

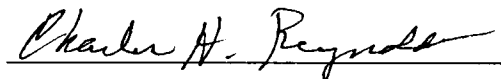
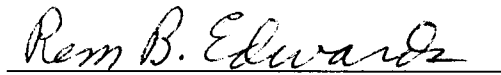
To the Graduate Council:

I am submitting herewith a dissertation written by Carl B. Mitchell entitled "Patenting Life: An Examination of Some Ethical Implications of Biopatents." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Philosophy.



Glenn C. Graber, Major Professor

We have read this dissertation
and recommend its acceptance:



Accepted for the Council:



Associate Vice Chancellor and
Dean of The Graduate School

**PATENTING LIFE:
AN EXAMINATION OF SOME
ETHICAL IMPLICATIONS OF BIOPATENTS**

A Dissertation
Presented for the
Doctor of Philosophy Degree
The University of Tennessee, Knoxville

Carl B. Mitchell
December 1997

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DEDICATION

To my wife, Nancy,

whose unflagging encouragement and constancy enabled me to

endure through the process of writing

and

to my parents, Mr. W. O. Mitchell and Mrs. Irma Lee Mitchell,

whose confidence in me never wavered.

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Finally, I must acknowledge colleagues at the American Association for the Advancement of Science and The Hastings Center. Both groups invited me to participate in dialogues on patenting biological materials. Those dialogues were a valuable crucible through which much of my thinking on this matter was shaped.

ABSTRACT

Patenting living organisms, including animals, human genes, cells, cell lines and body parts has become a major area of contention in the development of biotechnology at the threshold of a new millennium. The expansion of commercial biotechnology and the application of the machine metaphor in biology represents a paradigm shift opening the door for revaluation of biological materials. Competition in biotechnology led to the perceived need for intellectual property protection for the biotechnology industry. The patent system was a readily available mechanism for such protection. Patents grant a limited, exclusive property right (monopoly) in their subject matter. Intellectual property rights in biological materials are defended typically through backward-looking arguments (ala John Locke) or forward-looking arguments (ala consequentialism). *Diamond v. Chakrabarty* and *Ex parte Allen* are watershed events leading the United States Patent and Trademark Office to judge that "anything under the sun made by man" is patentable. Nevertheless, composition of matter patents entail a form of commodification of animal and human biological materials by rendering those materials commensurate exclusively with market values. The socially-based, idealistic, pluralistic theory of value proposed accounts for the rich and diverse ways we value animals, animal species, human beings, and human body parts. The application of this theory of value leads to the conclusion that these biological materials should not be subject to composition of matter patents.

PREFACE

Patenting living organisms, including human genes, cells, cell lines, and body parts, has become a major area of contention in the development of biotechnology at the threshold of a new millennium. Biotechnology is a global industry operating within a global economy, so the stakes are high. Sadly, the debate over patenting life often has generated more heat than light. Moreover, the controversy largely has ignored both the origin of contemporary notions of property rights and the plurality of values which inhere in living entities. Instead of attending to the plurality of values which we humans locate in living entities, discussions of intellectual property rights in the form of patent protection attend almost exclusively to economic valuation. The following pages attempt to explore in a systematic fashion the ethical issues at stake in the debate about patenting life.

Chapter 1 traces the rapid expansion of the biotechnology industry. Biotechnology as a recognized industry is a very recent phenomenon. Especially after the discovery of recombinant DNA technology at mid-century, the biotech industry enjoyed a vigorous reception in Western culture and increasing numbers of research dollars were pumped into biotech ventures. Furthermore, the industry turned to the patent process to protect intellectual property rights in biotechnological materials.

Chapter 2 rehearses briefly the history of the patenting process in its American context. Included in this discussion is an examination of the criteria for patent protection under United States law. Furthermore, the recent history of patenting living organisms, genes, cell lines, and whole organisms is reviewed.

Chapter 3 consists of a detailed examination of the values the United States Patent and Trademark Office (PTO) and the courts have viewed as important in the landmark cases in the history of patenting life. By examining the rationale of the PTO in granting patents on living entities and the values respected by the courts in adjudicating litigation on these patents, we are able to see more clearly how the patent process shapes the ways living entities are valued in the culture.

Chapter 4 explores the historico-philosophical development of property rights in the thought of John Locke. Lockean notions of property rights have informed the discourse on patenting in profound ways. Locke's labor-added theory of the acquisition of private property was relied on not only by Thomas Jefferson, one of the parents of American patent law, but also by more recent interpreters of patent provisions. Lockean property rights are found insufficient for the varied ways humans value living entities.

Chapter 5 examines the recent arguments for and against the patenting of living entities. This examination deals largely, but not exclusively, with documents produced by the now-defunct Office of Technology Assessment (OTA). The OTA was created by Congressional fiat in 1972 and was assigned the task of reporting to Congress on a plethora of issues ranging from biotechnology to global competitiveness to environmental protection. The OTA relied upon national scholars and policy experts in its assessment of law, medicine, philosophy, religion, health, and safety.

Chapter 6 reframes the discussion of property rights, patents, and the patenting of living entities in the context of a pluralistic theory of values. This section relies largely on the theoretical work of Elizabeth Anderson in her volume, *Values in Ethics and*

Economics (Harvard University Press, 1993). A pluralistic theory of value, it is argued, accords with our considered moral judgments concerning the ways we value living things. The problem of commodification is also examined and is shown to inappropriately regard modes of valuing living things as commensurable with economic modes of valuation. Finally, alternatives to composition of matter patents in biological materials are examined and additional areas for research are pointed out.

