources poured into the area must be used to conduct increasingly expensive and speculative research. Alas, doubling the

over incentives produced by overly broad patents.[275] Under-recognition on the other hand can promote only small incremental routine innovations without promoting the truly innovative inventions.[276]

Another reason to limit patent scope relates to Kitch's arguments for broad patents. Kitch has posited two main arguments for broad patents: coordination and reduction of competitive waste. Both of these propositions are arguably problematic. With regard to coordination, there has been little evidence to suggest that coordination actually occurs. If coordination exists, one would expect to find many examples where pioneers discriminately issue licenses to select inventors. On the contrary, Merges & Nelson have found that pioneers rarely grant selective, targeted licenses.[277] The norm is instead for patentees to grant broad, general licenses.[278] The second argument that Kitch posited for broad patents is that they reduce competitive waste.[279] On closer inspection,

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amount of incentives for cancer research, for example, does not guarantee a halving of the wait for a cure.

275 Some may believe that current patent incentives are not excessive, since the average profits of U.S. biotech and pharmaceutical industry do not necessarily greatly exceed those of other industries. *See* Merrill Matthews Jr., Policy Brief Prices, Profits and Prescriptions: The Pharmatech Industry in the New Economy (Washington Policy Center, 2001), http://www.washingtonpolicy.org/ HealthCare/PBMatthewsDrugPrices.html (noting that "It is true that most pharmaceutical companies are profitable—with profits averaging about 18 percent of revenue in 1999, according to Fortune magazine. Some critics cite those profits as evidence that drug companies are price gouging. . . . [Empirical data show however that] while it is true that many prescription drug manufacturers are profitable, and several have been consistently profitable over the years, those profits are not out of line with other successful New Economy companies and industries, and even some Old Economy companies, that deal in intellectual property or other patentable or copyrighted products."). However, as Landes and Posner have noted: "competition for monopoly rents will . . . tend to transform them into costs without necessarily producing commensurate social benefits." *See* LANDES & POSNER, *supra* note 16, at 315. Any extra profits (provided by windfall patents) would simply be spent on marketing or on more speculative research until the aggregate return of the entire industry appears comparable with other industries. *See id.* As George Stigler observed, "The prospects of monopoly pricing will lead to such a scale of investment in producing knowledge that it will return only the competitive rate of return on average." GEORGE J. STIGLER, THE ORGANIZATION OF INDUSTRY 124 (Irwin 1968). The important question is whether industry activities, funded in great part through patent monopolies, are worth the cost of the patent monopolies.

276 *See also supra* note 254.

277 *See* Merges & Nelson, *supra* note 79, at 873–75.

278 *Id.*

279 *See generally* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305 (1992) (arguing that patent doctrine should be understood as a way of avoiding wasteful races).

however, broad patents may not so much reduce competitive waste[280] as shift the competitive wastes to earlier stages of the innovation process.[281] When patent scope is broadened, the net competitive wastes may not be decreased. For example, the competition for a broad patent may only be shifted to earlier rounds in the innovation lifecycle. When patent scope is narrowed, the race for patents is re-shifted more evenly across and toward later stages the innovation lifecycle.

A benefit of re-shifting competition back toward later stages of the innovation lifecycle is that it helps inject a more rational decision making process into the innovation process. By concentrating incentives at too early a stage in an innovation lifecycle, broad patents force patentees to make innovation decisions at a time where temptations for speculation and hype are at their highest.[282] By spreading competition more evenly across the innovation life cycle, narrow patents allow decisions involving the deployment of innovation resources to be made more rationally when more is known about the technological landscape.[283]

Broad patents' alleged ability to reduce Kitch's alleged competitive waste may also turn out to be a red herring. Competitive waste is a natural part of competition. In few contexts outside of patents has competition been legitimately attacked on the ground of "competitive wastes." The cost of competitive waste is usually not viewed in isolation, but in aggregate with the benefits of competition.[284] There is plenty of proof evidence of the net overall merits of competition. Most of the Western economies—and now increasingly the global

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280 *See supra* note 261 and accompanying text.

281 *See* LANDES & POSNER, *supra* note 16, at 319–20, 324 (explaining how increasing patent scope may simply shift the patent race (for a broader patent) to an earlier period). For Kitch's response, see Edmund W. Kitch, *Patents, Prospects, and Economic Surplus: A Reply*, 23 J.L. & ECON. 205, 206 (1980).

282 *Cf.* Merges & Nelson, *supra* note 79, at 884 (urging careful scrutiny over patent scope, especially where great excitement over "new scientific and technological developments" exists, lest monopoly is conferred over an "invention [that] may diverge from 'prior art,' in the sense of actual technological accomplishments, and sweep the market, yet still be only a successful application of knowledge that is apparent to the scientifically sophisticated.").

283 Distributing competition throughout the process enables competing patentees to pursue innovations at more rational and opportune stages.

284 While competition can involve a duplication of resources, competition also does bring benefits such as inject vitality and promote success. Further, duplications of resources may also sometimes be exaggerated. For example, in a patent race, not all is lost even when an inventor loses out on a patent. *See* LANDES & POSNER, *supra* note 16, at 301 (observing that "the research expenditures by the losers of the race may not be wasted . . . for the expenditures will generate information that the losers may be able to use in other projects.").

economies, too[285]—are built on a strong foundation of free market and open competition.[286] Given the competitive baseline of most economies today, unless there is evidence to suggest that the balance between competitive waste and competitive benefits are balanced differently in the innovation and patent context, competition rather than command coordination should be the preferred model for creating innovations.[287]

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285 *See Happiness (and how to measure it)*, ECONOMIST, Dec. 23, 2006, at 13 (noting that "Market capitalism, the engine that runs most of the world economy, seems to be doing its job well.").

286 *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 156 (1989) (the Supreme Court stating that "free competition" is "the baseline" on which "the patent system's incentive to creative effort depends."); FED. TRADE COMM'N, *supra* note 4, at 1 ("Competition through free enterprise and open markets is the organizing principle for most of the U.S. economy. Competition among firms generally works best to achieve optimum prices, quantity, and quality of goods and services for consumers."); *id.* at 882 (While "[t]here is broad consensus on the significant role that . . . patents can play to spur innovation and to encourage the disclosure and commercial development of inventions . . . [t]he importance of competition as a spur to innovation also should be recognized."); Merges & Nelson, *supra* note 79, at 843–44 (concluding that, "[w]ithout extensively reducing the pioneer's incentives, the law should attempt at the margin to favor a competitive environment for improvements, rather than an environment dominated by the pioneer firm."). For a discussion concerning innovation policies, see generally R. Gilbert & G. C. Sunshine, *The Use of Innovation Markets: A Reply to Hay, Rapp and Hoerner*, 64 ANTITRUST L.J. 75 (1995); R. Gilbert & G. C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 ANTITRUST L.J. 569 (1995).

287 *See* D.O.J. and FTC, *Antitrust Guidelines for the Licensing of Intellectual Property*, at 7 (1995) (finding that concentrations of market power tend to reduce competition to innovate and retard progress); *see* FED. TRADE COMM'N, *supra* note 4, at 5 (explaining that barring strong justifications to the contrary, a competitive innovation system should be preferred); *id.* at 877 (arguing that "rivalry facilitates technical advance and unified control damps it."); Merges & Nelson, *supra* note 79, at 877–78 (noting that "when it comes to invention and innovation, faster is better" and that, "we are much better off with considerable rivalry in invention than with too little"). *See also* RICHARD R. NELSON & SIDNEY G. WINTER, AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE (Belknap Press of Harvard University Press, 1982); Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention, in* THE RATE AND DIRECTION OF ECONOMIC ACTIVITIES: ECONOMIC AND SOCIAL FACTORS, 609–26 (R. Nelson, ed., Princeton University Press, 1962); Richard R. Nelson & Sidney G. Winter, *Evolutionary Theorizing in Economics*, 16 J. ECON. PERSPECTIVES 23, 33–39 (Spring 2002). For an interesting counter point, see JOSEPH SCHUMPETER, CAPITALISM, SOCIALISM AND DEMOCRACY (Harper & Row, 1950)(1942) (arguing that large, monopolistic firms with access to deep resources are more innovative than small, resource-strapped start up companies).

D. The varying needs of technological fields

The cost-benefit analysis presented thus far has been discussed independently of specific technological or market characteristics of industries.[288] Recent studies suggest, however, that the technological and market context in which innovations take place should be taken into account in assessing the costs and benefits of patents.[289] Merges and Nelson abstracted three categories of

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288 This is justified since U.S. patent laws, at least in principle, apply uniformly to all fields. *See* Burk & Lemley, *supra* note 19, at 1576 (noting that "[w]ith only a few exceptions, the statute does not distinguish between different technologies in setting and applying legal standards."). *Cf. id.* at 1577 (noting however, that "[a] closer examination of patent law demonstrates that it is unified only in concept. In practice the rules actually applied to different industries increasingly diverge.").

289 *Id.* at 1578 (noting that the "fact that economic evidence, patent doctrine, and legal theory all vary by industry leads us to question whether patent law should explicitly attempt to tailor protection to the needs of specific industries, as many have suggested."); *id.* at 1576–77 (arguing that patent law, while allegedly uniform in principle, is already non-uniform in application); *id.*, at 1577 (concluding that "there is no reason to assume that a unitary patent system will optimally encourage innovation in the wide range of diverse industries that it is expected to cover."). This does not mean that patent law should be fragmented by industry. Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, art. 27(1), Dec. 15, 1993, 33 I.L.M. 81, 93–94 (prohibiting member states from discriminating the grant of patents by technology); Burk & Lemley, *supra* note 19,at 1578–79 (noting that "concerns about rent seeking and the inability of industry-specific statutes to respond to changing circumstances [suggest] . . . that we should not jettison our nominally uniform patent system in favor of specific statutes that protect particular industries."); *id.* at 1635–36 (observing for example that "Drug delivery systems might be thought of as medical devices, pharmaceuticals, or biotechnology; presumably a different law would apply depending on how the invention was characterized."); *id.* at 1634–38 (doubting whether judges or legislatures will get the industry specific policies right); Rochelle Cooper Dreyfuss, *Information Products: A Challenge to Intellectual Property Theory*, 20 N.Y.U. J. INT'L L. & POL'Y 897, 912–18 (1988) (cautioning against explicitly tailoring the patent regime to particular needs of industries). *See generally* Wesley M. Cohen, Richard R. Nelson & John P. Walsh, PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (National Bureau of Economic Research Working Paper No. 7552, 2000); Mark Schankerman, *How Valuable Is Patent Protection? Estimates by Technology Field*, 29 RAND J. OF ECON. 77 (1998); Robert Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL'Y 273, 275–76 (1998). *Cf.* Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 BROOKINGS PAPERS ON ECONOMIC ACTIVITY 783, 784–86 (observing that some industries depend more on patents than others for the appropriation of innovation returns); *id.* at 794–95 (presenting survey evidence polled from R&D managers to show that companies across industries rely on trade secrets to widely varying extents); Burk & Lemley, *supra* note 19, at 1584 (discussing that extent by which imitations pose a problem differs from field to field); Michael A. Carrier, *Un-*

innovation patterns under which patent scope should be evaluated. The three categories are fields with: 1) independent spheres of inventions; 2) mutually dependent, cumulative spheres of inventions; and 3) science-based (breakthrough-based) inventions that opens the door up to many follow-on innovations.[290]

1. Field with independent spheres of inventions

Fields with independent spheres of innovation, or "discrete innovations," involve innovations that take place independently of each other.[291] In such industries, the original pioneer typically develops all of the follow-on and related innovations associated with a pioneering innovation.[292] Examples include the traditional pharmaceutical and chemicals industries.[293] In pharmaceutical industries (this paper makes a distinction between the pharmaceutical and biotechnological field: pharmaceutical innovations typically involve the use of a naturally occurring substance as a new drug; biotechnological innovations (at least in principle) may involve the creation of a new molecule as a new drug),[294]

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raveling the Patent-Antitrust Paradox, 150 U. PA. L. REV. 761, 826–27 (2002) (noting that a weakened patent regime would damage some industries more than others).

