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An Examination of the Issues Surrounding Biotechnology Patenting and Its Effect Upon Entrepreneurial Companies

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Summary

The biotechnology industry is notable both for its heavy concentration of small businesses and its weighty research and development (R&D) expenditures. Given the small size and heavy expenses of many biotechnology firms, their ability to raise venture capital may be of some consequence. The patent law has been identified as a facilitator of these R&D financing efforts.

Although many observers believe that the patent law plays a significant role in the biotechnology industry, two principal issues have arisen regarding biotechnology patenting. First, observers have fundamentally questioned whether patents should be granted for living inventions, genetic materials and other biotechnologies. Ethical issues, concerns that biotechnology patenting promotes animal suffering and decreases genetic diversity, as well as regard for the traditional agricultural community animate many of these objections. Supporters of biotechnology patenting counter that trade secret protection is a less attractive social alternative, observe that patents have long been granted for biotechnologies, and question whether the patent law is the appropriate vehicle for technology assessment.

Commentators have also differed over the extent to which an inventor must show a specific, practical use for a biotechnology in order to be awarded a patent. Some observers favor a strict view of the utility requirement due to concerns over overlapping upstream patents that discourage research and commercialization. Others believe that the utility requirement should be applied leniently, stating that a strict view of utility will only lead to industry concentration and that biotechnology research tools cannot be meaningfully distinguished from other sorts of inventions.

Congress may choose to exercise oversight on these issues. Such consideration would likely include examination of U.S. commitments in international agreements along with other factors.

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This report was prepared under the supervision of Wendy H. Schacht.

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Introduction

Biotechnology may be broadly defined as the application of biological systems and organisms to technical and industrial processes.[1] The discipline of biotechnology may be traced to the 1944 identification of deoxyribonucleic acid (DNA).[2] This discovery commenced a significant research effort that culminated in the sequencing of the human genome in 2000.[3] The biotechnology industry has provided many new technologies, including diagnostic kits, DNA fingerprinting, protein synthesis, enzyme engineering, and transgenic plants and animals.[4] Many observers forecast that the completion of the human genome project will bring even more spectacular advances in the future.[5]

The biotechnology industry is notable both for its heavy concentration of small businesses and its weighty research and development (R&D) expenses. In 1998, a total of 1,283 biotechnology firms participated in the domestic biotechnology market. More than two-thirds of these firms employed fewer than 135 persons, and approximately one-third employed less than 50 persons.[6] The prominence of small biotechnology enterprises belies the enormous expenses that must be devoted towards R&D in this market. The U.S. biotechnology industry is one of the most research-intensive endeavors in the world, with $9.9 billion devoted to R&D in 1998.[7]

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[1] Young, Frank E., Biotechnology and the Federal Food and Drug Administration, *Forum for Applied Research and Public Policy* (1987), 80.

[2] Weston, Cliff D., "Chilling of the Corn: Agricultural Biotechnology in the Face of U.S. Patent Law and the Cartagena Protocol," 4 *Journal of Small & Emerging Business Law* (2000), 377.

[3] Zawislak, Mike, "Genome project is just the start, director says," *Chicago Daily Herald* (23 July 2000), 1.

[4] Weston, *supra* note 2, at 377.

[5] E.g., Atroley, Akansha, "Human Genome Project: Decoded," *Computers Today* (31 July 2000), 90.

[6] See Biotechnology Indus. Org., 1998-99 BIO's Guide to Biotechnology, available at [http://www.bio.org/aboutbio/guide2000/facts.html].

[7] Ibid.

Given their small size and heavy expenses, many observers believe that firms in the biotechnology industry rely upon their ability to raise venture capital.[8] The patent law has been identified as a facilitator of these R&D financing efforts. Absent patent rights, a biotechnology concern may have scant tangible assets to sell or license. By providing members of the biotechnology industry with enforceable proprietary interests in their inventions, the patent law is said to expedite capital infusion and technology transfer.[9]

Although many commentators believe that the patent law plays a crucial role in the biotechnology industry,[10] numerous legal, economic and policy issues have arisen concerning the patenting of biotechnology. This report considers these issues, emphasizing the effect of intellectual property rights upon small, entrepreneurial companies. This study first profiles the biotechnology industry, including a review of its principal technologies and need for R&D funding. It next provides an overview of the patent system and its relationship to the biotechnology industry. This report then reviews two principal patentability requirements, statutory subject matter and utility, and their application to biotechnologies. It closes with a discussion of legislative issues and options for biotechnology patenting.

This study suggests that patents play a significant role in the ability of small, entrepreneurial firms in the biotechnology industry to acquire capital for R&D. Experience teaches that investors may be wary of uncertainties surrounding patent rights, leading to diminished capital infusions into the biotechnology market.

The Biotechnology Industry: An Overview

The birth of the U.S. biotechnology industry dates to the founding of Genentech, Inc., in 1976.[11] Biotechnology today is a growing sector of the domestic economy. The industry essentially doubled in size between 1993 and 1999, generating $20 billion in revenues in 1999.[12] Biotechnology companies directly employed 150,800 persons in 1999, with an additional 286,600 persons employed by companies supplying goods or services to the industry.[13]

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[8] Weston, *supra* note 2, at 377.

[9] Merges, Robert P., "Intellectual Property and the Costs of Commercial Exchange: A Review Essay," 93 *Michigan Law Review* (1995), 1570.

[10] Goozner, Merrill, "Suit Puts Biotech Drug Sales on the Line Patent Trial May Spur Competition on Prices," *Chicago Tribune* (16 May 2000), 1.

[11] Gladwell, Malcolm, "Top Biotech Firm Sold to Swiss Company," *Washington Post* (3 Feb. 1990), A1.

[12] See Biotechnology Indus. Org., 1998-99 BIO's Guide to Biotechnology, available at [http://www.bio.org/aboutbio/guide1.html].

[13] Ernst & Young, *The Economic Contributions of the Biotechnology Industry to the U.S. Economy* (May 2000).

The domestic biotechnology industry includes a handful of large companies with a substantial market share.[14] However, "a typical biotech R&D company is a small start-up with all its financial and human resources invested in the development of one or two products or technologies."[15] It is often the case that a promising technology is discovered and preliminarily developed by a small enterprise. A large biotechnology firm then acquires the smaller enterprise, or its intellectual property rights, in order to bring the technology to market.[16]

Domestic enterprises enjoy a commanding position in the global biotechnology industry. The U.S. biotechnology industry is the acknowledged world leader in biomedical research, benefitting the health of U.S. citizens, creating tens of thousands of jobs and improving our balance of trade.[17] The biotechnology industry is also diverse, employing its technologies in medicine, industrial processes, environmental cleanup, food, agriculture and numerous other applications. A brief review of some principal biotechnologies follows.

Cloning

Biotechnology has recently introduced the technique of cloning. Cloning employs DNA from one animal to produce a genetically identical animal.[18] Cloned organisms may be created by fusing a cell from one organism with an immature reproductive cell from a second organism. The second cell is then stimulated to replicate. The cells, if placed into an appropriate womb, will result in the live birth of an animal genetically identical to the one from which the original DNA was taken. In the case of Dolly, the sheep cloned in 1997 in Scotland,[19] an udder cell was fused with an unfertilized egg cell from which the nucleus had been removed, and the cell mass grown was then implanted in a sheep womb.

Gene Therapy

Scientists may introduce a gene directly into a patient through a technique called gene therapy. This method involves the insertion of a gene into the cells of a gene-deficient patient, either to correct a genetic error or to introduce a new function

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[14] Graham, Lawrence S., "Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After Warner-Jenkinson Co. v. Hilton Davis Chem. Co.," 6 *Journal of Law and Policy* (1997) 741, 742 n.6 (observing that five biotechnology enterprises – Amgen, Chiron, Genentech, Quintiles, and Genzyme – collectively enjoyed a 70% market share in 1996).

[15] High Tech Publishing Co., "Profiles of Success in Biotechnology: A Competitive Analysis of Major Biotechnology Companies, Biotechnology Investment Opportunities," (1 Sept. 1992), available at 1992 WL 2773776 (Westlaw commercial database).

[16] Weston, *supra* note 2, at 377.

[17] See Mack, Connie, "President's poison pill hurts research," *Tampa Tribune* (17 April 1999), 19.

[18] "Firms Will Try to Clone Pigs," *Washington Post*, (24 July 1998), A24.