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INTRODUCTION

The amazingly rapid growth of genetic technology in the latter half of the twentieth century combined with the emergence and sizable expansion of the biotechnology industry over the past two decades has resulted in renewed philosophical reflection on the issues which form the intersection of genetics and ethics. The rise of industrial genetics in the last decades of the twentieth century spawned a new generation of ethical, legal, and social concerns. The values and policies which governed technological advances in the past are being strained by the innovations of the present and the anticipated developments in the future of biotechnology. One formidable focus of this stress is the patenting of living organisms.

For nearly two-hundred years the United States Patent and Trademark Office refused to grant patent protection for non-plant living organisms, "deeming them to be 'products of nature' and not statutory subject matter"¹ under United States law. In 1980, however, the United States Supreme Court broke new ground in its 5-4 ruling in *Diamond v. Chakrabarty*. Ananda Chakrabarty, a microbiologist at the University of Illinois, filed for a patent on behalf of General Electric Corporation for a novel bacterial strain that was capable of degrading components of crude oil, thus making the bacteria useful in cleaning up oil spills. Though the original patent application was filed in 1972, it was not until after

¹U. S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Patenting Life—Special Report*, OTA-BA-370 (Washington, DC: U. S. Government Printing Office, April 1989), p. 7. Hereafter, *Patenting Life—Special Report*.

a lengthy appeals process that the United States Court of Customs and Patent Appeals granted the patent, a decision which was conferred in 1979 and upheld by the U.S. Supreme Court on June 16, 1980.² In 1987, the U.S. Commissioner of Patents announced that “the Patent and Trademark Office now considers *nonnaturally occurring nonhuman multicellular living organisms, including animals*, to be patentable subject matter.”³ Less than a year later, in April 1988, the first animal patent was issued to Harvard University for the so-called “oncomouse” (U.S. 4,736,866). The patented mouse was genetically engineered to contain a cancer gene making it useful in human cancer research. E. I. du Pont de Nemours & Company was granted exclusive licensure to practice the patent. According to the now defunded Office of Technology Assessment (OTA), the patent specifically covers “a transgenic nonhuman eukaryotic animal (preferably a rodent such as a mouse) whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal . . .”⁴ That is to say, the patent was granted not only on a mouse and its progeny, but on *any mammal that has cancer genes inserted into its genome at an embryonic stage*. Thus, Du Pont effectively has a temporary monopoly on the use of “oncomammals.”

While whole human beings have not been patented yet, human genetic material is routinely patented. In July 1990, the California Supreme Court ruled that a patient whose diseased spleen had been used to produce patented cell lines had no right to the millions of

²*Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

³*Patenting Life—Special Report*, p. 12 Emphasis added.

⁴*Ibid.*

dollars potentially resulting from the sales of pharmaceutical products derived from the cell lines derived from his spleen. By September 4, 1993, the National Institutes of Health (NIH) had filed for patents on 6,122 gene fragments. NIH had not identified what role, if any, these fragments played in human physiology, but attempted to patent them so as to maintain control over their future use. The Patent and Trademark office refused to grant the patents. Although patenting of "gene fragments of unknown biological function" is presently disallowed, who knows what the future holds? In fact, the Patent Office is once again suggesting that such materials may be patentable.

Most of this territory is uncharted. Potential hazards abound in navigating these waters. For instance, Boston University Professor of Health Law George Annas has queried, "Since cloned human embryos are not persons protected by the constitution and theoretically at least could be as 'immortal' as cloned cell lines, could a particularly 'novel' and 'useful' human embryo be patented, cloned, and sold?"⁵

The patenting of living organisms—genes, cell-lines, and whole organisms—raises fundamental moral, social, and legal questions. The purpose of this dissertation is to explore the philosophical and ethical implications of patenting living organisms and other biological materials, attempting to offer resolutions to some of the dilemmas presented in biopatenting.

Patents on living organisms, it will be argued, are the result of a gargantuan shift in the way society values those organisms. For millennia living entities were viewed, by and

⁵George Annas, "Of Monkeys, Man, and Oysters," *Hastings Center Report* 17 (August 1987), p. 22.

large, as creations of God or products of nature possessing their own living essence or *élan vital*. More recently, however, the metaphors and symbols growing out of the new genetics have tended to conceive of cells as machines—complex biological machines—but machines nonetheless. Alteration of the sub-microscopic parts of the cell thereby constitutes a form of manufacture. The altered gene or engineered cell is treated as a product of manufacture. Once transformed conceptually from products of nature to products of manufacture, life-forms (organisms, genes, cells, organs, tissues, etc.) are valued differently than in the past.

Moreover, in Western culture, especially in the United States, products of manufacture, the fruits of invention, have been valued highly. Likewise, inventors themselves have received a certain celebrity status. Eli Whitney, the Wright brothers, Thomas Edison, and Albert Einstein are powerful symbols of the artificer's craft and skill. To their names are added the names of contemporary biotechnicians including James Watson, Francis Crick, Cohen and Boyer, and others. Innovation is rewarded in Western culture with both social and economic compensations. Incentive for innovation and a mechanism for compensation have been established by the patent system. Through the patent system an inventor is rewarded an exclusionary right to prevent others from using, selling, or manufacturing the object or process of his or her invention for a specified period of time.

The marriage of the art of invention and the shift in modes of valuing life-forms created a relatively new industry: biotechnology. A combination of two Greek words (*bios* and *techne*), "biotechnology" has become a potent moniker for human progress, not

to mention economic prosperity. While "biotechnology" may be used to define either a set of techniques or an emergent industry, it has become a commonplace in Western parlance.