290 Merges & Nelson, *supra* note 79, at 880. *See generally id*. at 884–916.

291 *See* Merges & Nelson, *supra* note 79, at 880 (introducing the concept of the "discrete invention model" where "an invention is discrete and well-defined, created through the inventor's insight and hard work . . . [where generally] the invention does not point the way to wide ranging subsequent technical advances . . . [or] define any broad prospect.").

292 For a more comprehensive analysis of the dynamics involved in fields with discrete innovations, see, e.g., Gallini & Scotchmer, *supra* note 245 at 62–65; Merges & Nelson, *supra* note 79, at 882 (describing how a "new chemical product is in most cases a discrete entity . . . like penicillin.").

293 Merges & Nelson, *supra* note 79, at 882 (describing how a "new chemical product is in most cases a discrete entity . . . like penicillin").

294 Pharmaceuticals deal with large molecule drug innovations. They employ typically a more traditional drug discovery process involving: the screening of hundreds of thousands of naturally occurring compounds to find a potential drug candidate (target) for a particular therapeutic purpose; testing and validating the drug targets to find a subset with the best combination of efficacy and safety characteristics; and inventing and implementing a mass production process to extract, purify or manufacture the compound (traditionally this typically involved a chemistry based process; more recently, pharmaceutical companies have also leveraged modern biotechnologies, including the use of recombinant organisms). Biotechnology, on the other hand, deal with small molecule drug innovations. Instead of screening for hundreds of thousands of naturally occurring compounds for potential drug targets, biotech companies typically "design" small molecules, based on insightful bimolecular knowledge, that interact with key elements of naturally occurring biochemical pathways in the human body.

once a drug is developed, the innovation is complete and stands on its own, with little to no follow-on innovations.[295] Where there are follow-on innovations (such as alternative uses of a compound for which the original pioneers had already obtained voluminous test data and gained tremendous expertise in manufacturing) the pioneer will generally make the follow-on innovations.[296]

Pharmaceutical product patents are now required throughout the world as part of the WTO TRIPS agreement.[297] Pharmaceutical product patents, however, are generally overly broad patents with respect to the contributions made by the underlying innovations. The development of a drug typically consists of three types of innovations: the selection of a set of suitable drug targets (i.e. drug candidates); the testing and verification of select targets offering the most efficacy and safety (e.g. FDA testing process); and the process of mass producing (using techniques including, for example, isolation, purification, chemical processing, and/or recombinant DNA techniques) a target under specified quality and cost constraints.[298] In the traditional pharmaceutical industry, rarely does an innovation actually involve the creation of a new substance, such as a novel molecular structure. Two types of method patents—one over the use of a compound such as for a specific therapeutic or diagnostic purpose and another over

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295 *See* Burk & Lemley, *supra* note 19, at 1617 (observing that "As a general rule, the scope of patents in the pharmaceutical industry tends to be coextensive with the products actually sold. Patents do not merely cover small components that must be integrated into a marketable product.").

296 *Cf.* Burk & Lemley, *supra* note 19, at 1617 (observing that "because much of the work occurs after the drug is first identified, it is important to give patentees the right to coordinate downstream changes to the drug. Prospect theory fits best in the pharmaceutical industry.")

297 For a summary of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights, see http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#nAgreement. For a recent discussion framing the issues raised by the agreements, see *Access to Medicines Intellectual property protection: impact on public health*, 19 WHO DRUG INFORMATION 236 (2005). *See* Burk & Lemley, *supra* note 19, at 1617 (stating that pharmaceutical product patents are awarded because they are seen to be "necessary to encourage drug companies to expend large sums of money on research years before the product can be released to the market.").

298 By far, the largest portion of the drug development cost is incurred during the clinical testing, during which a large number of lead compounds is whittled down to a select few offering stringent efficacy and safety characteristics. *See* Christopher P. Adams & Van V. Brantner, *The Real Cost of Drug*, *in* DRUG DEVELOPMENT 2006 23, 23–24 (Touch Briefings, 2006), *available at* http://www.touchbriefings.com/pdf/1842/Chris_Adams.pdf (discussing recent empirical studies on the real cost of the drug development process); http://www.fda.gov/cder/handbook/develop.htm (presenting an overview of the drug development process from the FDA perspective); http://nibr.novartis.com/OurScience/drug_development.shtml (presenting an overview of the drug development process from a private sector perspective).

a method such as for mass producing the compounds—should adequately incentivize most traditional pharmaceutical innovations.[299]

One reason that the award of overly broad product patents for pharmaceutical innovations has not lead to dramatic crises is that since pharmaceutical products advance mostly in independent spheres of innovations, the blocking effects of overly broad patents are not generally felt.[300] Another reason may be that the industry has come to rely on patents to compensate for not just innovation risks, but also extra-innovation factors such as the regulatory, market, and legal enforcement risks involved in taking a drug to market.[301] The use of patents to compensate for extra-innovation risks should not be cavalierly taken however.[302]

2. Fields with mutually dependent, cumulative spheres of inventions

Fields with mutually dependent, cumulative spheres of invention involve technologies that develop cumulatively and incrementally, often with a lot of mutual dependence.[303] The communications and semiconductor industries are

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299 *See* Golden, *supra* note 214, at 166.

300 *See* Merges & Nelson, *supra* note 79, at 881 (observing that in *discrete invention* industries, "possession by [a] firm of a proprietary lock on the invention is not a serious hindrance to inventive work by many other firms.").

301 Pharmaceutical patents are relied on by drug companies to compensate not just the cost of doing scientific research, but also the wide diversity of risks associated with bringing drugs to market (i.e. drug R&D), including regulatory, market, and legal enforcement risks. *See* MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT xv, 11-12 (1st ed. 2004) (observing that the major cost items of pharmaceutical businesses is not R&D, but "advertising and promotion, legal costs, and executive salaries."). The regulatory risks include the risks associated with a long FDA approval process. *Cf.* Burk & Lemley, *supra* note 19, at 1625 (noting that "Although the FDA imposes regulatory hurdles even on [generic drug manufacturers], the process is substantially more streamlined than it is for [the original pioneering patentee]."). Market risks include risks associated with creating a new market for a new drug. Enforcement risks include risks associated with defending patents and other legal issues such as antitrust.

302 *See supra* notes 216–222 and discussions therein (discussing how the patent system should be used to compensate only for technological risks because the patentability requirements, together with the PHOSITA standards, are geared toward resolving technological issues and because the returns on investments placed to overcome non-technological risks may not be nonexclusive and nonrivalrous).

303 *See* Merges & Nelson, *supra* note 79, at 881–82; Scotchmer, *supra* note 235, at 29.

prototypical examples.[304] The result of the cumulative nature of semiconductor innovations can be seen in the assembling of a microprocessor. A state-of-the-art microprocessor, for example, can feature a ground breaking proprietary technology, yet the chip cannot be built without leveraging a large number of prior, patented innovations.[305] To build a working state of the art processor, an inventor must negotiate a large number of licenses with numerous inventors.[306]

One concern in mutually dependent, cumulative technologies traditionally involves the transaction costs associated with assembling the numerous intellectual property assets needed to enable a real world application.[307] In computer and electronics related fields, mechanisms such patent and license pools however have developed to lower the transaction costs of intellectual property asset assemblage.[308] When competitors in the marketplace are mutually dependent on each others' intellectual properties, e.g., when innovators fall symmetrically on both sides of the rent seeking battle,[309] the incentive to hold out and rent seek against others becomes greatly reduced.[310] As an observer recently noted,

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304 *See* Merges & Nelson, *supra* note 79, at 893–94; Burk & Lemley, *supra* note 19, at 1620, 1629.

305 Many product-based industries are of this type since most products transcend and depend on a wide diversity of technologies. *See* Scherer, *supra* note 12, at 1363 (reporting a National Science Foundation–backed study that demonstrated that a "large number of research streams . . . had to converge" before the five new technologies studied, including the first oral contraceptive pill, became enabled).

306 *See id.*

307 *See supra* note 269 (discussing the anticommons problem).

308 *See generally*, *e.g.*, Gallini & Scotchmer, *supra* note 292, at 65–69 (for more details on the complex dynamics of IP licensing in fields with mutually dependent, cumulative spheres of inventions).

309 *See* Scherer, *supra* note 12, at 1363 (discussing the problem of rent seeking faced by barge owners traveling through different sections tolled by different operators along the Rhine River); SCOTCHMER, *supra* note 20, at 133–34 (discussing how blocking patents can lead to grid lock and stifle subsequent research as patentees hold out in seeking maximum royalties). *See generally* MANCUR OLSON, THE LOGIC OF COLLECTIVE ACTION (Harvard University Press 1965) (for more on the holdout problem).

310 *See* Burk & Lemley, *supra* note 19, at 1628 (discussing that when the dependence on IP is "symmetrical . . . patents tend to be used defensively," such that even if "companies each possess the power to exclude all others from the market . . . [t]hey rarely exercise this right . . . [but will] instead enter[] into broad cross-licensing deals . . . ."); Barton, *supra* note 14, at 1933 (noting that companies often acquire patents "so that they can deter litigation through the threat of reciprocal suit"); Heller & Eisenberg, *supra* note 16, at 700 (observing that "[w]hen the background legal rules threaten to waste resources, people often rearrange rights sensibly and create order through private arrangements"); Wesley M. Cohen, Carnegie Mellon University & National Bureau of Economic Research, Patents: Their Effectiveness and Role, Presentation for the FTC/DOJ Hearings on Competition and Intellectual Property

in cumulative industries, "patents are usually legal bargaining chips [for cross-licensing] rather than the traditional prize for winning a technology tournament [for blocking out a market]."[311] The cost of overly broad patents in cumulative, incremental industries is thus—like that of independent spheres of industry (though for different reasons)—relatively manageable.