[19] Walbolt, Kristen, "Dolly Has Three Mommies," *Sun-Sentinel (Ft. Lauderdale)* (2 March 1997), G8.

into the cell. The National Institutes of Health (NIH) first performed gene therapy on a human patient in 1990.[20] NIH scientists took blood cells from a four-year-old girl suffering from an immune disease caused by the lack of a specific enzyme, adenosine deaminase (ADA). They then introduced a functioning ADA gene into those cells, which were then returned to the patient's bloodstream.

Throughout the 1990's, thousands of patients were treated with various sorts of gene therapy on an experimental basis in the United States.[21] The death of a patient undergoing experimental treatment in late 1999 has chilled gene therapy efforts, however.[22] A subsequent inquiry revealed indications of unacceptable scientific conduct and monitoring.[23] These findings prompted both investigations by Congress and the Food and Drug Administration[24] as well as suspensions of similar gene therapy programs elsewhere.[25]

Genetically Modified Organisms

A specific gene may itself be used to endow its possessor with new properties or functions.[26] The agricultural division of the biotechology industry is based upon this technology. The typical Genetically Modified Organism (GMO) results from the insertion of a gene from one organism into another organism, conferring new properties upon the receiving organism. Widely known examples include insecticide-producing crops and rice enriched with vitamin A.[27] The use of GMOs in the United States has become widespread, with estimates that 33% of domestic corn and 50% of soybean crops are genetically modified.[28] Additionally, cotton and canola oil are major crops also consisting substantially of GMO strains.[29]

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[20] Culliton, Barbara J., "Gene Therapy Begins," 249 *Science* (1990), 1372.

[21] Weiss, Rick & Nelson, Deborah, "Teen Dies Undergoing Experimental Gene Therapy," *Washington Post* (29 Sept. 1999), A1.

[22] Wade, Nicholas, "Death Leads to Concerns for Future of Gene Therapy," *New York Times*, (30 Sept. 1999), A22.

[23] Friend, Tim, "Scientists Violated Gene Therapy Rules in Teen's Case, FDA Says," *USA Today* (9 Dec. 1999), A8.

[24] Stolberg, Sheryl G., "Senators Press for Answers on Gene Trials," *New York Times* (3 Feb. 2000), A25.

[25] "Firm Ordered to Stop Gene Therapy Studies," *Washington Post* (12 Oct. 1999), A8.

[26] See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (petroleum-eating bacteria).

[27] See Gillis, Justin, Monsanto Offers Patent Waiver, *Washington Post*. (4 Aug. 2000), A1; Weiss, Rick, Biotech Research Branches Out, *Washington Post*, (3 Aug. 2000), A1.

[28] Henson, Lori, "Fooling Mother Nature: Genetic Engineering Offers a World of Possibilities for Plants but Raises Questions About Ethics and Health," *Savannah Morning News* (9 Feb. 2000).

[29] Weston, supra note 2, at 377.

The Human Genome Project

The Human Genome Project is a publicly funded, international consortium of scientists engaged in identifying each of the approximately 100,000 human genes.[30] In the United States, the Human Genome Project was launched in 1990 under the auspices of the U.S. Department of Energy and the Department of Health and Human Services.[31] Private enterprise Celera Genomics, led by J. Craig Venter, also endeavored to sequence the human genome.[32]

On June 26, 2000, President Clinton and UK Prime Minister Tony Blair announced that the initial stage of the Human Genome Project had been completed. Growing understanding of the human genome will allow researchers to move from identifying genes to understanding their functions. In particular, scientists should increasingly possess the tools needed to identify the genes associated with diseases. This understanding should assist the development of new approaches for diagnosing, preventing and treating disease.[33]

Research Products

Fragments of DNA may also be used in basic and applied research. Because DNA is organized is a specific way,[34] a set DNA strand may be employed as a probe for the presence of the complementary strand. Researchers are thus able to use such genetic probes in experimental and diagnostic procedures to search for specific DNA and RNA sequences.

Living organisms, into which certain genetic dispositions have been engineered, also can be used in research.[35] A prominent example is the so-called "Harvard mouse," which has been rendered especially susceptible to cancer.[36] A similar mouse

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[30] Morse, Allison, "Searching for the Holy Grail: The Human Genome Project and Its Implications," 13 *Journal of Law and Health* (1999), 219.

[31] Ibid at 220.

[32] Golden, Frederic & Lemonick, Michael, "Mapping the Genome," 156 *Time* (3 July 2000), 18.

[33] Quinlivan, Beth, "The Genome Gold Rush," *Business Review Weekly* (28 July 2000), 104.

[34] See *Amgen v. Chugai*, 927 F.2d 1200, 1207 n.4 (Fed. Cir. 1991) ("DNA consists of two complementary strands of nucleotides, which include the four basic compounds adenine (A), guanine (G), cytosine (C), and thymine (T), oriented so that bases from one strand weakly bond to the bases of the opposite strand. A bonds with T, and G bonds with C to form complementary base pairs. This bonding process is called hybridization and results in the formation of a stable duplex molecule.").

[35] See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (describing insertion into bacteria of gene for petroleum-degrading enzyme); Ananda M. Chakrabarty, Microorganisms Having Multiple Compatible Degradative Energy- Generating Plasmids and Preparation Thereof, U.S. Pat. No. 4,259,444 (issued Mar. 31, 1981).

[36] See U.S. Patent No. 4,736,866 (12 April 1988) ("Transgenic Non-Human Mammals").

lacks a functional immune system, making it extremely useful for immunological and infectious disease research.[37]

Therapeutics

Therapeutic genetic inventions involve isolated genes or their protein products.[38] These proteins have broad applications to many diseases, including cancers, diabetes, osteoporosis, as well as AIDS and other infectious diseases.[39] For example, some hormonal deficiencies may be treated with doses of human growth hormone, a recombinant protein.[40] Biotechnologies have also allowed the more rapid and efficient manufacture of human insulin in order to treat diabetes.[41]

Clinicians may also use short, specific DNA sequences to search an individual's tissue or bodily fluid for the presence of a specific genetic element.[42] One application of DNA probes is in genetic screening. In this process, which is in a nascent stage of development, tendencies toward hereditary diseases can be determined by assaying the genetic make-up of a fetus or the prospective parents.[43]

Other biotechnologies include antibodies directed against specific proteins or organisms[44] and manufactured protein fragments bound by certain antibodies in an infected patient's bloodstream.[45] These products may be used in diagnostic assays. Such tests screen blood or other samples for indicators of pregnancy, cancer, human immunodeficiency virus infection and other medical conditions.

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[37] See Mouse Without Immunity: Genpharm Expects Patent for an Animal, N.Y. Times, May 9, 1992, at A39.

[38] Arnst, Catherine, "Inhale, Don't Inject," *Business Week*, (9 Feb. 1998), 74.

[39] Biotechnology Indus. Org., 1998-99 BIO's Guide to Biotechnology [http://www.bio.org /aboutbio/guide1.html].

[40] See, e.g., BioSepra New Technology Enables Large Scale Production of Gene Therapy Drugs, 6 BioAccess, July 1, 1998, available in 1998WL10755071.

[41] For example, bioengineered insulin is produced more efficiently and in greater purity. See Gillis, Justin "Biotech's Payday Arrives: After Costly, Uncertain Start, More Firms Are Turning A Profit," *Washington Post*, (5 July 1998), H01.

[42] Marcial,Gene G., "A New Remedy for What Ails Enzo?," *Business Week* (31 Aug. 1998), 54.

[43] Bronson, Gail, "Where's the Demand?," *Forbes*, (20 Oct. 1986), 138.

[44] See *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) (explaining the invention of antibodies for use in clinical detection of hepatitis).

[45] U.S. Patent No. 5,922,533 (13 July 1999) ("Rapid Assay for Simultaneous Detection and Differentiation of Antibodies to HIV Groups").

