# PATENTING OUR LIVES AND OUR GENES:

# WHERE DOES CONGRESS STAND IN THE COMING CLASH?

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## I. INTRODUCTION

In recent years, a proliferation of patent applications has been filed for living organisms, genes, and gene sequences. While an overwhelmed Patent & Trademark Office struggles to make sense of the deluge, medical and biotech researchers toil under the potential threat that the end results of their work may conflict with a current or future patent. The situation cries out for serious congressional study and consideration. Unfortunately, due primarily to the explosive social issues involved, Congress has chosen to sit on the sidelines abdicating its constitutional authority to the Executive and Judicial branches of our government.

## II. WHAT IS A PATENT?

### A. Historical Origins

A patent is a grant from the government to an inventor assuring him or her the sole right to make, use, and sell the invention for a certain period of time.[1] Several of American's key constitutional framers, including Thomas Jefferson and James Madison, believed that protecting inventions would spur scientific discovery. Following England's adoption of copyright laws protecting authors, they argued that America's Congress should be empowered to enact patent laws. For example, Thomas Jefferson argued that "ingenuity should receive a liberal encouragement."[2] Similarly, in the Federalist (No. 43), James Madison contended that strong patent laws would enhance "the public good."[3] Shortly before he became President of the United States, Abraham Lincoln opined that the patent laws were among the most valuable new inventions and discoveries

[1] Webster's II New College Dictionary (1999).
[2] Writings of Thomas Jefferson 75-76 (Washington ed. 1971).
[3] James Madison, Federalist No. 43, in Alexander Hamilton, James Madison, and John Jay, The Federalist Papers, Clinton Rossiter ed. p. 271-72 (New York: Mentor, New American Library 1961).

in the history of the world "on account of their great efficiency in facilitating all other inventions and discoveries."[4]

### B. Constitutional and Legislative Origins

Jefferson and Madison convinced the Constitutional Convention to include as part of Congress' expressly delegated powers the authority to enact laws "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[5] Immediately following the ratification of our Constitution, Jefferson authored The Patent Act of 1793, which defined the statutory subject matter as "any new and useful art, machine, manufacture, or composition of matters, or any new or useful improvement [thereof]."[6] Subsequent American patent statutes in 1836, 1870, and 1874 continued to employ Jefferson's broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact.[7] Consequently, the patent laws, as they are written today in 35 U.S.C. §100 et seq., are largely the work of Thomas Jefferson.

### C. The Purpose of Patents

The primary purpose of the patent laws is to encourage inventors by rewarding their heavy expenditures of time, money and energy. By granting a monopoly over the use of the invention for a period of years, the patent holder is able to retrieve his or her substantial sunk front-end investment. As noted by economist and jurist Richard Posner, "the manufacturer … will not sew if he won't be able to reap."[8]

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[4] Abraham Lincoln, "Second Lecture on Discoveries and Inventions" (February 11, 1959), in The Collected Works of Abraham Lincoln, vol. III, p. 361 (Rutgers Univ. Press 1953).
[5] United States Constitution, Article I, Section 1, clause 8.
[6] Act of February 21, 1793, §1, 1 Stat. 319.
[7] S.Rep. No. 1979, 82d Cong. 2d Sess., S (1952).
[8] Richard A. Posner, Economic Analysis of Law 43 (5th ed. 1998).

A secondary purpose of the patent laws is to encourage the full and timely disclosure of inventions to the public. Under 35 U.S.C. § 11, the Commissioner of the United States Patent and Trademark Office ("PTO") is empowered to print all patents and sundry other items ensuring full public disclosure. The PTO additionally serves as an office in the Department of Commerce "where records, books, drawings, specifications and other papers and things pertaining to patents and to trademark registrations shall be kept…"[9]

## III. KEY LEGAL DECISIONS CONCERNING BIOTECHNOLOGY PATENTS

### A. Patenting Living Organisms

In 1980, the United States Supreme Court first faced the issue of whether a live, human-made micro-organism is patentable under 35 U.S.C. §101 as a new "manufacture" or composition of matter.[10] The case dealt with microbiologist Ananda Chakrabarty's successful invention of "a bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway." The bacterium Chakrabarty created was capable of breaking down multiple components of crude oil. Chakrabarty and his licensee General Electric believed his bacterium could "have significant value for the treatment of oil spills."[11]

In a 5-4 decision, Chief Justice Burger determined that the patent statutes should be read broadly to allow the patenting of living micro-organisms. The Court held that Chakrabarty's bacterium was not "a hitherto unknown natural phenomenon, but [ ] a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name,

[9] 35 U.S.C. §1.
[10] Diamond v. Chakrabarty, 447 U.. 303 (1980).
[11] 447 U.S. 305.

character, and use."[12] The court added: "His discovery is not nature's handiwork, but his own; accordingly, it is patentable subject matter under §101."