3. Fields with science-based (breakthrough-based) inventions

Fields with science-based inventions involve scientific or technological breakthroughs that open up large areas of new opportunities for subsequent developments.[312] While science-based industries depend on breakthroughs, they are also cumulative in nature in that advances made in one round are heavily dependent upon advances made in previous rounds.[313] Recent examples of science-based industries include the biotechnological and superconductor industries.[314]

Unlike fields with independent spheres of invention or fields with mutually dependent, cumulative spheres of invention, the cost of overly broad patents can however be very high in science-based industries.[315] Pioneer patentees,

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Law in the Knowledge-Based Economy 14 (Feb. 20, 2002) (summarizing a recent Carnegie-Mellon survey of R&D laboratory managers on the effectiveness of patents in stimulating innovation, and observing that in industries where a group of firms owns all the patent rights underlying a particular product (e.g., a computer chip), this group of firms becomes mutually dependent on each other and more amicable to cross-licensing), *available at* http://www.ftc.gov/opp/intellect/cohen.pdf. *But see* Burk & Lemley, *supra* note 19, at 1614–15 (observing that even if a licensing solution exists, blocking claims raises transaction costs and can nevertheless represent a private tax for those who cannot bring their own patents to leverage others in a cross-licensing or patent-pooling scheme).

311 Henry S. Rowen, *Serendipity or Strategy: How Technology and Markets Came to Favor Silicon Valley*, *in* THE SILICON VALLEY EDGE: A HABIT FOR INNOVATION AND ENTREPRENEURSHIP 184, 190 (Chong Moon Lee et al. eds., Stanford University Press 2000).

312 *See* Merges & Nelson, *supra* note 79, at 908. Breakthrough-based industries are sometimes young industries that evolve to become mutually dependent, cumulative industries.

313 As Newton has famously remarked, "If I have seen further it is by standing on ye sholders of Giants." Letter from Isaac Newton to Robert Hooke (Feb. 5, 1675/6), *in* 1 THE CORRESPONDENCE OF ISAAC NEWTON, 1661–75, at 416 (H.W. Turnbull ed., 1959). In terms of industrial developments, most important technologies outside of traditional pharmaceuticals and chemical industries, at least in the long term, fit the cumulative model. *See* SCOTCHMER, *supra* note 20, at 134.

314 Merges & Nelson, *supra* note 79, at 904–05.

315 Merges & Nelson, *supra* note 79, at 884, 915 (noting that in science-based industries, "there is a real danger that allowing patent scope to be overbroad may enable the individual or firm

who have opened up new fields, typically have tremendous leverage over subsequent innovators in extracting high rents. The situation is worsened because the stakeholders in the industry do not depend on each other's intellectual property symmetrically as in cumulative, mutually dependent fields.[316] Due partly to the asymmetry of dependence, the incentive to reduce transaction costs in science-based industries may remain low to nonexistent.[317] Limiting the scope of a patent (to what is immediately enabled by each breakthrough) can help the situation by increasing, fragmenting and distributing intellectual property assets among more competing stakeholders, thereby increasing mutual dependence among them. The reduced power of a patentee to block out entire fields will

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who first came up with a particular practical application to control a broad array of improvements and applications," and emphasizing "the dangers of awarding overly broad patents early in the history of an industry founded on recent scientific advances").

316 In cumulative, mutually dependent industries, the creators of technologies are also consumers of technologies, forming a relationship of dependence that is symmetrical (mutual) among stakeholders. In science-based industries, the creators (e.g., research institutes) and consumers of technologies (e.g., device manufacturers) are usually distinct entities. *See* Scherer, *supra* note 12, at 1363 ("In biotechnology, the asymmetry of relevant actors' positions—ranging from university scientists through genome-researching firms, vector providers, and instrumentation makers to specific biopharmaceutical developers—is likely to make it more difficult to find a sufficient community of interest to organize comprehensive low-royalty cross-licensing."); SCOTCHMER, *supra* note 20, at 131 (noting that the dependence among stakeholders in science-based industries is often not symmetric.); Heller & Eisenberg, *supra* note 16, at 700 (observing that "[a] . . . subtle conflict in agendas arises between owners that pursue end-product development and those that focus primarily on upstream research. The goal of end-product development may be better served by making patented research tools widely available on a nonexclusive basis, whereas the goal of procuring upstream research funding may be better served by offering exclusive licenses to sponsors or research partners.").

317 *See* Burk & Lemley, *supra* note 19, at 1629 n.172 (explaining that the feasibility of "cross-licensing deals depend on the existence of a symmetrical relationship between the parties. Patentees that want to license their patents for royalties tend to be parties with asymmetric stakes. That is, they are individuals who do not sell products, 'licensing shops' whose primary output is patents, or older companies that are no longer major players in the marketplace."); Scherer, *supra* note 12, at 1362 ("Bargaining stalemates are especially likely when the discoverer of A has broad rights covering follow-on developments, but when A, like many basic scientific discoveries, has little or no commercial value by itself."). *See also* Heller & Eisenberg, *supra* note 16, at 698 (noting that "[i]n practice . . . [negotiating for cross licenses] requires overcoming transaction costs, strategic behaviors, and cognitive biases of participants, with success more likely within close-knit communities than among hostile strangers. Once an anticommons emerges, collecting rights into usable private property is often brutal and slow.").

increase the incentives of stakeholders to work with each other and to reduce the transactions costs associated with redistributing intellectual property assets.[318]

E. Historical lessons on proper patent scope

Scholars have debated the question of appropriate patent scope for a long time with little end in sight.[319] Basic questions, such as to what extent the patent system is actually incentivizing innovations, remain unsettled.[320] Understanding human motivations and behavior involves insights into an elaborate mix of constantly changing and evolving factors. An analytical framework can at best produce a useful heuristic but probably not a predictive theory. After studying a few seminal cases of broad patents and their effects on subsequent technological progress, Merges and Nelson offered some qualitative insights regarding proper patent scope.[321] A key observation is that in industries where the development of follow-on technologies is resource intensive or technologically uncertain, patent scope over the pioneering technology should be narrowly tailored to ensure that patent incentives and competition are preserved for subsequent phases of innovations.[322] Merges and Nelson have also noted that history offers many examples where broad patents have impeded follow-on devel-

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318 Admittedly this might raise anticommons concerns. But the cost of blocking out entire fields is arguably much higher than the cost of dealing with anticommons problems, especially in science-based or breakthrough-based fields. Also, as discussed earlier, anticommons problems can be managed. For example, anticommons problems may sometimes be reduced through the creation of mutual dependence upon stakeholders, which narrow patents can do.

319 *See generally*, *e.g.*, Frederic M. Scherer, *Nordhaus's Theory of Optimal Patent Life: A Geometric Reinterpretation*, 62 AM. ECON. REV. 422 (1972); WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND ECONOMIC WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (MIT Press 1969); Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347, 351 (2000) (arguing that the economics of innovation is much more complicated than is traditionally understood).

320 *See*, *e.g.*, STAFF OF S. SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 76–80 (Comm. Print 1958) (concluding that were there no patent system, it would be irresponsible to create one, but that since one does exist, it would be irresponsible to eliminate it); George L. Priest, *What Economists Can Tell Lawyers About Intellectual Property: Comment on Cheung*, *in* 8 RES. L. & ECON. 19, 24 (John Palmer & Richard O. Zerbe, Jr. eds., 1986) (concluding that there is little insight that economists can offer to reform intellectual property).

321 *See* Merges & Nelson, *supra* note 79, at 843.

322 *See id.* at 877–905. *See also* Richard R. Nelson, *Capitalism as an Engine of Progress*, 19 RES. POL'Y 193 (1990).

opments, but few, if any, examples where broad patents have facilitated the development of follow-on innovations.[323]

VI. THE PATH TO A MORE ENLIGHTENED GENE PATENT REGIME

Having discussed a framework for understanding patents, this section turns attention to applying some of the insights gained to the biotechnological context.

A. Reinvigorating the subject matter prohibition against the patenting of nature

Despite *Chakrabarty's* broad interpretation of subject matter eligibility,[324] the bright line, judicially constructed prohibition against the patenting of "laws of nature, natural phenomena, and abstract ideas" has never been overturned and continues in force.[325] According to the Supreme Court, the prohibition against the patenting of nature exists because "[a] principle, in the abstract, is a fundamental truth" and constitutes "a relationship that has always existed."[326] These "manifestations of laws of nature" are "part of the storehouse of knowledge" and are "free to all men and reserved exclusively to none."[327] In evaluating whether an algorithm constitutes a patentable "process," [328] the Supreme Court in *Parker v. Flook* suggested that subject matter requirements rest

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323 Merges & Nelson, *supra* note 79, at 844 (warning—after examining follow-on innovation patterns in industries as diverse as electric lighting, automobile, airplane, semiconductors and computers, and pharmaceuticals—that "[i]n many industries the efficiency gains from the pioneer's ability to coordinate are likely to be outweighed by the loss of competition for improvements to the basic invention."). *See also* Michele Boldrin & David Levine, *The Case Against Intellectual Property*, 92 AM. ECON. REV. 209, 209 (2002) (arguing that strong intellectual property protection may hurt rather than help innovation).

324 *See* Demain & Fellmeth, *supra* note 7, at 346 (arguing for a broad all-inclusive reading of subject matter eligibility where the subject matter requirement is set forth collectivity in sections 101 through 103.").

325 *See supra* note 82.

326 Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1852); Parker v. Flook, 437 U.S. 584, 593 n.15 (1978).

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

328 Computer-related, algorithm-based patent applications were traditionally disdained as attempts to patent laws of nature, natural phenomena and/or abstract ideas. For a long time patentees tried to characterize algorithms as patentable "process[es]" within the ambit of 35 U.S.C. § 101. The courts have since rejected the notion that mathematical or algorithmic-based inventions are per se ineligible subject matter. *See* State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373–74 (Fed. Cir. 1998).

on important policy considerations beyond the face of 35 U.S.C. § 101.[329] "The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect."[330] Nevertheless, the courts have never clearly articulated the policy underlying the prohibition against the patenting of nature[331] outside of occasional references to utility, novelty, and nonobviousness.[332]

One probable reason for the prohibition against the patenting of nature is the existence of extra-patent science-based incentives to incentivize discovery of basic knowledge.[333] Unlike the quid pro quo of patents where inventors get a

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329 *See* 437 U.S. at 593.

330 *Id.*

331 *See* Kane, *supra* note 24, at 745 n.211 (noting that scholars have observed that the policy bases for the prohibition against the patenting of nature have never been clearly elaborated by the Supreme Court); *id.* at 766–67 (describing that "[t]he inchoate nature of much public opposition to gene patenting has not yet found resonance in any theory [within the current legal framework]."). *See also* Robert A. Kreiss, *Patent Protection for Computer Programs and Mathematical Algorithms: The Constitutional Limitations on Patentable Subject Matter*, 29 N.M. L. REV. 31, 69–70 (1999); Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025, 1097 (1990).