The Role of R&D Funding in the Biotechnology Industry

The biotechnology industry has generated a variety of technical advances that have impacted fields ranging from agriculture, to health care, to the criminal justice system. These advances have not been achieved without costs, however. The significant presence of small firms, as well as substantial research and development expenses, suggest that capital infusions play an important role in the biotechnology industry. The need for funding looms largest for products intended for human medical use.[46] The typical biotech company generally requires $250 million to $500 million to fund a product from research to profitability.[47] Lengthy periods required for regulatory approval account for much of this expense.[48]

Despite the promise it holds for future developments, the biotechnology industry has recently encountered difficulty in attracting investors. One commentator recently observed that "venture capital is tough to come by at a time when investors are looking for quick payouts and have little patience for biotechnology, which seems to be plodding compared to Internet, software and telecommunications companies."[49] For example, during the first six months of 1999, biotechnology initial public offerings generated only $363 million, representing only about 10% of the $3.5 billion attracted by Internet and software companies.[50]

As a result, many industry observers believe that a strong patent portfolio is essential for capital infusion in the biotechnology industry.[51] Even a firm that does not yet market a product may be able to obtain income from its intellectual property. Rights may be sold or the technology licensed for development or research purposes, creating a revenue stream that supports additional research. Patent attorney Kenneth J. Burchfiel has characterized biotechnology as an industry whose wealth resides in its patents more than its products.[52]

Recent stock market movements suggest the significance of patent rights to investors. For example, on March 14, 2000, President Bill Clinton and UK Prime Minister Tony Blair issued a joint statement urging that "raw fundamental data on the human genome . . . should be made freely available to scientists everywhere."[53] A

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[46] See Biotechnology Indus. Org., 1997-98 BIO's Citizens' Guide to Biotechnology, available at [http://www.bio.org/aboutbio/guide1.html].

[47] Copperthite, Charlotte H. & Lerner, Michael J., "Creative Use of IP Portfolios Helps Secure Financing," *National Law Journal*(24 May 1999), C4.

[48] Ibid.

[49] Jacobs, Paul, "Money's There, but Hurdles Abound," *L.A. Times* (11 Oct. 1999), C1.

[50] Ibid.

[51] Biotechnology Indus. Org., 1997-98 BIO's Citizens' Guide to Biotechnology, available at [http://www.bio.org/aboutbio/guide1.html].

[52] Burchfiel, Kenneth J., *Biotechnology and the Federal Circuit* § 18.5 (1995).

[53] Gosselin, Peter G. & Jacobs, Paul, "Clinton, Blair to Back Access to Genetic Code," *Los*
(continued...)

number of biotechnology companies lost a substantial percentage of their market capitalization as investors sold shares in record numbers.[54] Among these enterprises were Human Genome Sciences, Inc, which fell 25% on the day on the announcement, and Incyte Pharmaceuticals, Inc., which fell 30%.[55] The chief concern of many sellers was that biotechnology patent rights would be weakened or subject to uncertainty.[56] The United States Patent and Trademark Office ("PTO") responded by issuing a press release on March 16, 2000, explaining that U.S. patent policy was unaffected by the joint statement. As the impact of the Clinton-Blair announcement was better understood, the stock prices of many biotechnology enterprises rose.[57]

The Clinton-Blair announcement was not an isolated incident. The market capitalization of many biotechnology and other high-technology enterprises has been impacted by patent-related developments. In a single day, CellPro Inc. lost 50 % of its stock market value following the Federal Circuit holding that CellPro Inc.'s Ceprate bone marrow transplant system infringed a competitor's patent.[58] Similarly, Visx, a manufacturer of laser medical devices, lost a patent dispute and watched its stock fall 40 % within one hour.[59] A successful settlement of a patent infringement lawsuit with Hitachi recently imparted substantial gains to Rambus Inc. stock.[60] Similarly, the stock of Odetics Inc. rose 24% upon news of a favorable jury verdict in its patent litigation against Storage Technology Corp. in 1998.[61]

These episodes suggest that individuals may be aware of a company's patent portfolio when making investment decisions. As a result, the strength or weakness of intellectual property rights, as well as the certainty associated with their creation and scope of granted rights, potentially impacts capital infusion into high technology markets such as biotechnology.

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[53] (...continued)
Angeles Times (14 March 2000), C1.

[54] Heberlein, Greg, "Market movers: Biotech bubble pops as Nasdaq falls 200," *The Seattle Times* (15 March 2000), C1.

[55] "Clinton/Blair gene patent announcement draws reaction," *Biotech Patent News* (1 March 2000).

[56] Heberlein, *supra* note 54.

[57] Woods, Bob, "Biotech Stocks Rebound After Analysts Address Clinton Speech," Newsbytes News Network (15 March 2000).

[58] Smith, Carol, "Stock in Bothell's CellPro Falls 50 Percent in Wake of Ruling," *Seattle Post-Intelligencer* (13 Aug. 1998), F5.

[59] Katz, John, "You Can Still Bet on Biotech," *Sunday Business (U.K.)*, (12 Dec. 1999), 28.

[60] Stewart, Janet Kidd, "Nasdaq Tumble Negates Week's Earlier Advance," *Chicago Tribune* (24 June 2000).

[61] "News of Court Verdict Pumps Up Odetics," *Los Angeles Times*, (31 March 1998), D24.

Core Principles of Patenting Biotechnology

The rate of patenting biotechnology has dramatically increased in recent years. More than 9,000 patents issued in the biotechnological arts in1998, as compared with just over 2,000 patents in 1988.[62] Patents concerning genetic materials are also being filed at a growing rate. On July 13, 2000, the Director of the Patent and Trademark Office (PTO), Q. Todd Dickinson, reported that approximately 20,000 patent applications concerning genetic materials were pending before the PTO.[63] He also explained that approximately 6,000 gene-related patents had already issued by that date, including 1,000 that were specifically drawn to human genes.[64]

The patenting process begins with the filing of an application at the PTO. In deciding whether to approve a patent application, a PTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[65] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute.[66] Among the more important requirements are that the invention must be novel and nonobvious. To be judged novel, the invention must not be fully anticipated by a prior patent, publication or other knowledge within the public domain.[67] A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.[68]

Beyond novelty and nonobviousness, two patentability requirements are of particular significance for biotechnology. First, the invention must be judged to comprise subject matter the patent law was designed to protect.[69] This gatekeeper to patentability is variously known as the requirement of "patent eligibility," "patentable subject matter," or "statutory subject matter."[70] A crucial biotechnology patenting issue is whether living inventions and genetic material are appropriately subject to the patent system. The debate concerning biotechnology patents is reviewed below.

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[62] Biotechnology Industry Organization, Total Patents Granted Per Year, available at [http://www.bio.org/aboutbio/guide2000/statistics.html#patents].

[63] Dickinson, Q. Todd, Statement, House Judiciary Committee, Subcommittee on Courts and Intellectual Property (13 July 2000), 5 (available at [http://www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/genomicpat.pdf]).

[64] Ibid.

[65] 35 U.S.C. § 112 (2000)

[66] These requirement apply to so-called "utility patents." The patent statues also allow for design patents, *see* 35 U.S.C. § 171 (2000), and plant patents, *see* 35 U.S.C. § 161 (2000). Subject matter and other patentability standards differ somewhat for these more specialized patent regimes.

[67] 35 U.S.C. § 102 (2000).

[68] 35 U.S.C. § 103 (2000).

[69] *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

[70] Adelman, Martin J. et al. *Patent Law: Cases and Materials* (Minnesota: West Publishing Co., 1998).

The other significant substantive patentability standard is the so-called utility requirement. This requirement is ordinarily satisfied if the invention is operable and provides a tangible benefit.[71] Although the utility requirement is readily met in most fields, it presents a more significant obstacle to patentability within biotechnology. Biotechnicians sometimes synthesize compounds without a precise knowledge of how they may be used to achieve a practical working result. When patent applications are filed claiming such compounds, they may be rejected as lacking utility within the meaning of the patent law. This report will later consider the utility requirement in some detail.

Once the PTO allows a patent to issue, the patent instrument is formally published.[72] Issued patents therefore present a full technical disclosure of the patented invention.[73] The patent proprietor then obtains the right for twenty years to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention.[74] The Patent Act allows these rights to be enforced in federal court. Unauthorized infringers may be enjoined and required to pay monetary damages in favor of the patentee.[75]

A few core points concerning the patent law should be noted here. First, the patent grant is in the nature of the right to exclude. A patent owner may prohibit others from employing the patented invention, but does not obtain the right to make or use the patented invention itself.[76] For example, simply because the PTO has granted an individual a patent on a gene therapy does not mean that the Food and Drug Administration has approved, or will approve, the practice of that therapy. In addition to the Food and Drug Administration, the Environmental Protection Agency and Department of Agriculture regulate the use of biotechnological inventions.[77]

Second, the patent right applies not only to full-fledged commercial activities, but also to most unauthorized experiments involving the patented invention. The patent statute itself contains no "experimental use" infringement defense analogous to the fair use privilege codified within the Copyright Act.[78] As a result, the United States Court of Appeals for the Federal Circuit has held that mere experimentation with the patented invention constitutes an infringing act, so long as this

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[71] 35 U.S.C. § 101 (2000); *see also Brenner v. Manson*, 383 U.S. 519 (1966).