The growth of biotechnology as an industry has not escaped the notice of either venture capitalists or the popular media. For instance, a 1992 *Business Week* cover story entitled "Biotech: America's Dream Machine" spotlighted the explosion of recombinant DNA technology.⁶ The authors observed that in 1991 six biotechnology companies with the word "immune" in their name saw gains of 60 percent to 1200 percent during one twelve-month period. Revisiting the subject in 1995, *Business Week* characterized two entrepreneurs of biotechnology as "The Gene Kings."⁷ Similarly, following a firestorm of controversy touched off by the announcement that Ian Wilmut and colleagues in Edinburgh, Scotland had cloned the first mammal, the media dubbed the next century "The Biotech Century," prophesying that "biology will define progress in the 21st century."⁸

Massive expenditures of human and financial resources are required to move potentially profitable technologies from the scientist's bench to the physician's office or the pharmacist's shelves. Nobel-laureate Arthur Kornberg maintains that "To bring a drug to market now takes, on average, more than ten years, at a cost in excess of \$300 million and with an expected market lifetime of relatively few years, owing to competition from

⁶Joahn O'C. Hamilton, Emily T. Smith, Larry Armstrong, Geoffrey Smith, and Joseph Weber, "Biotech: America's Dream Machine: Will it Become the Dominant Growth Industry of the 1990s?," *Business Week* (March 2, 1992), pp. 66-74.

⁷John Carey, Joan O'C. Hamilton, Julia Flynn, and Geoffrey Smith, "The Gene Kings," *Business Week* (May 8, 1995), pp. 72-78.

⁸See the cover of *Business Week* (March 10, 1997).

new technology and the limited patent life.”⁹ Without some mechanism for protecting their investments, those who fund biotechnology are unlikely to invest in developing marketable therapies. At the same time, patenting life-forms for the purpose of marketable products alters the way we have traditionally valued living things and their parts. Essentially, living organisms and their biological materials come to be valued economically; market values attach to materials which were previously the objects of other sorts of values. Part of the discussion below focuses on the nature and implications of this transfer of value.

Embedded in the patent process is a particular conception of property rights. In fact, evidence seems clear that the policies of the Patent and Trademark Office have been shaped significantly (and perhaps unknowingly) by Lockean notions of the “value-added” right to ownership of private property. Locke’s notions of property are the subjects of a substantial literature in philosophy. Recent work, including the analysis in this dissertation, points to the inadequacy of Lockean property rights to prescribe adequate policies for patenting living organisms.

The ways humans value animate living things differs from the ways we value inanimate living entities and non-living entities. The patent process derives from one form of valuation, namely, economic valuation. Through the patent process market values are attached to living entities in a unique fashion.

⁹Arthur Kornberg, *The Golden Helix: Inside Biotech Ventures* (Sausalito, CA: University Science Books, 1995), p.256.

CHAPTER 1

THE EXPANSION OF BIOTECHNOLOGY AND PROLIFERATION OF BIOPATENTS

1.1 The Biotechnological Explosion

While a little over a decade and a half ago it was unclear whether or not there was a biotechnology industry as such, few would question that today biotechnology is big business. In 1984, the Office of Technology Assessment (OTA) opined: "It is important to recognize that there is no 'biotechnology industry.' Biotechnology is a set of technologies that can potentially benefit or be applied to several industries."¹ Nevertheless, contemporary participants in biotechnology most certainly view their work as part of a recognizable industry or, even, "metaindustry."² Says Nobel-prize-winning geneticist Arthur Kornberg,

Genetic engineering and associated technologies have brought about the most revolutionary advances in the history of biological and medical science. Applications of this genetic and chemical knowledge created a biotechnology industry with vast economic and social potential. The biologists and biochemists who invented these new technologies in their academic laboratories came to the forefront of entrepreneurial ventures to use this knowledge to develop drugs and devices for the diagnosis, prevention, and treatment of disease.³

¹*Commercial Biotechnology: An International Analysis* (Washington, DC: U. S. Congress, Office of Technology Assessment, OTA-B-218, January, 1984), p. 72.

²Robert Bud, *The Uses of Life: A History of Biotechnology* (Cambridge: Cambridge University Press, 1993), p. 190.

³Arthur Kornberg, *The Golden Helix: Inside Biotech Ventures* (Sausalito, CA: University Science Books, 1995), p. ix.

Kornberg points out that by 1993 there were nearly 1,300 biotechnology firms in the United States, employing over 80,000 individuals, with sales of \$6 billion annually.⁴ The Biotechnology Industry Organization (BIO), whose purpose it is to lobby legislators on issues related to the industry, presently maintains an office in Washington, D.C. BIO represents over 600 biotechnology companies, academic institutions, state biotechnology centers, and other organizations in 47 states and more than 20 countries.⁵

Indeed, biotechnology may be a set of techniques, but at the threshold of the third millennium, we must also acknowledge that biotechnology is a recognizable, market-driven, corpus of businesses whose primary purpose is to make profits.⁶ As Colin Ratledge stated, "Biotechnology is not then a science: it is a means of applying science for the benefit of man and society. In practice, this means that biotechnology is used to make

⁴Ibid., p. 1.

⁵The Biotechnology Industry Organization (BIO) is the world's largest trade organization to serve and represent the emerging global biotechnology industry. According to Carl Feldbaum, president of BIO, "biotechnology has become a significant economic force, with more than 1,300 companies, nearly \$13 billion in annual revenues and more than 100,000 people on its direct payroll." *BIO Editors' and Reporters' Guide to Biotechnology 1996-1997* (Washington, DC: Biotechnology Industry Organization, 1996), p. 1.