Justice Brennan, writing for the four dissenters, argued that the Plant Patent Acts of 1930 and 1970 evidenced Congress' understanding that 35 U.S.C. §101 "does not include living organisms." If living organisms were included, Brennan contended, then the Plant Patent Acts wold have been unnecessary and superfluous. He further emphasized that Congress had expressly excluded bacteria from the coverage of the 1970 Act. [13] Justice Brennan concluded: "It 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."[14]

The Chakrabarty decision has ignited criticism from diverse sources. Dr. Leon Kass, for example, believes the Court's decision was legally and morally incorrect.[15] I agree with Dr. Kass. What I find most distressing, however, is that Congress has not spoken since the decision, but simply has allowed the Chakrabarty decision to become the law. In effect, Congress has taken the easy way out, and abdicated its constitutional authority to five unelected Supreme Court Justices in an area that "uniquely implicates matters of public concern." Legislation by abdication does not serve the interests of Americans in such profound questions as whether a single individual or corporation can own new forms of life.[16] As citizens, we must demand more from our elected officials.

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[12] 447 U.S. 309-10.
[13] 447 U.. at 321.
[14] 447 U.S. at 322.
[15] Dr. Leon R. Kass, Toward a More Natural Science: Biology and Human Affairs, 143-53 (The Free Press 1985).
[16] See e.g., U.S. Patent No. 4,736,866 (April 12, 1988), granting patent protection to Harvard University for an "oncomouse," a mouse genetically engineered to be unusually susceptible to cancer.

### B. Patenting Genes and Gene Sequences

Since 1980, as Congress has sat by idly, and abdicated its constitutionally delegated legislative role, the PTO and courts have granted patent protection to a variety of biotechnical innovations and research techniques that historically have fallen outside the field of patentable products. One of the hottest biotechnology patent battles today involves the patenting of genes and gene sequences. For example, on January 5, 2001, the PTO issued its final Utility Examination Guidelines and Guidelines for Patent Applications under the "Written Description" requirement of 35 U.S.C. §112 ¶1.[17] As part of its effort, the PTO opined that partial sequences of genes or Expressed Sequence tags ("ESTs") are patentable subject matter. Consequently, a gene sequence is now ostensibly patentable if the patent discloses a single specific, substantial and credible utility such as the ability "to produce a useful protein or if it hybridizes near and serves as a marker for a disease gene."[18]

In issuing patents for genes and gene sequences, the PTO has deferred to industry and scientific community arguments that genes should be patentable since they can be isolated, purified, characterized and put into commercially useful formats to develop new diagnostics and therapeutics. The PTO's decision overlooks that the patent laws prohibit patenting anything that is "natural," such as rare Amazon plants with medicinal properties.[19] Furthermore, in reaching this decision, in the absence of meaningful congressional input or direction, the PTO has created a logistical and practical nightmare. In the last five years, the PTO has received over 90,000 applications for patents for genes, parts of genes, and all manner of molecular compounds.[20] Human Genome Sciences ("HGS") in Rockville, Maryland, alone, has applied for more than 7,000 patents on human genes,

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[17] See 66 Federal Register at 1099 (2001).
[18] See 66 Federal Register at 1094.
[19] See Richard Lewontin, It Ain't Necessarily So: The Dream of the Human Genome and Other Illusions at 163-64; 181 (New York Review Books 2000).
[20] The Business Week 50, at 169 (Spring 2001).