[72] 35 U.S.C. § 122 (2000). 1999 amendments to the Patent Act also call for the publication of certain pending patent applications eighteen months after the date they are filed. Ibid.

[73] 35 U.S.C. § 112 (2000).

[74] 35 U.S.C. § 271 (2000).

[75] 35 U.S.C. §§ 283, 284 (2000).

[76] Chisum, Donald S., et al., *Principles of Patent Law* (Foundation Press, New York 1998), 4-6.

[77] Biotechnology Industry Organization, "Some Facts About Biotechnology," available at [http://www.bio.org/aboutbio/guide2000/facts.html].

[78] See 17 U.S.C. § 107 (2000).

experimentation holds the potential to impact the patent holder negatively.[79] The court concluded that only the use of the patented invention wholly for "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" may possibly be exempted from infringement liability.[80] Given the expenses associated with biotechnology R&D, increasing collaboration between industry and academia, and ultimately commercial motivation of most researchers, successful use of this so-called experimental use defense is unlikely.[81]

Finally, the PTO bases its patentability determinations only upon the relatively limited criteria set forth in the Patent Act. These criteria include whether the patent application appropriately discloses and claims the invention for which protection is sought, as well as the impact of the novelty, nonobviousness, statutory subject matter and utility requirements upon the claimed invention.[82] The PTO is not statutorily authorized to consider other issues, such as whether the patented invention may be licensed to ensure access by researchers and other interested parties, when making this decision.[83]

The Patent Eligibility of Living Inventions and Genetic Materials

The issue of whether living organisms are merely unpatentable products of nature, or whether ethical or policy concerns should bar their patenting, continues to command public attention. As with other sorts of inventions, the governing statute is section 101 of the current patent law, the Patent Act of 1952, which is codified in Title 35 of the United States Code. Section 101 allows patents to be granted for any "process, machine, manufacture, or composition of matter." As a result, an invention is eligible for patenting if it is a "process," which the Patent Act defines as a "process, art or method."[84] Alternatively, the invention may be a "machine," which has been interpreted to include any apparatus;[85] a "composition of matter," including synthesized chemical compounds and composite articles;[86] or a "manufacture," a broadly oriented, residual designation.[87]

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[79] *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984).

[80] Ibid at 863.

[81] Karp, Jonathon P., "Experimental Use as Patent Infringement: The Impropriety of a Broad Exception," 100 *Yale Law Journal* (1991), 2169 (observing that courts apply the experimental use doctrine restrictively).

[82] See supra notes 65-71 and accompanying text.

[83] Dickinson, *supra* note 63, at 5.

[84] 35 U.S.C. § 100(b) (2000).

[85] *Nestle-Le Mur Co. v. Eugene, Ltd.*, 55 F.2d 854 (6th Cir. 1932).

[86] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[87] Ibid.

Under the literal language of the Patent Act, most biotechnologies would qualify as either a composition of matter or process. Genetic materials are at bottom chemical compounds, albeit very complex ones, that are considered to be compositions of matter.[88] Illustrative is the patent application at issue in *In re Deuel*,[89] which claimed a "purified and isolated DNA sequence consisting of a sequence encoding human heparin binding growth factor of 168 amino acids having the following amino acid sequence: Met Gln Ala . . . [the remainder of the lengthy amino acid sequence is omitted here]." An inventor could also obtain a process patent directed towards the techniques of biotechnology. For example, in *In re O'Farrell*,[90] the patent applicant claimed a "method for producing a predetermined protein in a stable form in a transformed host species of bacteria."

Despite the broad statutory language, the courts had traditionally crafted several exceptions to patentability. One significant restriction is that a "product of nature"–a preexisting substance found in the wild–may not be patented *per se*. For example, an individual may not obtain a patent on a new variety of plant found in a remote part of the Amazon Basin, even if the existence of this plant was previously unknown.[91]

However, the courts have also established that significant artificial changes to a product of nature may render it patentable.[92] By purifying, isolating or otherwise altering a naturally occurring product, an inventor may obtain a patent on the product in its altered form.[93] The rule that patents may be granted for altered products of nature renders patentable many inventions of biotechnology, including genetic materials and proteins. For example, in *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[94] the patentee claimed a "purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin."[95]

With the scope of patentable subject matter limited, one expert has concluded that a properly issued patent cannot give rights over a gene as found in a person's chromosomes. The artificial nucleic acid construct claimed by the patent would not be the same as found in a living organism.[96]

Patent protection may also be obtained on so-called living inventions. The leading Supreme Court opinion on the subject, the 1980 decision in *Diamond v.*

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[88] *See Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991).

[89] 51 F.3d 1552 (Fed. Cir. 1995).

[90] 853 F.2d 894 (Fed. Cir. 1988).

[91] *See, e.g., Ex parte Latimer*, 1889 Comm'r Dec. 13 (1889).

[92] *See, e.g., Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991).

[93] *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

[94] 927 F.2d 1200 (Fed. Cir. 1991).

[95] U.S. Patent No. 4,703,008 (27 Oct. 1987) ("DNA sequences encoding erythropoietin").

[96] Henner, Dennis J., Statement, House Judiciary Committee, Subcommittee on Courts and Intellectual Property (13 July 2000).

Chakrabarty concluded that a genetically engineered microorganism was patentable.[97] *Diamond v. Chakrabarty* involved the PTO rejection of Dr. Ananda Chakrabarty's claims towards an artificially generated bacterium with the ability to degrade crude oil. At the Supreme Court, the PTO Solicitor's chief argument was that because genetic technology could not have been foreseen at the time the patent statute was drafted in the early 1950's, the resolution of the patentability of such inventions should be left to Congress. On its way to reversing the PTO decision, the Court disagreed: "A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability."[98] The Court also dismissed concerns over the possible perils of genetic research. It stated that researchers would assuredly pursue work in biotechnology whether their results were patentable or not, and the regulation of genetic research was a task that also fell to the legislature.[99]

Following the lead of the Supreme Court, the PTO Board has held that an artificial animal life form constitutes patentable subject matter. In *Ex parte Allen*,[100] the Board reasoned that a claimed polyploid Pacific oyster constituted a non-naturally occurring manufacture or composition of matter within the meaning of § 101. Contemporaneously, PTO Commissioner Donald Quigg issued a formal notice, stating that non-naturally occurring, non-human multicellular living organisms are patentable subject matter.[101] Among the notable patents the PTO issued in keeping with this notice concerned the Harvard mouse, which was genetically engineered to be susceptible to cancer.[102]

The PTO notice did advise that "the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution."[103] This statement appears consonant with the Thirteenth Amendment, which provides that "[n]either slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States."[104] The Commissioner further advised that claims directed to a non-plant multicellular organism which would include a human being within its scope should include the limitation "non-human" to avoid a § 101 rejection.

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[97] 447 U.S. 303 (1980).

[98] 447 U.S. at 316.

[99] 447 U.S. at 317.

[100] 2 USPQ2d 1425 (Board of Patent Appeals and Interferences 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988) (nonprecedential).

[101] *See* 1077 *PTO Official Gazette* 24 (21 April 1987).

[102] U.S. Patent No. 4,736,866 (12 Apr. 1988) ("Transgenic non-human mammals").

[103] 1077 *PTO Official Gazette* 24 (21 April 1987).

[104] U.S. Constitution, Amendment XIII.

Objections to Patenting Biotechnology

Several objections have arisen to patenting the inventions of biotechnology. Most of these objections have been raised with regard to human genetic materials and genetically modified organisms, but they typically apply with varying force to other biotechnologies. A central position of many commentators is that the grant of proprietary rights for these inventions is degrading and inappropriate. These concerns principally stand on ethical, moral and theological grounds.