332 *See* Kane, *supra* note 24, at 763 (noting that "the courts, including Alappat, State Street, and AT&T, increasingly relied on the utility doctrine to [assess § 101 subject matter eligibility]."); *State St.*, 149 F.3d at 1374 (stating that abstract ideas, by themselves, are not patentable because they are not useful); *Parker*, 437 U.S. at 593 (analyzing subject matter eligibility in terms of novelty); *Funk Bros.*, 333 U.S. at 130 (stating that "[h]e who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the *application of the law of nature to a new and useful end*") (emphasis added). Many of these arguments are paradoxical. For example, with respect to novelty, while a natural fact may not be novel, the knowledge of that fact, which is recently discovered, should be considered novel for patentability purposes. Further, with respect to utility, judging from the intensity of the debates surrounding subject matter patentability, one cannot but infer that knowledge about scientific principles or the natural world are useful, perhaps only too useful.

333 *See* LANDES & POSNER, *supra* note 16, at 306–07 (observing "[i]n effect, basic research is incentivized by a reward system that involves prestigious academic appointments, lecture fees, grants that reduce teaching loads, and the prospect of Nobel and other prizes, while applied research . . . is incentivized by intellectual property rights"); Golden, *supra* note 214, at 110 (observing that "even in the present age of 'entrepreneurial science' and even within industry itself, the values and incentives that motivate biotechnology researchers tend to be closer to the 'public sector values' associated with university-based science than to the values associated with a market-oriented focus on maximum financial profit."); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 Nw. U. L. Rev. 77, 89–94 (1999); Stephen M. Maurer and Suzanne Scotchmer, *Procuring Knowl-*

right to monopolize in return for disclosure of discoveries, in science, in return for academically valuable assets such as fame, prestige, and recognition, scientists make and share with the world discoveries they have made about the world.[334] If incentives already exist to incentivize scientific discoveries, there is little reason to incentivize such activities again with patents, especially in light of the costs discussed above.

Another reason for the prohibition relates to the preemptive effects patents over nature can have over innovations.[335] The Supreme Court has noted that laws of nature, natural phenomena, and abstract ideas, "though just discovered, . . . are the basic tools of scientific and technological work."[336] The value of a maintaining a base of scientific commons knowledge unencumbered by intellectual property is widely known.[337] Thus, patentees must not be allowed to

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edge, 15 INTELLECTUAL PROPERTY AND ENTREPRENEURSHIP: ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND GROWTH 1 (Gary D. Libecap ed., 2004), *available at* http://socrates.berkeley.edu/~scotch/prizes.pdf (providing a good overview of various incentives to promote technological progress); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 180–85 (1987). *See also generally* ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS (Norman W. Storer ed., University of Chicago Press 1973); discussions surrounding *infra* notes 367–378.

334 LANDES & POSNER, *supra* note 16, at 306–07.

335 *See* Diamond v. Diehr, 450 U.S. 175, 187 (1981) (holding a claim involving an equation to be eligible subject matter because it did "not seek to pre-empt the use of [an] equation," but instead only sought to "foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process"); *In re* Bergy, 596 F.2d 952, 988 (C.C.P.A. 1979) (Baldwin, J., concurring) (stating "that claims which directly or indirectly preempt natural laws or phenomena are proscribed, whereas claims which merely utilize natural phenomena . . . to accomplish new and useful end results define statutory inventions"); AT&T Corp. v. Excel Commc'ns., Inc., 172 F.3d 1352, 1358 (Fed. Cir. 1999) (holding a claim involving a mathematical algorithm to be eligible subject matter "[b]ecause the claimed process applies the Boolean principle to produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle. . . .").

336 Gottschalk v. Benson, 409 U.S. 63, 67 (C.C.P.A. 1972). *See also Diamond*, 450 U.S. at 191–92 (explaining that while abstract principles are not subject matter eligible, applications of abstract principles may be); *but cf. State St.*, 149 F.3d at 1373 (pronouncing that "[u]npatentable mathematical algorithms . . . are merely abstract ideas constituting disembodied concepts or truths that are not 'useful.' . . . [T]o be patentable an algorithm must be applied in a 'useful' way. . . . [A] practical application of . . . a mathematical algorithm . . . [is patentable because] it produce[s] 'a useful, concrete and tangible result.'").

337 *See* Eisenberg & Nelson, *supra* note 118, at 92–93.

> Broad claims on early discoveries that are fundamental to emerging fields of knowledge are particularly worrisome in light of the great value, demonstrated time and again in the history of science and technology, of having many independent minds at work trying to advance a field. Public science has flourished

claim every "substantial practical application" of an abstract idea if such practice would in effect constitute "a patent on the [idea] itself."[338]

In general, the bright-line prohibition against the patenting of nature does not necessarily flow from the Constitutional mandate to "promote the Progress of Science and useful Arts" since the clause makes no mention of whether nature should be patentable.

The prohibition however can be seen as a good *proxy rule* to carrying out a full-fledged cost and benefits analysis on whether patenting natural phenomenon promotes the arts. As many have argued[339] there seems to be a natural distinction between an "invention" and "discovery," where discoveries should not be patented while inventions could. Discoveries are knowledge about nature gained through objective observation of nature.[340] In making discoveries, scientists look to gain field-opening, breakthrough-type insights into nature that earn them great *fame*, *prestige* and *honor*; impact on society and financial rewards

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> by permitting scientists to challenge and build upon the work of rivals. Intellectual property rights to fundamental discoveries threaten to limit the number of players in the system at an early stage, thereby diminishing its power.

Id.; *see also* Arti Rai, *Genome Patents: A Case Study in Patenting Research Tools*, 77 ACAD. MED. 1368, 1369 (2002) (arguing that "the most important research tools are fundamental research platforms that open up new and uncharted areas of investigation").

338 *Gottschalk*, 409 U.S. at 71–72. Preemption, however, does not dispositively determine subject matter eligibility. After all, to incentivize truly groundbreaking innovations, the patent system must be prepared to award patents with broad preemptive powers where appropriate, subject to "the principles of equity." *See* eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1840 (2006), where, in a pivotal 2006 decision, the Supreme Court reversed the Federal Circuit's pro-patentee, property-driven ruling that an injunction can automatically issue based on a finding of infringement, and the trial court's pro-infringer, policy-driven ruling that an injunction may be denied on the basis that the patentee does not practice the invention. *Id.* at 1840–41.

339 *See* Demaine & Fellmeth, *supra* note 7, at 374-77 (distinguishing inventions from discoveries on basis of an "inventive step"); Ferry, *supra* note 57, at 266 (quoting Dr. John Sulston, 2002 Winner of the Nobel Prize in Medicine or Physiology, to say: "[t]he genome sequence is a discovery, not an invention.").

340 *See* Carlotta Piscopo & Mauro Birattari, *Invention vs. Discovery: A critical discussion*, 2–3 (2002), *available at* http://iridia.ulb.ac.be/~meta/downloads/PisBir2002_ds.pdf (describing the traditional understanding of "discovery" as a process by which insight into nature is extracted directly from objective observations about nature). Piscopo and Birattari would argue, however, that the distinction between discovery and invention is much more blurred than traditionally believed. Under their theory, scientists do not so much passively derive laws of nature from empirical evidence as "invent" laws of nature, searching for theories—through a trial and error process as tedious as that involved in inventing—that are most consistent with the observed phenomena.

are often of secondary concern.[341] Inventions on the other hand are tools and applications of knowledge created in furtherance of a human goal.[342] In making inventions, inventors hope to devise ingenious methods or contraptions that are highly useful and prized by society, potentially bringing financial returns. Because scientific knowledge tends to reflect natural principles and facts and is often expressed in absolute terms, it is in general very difficult to work around when monopolized.[343] Inventions, on the other hand, can constitute but one of many ingenuous approaches to accomplish a humanly worthwhile goal where the extent of a workaround is limited only by the extent human ingenuity.[344]

Another *proxy rule* to a full-fledged the cost and benefit analysis of patenting may be the perspectives of many of today's leading scientists and technologists.[345] Scientists' and technologists' intuitions about incentives are impor-

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341 DEREK BOK, UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION 18 (Princeton University Press 2005) (2003) (noting that "[s]cholars, especially in the traditional disciplines, have deliberately chosen academic life in preference to the ways of commerce, in part because they look upon the search for truth and knowledge as a worthier calling than the quest for material wealth").

342 The intuition that discoveries are somehow "gained" through observations while inventions are "created" tools may help to explain the tendency of the law to sometimes evaluate subject matter in terms of novelty. *See also* discussions surrounding *supra* note 326 (explaining that basic knowledge cannot be patented as basic tools of future innovations).

343 *See* Heller & Eisenberg, *supra* note 16, at 700 (warning that the holdout problem associated with gene patents may be especially serious because of a "lack of substitutes for certain biomedical discoveries (such as patented genes or receptors)" where it may be impossible "to invent around patents [covering] the genetic bases of diseases as they occur in nature"); NAT'L RESEARCH COUNCIL, *supra* note 64, at 25 n. 13 (noting that patents over biological material (as opposed to laboratory equipments), make be especially difficult to invent around); Jordan Paradise, Lori Andrews, & Timothy Holbrook, *Patents on Human Genes: An Analysis of Scope and Claims*, 307 SCIENCE 1566, 1566 (2005) (observing that "[g]ene patents, especially, limit what can be done in the realm of scientific research and medical care because there are no alternatives to a patented gene in diagnosis, treatment, and research (*citations omitted*). When gene patents are granted improperly and in an overly broad manner, those problems are compounded."); *supra* notes 56–60 and 335–338 and accompanying text (discussing how patents involving basic knowledge can create especially perverse "*preemptive*" effects on subsequent innovations).

344 *See* Merges & Nelson, *supra* note 79, at 853–68 (discussing various scenarios where workarounds are considered "equivalents" and thus not allowed, and considered "non-equivalents" and allowed); Katz & Shapiro, *R & D Rivalry with Licensing or Imitation*, 77 AM. ECON. REV. 402 (1987) (exploring the costs and benefits of inventing around v. licensing).

345 Scientists' and technologists' intuitions about incentives are relevant because it is their incentives that patent system is ultimately addressing. Their insights into preemptive effects are also relevant because as leaders in their respective fields, they are among the best positioned to gage the effects that can result from monopoly over such knowledge.

tant because it is their incentives that the patent system is ultimately addressing. Their insights are also important because they are well positioned to gauge the effects that can result from monopoly over knowledge in their areas of expertise. Many experts in the biomedical field have publicly announced that they are against the patenting of genes.[346] From their perspectives, most of today's genomic innovations, involving sequencing of gene fragments or the mapping of gene functions, appear to be more discoveries than inventions.[347] Genes have existed nearly as long as there has been life on this planet. Genes hold unlimited promise for future advancements in understanding all biological pathologies and conditions.[348] While there is an infinite amount of knowledge that can be derived from genes, there is only a fixed number of genes. Thus, genetic knowledge may represent the very type of basic fundamental knowledge where proprietarization can actually adversely impact long-term innovations.[349]

In summary, subject matter eligibility constitutes the "gate keeping" function of the patent system, presenting in broad strokes what ought to be incentivized and what ought not to be under the ambit of the patent system. While important, the prohibition should not be applied as a simple exercise in semantics. As discussed earlier, the characterization of what is "natural" and "man-made" often depends heavily on the level of granularity at which innovations are evaluated. In any analysis, the existence of science-based incentives and the potential high cost of proprietarization should be taken into account. Furthermore, while science's distinction between discovery and invention and insights into the preemptive effects of patenting scientific knowledge should not be dispositive on the issue of eligible subject matter, scientists' concerns about genomic patents should represent an invaluable wakeup call that the law should not ignore.