⁶It should be said that "making money" is not necessarily negative. In fact, the most charitable reading of the biotechnology industry's goals leads one to the conclusion that the industry has very altruistic goals. For instance, Amgen (Applied Molecular Genetics), the world's largest independent biotechnology company, identifies its mission "To be the world leader in developing and delivering important, cost-effective therapeutics based on advances in cellular and molecular biology." Similarly, Amgen declares, "Our primary purpose is to bring meaningful improvement to the lives of patients through our products." *Amgen's Mission, Goals & Values* (http://wwwext.Amgen.com/cgi-bin/genobject/amgenValues/tigo_8AIFId).

money—or in certain instances—to save money.”⁷ Biotechnology promises to remain quite lucrative. *Genetic Engineering News* noted in December 1995 that U. S. sales of biotechnology products are expected to grow at an average annual rate of approximately 12 percent, from \$10 billion in 1996 to \$32 billion in 2006.⁸ This neo-entrepreneurial science did not arise *ex nihilo*, however. The roots of biotechnology reach deep under the substrata of the human, and especially the Western, drive for invention and innovation.

Sheldon Krimsky of Tufts University maintains that “biotechnology has been part of the human repertoire of techniques since the dawn of civilization.”⁹ Biotechnology, “any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses,”¹⁰ has been part of the human experience since the Sumerians (7000 BC to 5000 BC) used

⁷Colin Ratledge, “Biotechnology: The Socio-economic Revolution? A Synoptic View of the World Status of Biotechnology,” in E. J. Da Silva, C. Ratledge, and A. Sasson, *Biotechnology: Economic and Social Aspects* (Cambridge: Cambridge University Press, 1992), p. 1. Interestingly, Ratledge maintains that “Altruistic biotechnology does not exist or if it does it simply consumes money and does not generate it” (p. 3).

⁸“Double-Digit Growth Predicted for Biotechnology Products in the Next Decade,” *Genetic Engineering News* (December 1996), p. 6. The entrepreneurial aspects of biotechnology most assuredly affect the methodology used by those who function within its environs. For instance, Kornberg and others point out that the so-called “targeted research” agenda may have deleterious consequences on future discovery. Cf. “Pros and Cons of Biotech Ventures,” Chapter 8 of Kornberg, *The Golden Helix*, pp. 231-258.

⁹Sheldon Krimsky, *Biotechnics and Society: The Rise of Industrial Genetics* (New York: Praeger Publishers, 1991), p. 23.

¹⁰*Commercial Biotechnology*, Summary, p. 6.

microbes in beer-making and the Egyptians (4000 BC) invented leavened bread.

Nevertheless, the ascension of biotechnology is of relatively recent vintage.

“Biotechnology” has a rich and varied, though contemporary, history. Robert Bud, historian with The Science Museum of London, describes the origins of biotechnology in his thorough treatise, *The Uses of Life: A History of Biotechnology*.¹¹ “Today,” says Bud, “the best-known definition [of “biotechnology”] is perhaps that spelled out by the Organization for Economic Co-operation and Development (OECD): ‘biotechnology is the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services.’”¹² Biotechnology’s recent incarnation had its beginnings in the period surrounding World War I with the development of zymotechnology in the brewing industry. Yet, it was not long until zymotechnology evolved into biotechnology in the quest to engineer nature “to provide goods and services.” Bud locates the first reference to the cognates of “biotechnology” in the use of the German word “*Biotechnik*” by Gustav Tornier in 1901 at the *Internationalen Zoologen-Congresses zu Berlin* (World Zoological Congress in Berlin). Tornier described living organisms as “*Bioten*” and the manipulation of living organisms

¹¹Robert Bud, *The Uses of Life: A History of Biotechnology* (Cambridge: Cambridge University Press, 1993).

¹²Ibid., p. 1. More importantly, perhaps, Bud comments: “‘Bio’ suggests natural; it connects all those living things whose lives, it often seems, would be better but for the human species. By contrast, ‘technology’ evokes human control over nature. The combination of the two has often seemed deeply disturbing, even monstrous, as amalgams of people and machines have been described” (p. 2, 3).

technologically as "*Biontotechnik*."¹³ This terminology was adopted by biologist Wilhelm Roux and found its way into his 1910 dictionary, *Terminologie der Entwicklungsmechanik der Tiere und Pflazen*.¹⁴ One of Roux's students who immigrated to the United States, Jacques Loeb, innovator of parthenogenesis, hoped to discover a "*Technik der lebenden Wesen*" (a technology of living matter).¹⁵ Bud comments on Loeb: "Loeb himself was cautious, yet to him, as to Roux, the lines between the animate and inanimate were arbitrary."¹⁶

Not until the second decade of the twentieth century was the term "*Biotechnik*" coined officially. Both an Austrian social critic, Rudolph Goldscheid, and botanist-turned-philosopher, Raoul Francé, used the term in 1911 and 1918 respectively. While it is beyond the scope of this present work to distinguish the ways these two harbingers of biotechnology defined "*Biotechnik*," it is important to note that its use was not entirely univocal.¹⁷

¹³Ibid., p. 53.

¹⁴Wilhelm Roux, et al., eds., *Terminologie der Entwicklungsmechanik der Tiere und Pflazen* (Leipzig: Wilhelm Engelmann, 1912), p. 66. Cited in Ibid., p. 53.

¹⁵Ibid.

¹⁶Ibid., pp. 53, 54.