Some individuals believe that patenting biotechnology devalues the worth and dignity of living beings. These commentators believe that biotechnology patents would allow individuals to obtain an ownership right in another sentient being. From this perspective, such a patent right is akin to slavery and morally wrong.[105]

Other observers have identified a fundamental right of species and individuals to biological integrity. Biotechnology activist Jeremy Rifkin, for example, has expressed concerns that the patenting of genetic materials reduces living beings to mere bundles of information. When living creatures are abstractly expressed as claims in a patent instrument, Rifkin urges, the notion of manipulating them at a fundamental level becomes more palatable.[106]

Theological arguments have also been raised against patenting biotechnology. Some observers believe that reverence for life is eroded by economic pressures to view living beings and genetic materials as industrial products. Noting these theological concerns, Reverend Wesley Granberg-Michaelson identified

> a background of Judeo-Christian thinking about how we relate to the natural environment. In a nutshell that background says that we have a responsibility for preserving the integrity of that creation, and for working with it to preserve its intrinsic values . . . . [T]he doctrine of trust in legal parlance is synonymous about the relation of creation to humanity. The Judeo-Christian view says that the creation is, in essence, held in trust; there are limitations on what we can do. We have a responsibility to see that its integrity is preserved. This background has led to legislation such as endangered species laws, animal welfare laws, laws regarding environmental quality.[107]

Others are concerned that biotechnology patenting places the values of the traditional agricultural community at stake. They explain that patenting may cause a handful of large, multinational enterprises to control genetically modified animals,

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[105] See Clark, Margaret, "This Little Piggy Went to Market: The Xenotransplantation and Xenozoonose Debate," 27 *Journal of Law and Medical Ethics* (1999), 137.

[106] Rifkin, Jeremy, *The Biotech Century: Harnessing the Gene and Remaking the World* (1998), 214-15.

[107] *See* Patents and the Constitution: Transgenic Animals, Hearings Before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary, 100th Cong., 1st Sess. 399 (1987).

seeds and other fundamental tools of the farmer. While farmers could previously employ resources at their own disposal, they may now be dependent upon others to obtain seeds. Some observers also believe that plants and animals with increased production efficiencies will reduce the number of farmers needed.[108]

Other concerns over biotechnology patenting are instrumental in character. Some commentators believe that allowing patents on living inventions, genetic materials and other biotechnologies will encourage their continued commercial development.[109] Others are concerned that granting patents lends an aura of legitimacy to biotechnology.[110] In either case, this set of concerns about patenting biotechnology echoes concerns about the impact of biotechnology more generally. Although such arguments are numerous and diverse, some of the principal objections are summarized here.

During his June 26, 2000, remarks commemorating the completion of the first survey of the human genome project, President Clinton noted several common concerns regarding the identification of genetic information. As explained by President Clinton:

> We must ensure that new genome science and its benefits will be directed toward making life better for all citizens of the world, never just a privileged few.
>
> As we unlock the secrets of the human genome, we must work simultaneously to ensure that new discoveries never pry open the doors of privacy. And we must guarantee that genetic information cannot be used to stigmatize or discriminate against any individual or group.[111]

Other observers oppose patents on genetically modified organisms due to their belief that they contribute to animal suffering. They cite such instances as the incorporation of the bovine growth hormone gene into pigs. This gene encourages an increased lean to fat ratio that produces a healthier meat product. Animals expressing the gene were found to be lethargic, arthritic, and possessing an heightened vulnerability to stress.[112] Other biotechnologies, such as the Harvard mouse, dramatically increase the likelihood an animal will experience disease and suffering.[113]

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[108] Dresser, Rebecca, "Ethical and Legal Issues in Patenting New Animal Life," 28 *Jurimetrics* (1988), 399, 422.

[109] *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1979).

[110] Naik, Paul S., "Biotechnology Through the Eyes of an Opponent: The Resistance of Activist Jeremy Rifkin," 5 *Virginia Journal of Law and Technology* (2000), 86.

[111] The White House, Office of the Press Secretary, "Text of Remarks on the Completion of the First Survey of the Human Genome Project" (25 June 2000) (available at [http://www.whitehouse.gov]).

[112] Chiapetta, James R., "Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute," 20 *William Mitchell Law Review* (1994), 155.

[113] See supra notes 34-36 and accompanying text.

Other commentators have expressed concerns over diminishing genetic diversity. According to Jeremy Rifkin, while biotechnology may provide gains in the short run, the long term consequences include the depletion of genetic stock. In his view, because biotechnology would may lead to the development of "optimal" plants and animals, the gene pool will suffer for lack of variety. These specialized breeds may be susceptible to unknown weaknesses and not be sustainable.[114]

Observers have also noted the environmental hazards associated with release of artificial entities. The consequences of the release of genetically modified organisms are difficult to predict. As living entities, these organisms may reproduce, mutate and migrate once released into the environment. Artificial products may also result in deleterious interactions with other animals and plants in uncertain ways.[115]

Benefits of Patenting Biotechnology

Proponents of biotechnology patenting offer numerous arguments in favor of their position. First, they observe that patent rights provide the right to exclude others from practicing the claimed invention.[116] Patent ownership does not provide an affirmative right to market the technology. These commentators believe that disallowing patents to issue on biotechnologies may decrease research and development efforts, but would neither suppress biotechnology nor allow meaningful control on the manner in which biotechnologies are employed.

Observers such as Professor Robert P. Merges have further stated that the patent system is not the proper vehicle for technology assessment.[117] He explains that the patent system has a more basic goal: "to promote the progress of science and useful arts," as stated in the Constitution.[118] As a result, Professor Merges believes that potential social consequences of biotechnologies are better addressed through regulatory regimes. Agencies such as the Food and Drug Administration could review health and environmental hazards. Scientists could establish seed banks to preserve the genetic variety of various crops, for example, or establish protocols to address concerns over privacy. In the view of Professor Merges, these measures have little to do with patents.

In deciding to uphold PTO decisions to grant patents on living inventions, the courts have also observed that patents have long been granted on living inventions. Exemplary is the 1873 patent issued to Louis Pasteur on "yeast, free from organic germs of disease, as an article of manufacture."[119] Microbiological processes have been used for centuries in order to make wine, age tobacco, bate leather, digest

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[114] See Naik, supra note 110, at 23.

[115] Ibid at 26.

[116] See supra notes 74-77 and accompanying text.

[117] Merges, Robert P., "Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies," 47 *Maryland Law Review* (1998), 1051.

[118] U.S. Constitution, Article I, clause 8, section 8.

[119] *Diamond v. Chakrabarty*, 447 U.S. 303, 314 n.9 (1979).

sewage and for numerous other applications, and many of these techniques have been patented in the United States.[120]

Attorney James R. Chiapetta believes that the denial of patent protection would not dampen enthusiasm for biotechnology development. Instead, he asserts, this step would merely encourage inventors to maintain biotechnologies as trade secrets. The concealment of the workings of biotechnologies would only hinder the development of regulatory measures that would reduce any perceived threats of harm.[121]

Mr. Chiapetta also explains that a purpose of the patent system is to enhance industrial efficiency. Part of this process can be the obsolescence of older technology as a result of innovative advances. Mr. Chiapetta finds it unfortunate that biotechology may place further strains on the viability of the traditional family farm, but observes that biotechnologies are hardly unique in this regard. Many technical, economic and social factors are leading to fewer and larger farms within the United States, and he argues that biotechnology should not be singled out within the patent law for this reason.[122]

Proponents of biotechnology patenting also observe that this prospect appears rather benign in the face of current social norms. According to LeRoy Walters, Ph.D., Director of the Kennedy Institute of Ethics at Georgetown University, given that individuals routinely buy, sell, breed, confine, eat and perform research on plants and animals, the practice of patenting them does not seem particularly worrisome.[123]

A number of scientific commentators have dismissed the notion of species integrity as specious. For example, Dr. Oliver Smithies of the University of Wisconsin explained that many mammalian species with no possible means of inter-breeding have remarkably similar genomes.[124] Dr. Smithies further observed that inter-species genetic transfer has occurred naturally, albeit rarely, without human intervention through viral and other microbial agents. Dr. Finnie A. Murray of Ohio University has explained that all species are constantly evolving; no species has a fixed genome, and genetic plasticity is a fundamental property of living beings.[125] As a result, many observers do not believe that artificial inter-species genetic transfers can be said to violate any fundamental norm of genetic integrity.

Other commentators have also noted that traditional breeding programs often perpetuate genetic defects. One expert points out that purebred cats, dogs and horses

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[120] See *In re Bergy*, 563 F.2d 1031, 1038 (CCPA 1977).

[121] Chiapetta, *supra* note 112, at 155.

[122] Ibid.

[123] Patents and the Constitution: Transgenic Animals, Hearings Before the Sub-committee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary, 100th Cong., 1st Sess. 389 (1987).

[124] National Institutes of Health, "Recombinant DNA Research, Actions Under Guidelines," 50 *Federal Register* 9760 (11 March 1985).