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346 *See supra* notes 58–64.

347 *See supra* notes 56 and 57. *See also* R. Stephen Crespi, *Patents on genes: clarifying the issues*, 18 NAT. BIOTECH. 683, 683 (2000) (noting that "[t]hose who oppose patents on genes usually give four main reasons for their position: (1) Genes exist in nature and therefore, as our natural heritage, they should not be "owned" by any individual or group. (2) *Genes are discoveries and not inventions*. (3) Because of their existence in nature, genes cannot be "new." (4) Gene isolation and cloning is now such a well-established technique that it is no longer inventive to do it." (emphasis added)).

348 *See also* Adelman, *supra* note 16, at 1022.

349 *See* Kane, *supra* note 24, at 752 (asserting that "the genetic code should be characterized as a law of nature, based on its essential attributes, its historical treatment in scientific literature and public discourse, and its centrality in modern molecular biology. This is true apart from any questions related to patent law.").

B. Evaluating innovations by and limiting patent scope to the actual contribution made to the state of the art

Even if genomics innovations did require patents to incentivize and may be considered eligible subject matter, a second reason genomic patents should not be allowed today is that they cover more than the contribution typically made to the art by today's innovations. Biotechnology is a science-based industry that develops in cumulative technological rounds. To effectively incentivize an entire chain of innovations and not just one particular phase, incentives given at each stage should be narrowly limited to the contributions actually made to the art. Discussed *infra* are many reasons why narrow patents rather than broad patents can better serve the needs of science-based fields such as biotechnology.[350]

First, the inherent uncertainties associated with science-based industries suggest that competition rather than central coordination should be the preferred model for incentivizing innovations.[351] In a science-based field like the biotech-

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350 *See* Merges & Nelson, *supra* note 79, at 915; Scherer, *supra* note 12, at 1364.

351 *See* Merges & Nelson, *supra* note 79, at 873 (arguing that competition should be favored over coordination in most technological areas); Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 619–20 (Nat'l Bureau of Econ. Research ed., Princeton University Press 1962) (arguing that competition spurs innovation more effectively than monopoly because companies in a competitive marketplace are forced to innovate to survive while monopolists are not); Mark A. Lemley & Lawrence Lessig, *The End of End-to-End: Preserving the Architecture of the Internet in the Broadband Era*, 48 UCLA L. REV. 925, 960–62 (2001) (arguing that the Internet developed as well as it did because it was promoted by competitions rather than monopolies); Lemley & Lessig, *supra*, at 932–38 (arguing that the open nature of the Internet promoted innovation much better than centralized control by the telecommunications model); Howard A. Shelanski, *Competition and Deployment of New Technology in U.S. Telecommunications*, 2000 U. CHI. LEGAL F. 85, 87 (concluding from ten empirical studies that competition in the telecommunications industry spurred innovation better than monopolies); Burk & Lemley, *supra* note 107, at 1606 (noting that "many have argued that in some industries the freedom from patents is much more important to innovation than the incentive provided by patents"); John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, PATENTS IN THE KNOWLEDGE-BASED ECONOMY 291 n.11 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (noting that it is "well recognized in the economics of innovation [] that, given a technological objective (e.g., curing a disease) and uncertainty about the best way to attain it, that objective will be most effectively achieved to the extent that a greater number of approaches to it are pursued (citation omitted)"). *But see generally* WILLIAM J. BAUMOL, THE FREE MARKET INNOVATION MACHINE: ANALYZING THE GROWTH MIRACLE OF CAPITALISM (Princeton University Press 2002) (arguing that oligopoly spurs innovations better than either competition or monopoly).

nology industry,[352] it is difficult for a leader in one round of the innovation lifecycle to maintain the type of leadership needed to effectively coordinate successive rounds because each round offers unique and diverse challenges.[353] Thus it is ineffective for the law (e.g., the USPTO) to try to select[354] *ex ante* an inventor deserving of an early grant of a broad patent to coordinate subsequent innovations.[355] Instead of coordination, a model built on vigorous competition among multiple well-qualified, well-incentivized parties throughout all stages of the innovation process represents a more effective approach.[356] Narrow patents spur

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352 Jackson, *supra* note 12, at 6 (noting that because genes "encode information—a portion of the programming that makes life possible—they have a range of potential uses that continues to expand as we learn more and more about biotechnology. This "hybrid" nature—that a gene sequence is both technology and information—can make it difficult to judge the scope of a sequence patent and, as a result, make its effect on innovation difficult to predict.").

353 *See* Scherer, *supra* note 12, at 1362 ("[T]he kinds of competence needed for follow-on work may be quite different from what was needed to make the initial discovery. The different capabilities of university researchers as compared with industrial R&D teams are an obvious example."); Jackson, *supra* note 12, at 15 (observing that the expertise needed for gene isolation and subsequent applications involving the gene fragment are drastically different.); Dutfield, *supra* note 20, at 1–2 (noting that "biotechnology research and development is risky and expensive."); Scherer, *supra* note 12, at 1362 ("[A] single entity is not likely to perceive and back financially all the various derivative development possibilities.").

354 This would constitute a quasi-Kitchian approach where a government agency, instead of a pioneering patentee, takes on the responsibility of helping to coordinate follow-on innovations. *See* Adelman, *supra* note 16, at 994.

355 *See* Frank H. Easterbrook, *Who Decides the Extent of Rights in Intellectual Property?*, EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 405, 408 (Rochelle Cooper Dreyfuss et al. eds., Oxford University Press 2001) (observing that "[i]f firms that put millions of dollars on the line cannot make reliable decisions about technology, what would make us think that scholars [or policy makers] with *no* money on the line do well at devising legal rules to govern technology?"); Rowen, *supra* note 311, at 186 (noting that "[t]here are circumstances in which central control of technology is appropriate, indeed essential, as in the Manhattan Project during World War II or the race to the moon. But the record shows that when there is rapid technological change, as in the computer industry, and much uncertainty about which of many possible paths will be successful, a decentralized system in which many ventures are tried is more likely to succeed than a centralized one.").

356 *See* Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL'Y 273, 280 (1998) (observing that because of the unpredictability of biotechnological innovations, firms often find it more effective to spin-off companies to develop follow-on innovations); LANDES & POSNER, *supra* note 16, at 319 (noting that, partly because the future of technologies are so hard to predict, even [t]he original prospector may have a flawed conception of the optimal path of development"). *See also Symposium On Bioinformatics and Intellectual Property Law: The Proper Scope of IP Rights In The Post-Genomics Era*, 8 B.U. J. SCI. & TECH. L. 233, 234 (2001) (noting that "in the area of biotechnology, in general, over the last twenty years, all predic-

competition by preserving incentives of innovation throughout the innovation process, thus attracting many stakeholders with a wide range of aptitude and resources to participate throughout the entire innovation process.[357]

The advantage of broad patents in helping to internalize the benefits of innovation to original pioneers may also be overblown in uncertain industries such as biotechnology. While pioneers may indeed factor the internalization of potential follow-on benefits into their original incentives to innovate, such factors would arguably play a marginal role in uncertain, highly unpredictable science-based industries,[358] given the difficulty[359] of predicting technological trajec-

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tions have had an irritating habit of being completely wrong"). For some notoriously embarrassing examples illustrating the foolishness of being a sage in predicting technological directions, *see Things People Said: Bad Predictions*, http://www.rinkworks.com/said/predictions.shtml ("I think there is a world market for maybe five computers." (Thomas Watson, Chairman of IBM, 1943); "Where a calculator [today] is equipped with 18,000 vacuum tubes and weighs 30 tons, computers in the future may have only 1,000 vacuum tubes and weigh only 1.5 tons." (Popular Mechanics, 1949); "I have traveled the length and breadth of this country and talked with the best people, and I can assure you that data processing is a fad that won't last out the year." (Editor in charge of business books for Prentice Hall, 1957); "But what . . . is it good for?" (Engineer at the Advanced Computing Systems division of IBM, commenting on the microchip, 1968); "There is no reason anyone would want a computer in their home." (Ken Olson, Present, Chairman and founder of Digital Equipment Corp., 1977); "640K ought to be enough for anybody." (Bill Gates, CEO of Microsoft, 1981)).

357 This may raise some anticommons concerns. *See supra* note 264 (discussing the anticommons problem); *but see supra* notes 268 and 269 (discussing ways of alleviating the anticommons problem); *infra* notes 363–365 (discussing natural market forces that arise to help alleviate the anticommons problem); *supra* note 206(finding little empirical evidence of the anticommons problem in biotechnology). It may also come as a surprise to some that a patent in itself is not anti-competitive. *See* FED. TRADE COMM'N, *supra* note 4, at 9 (observing that "[p]atents do not [necessarily] . . . confer monopoly power on their holders, and most business conduct with respect to patents does not 'unreasonably restrain' or serve to monopolize markets"); HERBERT HOVENKAMP, ECONOMICS AND FEDERAL ANTITRUST LAW § 8.3, at 219 (West 1985) (noting that "[m]any patents confer absolutely no market power on their owners . . . . The economic case for 'presuming' sufficient market power . . . is very weak."); 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 4.2 (Supp. 2007) (suggesting that it is rare for patents to confer market power); Panel Discussion, *The Value of Patents and Other Legally Protected Commercial Rights*, 53 ANTITRUST L.J. 535, 547 (1985) (reporting that "[s]tatistical studies suggest that the vast majority of all patents confer very little monopoly power . . . "); William Montgomery, Note, *The Presumption of Economic Power for Patented and Copyrighted Products in Tying Arrangements*, 85 COLUM. L. REV. 1140, 1156 (1985) (noting that "[m]ore often than not, however, a patent or copyright provides little, if any, market power").

358 *See generally*, *e.g.*, Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive*

tories.[360] Many innovations start out innocuous only to make a large impact later, while many hyped innovations turn out to not make much impact at all.[361] In such circumstances, pioneers would more likely base their decisions to innovate on the immediate benefits of their invention rather than some distant, speculative follow-on benefits.

Narrow patents also help to check the problem of over-hype that can be particularly endemic to breakthrough-driven fields such as biotechnology.[362] Because of hype and speculation, the temptation to over-recognize any one individual round by creating overly broad patents is great in biotechnology. Narrow patents help to instill discipline in the patenting process by limiting patent scopes to what have been explicitly invented (i.e. enabled). While limiting patent scope can create anticommons problem by potentially increasing the number of patents awarded, the anticommons problem in biotechnology[363] may also be overblown. Other cumulative industries, such as software and semiconductors,

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Remedies, 97 MICH. L. REV. 985 (1999) (evaluating patent incentives in the context of uncertainty and delay).

359 *See supra* note 356 and accompanying text.