¹⁷Intriguingly, one of Francé's friends, Adolf Wagner, said in a 1925 *festschrift* that *Biotechnik* "is only an idea, a word, but one of those which unifies an entire world." Adolf Wagner, "*Biotechnik and Plasmantik*," in *Der Begründer der Lebenslehre Roul Francé: Eine Festschrift zu seinem 50 Geburtstag* (Stuttgart: Walter Seifert, 1925), p. 7. Cited in Bud, *The Uses of Life*, p. 61.

In 1921, influenced by the ideas of Francé, Patrick Geddes introduced the term “biotechnic” to the English-speaking world. Though he made use of the notion with increasing frequency, never giving attribution to Francé, Geddes never took credit for originating the term, according to Bud.¹⁸ A botanist by training, Geddes began to be interested in the evolution of societies; in particular, the evolution of urbanization and industrialization. Even before the turn of the century, Geddes borrowed the archeological taxonomy of epochal identification and described the industrial age as divided between the “paleotechnic” and “neotechnic” eras. The paleotechnic age was realized by the invention of the coal-burning steam engine. Contrariwise, the neotechnic age was realized by the cleaner and pervasive use of electricity. A future epoch in human civilization Geddes described as the “geotechnic” age; an age in which “technology would harmonize with the earth’s needs.”¹⁹ Geotechnics had a decidedly ethical dimension for Geddes. As he put it, “Geography is descriptive science (*geo* earth, *graphy* describe); it tells what *is*. Geotechnics is applied science (*geo* earth, *technics* use); it shows what *ought to be*.”²⁰

Bud discovered that though Geddes had referred to the concept of biotechnics as early as 1917 with the publication of *The Coming Polity*,²¹ it was not until 1923 that Geddes defined “biotechnics” as composed of “agriculture, medicine, hygiene, and

¹⁸Ibid., p. 66.

¹⁹Ibid., p. 68.

²⁰Benton Mackaye, *From Geography to Geotechnics* (Urbana: University of Illinois Press, 1968), p. 22. Cited in Ibid., p. 68.

²¹V. V. Branford and Patrick Geddes, *The Coming Polity*, 2nd edition (London: Le Play House, 1919), pp. 267-268.

eugenics.”²² The publication in 1926 of the *Encyclopaedia Britannica* Supplement was, however, the occasion for the popularization of the term “biotechnic.” There, J. A. Thomson attributed the origin of the word to Patrick Geddes and “explained that it meant the use of biological organisms for the benefit of man.”²³ Biotechnics as a concept continued to evolve through the work of J. B. S. Haldane, Julian Huxley, Lancelot Hogben, and Lewis Mumford.

In his monumental study, *Technics and Civilization*,²⁴ Lewis Mumford, a devotee of Geddes, chronicled four stages in the history of human technological invention. Each stage represents phases in the effort to utilize special resources and raw materials in the development of the so-called “machine age.” The first stage was what Mumford called the age of eotechnics— “the dawn of the age of modern technics.”²⁵ Eotechnics embodied the era of water and wood, when human production consisted in the manipulation of the forces of nature. Windmills and waterwheels harnessed the energy which had been the objects of veneration and terror: wind and water. Wood was used for building in the eotechnic era, but more importantly, during this period all three (wind, water, and wood) were combined to manufacture boats and ships.

²²Bud, *The Uses of Life*, p. 69.

²³J. A. Thomson, “Biology,” *Encyclopaedia Britannica* Supplement to the 11th edition, 1 (1926), pp. 383-85. Cited in *Ibid*.

²⁴Lewis Mumford, *Technics and Civilization* (New York: Harcourt, Brace and Company, 1934).

²⁵*Ibid.*, p. 109.

The next phase, the paleotechnic phase, resulted in the industrial revolution. Coal and iron were employed to produce the energy requisite for mass production. Mumford maintained that the paleotechnic age reached its apogee in "the great industrial exhibition in the new Crystal Palace at Hyde Park in 1851: the first World Exposition, an apparent victory for free trade, free enterprise, free invention, and free access to the world's markets by the country that boasted already that it was the workshop of the world."²⁶

The third stage was the neotechnic era. During this phase in the evolution of the machine, electricity became a new form of energy. At the same time, the neotechnic stage saw the invention of a host of new synthetic compounds, including celluloid, bakelite, and synthetic resins. Furthermore, the high level of conductivity required by the use of electricity led to the exploitation of copper and aluminum. The neotechnic age also celebrated the invention of the internal combustion engine, a revolutionary innovation indeed.

Finally, Mumford pointed to what he called the "biotechnic period, already visible over the edge of the horizon."²⁷ This stage would be characterized, he argued, by a "completer integration of the machine with human needs and desires . . ."²⁸

Mumford further argued that the machine "devaluated" rarity (because machines could produce a million copies of the master model), age (because machines placed emphasis on adaptation and innovation), and archaic taste (because machines established

²⁶Ibid., p. 155.

²⁷Ibid., p. 353.

²⁸Ibid.

new standards of value). The upshot of the evolution of the machine, for Mumford, meant that "we cannot intelligently accept the practical benefits of the machine without accepting its moral imperatives and aesthetic forms."²⁹ Whether Mumford was doing the work of social theorist or cultural prophet is beyond the scope of this present work. In any case, he seems to have been prescient in his prediction that "technics, instead of benefiting by its abstraction from life, will benefit even more greatly by its integration with it."³⁰ The emergence of biotechnology is a case in point.