[125] Ibid.

often suffer from a variety of genetic defects leading to diseases ranging from metabolic disorders to arthritis.[126] Genetic engineering potentially avoids these problems by allowing expression of a single desirable trait without concomitant selection of others.[127] In arguing that biotechnology may be put to work to diminish animal suffering, some observers have pointed to the genetically engineered transgenic chicken that resists avian leukemia virus. The result has been healthier birds and significant savings to the chicken industry.[128]

Finally, proponents of patenting in this field point to the many gainful advances already achieved by the biotechnology industry. The continued availability of patent protection may encourage innovation and product development, proponents say, yielding concomitant social benefits. Although many of these commentators are cognizant of concerns for animal results, they regard the treatment of human diseases and the amelioration of human suffering as a primary moral imperative.[129]

The Chimera Application

A team of inventors decided to place the issue of biotechnology patenting squarely before the PTO and the courts. In conjunction with biotechnology activist Jeremy Rifkin, cellular biologist Dr. Stuart Newman filed a patent application on December 18, 1997, claiming a method for combining human and animal embryo cells to produce a single embryo.[130] This embryo could then be implanted in a human or animal surrogate mother, resulting in the birth of a "chimera," or mixture of the two species. The Newman-Rifkin application specifically mentions chimeras made in part from mice, chimpanzees, baboons, and pigs. The PTO has rejected the application on several grounds, among them ineligible subject matter under § 101, although final administrative action has not yet happened.[131] No matter what the ultimate disposition of their application, Newman and Rifkin may once more bring the debate on the patentability of living inventions into the judicial system.

The Utility Requirement

Section 101 of the Patent Act also mandates that patents issue only to "useful" inventions. Utility ordinarily presents a minimal requirement that the invention be

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[126] 50 Federal Register at 9763 (statement of Dr. Fox).

[127] Chiapetta, supra note 112, at 180.

[128] Ibid at 183 (citing savings of an estimated $50 million to $100 million per year).

[129] 50 Federal Register at 9764 (statement of Dr. Friedman).

[130] Magnani, Thomas A., "The Patentability of Human-Animal Chimeras," 14 *Berkeley Technology Law Journal* (1999), 443.

[131] Bureau of National Affairs, "Patent and Trademark Office: Patent Application is Disallowed as 'Embracing' Human Beings," *Patent, Copyright and Trademark Journal* (17 June 1999), 203.

capable of achieving a pragmatic result.[132] Patent applicants need only supply a single, operable use of the invention that is credible to persons of ordinary skill in the art.

As demonstrated by Justice Story's 1817 instructions to the jury in *Lowell v. Lewis*[133] and *Bedford v. Hunt*,[134] the notion of utility is a longstanding feature of United States patent law. In *Lowell*, Justice Story remarked:

> All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word "useful", therefore, is incorporated into the act in contradistinction to mischievous or immoral. . . . But if the invention steers wide of these objections, whether it be more or less useful is a circumstance very material to the interest of the patentee, but of no importance to the public. If it be not extensively useful, it will silently sink into contempt and disregard.

Under Justice Story's view, the utility requirement does not provide a significant place for technology assessment. Outside of the most narrow limits, valuation of the invention is left to the market rather than to the mechanisms of the patent law.

Historically, courts employed the utility requirement to strike down patents concerning inventions that were judged to be immoral or fraudulent. A handful of early decisions invalidated patents on inventions intended for use in gambling or other disfavored activities. A patented toy automatic race course,[135] lottery devices[136] and a slot machine[137] were among those held to lack utility because their functions were judged unwholesome. Inventions that were designed to mislead consumers were similarly invalidated.[138]

The modern view is that so long as the invention may be put to a single lawful use, it possesses utility within the patent statute. Representative of the contemporary position is the Federal Circuit opinion in *Juicy Whip, Inc. v. Orange Bang, Inc*.[139] The plaintiff, Juicy Whip, held a patent concerning a post-mix dispenser that included a transparent bowl. According to the patent, the bowl was filled with a liquid that appeared to be the beverage available for purchase. While the bowl was arranged in such a way that it seemed to be the source of the beverage, in fact no fluid connection existed between the bowl and the beverage dispenser at all. Instead, the beverage was mixed immediately prior to each beverage sale. The district court struck Juicy Whip's patent on the ground of lack of utility, reasoning that the patented invention acted to deceive consumers.

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[132] *Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396 (1873).

[133] 15 Fed. Cas. 1018, 1019 (No. 8568) (C.C. Mass. 1817).

[134] 3 Fed. Cas. 37 (No. 1217) (C.C. Mass. 1817).

[135] *National Automatic Device Co. v. Lloyd*, 40 F. 89 (N.D. Ill. 1889).

[136] *Brewer v. Lichtenstein*, 278 F. 512 (7th Cir. 1922).

[137] *Schultze v. Holtz*, 82 F. 448 (N.D. Cal. 1897).

[138] *Richard v. Du Bon*, 103 F. 868, 873 (2d Cir. 1900).

[139] 185 F.3d 1364 (Fed. Cir. 1999).

The Federal Circuit reversed on appeal, concluding that the fact that one product can be altered to make it look like another is in itself a specific benefit sufficient to satisfy the statutory requirement of utility. The appeals court reasoned that many valued products, ranging from cubic zirconium to synthetic fabrics, are designed to appear as something that they are not.[140] The Federal Circuit further concluded that the utility requirement does not direct the PTO or the courts to resolve issues of product safety or deceptive trade practices, which were left to such agencies as the Federal Trade Commission or the FDA.[141]

As a result of decisions such as *Juicy Whip*, in most technical fields the utility requirement is employed merely to sift out utterly incredible inventions from the domain of patentability. For example, the utility requirement has led to the rejection of patents claiming a perpetual motion machine[142] and a method of slowing the aging process.[143]

In modern practice, the utility requirement most often comes into play in the fields of biotechnology and chemistry. In these disciplines, inventors often synthesize a new compound, or a method of making a new compound, without a preexisting knowledge of a particular use to which the compound may be put. Scientists may generate a compound based on their knowledge of the behavior of related pharmaceutical compounds, for example, or may wish to isolate a fragment of genetic material for which some application may develop in the future. However, at the time the inventor generates the compound, no precise knowledge of the compound's utility is known.

Today there are considerable incentives for biotechnicians to obtain patent protection on compounds of interest as soon as possible. For example, in the case of medical treatments, food and drug authorities require extensive product testing before the pharmaceutical can be broadly marketed. Before investing time and effort on laboratory testing and clinical trials, biotechnology concerns desire to obtain patent rights on promising compounds even where their particular properties are not well understood. But when patent applications are filed too close to the laboratory bench, inventors have discovered that the utility requirement can pose a considerable hurdle.

The Supreme Court opinion in *Brenner v. Manson* addressed such a situation.[144] The inventor Manson filed a patent application claiming a method of making a known steroid compound. Although the particular compound Manson was concerned with was already known to the art, chemists had yet to identify any setting in which it could be gainfully employed. However, it was known that another steroid with a very similar structure had tumor-inhibiting effects in mice, Manson's new method of making the compound was a research tool of interest to the scientific community.

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[140] Ibid at 1367.

[141] Ibid at 1368.

[142] *Newman v. Quigg*, 877 F.2d 1575, 11 USPQ2d 1340 (Fed. Cir. 1989).

[143] *Ex parte Heicklin*, 16 USPQ2d 1463 (BPAI 1990).

[144] 383 U.S. 519 (1966).

The Patent Office Board affirmed the examiner's rejection of the application. The Board reasoned that because Manson could not identify a single use for the steroid he produced, the utility requirement was not satisfied. The Board was unimpressed that a similar compound did have beneficial effects, noting that in the unpredictable art of steroid chemistry, even minor changes in chemical structure often lead to significant and unforeseeable changes in the performance of the compound. Manson appealed to the Court of Customs and Patent Appeals, which reversed. Key to the court's reasoning was that the sequence of process steps claimed by Manson would produce the steroid of interest. According to the Court of Customs and Patent Appeals, because the claimed process worked to produce a compound, the utility requirement was satisfied.

The Supreme Court, however, reversed. The Court took issue with Justice Story's understanding that the utility requirement is fulfilled so long as the claimed invention is not socially undesirable. At least within the context of scientific research tools, the Court imposed a requirement that an invention may not be patentable until it has been developed to a point where "specific benefit exists in currently available form."[145] Chief among the Court's concerns was the breadth of the proprietary interest that could result from claims such as those in Manson's application. "Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. . . . . Such a patent may confer power to block whole areas of scientific development, without compensating benefit to the public."[146] The Court closed by noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. 'A patent system must be related to the world of commerce rather than to the realm of philosophy.'"[147]

Although *Brenner v. Manson* appears to take a strict view of the utility requirement, a more recent Federal Circuit opinion on utility, *In re Brana*,[148] suggests a more limited role. Like Manson, Brana claimed chemical compounds and stated they were useful as antitumor substances. The scientific community knew that structurally similar compounds had shown antitumor activity during both *in vitro* testing, done in the laboratory using tissue samples, and *in vivo* testing using mice as test subjects. The latter tests had been conducted using cell lines known to cause lymphocytic tumors in mice.