360 If the follow-on innovations are really that predictable, the pioneer would probably, simply on first mover advantage of having expertise in the area, be the party most likely to make and corner the envisioned follow-on innovations even without patents, rendering the issuance of broad patents either unnecessary or also inadvisable.

361 For examples of duds from Popular Mechanics, see Mary Seelhorst, *Greatest Hits (and Misses) of Popular Mechanics: Celebrating 100 Years of Prediction in Our Pages, Which Ones Hit the Mark—and Which Ones Didn't*, POPULAR MECHANICS, January 1, 2002 (1928: predicting that 50–100 years into the future, "milk and butter will be derived from kerosene instead of cows"; 1932: agreeing with Churchill that "[w]e shall escape the absurdity of growing a whole chicken in order to eat the breast or wing, by growing these parts separately under a suitable medium"; several times since 1940: predicting the existence of a flying car in every American garage; 1941: predicting in less than 50 years a nuclear powered car that will drive "5,000,000 miles without refueling"; 1950: predicting that people will all be living in mobile homes made of synthetic materials since, by 2000, natural resources such as "wood, brick and stone [will become] too expensive" for such uses; 1954: predicting that by 2004 "[a]ir transportation [will make] the multi-family apartment house obsolete, as each family now needs a private landing strip").

362 *See* Merges & Nelson, *supra* note 79, at 883–84 (noting that patent scopes need to be carefully scrutinized in science-based industries because "scientific developments tend to narrow and focus perceived technological opportunities . . . [where] it is anticipated that the first to apply a scientific finding will get a patent of considerable scope.").

363 *See* Heller & Eisenberg, *supra* note 16, at 698–99 (identifying the anticommons problems in biomedical research); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 192–94 (2001) (arguing that upstream patents in biotechnology could impede subsequent research).

have shown that symmetrical mutual dependence of intellectual property can foster mechanisms such as patent and license pools that minimize the transaction costs associated with the redistribution of intellectual property assets.[364] Narrow patents help to create precisely the type of mutual, symmetrical dependence that increases the chance that all parties involved in the innovation process will share their intellectual property jackpot. Decreased transaction costs, realized in response to the fragmentation of intellectual property assets, increases the chance that intellectual property assets will be optimally distributed for subsequent use without the need for an accurate initial distribution of intellectual property assets.[365]

Given the relative high cost of broad patents and the benefits of narrow patents in cumulative fields—and recent studies that show many research-intensive industries do not rely as heavily on intellectual property protection to incentivize research and development as was commonly believed[366]—the use of narrow patents appears to be a wise, balanced approach to incentivize gene based innovations.

C. Bayh-Dole and the modern innovations landscape

Prior to 1980, many of the discoveries made in universities under federal grants were considered public knowledge and not patented; the few innovations that were patented belonged to the government, and of the few that were licensed,[367] most were subjects of non-exclusive licenses.[368] To increase the

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364 *See* Heller & Eisenberg, *supra* note 16, at 700 (noting that "[p]erhaps [the anticommons problem] in biomedical research will recede as licensors and licensees gain experience with intellectual property rights and institutions evolve to help owners and users reach agreements. The short-term costs from delayed development of new treatments for disease may be worth incurring if fragmented privatization allows upstream research to pay its own way and helps to ensure its long-run viability.").

365 *See* discussions surrounding *supra* notes 240–248.

366 *See* Zvi Griliches et al., *The Value of Patents as Indicators of Inventive Activity*, ECONOMIC POLICY AND TECHNICAL PERFORMANCE 97, 120 (Partha Dasgupta & Paul Stoneman eds., Cambridge University Press 1987) (finding that "[w]hile the aggregate value of patent rights appears to be quite high, it is estimated to be only of the order of 10 to 15 percent of total national expenditures on R&D. Hence it is unlikely to be the major factor in determining the overall level of [innovations]."); F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 447 (2d ed. 1980) (describing under what conditions firms may find investment in innovation profitable even without patent protection).

367 *See* Scott Shane, *Encouraging University Entrepreneurship? The Effect of the Bayh-Dole Act on University Patenting in the United States*, 19 J. BUS. VENTURING 127, 132 (2004) (noting that most pre-Bayh-Dole patents were unlicensed).

incentives of the private sector to commercialize university-made discoveries, the Bayh-Dole Act incentivized universities to take title to their discoveries and to arrange for exclusive licenses where appropriate.[369] Much has been made of how the Bayh-Dole Act has promoted close collaborations between academia[370] and industry.[371] Given the preceding discussions on the economics of incen-

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368 *See* Jennifer A. Henderson & John J. Smith, *Academia, Industry, and the Bayh-Dole Act: An Implied Duty to Commercialize* 2 (Oct. 2002), http://www.chemistry.org/portal/a/c/s/1/resources?id=f905c06c69cd11d7f2c16ed9fe800100. *See also generally* SHEILA SLAUGHTER & GARY RHOADES, ACADEMIC CAPITALISM AND THE NEW ECONOMY: MARKETS, STATE, AND HIGHER EDUCATION (Johns Hopkins University Press 2004); DAVID C. MOWERY ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES 127–59 (Stanford Business Books 2004) (surveying the effects of Bayh-Dole on research and patenting processes in American universities).

369 *See* Henderson & Smith, *supra* note 368, at 3.

370 One of the primary purposes of universities is "to promote inquiry and advance the sum of human knowledge." Am. Ass'n of Univ. Professors, *1915 Declaration of Principles on Academic Freedom and Academic Tenure*, POL'Y DOCUMENTS & REPS. app. 1, at 295 (9th ed. 2001).

371 *See* Shane, *supra* note 367 at 132 (discussing the Bayh-Dole Act and issues that arise). In fiscal year 2004, largely as a result of university-industry technology transfer initiatives promoted under Bayh-Dole, 159 U.S. universities executed some 3928 new licenses, obtained more than 3800 U.S. patents, and reaped over $1 billion in *net* patent licensing income. ASS'N OF UNIV. TECH. MANAGERS, AUTM U.S. LICENSING SURVEY: FY 2004, SURVEY SUMMARY ii, 22, 26 (2005), *available at* http://www.autm.net/events/File/FY04 Licensing Survey/04AUTM-USLicSrvy-public.pdf. In contrast, in 1991, only ninety-eight responding universities garnered a mere $123 million in *gross* licensing income. ASS'N OF UNIV. TECH. MANAGERS, AUTM LICENSING SURVEY: FY 1991–FY 1995: A FIVE YEAR SURVEY SUMMARY OF TECHNOLOGY LICENSING (AND RELATED) PERFORMANCE FOR U.S. AND CANADIAN ACADEMIC AND NONPROFIT INSTITUTIONS, AND PATENT MANAGEMENT FIRMS 10, 14 (1996), *available at* http://www.autm.net/events/File/Surveys/91-95AUTMLicSurvey Public.pdf. Nevertheless, the increase in licensing activities alone does not necessarily reflect substantive technology progress. While increases in licensing may be indicative of technological innovation, it may also be indicative of legal gamesmanship. *See* Shane, *supra* note 367, at 129, 133, 148. There is evidence that shows that universities select technologies to patent based not on their technological merit but on the expected returns from licensing. *See id.* at 129–31. Similarly, businesses may be looking for university licenses not as a means to obtain new technologies but as a legal tool to gain a competitive edge over competitors. The use of patents as arbitrage rather than a tool for advancing technology is not new. Many patentees (i.e., "patent trolls") have successfully raised significant revenues by licensing unused, patented technologies to those who uses the technologies. *See* Barton, *supra* note 14, at 1933 (noting that "[b]uilding the portfolio requires enormous legal cost but contributes little to research incentives"). *See also generally* KEVIN G. RIVETTE & DAVID KLINE, REMBRANDTS IN THE ATTIC: UNLOCKING THE HIDDEN VALUE OF PATENTS (Harvard Business School Press 2000). The practice can become problematic if the typical licensing pattern involves the licensing of a patent that has lied dormant in the patent vault (with no one ever reading it) to a

tives, the question whether recent legal developments such as Bayh-Dole have changed the balance between patent and science-based incentives is appropriate.

The short answer is no. While the Bayh-Dole Act may have changed the procedures by which researchers disclose innovations in universities,[372] and is not without its share of supporters and detractors, [373] it has not supplemented

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licensee who had created the invention independently. It may also be problematic to have businesses focused solely on inventing technologies on paper (in the form of patents), wait for the technology or marketplace to mature, and try to extort royalties from companies who independently invented the technology later when the technology or marketplace becomes mature.

372 *See* Jerry G. Thursby & Marie C. Thursby, *Who Is Selling the Ivory Tower? Sources of Growth in University Licensing*, 48 MGMT. SCI. 90, 93 (2001) ("Half of the firms in our industry survey noted that they include delay of publication clauses in at least 90% of their university contracts. The average delay is nearly four months, and some firms require as much as a year's delay.").

373 *See*, *e.g.*, Opinion, *Innovation's Golden Goose*, THE ECONOMIST TECHNOLOGY QUARTERLY, Dec. 14, 2002 (noting that "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980."); *Patent Act of 2005: Hearings Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 109th Cong. 22–23 (2005) (statement of Carl Gulbrandsen, Managing Director, WARF) (summarizing the results of successful university patents); 150 CONG. REC. S2559 (daily ed. Mar. 10, 2004) (statement of Sen. Leahy) (noting the benefits of collaborations between university and industry); ASS'N OF UNIV. TECH. MANAGERS, AUTM LICENSING SURVEY: FY 2003, SURVEY SUMMARY 2, 4–11 (Ashley J. Stevens & Frances Toneguzzo eds., 2004), *available at* http://www.autm.net/events/File/Surveys/03_Abridged_Survey.pdf (describing successful products that have resulted from technology transfer); Gary Rhoades, *Capitalism, Academic Style, and Shared Governance*, ACADEME, May–June 2005, *available at* http://www.aaup.org/publications/Academe/2005/05mj/05mjrhoa.htm (arguing that the new regime of academia-industrial collaboration features the right "market rules, and that its operation serves the interests of higher education and the larger society"); E. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 JAMA 473, 478 (2002) (discounting attacks against Bayh-Dole by observing that scientists hoarded data, inhibiting general research for private gain even before Bayh-Dole). *But see* Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217, 218–19 (2006) (arguing that patents have stifled knowledge sharing in academia and suggesting patent reforms to solve the problem); Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1726 (1996) (positing that the patenting of upstream research tools calls into question the appropriateness of public funding to support such research); Rifkin, *supra* note 1, at 55–56 (presenting anecdotal evidence that University patenting has a chilling effect on research); Clovia Hamilton, *University Technology Transfer and Economic Development: Proposed Cooperative Economic Development Agreements Under the Bayh-Dole Act*, 36 J. MARSHALL L. REV. 397, 415 (2003) (noting that the Bayh-Dole collaboration with industry may compromise the integrity of basic academic research); Angell, *supra* note 301, at 8 (observing that "[w]hile Bayh-Dole was clearly a bonanza for big pharma and the biotech industry, whether its enactment was a net

or replaced academic and science-based incentives.[374] The main purpose of the Bayh-Dole Act is to promote the transfer of technology from academia into industry, not to replace academic research with industrial research.[375] American academic universities continue to rank among the world's most dynamic and innovative institutions.[376] Science, particularly endeavors centered on the biological sciences, continues to rank among the most exciting and high impact of human endeavors. If the twentieth century was the century of physics (producing breakthroughs that led to advances from fields as diverse as atomic energy and modern electronics), the twenty-first century is the century of biotechnology, as pundits have penned.[377] The unrelenting breakneck speed at which science is progressing and the limitless possibilities the science holds should be indicative of the continued vitality of traditional academic, science-based incentives[378] and not of its demise.[379]

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benefit to the public is arguable."); Irwin Feller, *Universities as Engines of R&D Based Economic Growth: They Think They Can*, 19 RES. POL'Y 335 (1990) (describing the tensions brought forth by the Bayh-Dole Act between industry and academia values); Yong S. Lee, *Technology Transfer and the Research University: A Search for the Boundaries of University-Industry Collaboration*, 25 RES. POL'Y 843 (1996) (assessing how the potential for commercialization brought by Bayh-Dole may be re-shaping academic norms); Peter Mikhail, 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, 383–84 (2000) (suggesting that the exclusive licensing of technology supported by federal funds unreasonably limits access to research tools); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 291 (2003) (arguing for greater discretion to grant non-exclusive licensing of federally funded inventions).