Bud maintains that the publication of *Technics and Civilization* was a major impetus in the development of biotechnics in the United States.³¹ By 1936, a research and educational program in "biological engineering" had been initiated at the Massachusetts Institute of Technology. Less than a decade later, the University of California at Los Angeles and the University of California at Berkeley had engineering programs specializing in various "technologies."³²

Simultaneously, following World War I, industrial microbiology saw significant expansion. Japan, one of the most biotechnologically advanced societies in the world, was producing ethanol as a substitute for oil by 1935 and after World War II, the United States began producing pharmaceuticals as the age of antibiotics evolved.³³ During this epoch,

²⁹Ibid., p. 355.

³⁰Ibid., p. 254.

³¹Bud, *The Uses of Life*, p. 83.

³²Ibid., p. 87.

³³Krimsky, *Biotechnics and Society*, p. 24.

biotechnology was largely constrained by the boundary conditions of nature. Yet, clearly a novel and powerful industry was under cultivation. "The close links between medical care and chemical engineering were consolidated by wartime discoveries of the microbial antibiotics, above all penicillin."³⁴

The union of medicine, engineering, and agriculture produced the modern biotechnology industry. By 1947, "biological engineer" and "biochemical engineering" were neologisms gaining increasing frequency in the literature. By the mid-1960s, graduate programs in biochemical engineering had been developed in at least five U.S. universities. These programs trained researchers for the emerging pharmaceutical and food industries. The era of bioengineering was in its ascendancy. Soon, chemical engineering would be seen as the preeminent method of "inquiring into the nature of biological systems themselves."³⁵ Inquiry would lead rapidly to manipulation.

The marriage of engineering and medicine yielded fertile ground in which to cultivate this growth industry. The 1970s witnessed the development of the new genetics and provided a novel field for application of the techniques which could, by then, be called, "biotechnology." In its 1984 report to Congress, *Commercial Biotechnology: An International Analysis*, the Office of Technology Assessment opined,

In the past 10 years, dramatic new developments in the ability to select and manipulate genetic material have sparked unprecedented interest in the industrial uses of living organisms. Following the first successful directed insertions of foreign DNA in a host micro-organism in 1973, scientific researchers in the United States and other countries began to recognize the potential for directing the

³⁴Bud, *The Uses of Life*, p. 101.

³⁵Ibid., p. 101.

cellular machinery to develop new and improved products and processes in a wide diversity of industrial sectors.³⁶

By the 1980s, then, the commercialization of biotechnology was seen as critical to the fortunes of the United States. John H. Gibbons, former director of the Office of Technology Assessment, said in the same report to Congress,

A well-developed life science base, the availability of financing for high-risk ventures, and an entrepreneurial spirit have led the United States to the forefront in the commercialization of new biotechnology, but continuation of the initial preeminence of American companies in this field is not assured. Japan is likely to be the leading competitor of the United States, followed by the Federal Republic of Germany, the United Kingdom, Switzerland, and France.³⁷

The narrative of biotechnology is varied and complex. Nevertheless, after tracing the lineaments of this history, several preliminary observations seem warranted. First, the evolution of biotechnology is part of a larger historico-cultural revolution(s). Mumford accurately locates the biotechnic age as the culmination of a series of pre-industrial and industrial revolutions. Second, the “machine” metaphor became a powerful conceptual apparatus for the biotechnological revolution. Third, a shift in the mode of valuing living things occurred during this period. The engineering model applied to biology contained an implicit paradigm shift in the way organisms, tissues, cells, and genes were valued.

1.2 Public Perceptions of Biotechnology

Biotechnology does not enjoy a univocal reputation among the American public. Consequently, industry representatives and policy makers have spent considerable energy

³⁶*Commercial Biotechnology*, Summary, p. 6.

³⁷*Commercial Biotechnology*, p. 3.

trying to monitor societal attitudes about the use of biotechnology. A fairly lengthy section of *Commercial Biotechnology* focused on "public perception."

Citing two surveys in the 1970s, the OTA reported that among adults ages 26 to 35 years, about two-thirds of respondents opposed the use of recombinant DNA technology on any life form. Similarly, in a 1979 National Science Board survey of 1,635 adults, sixty-five percent of those responding believed that studies related to creating new life forms should not be conducted.³⁸

Surveys in the early 1980s showed that by 1982 seventy percent of the public had heard of "genetic engineering" and that from 1981 to 1982 the percentage of those who believed the benefits of genetic engineering outweigh the risks had risen from 31 percent to 39 percent.³⁹

More recently, an OTA-commissioned Harris poll conducted in 1986 and published in *New Developments in Biotechnology: Public Perceptions of Biotechnology*, found that sixty-two percent of those surveyed thought that the benefits of biotechnology outweighed the risks. Fifty-five percent of respondents were willing to risk isolated ecological damage, such as the extinction of individual plant or fish species, at risk levels of 1 in 1,000, as long as the potential risks are known. Sixty-eight percent were not opposed to using recombinant DNA technology to produce hybrid plants and animals, while twenty-four percent opposed such alterations on moral grounds.

³⁸Ibid., p. 496.

³⁹Ibid., p. 497.

The same survey showed that forty-two percent of those surveyed thought that altering human genes to combat disease would be morally wrong. Fifty-two percent favored the alteration of human genes to fight disease. As many as seventy-seven percent said they would favor using biotechnology to prevent a child from inheriting a birth defect. Interestingly, only thirteen percent were willing to allow companies themselves to make the final decisions about the suitability of large-scale applications of genetically engineered organisms.⁴⁰

Public perceptions of biotechnology in general and recombinant DNA technology in particular are important measures of both the potential for future funding and the acceptance of the applications of these technologies in the form of new drugs, medical therapies, and food products. In turn, overall public approval is necessary for U. S. biotechnology to remain competitive in the global marketplace.