The PTO Board rejected the application for lack of utility, and on appeal the Federal Circuit reversed. Among the objections of the PTO was that the tests cited by Brana were conducted upon lymphomas induced in laboratory animals, rather than real diseases. The Federal Circuit responded that an inventor need not wait until an

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[145] Ibid at 534-35.

[146] Ibid at 535.

[147] Ibid at 536 (quoting *Application of Ruschig*, 343 F.2d 965, 970 (CCPA 1965)).

[148] 51 F.3d 1560 (Fed. Cir. 1995).

animal or human develops a disease naturally before finding a cure.[149] The PTO further stated that Brana cited no clinical testing, and therefore had no proof of actual treatment of the disease in live animals. The Federal Circuit found that proof of utility did not demand tests for the full safety and effectiveness of the compound, but only acceptable evidence of medical effects in a standard experimental animal.[150]

The holding of *Brana*, along with its failure to discuss or even cite *Brenner v. Manson*, suggests that the Federal Circuit has adopted a more liberal approach to the utility requirement than did the Supreme Court.[151] The Federal Circuit did indicate that, in cases where the invention lacks a well-established use in the art, the applicant must disclose a specific, credible use within the patent's specification.[152]

Brenner v. Manson and *Brana* were chemical cases. The PTO applies the utility requirement to the analogous discipline of biotechnology as well. Inventors often seek patent protection on biological compounds soon after they have been synthesized. Such compounds include complementary DNA ("cDNA"), which corresponds to proteins used by human cells, and expressed sequence tags ("ESTs"), DNA sequences that correspond to a small portion of each cDNA. Because this nascent field is highly unpredictable, the functions of cDNA fragments and ESTs are usually unknown at the time they are discovered. Yet they remain extraordinarily valuable for their potential uses, and scientists from private industry, government facilities and university laboratories alike have marketed these research tools for commercial sale. The patentability of these genetic materials has proven controversial. While *Brenner v. Manson* holds that serious scientific interest alone does not fulfill the utility requirement, *Brana* and other Federal Circuit opinions suggest a more lenient posture.

In an attempt to address cDNA, ESTs, and other biotechnology patents, the PTO published "Revised Interim Utility Examination Guidelines" in the Federal Register on December 21, 1999.[153] The 1999 utility guidelines require all patent applicants to identify explicitly a specific, substantial and credible utility for their inventions, unless such a utility is already well-established. According to PTO Director Q. Todd Dickinson, "the Patent Office has raised the bar to ensure that patent applicants demonstrate a 'real world' utility. One simply cannot patent a gene itself without also clearly disclosing a use to which that gene can be put. As a result, we believe that hundreds of genomic patent applications may be rejected by the USPTO, particularly those that only disclose theoretical utilities."[154]

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[149] Ibid at 1565.

[150] Ibid at 1568.

[151] Machin, Nathan, "Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act," 87 *California Law Review* (1999), 421, 432.

[152] 51 F.3d at 1564-68.

[153] United States Patent & Trademark Office, "Revised Utility Guidelines," 64 *Federal Register* (22 Dec. 1999), 71440.

[154] Dickinson, supra note 63, at 4.

Director Dickinson explained the meaning of terms "specific, substantial and credible" in the context of the utility requirement as follows:

> · An asserted utility is credible unless the logic underlying the assertion is seriously flawed, or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. For example, at least some nucleic acids might be used as probes, chromosome markers, or diagnostic markers. Therefore, the *per se* credibility of assertions regarding the use of nucleic acids is not usually questioned. However, even if credible, at least one asserted utility must also be both specific and substantial.
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> · A utility is specific when it is particular to the subject matter claimed. For example, a polynucleotide said to be useful simply as a "gene probe" or "chromosome marker" does not have specific utility in the absence of a disclosure of a particular gene or chromosome target. Similarly, a general statement of diagnostic utility would ordinarily be insufficient to meet the requirement for a specific utility in the absence of an identification of what condition can be diagnosed.
>
> · A substantial utility is one that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, basic research that uses a claimed nucleic acid simply for studying the properties of the nucleic acid itself does not constitute a substantial utility.[155]

Many observers have greeted the new PTO Guidelines favorably. The former Director of the National Institutes of Health (NIH), Dr. Harold Varmus, stated that he was "very pleased with the way [the PTO] has come closer to [the NIH's] position about the need to define specific utility."[156] Dr. Francis Collins, Director of the National Human Genome Research Institute, has said that the new utility guidelines are "quite reassuring in terms of making sure that we end up with an outcome where the patent system is used to provide an incentive for research and not a disincentive."[157] In addition, Dr. Craig Venter, the President and Chief Scientific Officer of Celera Genomics Corporation, recently stated that he was "pleased to see [the PTO] is raising the bar" on gene patents.[158]

An interesting aspect of the new PTO Utility Guidelines is their compatability with the governing case law. Although each application must be considered on its own merits, the Guidelines appear to be closer to the holding of *Brenner v. Manson* than *Brana.* It is unclear how the Federal Circuit would rule on a utility-based

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[155] Ibid at 4-5.

[156] Ibid at 5.

[157] Ibid.

[158] Ibid.

rejection under the PTO Guidelines in light of its holding in *Brana.*[159] In this vein, PTO Deputy Assistant Commissioner for Patent Policy Stephen G. Kunin has expressed his view that "it may remain for the Board of Patent Appeals and Interferences and the federal courts to determine the true scope of the substantiality criterion of the utility requirement on a case-by-case basis."[160]

Proponents of a Strict Utility Standard

Some legal and scientific commentators have expressed concern that proprietary interests in scientific knowledge will impede research efforts overall. Following the lead of *Brenner v. Manson*, Professors Heller and Eisenberg have invoked the "tragedy of the anticommons" to argue against the patenting of genetic materials.[161] The "tragedy of commons" is a familiar metaphor for many economists, lawyers and scientists. A resource is prone to overuse in a tragedy of the commons when too many owners each have a privilege to use a given resource and no one has a right to exclude another. Overpopulation, air pollution, and species extinction result from tragedies of the commons.

In a mirror image of the tragedy of the commons, a resource may be prone to underuse in a "tragedy of the anticommons." In this circumstance, multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use. Transaction costs, strategic behaviors, and the cognitive biases of participants often prevent individuals from reaching a socially optimal agreement allocating property rights. Use of the resource then becomes difficult or impossible.

Professors Heller and Eisenberg argue the granting of intellectual property rights to early research results holds the potential to create a tragedy of the anticommons in biomedical research. They specifically identify two mechanisms through which patents on gene fragments may hinder innovation. First, too many concurrent fragments of intellectual property rights may hinder the exploitation of potential future products. In a spiral of overlapping patent claims held by different individuals, one enterprise may own a patent on a raw genomic DNA fragment, another on the corresponding protein, and yet another on a diagnostic test for a genetic disease. Professors Heller and Eisenberg explain that each 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.

Second, upstream patent owners may be able to stack licenses on top of the future discoveries of downstream users. The use of reach-through license agreements on patented research tools is exemplary. These covenants give the owner of a patented invention, used in upstream stages of research, rights in subsequent downstream discoveries. Such rights may take the form of a royalty on sales that

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[159] Kunin, Stephen G., "Written Description Guidelines and Utility Guidelines," 82 *Journal of the Patent and Trademark Office Society* (2000), 77.

[160] Ibid at 100.

[161] Heller, Michael A. & Eisenberg, Rebecca S., "Can patents deter innovation? The anitcommons in biomedical research," 280 *Science* (1 May 1998).

result from use of the upstream research tool, an exclusive or nonexclusive license on future discoveries, or an option to acquire such a license. Professors Heller and Eisenberg contend that reach-through license agreements may lead to an anticommons as upstream owners stack overlapping and inconsistent claims on potential downstream products.

Proponents of a Lenient Utility Standard

Others have urged that originators of research tools too require a return on investment, and that allowing patents only on final products would further industry concentration.[162] If independent researchers and research enterprises were unable to patent their discoveries, then they might have no option but to join large companies capable of seeing this earlier research through to a completed product. This trend might chill the market for preliminary genetic materials and ultimately diminish research.