165 of which have been issued.[21] HGS software now automatically prepares a patent application as a new gene sequence and function is "discovered." HGS's software is now generating over 400 additional patent applications each month! Where will it end?[22]

### C. Patenting of Research Techniques for Genetic Alteration

"Only after George W. Bush's speech [on human embryonic stem cell research] did America learn that the University of Wisconsin owns the patent for human embryonic stem cells isolated in the laboratory."[23] Similarly, various critical recombinant DNA research techniques now are patented.[24] The practical problem developing is that "an increasing number of blocking patents and potential litigation situations" are forcing researchers "to seek licenses from multiple owners."[25]

Any researcher or company seeking to develop a new diagnostic or therapeutic treatment conceivably could be attacked by scores of owners of gene, gene sequence, or gene handling patents claiming that knowledge of their gene or technique was employed or implicated in their research efforts. Furthermore, as companies create and market databases of patented genes and gene sequences, the costs for obtaining basic background information for genomic and proteiomic research could become staggeringly high. Although it is uncertain what the effect of so many blocking patents will be on basic genetic and medical research, it is quite certain that the courts and attorneys will be excessively busy fighting expensive and time-consuming legal battles, as a result of Congress' legislative silence and constitutional irresponsibility.

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[21] The Business Week 50, at 168 (Spring 2001).

[22] It is especially ironic that at the same time that Congress is completely abdicating its constitutional role in legislating patent issues, it has cut back dramatically on the resources of the PTO. The beleaguered and aging PTO staff cannot possibly deal with so many applications in any pragmatic or meaningful way. Thus, Congress is exacerbating the chaos and confusion its irresponsibility is creating at a critical time during the exploding biotechnology revolution.

[23] Evan P. Schultz, "Who Owns Global Cures?" October 8, 2001 Legal Times at p. 26.

[24] See e.g., a discussion concerning the legal battles over the patent rights for the polymerase chain reaction ("PCR") method for making copies of a section of DNA. The litigation, which began in 1990, is still going on. October 8, 2001 Intellectual Property (Legal Times) at p. 18.

[25] Michelle S. Marks, David B. Schmickel, and Michael D. Bednarek, "Unity in the Gene Pool," October 8, 2001 Intellectual Property (Legal Times) at 50.

### D. Patenting of Human Tissues and Blood Samples

Genetic activists now are claiming that since individuals own their own bodies, they should have patent rights for any of their personal blood or tissue samples used in medical research.[26] Patient-rights groups argue that holding patents over their blood and tissues will guarantee them a seat at the table in deciding how such samples are used, and ensure that they are fairly compensated for their unique contributions. Pharmaceutical companies counter that the added complexity of donor patient patents will cut into the biotech and biopharma industries' efficiencies and productivity. Again, one wonders where Congress stands.

## IV. WHAT ARE THE SOCIAL CONSEQUENCES OF RECENT BIOTECH PATENTS?

### A. The Case for Broad Biotech Patents

As discussed earlier, the United States historically has recognized constitutionally, legislatively, and judicially that inventors should be rewarded for their efforts and ingenuity. The concept of "appropriability" increasingly is employed by economists seeking broader patent rights.[27] Unless firms or individuals can appropriate or capture sufficient returns from their risky investments in developing new products or processes, they will lack the incentive to make such investments.

Patent rights proponents note that the average cost of developing a new pharmaceutical ranges from $500-$800 million. Only 26 new drugs were approved by the FDA for consumer use in 2000, and 13 already have been pulled off the market. If pharmaceutical companies were unable to recover their substantial sunk research and development costs through patent protections or successful drugs, research and development investment could drop radically endangering future discoveries. The biotechnology and pharmaceutical industries argue that the fast-pace of discovery

[26] See e.g., Matt Fleischer, "Patent Thyself," The American Lawyer, June 2001, at 84.
[27] See e.g., Richard M. Brunell, Appropriability in Antitrust: How Much Is Enough?, 69 Antitrust Law Journal 1, 2-3 (2001).

and characterization of genes and their impact in the acceleration of drug development and the availability of new drugs and diagnostics is a testament to how well patents have worked in encouraging and buttressing successful research and development. Finally, patent rights proponents add that by requiring publication and public disclosure, patents catalyze new discoveries related to the original patented discovery.