1.3 The Incentive for Patent Protection

Competitiveness in biotechnology, it is argued, depends upon encouraging venture capitalists to invest in biotechnological research and development, and providing a means of protecting that investment once it has been made. Historically, the vehicle by which technological invention has been encouraged and protected has been the patent system. While a more detailed account will be given of the patent system in the next chapter, it is

⁴⁰*New Developments in Biotechnology: Public Perceptions of Biotechnology* (1987). Cited in Michael W. Fox, *Superpigs and Wondercorn: The Brave New World of Biotechnology . . . and Where It All May Lead* (New York: Lyons & Burford, Publishers, 1992), pp. 52-53.

important to see at this point that the biotechnology industry regards patent protection as necessary to its economic health and well-being. "With all its faults, the patent system is still the best means to assure that discoveries will be rewarded. Without patent protection, there would be insufficient incentive for the enormous amounts of private investment required in biotech ventures,"⁴¹ says Arthur Kornberg, Professor Emeritus of Biochemistry at Stanford University School of Medicine.

Patents are part of a larger system of legal protections for intellectual property. In addition to patents, intellectual property may be protected by maintaining secrecy (trade secrets), by issuing a copyright (for written materials), and by trademark protection (for logos and trade names). Most industry representatives and policy makers would agree with the OTA's view that,

In the final analysis, the U. S. intellectual property system appears to offer the best protection for biotechnology of any system in the world, thus providing the United States with a competitive advantage with regard to this factor. This advantage results from the fact that the system provides the widest choice of options for protecting biotechnological inventions, the broadest scope of coverage, and some of the best procedural safeguards.⁴²

At the same time, the fact that biotechnology is part of a global enterprise and economy renders problematic the harmonization of international intellectual property law. Many researchers and companies cite protection of intellectual property as being of utmost importance to preserving competitiveness in biotechnology. This is less a domestic issue than an international one as U. S. law provides broad protection for those who invent new

⁴¹Arthur Kornberg, *The Golden Helix: Inside Biotech Ventures* (Sausalito, CA: University Science Books, 1995), p. 234.

⁴²*Commercial Biotechnology*, Summary, p. 20.

and useful processes and products. However, as markets in biotechnology become increasingly global, issues arise regarding subject matter protection, harmonization of patent procedure, and the context of intellectual property in international trade.”⁴³ (See OTA report, *Patenting Life*)

Nevertheless, the patenting of living organisms—the stuff of biotechnology—has a controversial history in both U.S. and International jurisprudence. Disputes over what should or should not be patentable subject matter have been several. At stake, many biotechnologists argue, is the long-term well-being of the industry on one hand, and, therefore, the potential for new products, including disease-treating therapies on the other. Critics of biotechnological patents maintain either that the benefits of patenting life forms do not outweigh the risks or that “patenting life” violates fundamental ethical norms. Whether or not U.S. competitiveness is compromised or funding for biotechnology is threatened, it is wrong, critics argue, to patent some or all living things. The goal of the remainder of this project is to elucidate and analyze the arguments offered on both sides of this debate. In order to do so, however, it is necessary to explore as comprehensively as possible the history and nature of patenting as it applies to living things.

⁴³*Biotechnology in a Global Economy*, p. 23.

CHAPTER 2

PATENTABLE SUBJECT MATTER AND THE PTO

2.1 A Brief History of Patents

Laws permitting the protection of intellectual property are firmly ensconced in American jurisprudence. In Article I, Section 8 of the U.S. Constitution, Congress is given the power “. . . [t]o promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹ Interestingly, this is the only direct reference to science in the Constitution.²

This clause notably embraces both forms of intellectual property prevalent at the time: writings and discoveries. Authors sought copyrights for their writings and inventors sought patents for their discoveries. More recently, intellectual property law has provided protection for trademarks, semiconductor chips, and computer software.

From the beginning of the American experiment, citizens of the New World encouraged innovation. Several colonies enticed foreign industries to the New World by offering monopolies to those who might be willing to establish manufacturing facilities on

¹U. S. Constitution, Art. I, § 8, clause 8.

²This observation is made by I. Bernard Cohen in his *Science and the Founding Fathers: Science in the Political Thought of Thomas Jefferson, Benjamin Franklin, John Adams, and James Madison* (New York: W. W. Norton, 1995), p. 238. Furthermore, Cohen observes that “In the eighteenth century, the word ‘science’ was used to denote any branch of organized or demonstrated knowledge and had not acquired the present more restricted sense of the physical or biological or earth sciences” (p. 281).

American soil. Monopolies were outlawed by the "Body Of Liberties" adopted in 1641 by the General Court of Massachusetts, except "... of such new inventions as are profitable to the country, and that for a short time."³ Saltmakers were among the first patent holders in the New World. In 1641, Samuel Winslow was granted a ten-year monopoly on his particular method of salt production. The only proviso was that Winslow had one year to set up his salt works. Winslow's patent prohibited anyone else "from making this article except in a manner different from his."

In 1646, Joseph Jenks received the first machine patent granted in America. His petition to the general court of the Commonwealth of Massachusetts stated:

Whereas the Lord hath been pleased to give me knowledge in making, and erecting of engines of mills to go by water for the speedy dispatch of much work with few men's labor in little time my desire is to improve this talent for the public good and benefit and service of this country: to which end my intention and purpose (if God permit) to build a mill for making of scythes; and also a new invented sawmill, and divers other engines for making of divers sorts of edge tools.⁴

Jenks made his appealed to the court for patent protection in the form of the following request:

Now your petitioner doth humbly beseech this honored court that you would please grant me this privilege—that no other person shall set up or use any such new invention or trade for the space of 14 years without my license . . . lest your petitioner have expended his estate, study, and labor and have brought things to perfection, another when he seeth it, maketh the like; and so I lose the benefit of that I have studied for many years before which will tend to my great damage if not utter undoing.⁵

³"Outline History of the United States Patent Office," *Journal of the Patent Office Society* 18 (July 1936), p. 36.