Commentators further note that research tools are subject to a lively market within the biotechnology industry. Many enterprises are interested in purchasing research tools, and as a result many enterprises are engaged in making them. Attorney Scott A. Chambers says that describing these products as preliminary and arising within the "realm of philosophy" is simply inaccurate.[163]

Those in favor or a more porous utility standard also argue that research products do not present a special case. They observe that patented products and processes often are later found to possess additional, more valuable uses than those named in the original patent. In such cases advance knowledge of one particular use does not somehow restrain the patentee's proprietary interest in those additional applications. For example, the chemical compound nitroglycerine, originally developed as an explosive, was later found to be useful as a heart medication. If an inventor had obtained a patent on the nitroglycerine compound itself, then he would continue to possess a proprietary interest in that compound no matter what applications were discovered for it. Whether characterized as a basic research tool or an applied technology, any invention potentially serves as the basis for later developments.[164]

Finally, observers have noted that arguments similar to those of Professors Heller and Eisenberg have been made in the past. The techniques of polymer chemistry, for example, involve the use of long chains of basic compounds. During the emergence

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[162] *See generally* Eisenberg, Rebecca S., "Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing," 3 *University of Chicago Law School Roundtable* (1996), 560.

[163] Chambers, Scott A., "Comments on the Patentability of Certain Inventions Associated With the Identification of Partial cDNA Sequences," 23 *American Intellectual Property Law Association Quarterly Journal* (1995), 59.

[164] Jaffe, Adam B., *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process* (Cambridge, Massachusetts: National Bureau of Economic Research, Aug. 1999), 27.

of polymer chemistry several decades ago, some critics argued that granting broad generic claims on basic polymers would allow a few enterprises to own the building blocks of the industry. These critics claimed that this monopolization by a few would slow progress. According to some contemporary commentators, these perceived concerns never materialized with regard to polymers, and are unlikely to occur in the contemporary biotechnology industry.[165]

Legislative Issues and Options

Patents play an important role within the modern biotechnology industry. Some observers believe that, particularly for entrepreneurs and small, entrepreneurial biotechnology firms, patents facilitate capitalization and therefore support technological advance.[166] Experience also suggests that legal uncertainties regarding biotechnology patents may impact the ability of enterprises to acquire funding for their research and development efforts. However, other commentators remain deeply concerned over the implications of patenting living inventions, genetic materials and other biotechnologies, as well as the patenting of biotechnological inventions with unknown or speculative utilities. Patent reform legislation holds the possibility for resolving these concerns. Should Congress choose to review the progress of biotechnology, there are at least two patent issues it could consider: patent eligibility and the utility requirement.

Patent Eligibility

The potential for limiting the patentability of living inventions is moderated by several factors. One source of restraints consists of international agreements to which the United States is a signatory. Two international agreements that speak towards intellectual property rights, the North American Free Trade Agreement (NAFTA)[167] and the Trade-Related Aspects of Intellectual Property Rights of the World Trade Organiziation ("TRIPS Agreement"),[168] are worthy of note here. Article 1709(1) of NAFTA provides that signatory states "shall make patents available for any inventions, whether products or processes, in all fields of technology." Article 27(1)

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[165] Dickinson, *supra* note 63, at 6.

[166] Biotechnology Industry Organization, Legislative Issues: Intellectual Property Protection, available at [http://www.bio.org/aboutbio/guide2000/guide_legislative.html#intellectual property protection] ("Because biotech companies depend on private investments, patents are among the first and most important benchmarks of progress in developing a new biotechnology product.").

[167] See North American Free Trade Agreement, Dec. 17, 1992, Can.-Mex.- U.S., 32 I.L.M. 289 (1993), 32 I.L.M. 605 (1993), reprinted in The NAFTA (U.S. Gov't Printing Office ed., 1993); see also North American Free Trade Agreement Implementation Act, Pub. L. No. 103-182, 107 Stat. 2057 (1993) (implementing necessary changes in U.S. law to comply with NAFTA and reprinting the agreement).

[168] See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 66, para. 1, Legal Instruments–Results of the Uruguay Round vol. 31; 33 I.L.M. 81 (1994).

of the TRIPS Agreement reads similarly. This language confirms the broad sense of patent eligibility under current U.S. law.

Both NAFTA and the TRIPS Agreement do allow signatory states to exempt higher life forms from the patent system. As further stated in Article 1709(3) of NAFTA, a signatory may exclude from patentability "plants and animals other than microorganisms" and "essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production." Article 27(3) of the TRIPS Agreement reads almost identically.

The impact of these exceptions is that a signatory may disallow patents from issuing on living entities other than microorganisms. Thus, microscopic organisms such as bacteria, viruses and protozoa must be classified as patentable. Signatories may, but need not, issue patents on higher life forms ranging from genetically modified rice to the Harvard mouse.

Signatories to NAFTA and the TRIPS Agreement may also deny patents to processes that are deemed "essentially biological" in character. Whether a particular process is "essentially biological" depends upon the degree of artificial activity required to perform the process. A method of selectively breeding animals by selecting particular animals and bringing them together would likely be deemed "essentially biological" and therefore may be held unpatentable. However, a method of treating a plant to improve its yield, such as a method of pruning a tree, would not be judged "essentially biological" due to the more significant degree of human intervention.[169] Excluding this later sort of process from patentability would not comport with NAFTA or TRIPS Agreement. U.S. law arguably includes this exception already, given case law requiring that biotechnological inventions be subject to artificial invention in order to be patentable.[170]

Should Congress choose, it could take an approach other than that suggested by case law and PTO practice by making certain biotechnologies unpatentable. Numerous patent applications have been filed on a variety of biotechnological inventions. These applications have resulted in many issued patents, and some of these patents have been litigated in the courts. Legislation affecting these patents would prompt concerns over governmental takings under the Fifth Amendment.[171]

Limiting biotechnology patenting would counter prevailing trends within the patent community both domestically and abroad. As suggested by the recent patenting of methods of doing business, many patent systems are tending towards an increasingly broad scope of patentable subject matter.[172] Biotechnologies are

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[169] European Patent Office, *Guidelines for Examination*, Part C, Chapter IV (1995), 39.

[170] *See supra* notes 92-95 and accompanying text.

[171] U.S. Constitution, Amendment V ("[N]or shall private property be taken for public use, without just compensation."). See *James v. Campbell*, 104 U.S. 356, 358 (1881) (stating that a patent "confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation").

[172] U.S. Library of Congress, Congressional Research Service, *Patents on Methods of Doing*
(continued...)

generally patentable in Japan, and after several years of debate the European Parliament issued a Directive approving biotechnology patents.[173]

The Utility Requirement

The utility requirement is judge-made law. Its only statutory mooring is the term "useful" recited in § 101 of the Patent Act. Although the PTO has issued Utility Guidelines, Congress has never elaborated on the utility requirement. The concern of many actors within the biotechnological industry that the utility requirement be calibrated appropriately,[174] concern within the research community that some patents could provide a disincentive for further research, and arguable inconsistencies within the case law,[175] suggest that these issues may draw congressional interest.

Congress could examine whether the definition of patentable utility should be legislatively specified. For example, the Patent Act could list the pertinent factors suitable for demonstrating the utility of expressed sequence tags ("ESTs"). PTO Deputy Assistant Commissioner for Patent Policy Stephen G. Kunin has suggested that pertinent factors include knowledge of the corresponding mRNA sequence, protein coding sequence or genomic sequence; whether there are sequence polymorphisms linked to the corresponding genomic location; the function of the protein encoded by the corresponding messenger Rnucleic acid ("mRNA"); the phenotype of a mutation in the corresponding gene; the tissue distribution of the corresponding mRNA and tissue-specific expression levels; and the map location of its corresponding genomic sequence.[176] A recurring complaint is that patent applicants specify minimal and rather abstract utilities, such as the possible use of an EST merely as a probe or marker.[177] Congress could resolve whether these uses fulfill the patentable utility requirement. Some caution, however, that specifying such technical detail in law has drawbacks to the extent the law would need to be amended in order to reflect changes in rapidly evolving technologies.

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[172] (...continued)
Business, by John R. Thomas, Report RL30572, 1 June 2000, 1-3.

[173] See Dotson, Darrell G., "The European Controversy Over Genetic-Engineering Patents," 19 *Houston Journal of International Law* (1997), 919.

[174] See supra notes 156-58 and accompanying text.

[175] See supra notes 151-52 and accompanying text.

[176] Kunin, supra note 159, at 99.

[177] Ibid.