374 *See* Shane, *supra* note 367, at 128 (reporting that the Bayh-Dole Act has not been responsible for the increase in academic entrepreneurial activity since 1980 and that any increase in commercially oriented university activities, such as patenting and licensing, has been driven instead by contemporaneous shifts in intellectual property laws and regimes for funding academic research, (citing Rebecca Henderson et al., *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965–1988*, 80 REV. ECON. & STATS. 119 (1998); 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 (2001); David C. Mowery & Arvids A. Ziedonis, *Academic Patent Quality and Quantity Before and After the Bayh-Dole Act in the United States*, 31 RES. POL'Y 399 (2002)); Willison & MacLeod, *supra* note 264, at 261 (observing that R&D "[e]ffort is placed disproportionately on discoveries that would maximize profits to the inventor, by targeting large, potentially lucrative markets, rather than on discoveries that would maximize benefit to society").

375 *See* 35 U.S.C. § 200 (2006).

376 *See* Adrian Wooldridge, *Why American Universities Will Lead the World*, THE ECONOMIST (Nov. 23, 2005); Angell, *supra* note 301, at xvii, 56-57, 65.

377 *See* Shane, *supra* note at 367, at 1.

378 The observation that many universities are moving to patent more and more basic discoveries does not necessarily mean that science is increasingly driven by patent incentives. Many

Nevertheless, the Bayh-Dole Act has promoted a peculiar, nontraditional brand of patents.[380] Unlike either traditional quid pro quo-based patents or Kitch's broad coordination patents, Bayh-Dole patents are used to incentivize the implementation, not creation, of innovations.[381] The inventions covered by Bayh-Dole patents are, after all, innovations that would have emerged in the universities even without patents. A university obtains a patent over a drug target not because its researchers need patent incentives, but because businesses need assurances of some monopoly protection to commit the resources needed

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universities may simply be driven to patent for defensive purposes. *See* Heller & Eisenberg, *supra* note 16, at 698–99 (noting that "[r]esearchers and their institutions may resent restrictions on access to the patented discoveries of others, yet nobody wants to be the last one left dedicating findings to the public domain"); Symposium, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy Executive Summary*," 19 BERKELEY TECH. L.J. 861, 868 (2004) (noting that many companies are forced to play patent game and create "defensive patents" that "have no . . . innovative value in and of themselves" to avoid being sued even though resources "could have been better spent on developing new technologies."); Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future After Festo*, 19 BERKELEY TECH. L.J. 1157, 1203 (observing that "the patent system operates only as a tax on innovation" as many businesses now patent not to disclose innovations, but to play the patent game to prevent litigation claims); *see* text surrounding *supra* note 311 (observing that patents in cumulative industries are used more often as leverage for cross-licensing than as tools to block out a market).

379 *See*, *e.g.*, Scherer, *supra* note 27, at 1355 (reporting that the private funding of R&D only accounted for three additional percentage points of the total academic R&D research budget); Darren E. Zinner, *Medical R&D at the Turn of the Millennium*, 20 HEALTH AFF. 202, 205 exhibit 4, *available at* http://content.healthaffairs.org/cgi/reprint/20/5/202.pdf (reporting that despite the huge resources committed by the private sector, up to two-thirds of drug R&D is still done by academia and federal agencies rather than private industry); Citizen.org, *Rx R&D Myths: The Case Against The Drug Industry's R&D "Scare Card"*, PUBLIC CITIZEN'S CONGRESS WATCH 8–10 (Washington, D.C., July 2001), *available at* http://www.citizen.org/documents/ACFDC.pdf (observing that despite massive private expenditures, most drug breakthroughs come from academia and federal agencies rather than private industry).

380 David C. Mowery et al., *The Effects of the Bayh-Dole Act on U.S. University Research and Technology Transfer*, INDUSTRIALIZING KNOWLEDGE: UNIVERSITY-INDUSTRY LINKAGES IN JAPAN AND THE UNITED STATES 269, 274 (Lewis M. Branscomb et al. eds., Cambridge, Mass: MIT Press 1999) (suggesting that the economic theory behind the Bayh-Dole Act is "based on little evidence").

381 *See* Burk & Lemley, *supra* note 107, at 1605 (stating that "the only reason we need intellectual property rights is to create ex ante incentives, not ex post control rights"). *Cf.* Barton, *supra* note 14, at 1933 (lamenting that current law "appears to assume that the normal scientific and engineering development process should be rewarded by a patent."); Eisenberg and Nelson, *supra* note 337, at 94 (arguing that "[p]atents on inventions with clear practical applications may well facilitate product development, but patents on discoveries that may spur future basic research impose serious costs on the scientific enterprise and are much harder to justify. The Bayh-Dole Act ignores this distinction . . . .").

to commercializing the drug target.[382] If traditional quid pro quo patents can be thought of as legal rights rewarded quid pro quo for enabling new technologies, and if Kitch's coordination-motivated patents seen as *ex ante* permits to develop yet-to-be-enabled technologies,[383] then Bayh-Dole patents can be viewed as *ex ante* permits to carve out yet-to-be-commercialized technological markets for development.

One potential problem with Bayh-Dole is that if the goal of patents is now to incentivize commercialization rather than creations of innovations,[384] patents should presumptively be awarded irrespective of whether a "new" discovery or invention us made, but rather whenever proprietarization of knowledge (including well-known knowledge)[385] could help to advance commercialization developments. Furthermore, patent terms might also be made indefinite (novelty would now have no relevance) ; what is more important is if patenting helps businesses to recoup commercialization investments.[386] The break up of previously commons knowledge piecemeal into proprietary bits however can produce real costs and should not be taken cavalierly.[387] If a less drastic option than proprietarizing scientific commons knowledge exists to incentivize businesses to commercialize commons knowledge, that option should be considered.[388]

The importance of distinguishing between incentives for innovations and incentives for commercialization can best be seen through an example.[389]

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382 For example, Yale would not have been able to commercialize its aids treatment drug d4T without possessing the patents needed to attract partnership with the private sector, in this case Wyeth-Ayerst Pharmaceuticals. *See* Dervan, *supra* note 12.

383 *See* Burk & Lemley, *supra* note 107, at 1604 (observing that "on Kitch's theory one might think it appropriate to assign rights to prospect for inventions to companies even before they have invented anything").

384 See *supra* notes 216–222 and accompanying text for discussion on why patents should not be used to compensate for extra-innovation risks, including commercialization risks.

385 There are certainly some who oppose the proprietarization of commons knowledge, however. *See*, *e.g.*, http://www.pubpat.org/.

386 *Cf.* Copyright Term Extension Act of 1998, Pub. L. No. 105-298, 112 Stat. 2827 (1998) (codified as amended 17 U.S.C. §§ 108, 203, 301–04) (or somewhat pejoratively, "the Mickey Mouse Protection Act").

387 *See supra* notes 225–227 and accompanying text (discussing the foundation of a property-based IP system); *supra* note 264 and accompanying text (discussing anticommons concerns).

388 It is either unnecessary or ill-advised to issue patents for inventions that would have emerged without patents. *See* LANDES & POSNER, *supra* note 16, at 22, 24.

389 See also *supra* notes 219-222 and accompanying text (discussing why patents should not be used to compensate for extra-innovation risks).

Hypothetically, consider the instance of a producer looking to sell cameras on a newly discovered island where the natives had not been exposed to the modern world. The natives have adopted all the intellectual property laws and rules of the United States. A producer would like to commercialize a generic, basic film-based camera, but is concerned that while the natives have generally shown great interest in photography, they also seem to harbor deep suspicions that the cameras used to shoot human subjects might unsuspectingly capture the subjects' "souls." The photography market on the island has hence been greatly underdeveloped. No company has yet been willing to spearhead a marketing effort to "educate" the natives about the safety of human subject photography. The producer, too, has been hesitant about committing tremendous resources needed to be the market pioneer.

The producer does not want to take the lead only to have imitators free ride off the company's pioneering marketing efforts by later jumping into the market with their own cameras. According to industry sources, a competitor with their own lines of proprietary cameras has been waiting and planning to do exactly that. To incentivize our producer to take that marketing plunge, should the natives award our producer a patent over the basic, generic, film-based camera? If the natives took the policies of Bayh-Dole to proprietarize a previous commons resource to heart, they probably would. However, awarding a patent over previously unpatented technologies would both over-protect and under-protect the producer. It over-protects because the producer would privatize knowledge beyond the scope of its need. With a generic camera patent, the producer may corner the entire film-based camera market, including the market for non-human subject photography, even though the producer did not have to expend resources on expensive "educational campaigns" to create the non-human subject photography markets. It also under-protects because the producer is not protected against potential competitors who can free ride off of the producer's marketing efforts by jumping in later with their proprietary, non-generic versions of cameras after the market for human subject photography has been developed. What is really needed in this case is not a patent over otherwise commons knowledge, but a commercialization permit that can compensate entities for taking on commercialization risks such as being a marketing pioneer.[390] The same observation applies in other contexts, including Bayh-Dole patents covering previously commons scientific knowledge or broad pharmaceutical product patents justified on the grounds of extra-innovation risks. When extra-innovation risks exist (such as commercialization risks), instead of patents, it

[390] *See also supra* notes 216–222 and discussions therein (discussing why the patents should not be used to compensate for extra-innovation risks).

may be more appropriate to create special monopolies that specifically address those risks.

VII. PRESENTING A GENE PATENT REGIME POST-*NATURAL EXTRACTS DOCTRINE*

This paper has discussed the broad economic, legal, and technological issues associated with patents, particularly genomic patents. Despite the complexity of the issues discussed, one simple way to reform the patent system may simply be to eliminate the *natural extracts doctrine*, followed by reforms to reinvigorate the prohibition against patents on nature, and ensure that a patent's scope is limited to the enabled invention. This section presents a framework of what such a reformed gene patent regime might look like.