### B. The Case Against Broad Biotech Patents

A strong moral case against patenting life in any form can be made. As Dr. Leon Kass asks, "Is it not clear, if life is a continuum, that there are no visible or clear limits once we admit living species under the principle of ownership?"[28] Pragmatic arguments can be added such as who will be responsible for a new life form that has not co-evolved with the rest of the environment. What if a new bacterium or virus runs amok destroying other life forms and ecosystems? As Dr. Kass notes, no patent holder could ever guarantee complete safety.[29]

The recent proliferation of blocking patents also raises grave concerns for future biomedical research and development. One must now wonder whether licensing, transaction and litigation costs will significantly restrict access to the research tools and materials necessary for technological advance. One legal commentator has argued that the current regime of biotechnology patent protections "is likely to close off much of the genetic commons to small firms that have been the indispensable catalysts of most fundamental innovation in the biotechnology sector."[30]

The biotechnology revolution also is sparking a technology transfer rage that could jeopardize the independence and pure research motives of universities and non-profits. As distinguished Harvard biologist Richard Lewontin notes: "No prominent molecular biologist of my acquaintance is without a financial stake in the biotechnology business. As a result, serious conflicts

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[28] Dr. Leon Kass, Toward a More Natural Science, at p. 151.
[29] Ibid.

of interest have emerged in universities and in government service."[31] One wonders whether such a system can produce the independent thinkers our society desperately needs to guide the biotechnology revolution. As stated by Karen Charman: "Few academics are willing to openly criticize biotechnology for fear of retribution from biotech boosters."[32]

Finally, the sheer cost of pharmaceuticals and emerging medical technologies must be considered. The recent anthrax scare highlighted the problems of gaining mass distribution for drugs like Bayer's Cipro, which is protected by a patent. Recently, however, on July 12, 2001, the United States House of Representatives rejected 269 to 157, after only one hour of debate, legislation that would have allowed American wholesalers and pharmacies to import FDA-approved American-made drugs that are sold overseas.[33] Furthermore, the escalating battles involving generic and patented brand name pharmaceuticals show no signs of going away in the next decade.[34]

## V. THE NEED FOR SERIOUS CONGERESSIONAL STUDY AND ACTION

Congress must seriously study the issues surrounding recent biotechnology patents and start taking action. The social consequences of recent biotechnology patents cannot be left to the Executive and Judicial branches of our government simply because Congress believes the issues are too politically sensitive. Congressional abdication of its constitutionally delegated responsibilities is unacceptable in such crucial matters of public concern as the patenting of life and gene sequences.

In order to minimize the costs to society of twenty-first century medical care, and to protect the public against serious technological risks, I believe Congress should first statutorily reverse the

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[30] Jonathon Barnett, Cultivating the Genetic Commons: Imperfect Patent Protection and the Network Model of Innovation, 37 San Diego Law Review 987 (2000).

[31] Richard L. Lewontin, It Ain't Necessarily So: The Dream of the Human Genome And Other Illusions, at p. 163.

[32] Karen Charman, "Spinning Science Into Gold," July/August 2001 Sierra at p. 43.

[33] Interestingly, members who voted against the legislation received, on average, more than three times as much in campaign contributions from the pharmaceutical lobby as members who voted for the legislation. See e-mail of Nick Wills-Johnson, Institute for Research into International Competitiveness, to Tom Horton.

Supreme Court's Chakrabarty decision, and pass legislation stating that living organisms may not be patented. Congress should further legislate that genes and gene sequences are natural products of nature that are not patentable subject matter. Congress should then dramatically increase the resources allocated to the PTO, so that its offices are not overwhelmed by impossible demands. To lower barriers to entry, Congress should require the mandatory licensing of key blocking biotechnical patents at reasonably royalty rates.[35] As argued by Jonathon Barnett, "a patent regime that lacks the threat of compulsory licensing may allow large firms to integrate vertically upstream, acquire a patent portfolio that erects insurmountable entry barriers to small firms, and ultimately slows down the rate of fundamental innovation."[36] Finally, such legislation should be supplemented by vigorous antitrust enforcement against mergers, acquisitions, patent pools, and other business activities that seek to consolidate market power over pharmaceutical patents, research techniques, and genomic data bases.[37]

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[34] See e.g., FTC Press Release of October 11, 2000, "FTC to Study Generic Drug Competition."

[35] Such legislation undoubtedly would spark massive litigation under the Fifth and Fourteenth Amendments to the Constitution, which prohibit "takings" of property without just compensation.

[36] Jonathon Barnett, supra, 37 San Diego L. Rev. at 1055.

[37] The FTC has announced public hearings beginning in January 2002 on "Competition and Intellectual Property Law and Policy in the Knowledge Based Economy." The hearings will focus primarily on the implications of antitrust and patent law and policy for innovation and other aspects of consumer welfare. Fed. Reg. Notice of 11/26/01.