Gene related innovation today includes a whole spectrum of genetic discoveries and inventions, including: the identification, isolation and sequencing of genes; the identification of gene functions; and the use of genes as research tools and for diagnostic[391] and therapeutic[392] applications. Given today's technological landscape, a method-based rather than a product-based patent regime can probably adequately incentivize current genomic innovations without impeding future innovations[393] and appears to be the approach that the Germans and French are headed.[394]

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391 For example, measuring a person's gene expression profiles to diagnose a biological condition or pathology, or using a person's genomic profiles to predict the person's susceptibility to diseases.

392 For example, using gene profiles of diseased persons to discover potential drug targets, or using a person's unique genomic signatures to inform doctors in prescribing personalized medicines.

393 Method patents are not necessarily watered down patents. Consider the controversy over US patent number 6,647,341, which claimed a technique to enable researchers to distinguish between two types of leukemia using a DNA microarray technique. *See Patent Sprawl: From Genes to Gene Interpretation*, 302 SCIENCE 1878, 1878 (2003) (discussing grave concerns over patent 6,647,341). Under the framework discussed in this section, processes such as the microarray technique would be eligible subject matter (to be patentable, it needs to also satisfy all the other patentability requirements, including nonobviousness and enablement). It represents a real world example where method patents have real teeth and can even present worrisome *preemptive* effects. Note that patents with strong preemptive effects are not *per se* bad. *See supra* note 338 (observing that to incentivize truly groundbreaking innovations, the patent system must be prepared to award patents with broad preemptive powers where appropriate).

394 Graham Dutfield, *DNA patenting: implications for public health research*, 84 BULLETIN OF THE WORLD HEALTH ORG. 388, 390 (May 2006), *available at* http://www.who.int/bulletin/volumes/84/5/388.pdf.

Under this regime, gene fragments, such as DNA, cDNA, RNA, EST, and SNP that are derived from an organism's genome, are products of nature and hence *per se* ineligible subject matters.[395] The identification of a gene function *per se* is also per se ineligible because a gene's function represents a natural principle of biology. However, the application of a gene function, if the application is a non-obvious application of knowledge of a gene function, may be patentable.[396] The use of genes for specified diagnostic or therapeutic purposes

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[395] There are several types of isolated genomic fragments, including ESTs, SNPs, and cDNAs. It can be argued that isolated fragments are distinguishable from natural fragments in several ways and hence should be considered artificial and patentable. First, the isolated fragments, derived from mRNAs, typically consist of only expressed gene sequences (so-called exons), stripped of the so-called introns (or junk DNA sequences) contained in the natural genome. Second, extracted sequences are usually kept in the form of stable cDNA libraries, not natural RNAs or chromosomal DNAs. Regarding the first point, while it is true that genomic DNAs contain both introns and exons, a molecule representing exons does not necessarily indicate the molecule is manmade. For example, mRNAs represents only exon sequences also and are known to indisputably exist naturally in the cell cytoplasm. Further, the issue of whether the nonexistence of introns should render a product manmade is also susceptible to the level of granularity at which isolated gene products are examined. For example, at a low enough level of granularity. Regarding the second point, it is important to note that the cDNA molecule is not per se a human construct. The "complementary" nature of cDNA is more descriptive of the technique used to derive cDNA than the molecule itself. cDNA is *complementary* in the sense that it is synthesized from a mature mRNA template to form a *complementary* copy of the original gene. cDNA is normal DNA in all respects of the molecule. While the use of DNA to copy and store mRNA information may have been a uniquely human, artificial construct, the resulting molecule formed is not. Finally, irrespective of the above arguments, a third independent argument exists against the patenting of genomic molecules. Under the modern genomics paradigm, genomes are studied primarily for its information. Such information should be considered part of nature, irrespective of the chemical form in which the information is embedded. Allowing the patenting of these chemical effectively represents the patenting of the natural genome itself since it is through these molecules that genes can be studied and manipulated. *See supra* note 24; *see also* Andrews, *supra* note 50, at 803 (observing that "[t]he useful properties of a gene's sequence . . . are not ones that scientists have invented, but instead, are natural, inherent properties of the genes themselves.").

[396] The author concedes that distinguishing between an obvious and a nonobvious application of biological knowledge may not be simple. *See*, *e.g.*, Demaine & Fellmeth, *supra* note 7, at 379 (noting that "[b]iotechnology differs from other kinds of commercial enterprises insofar as the most fundamental basis of its value is often the discovery of preexisting building blocks of nature, with little emphasis on originality in terms of invention of products except at the level of applied biotechnology."). To make matters worse, from an economics of incentives perspective, it is potentially possible that some biochemical pathways are studied not because they are "scientifically interesting" but only because such knowledge confers economically valuable capabilities to diagnose or treat a human disease or condition. Patents can arguably play an important role to incentivize the research of such pathways, even if such pathways constitute natural phenomena. A detailed discussion of this issue is beyond the

may thus be patentable.[397] For example, in a DNA microarray application, the use of a set of genomic fragments used to genetically diagnose a disease may be patentable even if the set of genes, as natural products derived from a natural genome, is not patentable.[398] Similarly, the use of genomic fragments to diagnose a disease may also be patentable even if the fragments of genes, as natural products derived from a natural genome, are not. In addition, the techniques used to isolate a gene fragment or study a gene function may also constitute eligible subject matter even if the actual isolated fragments are not.[399]

The emphasis on method patents also has implications for the broader pharmaceutical industry. Without the *natural extracts doctrine*, large molecule drug targets that are merely purified products from nature would no longer constitute eligible subject matter. Since most pharmaceutical innovations involve the invention of a novel purification or manufacturing technique, or discovery of a novel use of a naturally derived compound, method patents would continue to incentivize today's pharmaceutical innovations. In fact, method patents match better the scope of the actual contributions made by pharmaceutical companies today. For example, by discovering a novel use of a compound—as evidenced by the selection, testing and verification through an FDA-sanctioned process of

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scope of this paper, but the author contends that the situation described above is a very marginal case. The vast majority of the time, science based incentives (e.g. prestige, fame, and recognition) should ensure that scientists find that all biochemical phenomena that underlie real human diseases or conditions of interest to study—without patents. Science-based incentives should enable the creation of a core corpus of commons scientific knowledge on which later drugs or diagnostics applications can be built. In most cases, there would still be a role for patents because much more needs to be done beyond the creation of the core corpus of commons scientific knowledge —such as finding the precise variation of molecular structure as drug targets, characterizing the precise dosage needed to treat a condition under fixed parameters of efficacy and safety, or designing a specific technique to diagnose a condition with specified accuracy.

397 For example, if it is known that one particular gene causes a particular disease and that the gene is never involved in another other biochemical pathway, then the use of the expression of that gene to diagnose the disease may not be patentable if a person of ordinary skill in the art would have considered such an application to be an obvious application of a nonpatentable knowledge about nature. (A device used to detect and make the diagnosis may nevertheless be patentable however). Suppose however that a complex network of gene is implicated in a disease and that researchers cannot identify any single one gene or set of genes that is always expressed when the disease is implicated, then the use of a subset set of genes that can accurately diagnose the onset of a disease may be patentable.

398 Note, some microarrays rely on artificially designed gene probes (e.g. Affymetrix) and not natural genomic fragments as biological assays. In such cases, the gene probes constitute artificial manmade artifacts and may be eligible for product gene patents.

399 To be patentable, the invention still needs to meet other patentability requirements, such as nonobviousness.

the use of a specific compound for specified diagnostic or therapeutic purposes—what a pharmaceutical company is contributing involves typically discovering or inventing specified uses of a product—not the product itself. For these innovations, method patents would be more than adequate. Product patents will only be justified when a *bona fide* new bio-molecule has been created as viewed from the perspective of a person skilled in the art.[400]

The reinvigoration of eligible subject matter and the consequential limiting of patent scope to contribution made to the art will help to curb many of the concerns the Federal Circuit has regarding vague, overly-broad biotechnology patents.[401] As Judge Lourie noted, many researchers can patent a gene product by mere acknowledgement of a DNA plus a particular function, which "has been postulated since, perhaps, Mendel . . . ."[402] This predicament can be eliminated when it is required that genetic innovations being patented constitute real and *bona fide* contributions to science and further are of the type of inventions that is not already properly incentivized by science-based incentives.

VIII. CONCLUSION

As science and technology play ever-increasing roles in promoting societal welfare, a well-designed patent policy plays a more and more crucial part in fostering societal well being. At stakes are advances in science and biomedicine that can dramatically lengthen and improve the quality of people's lives. This paper has discussed some of the economic, legal, and technological issues surrounding the issuance and use of patents, especially those in the context of biotechnology. In science-based, cumulatively developed fields such as biotechnology, patents must incentivize contribution to the arts. Long-term progress requires contribution to the art to be properly evaluated and incentivized at every stage since the future progress is almost always built on the edifices laid down in the previous stage of development.

The *natural extracts doctrine* was originally created as a limited exception to the prohibition against the patenting of nature to allow for the patenting of a narrow group of natural products for pharmaceutical applications. Unfortunately, the doctrine has been expanded to apply to contexts far beyond what was originally envisioned, in the process misconstruing broad areas of science and innovations and threatening to impede the progress of entire fields. A doctrine like the *natural extracts doctrine* has misconstrued the technological landscape,

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400 *See supra* note 196 and accompanying text.

401 *See supra* notes 144–147.

402 Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 974 (Fed. Cir. 2002).

failed to appreciate modern shifts in scientific paradigms, mischaracterized contributions made by alleged innovations, and in general codified outdated science into the law.

Genes, as the templates that govern all biological processes, hold a new key to studying, understanding, and manipulating biological phenomena with an unprecedented degree of precision and control. While an unlimited amount of knowledge and power wait to be derived from the study and manipulation of genes, there are only a fixed number of genes. Perhaps for this reason alone, it may be preferable to allow patents to cover the gene applications rather than the genes themselves. Many leading scientists have raised vocal oppositions to the patenting of genes. The author believes that genomic patents (i.e., gene product patents) should categorically be considered ineligible subject matter. Instead of gene product patents, method patents over novel techniques to isolate genes and/or patents over novel diagnostic or therapeutic techniques should be relied upon. These patents more accurately capture the true contributions being made and more effectively incentivize genomic innovations in the long term.

To reverse the damage and legal confusion that decades of application of the *natural extracts doctrine* has produced, this doctrine must be promptly abandoned or at least radically limited. In building a post-*natural extracts doctrine* patent regime, the subject matter eligibility requirement should be reinvigorated, and quid pro quo enablement based patent scope should be more strictly enforced. Finally, policy makers and judges alike should understand that the patent system is not an all-encompassing industrial policy regime meant to compensate for extra-innovation risks. While a long litany of risks often present themselves on the uncertain road from the creation of enabled technologies to the commercialization of these technologies, the use of the patent system to compensate for extra-innovation risks (such as commercialization risks) is often accomplished only by misconstruing the underlying science, unnecessarily distorting patent incentives and impeding technological progress in the long term. These should all be avoided if possible.