⁴*Ibid.*, p. 38.

⁵*Ibid.*

In the post-Revolutionary period, South Carolina was the first state to attempt general patent legislation. In 1784, the state adopted policy which would provide both for copyright protection and 14-year patent protection for machinery.⁶ While a number of states, including South Carolina, Pennsylvania, Virginia, enacted patent laws, there was still no national legislation on the subject.

Delegates from the various states met together to formulate the Constitution on May 14, 1787. Just over three months later James Madison of Virginia and Charles C. Pinckney of South Carolina proposed that Congress be permitted to grant protections for inventors and authors through patents and copyrights.⁷ On September 5th of the same year the proposals were reported out of the Committee on Detail and adopted unanimously.⁸ The Constitution was signed by the delegates on September 11, 1787, and included the provisions for patents and copyrights found in Article 1, Section 8.

The subject of intellectual property protection occupied what later became known as *The Federalist* papers when Madison commented on the miscellaneous powers of

⁶“And be it further enacted by the authority aforesaid, that the inventors of useful machines shall have a like exclusive privilege of making or vending their machines for the like term of 14 years, under the same privileges and restrictions hereby granted to and imposed on the authors of books.” Ibid.

⁷Warshofsky has observed that just five days after Madison and Pinckney submitted their proposals John Fitch made the maiden voyage of the first steamboat down the Delaware River, “forestalling any latent objections to the provision” for patents. Fred Warshofsky, *The Patent Wars: The Battle to Own the World's Technology* (New York: John Wiley and Sons, 1994) p. 37.

⁸U. S. Department of Commerce, Patent and Trademark Office, *The Story of the U. S. Patent and Trademark Office* (Washington, DC: U. S. Department of Commerce, 1988), p. v.

Congress, including the power “to promote the progress of science and useful arts ...”

Said Madison,

The utility of this power will scarcely be questioned. The copy right of authors have been solemnly adjudged in Great Britain to be a right at common law. The right to useful inventions, seems with equal reason to belong to the inventors. The public good fully coincides in both cases, with the claims of individuals. The States cannot separately make effectual provision for either of the cases, and most of them have anticipated the decision of this point, by laws passed at the instance of Congress.⁹

Congress enacted the first general patent statute in 1790 through the encouragement of then president George Washington.¹⁰ “For the first time in history the intrinsic right of an inventor to profit from his invention [was] recognized by law.”¹¹

Patents were authorized for “any useful art, manufacture, engine, machine, or device, or

⁹“Publius,” The Federalist XLIII, *Independent Journal* (January 23, 1788), reprinted in *The Debate on the Constitution: Federalist and Antifederalist Speeches, Articles, and Letters During the Struggle over Ratification*, Part Two (New York: The Library of America, 1993), p. 71.

¹⁰According to Cohen, on June 23, 1789, a bill authorizing a general patent act was introduced. Congress adjourned, however, without taking any action on the bill. In January of 1790, George Washington “addressed the need for encouraging inventions.” Cohen, *Science and the Founding Fathers*, p. 243. Argued Washington: “The advancement of agriculture, commerce, and manufactures, by all proper means, will not, I trust, need recommendation, but I cannot forebear intimating to you the expediency of giving effectual encouragement, as well to the introduction of new and useful inventions from abroad, as to the exertions of skill and genius in producing them at home and of facilitating the intercourse between the distant parts by a due attention to post office and post roads. Nor am I less persuaded that there is nothing which can better deserve your patronage than the promotion of science and literature.” “Outline of the History of the United States Patent Office,” p. 60-61.

¹¹U. S. Department of Commerce, *The Story of the U. S. Patent and Trademark Office*, p. 1. Note that the author(s) of this official document of the PTO use the language of “intrinsic right” to describe patent protection. More will be said about this language in subsequent chapters.

any improvement therein not before known or used.”¹² Under this statute the regulatory agents or Patent Board who granted patents consisted of the Secretary of State (Thomas Jefferson), the Secretary of War (Henry Knox), and the Attorney General (Edmund Randolph). Each agent had power to grant a patent in the name of the United States.

Cohen argues that Article 1, Section 8 of the Constitution is “a curious hodgepodge.”¹³

First there is stated the need to “promote the Progress of Science and the useful Arts.” But then it is said that the means of achieving this bipartite goal is “by securing for limited Time” to “Inventors the exclusive right to their . . . Discoveries” and to “Authors” a similar “exclusive Right” to their “Writings.” A good case can perhaps be made that granting patents to inventors would promote “the Progress of . . . useful Arts,” but it is difficult to see how such patents might equally promote “the Progress of Science.” The greatest scientific advances—Newton’s rational mechanics and gravitational cosmology, the Newtonian mathematics of the calculus, Linnaeus’s system of classification of plants—had no aspect that would have been patentable, and hence the granting of patents would hardly have been a stimulus to their production.¹⁴

According to Cohen, Article 1, Section 8 is a somewhat conflated statement of the original provisions suggested by Pinckney and Madison. These provisions were submitted to a committee which would recommend a final form to the Committee of Style. Economy of space and expression was, Cohen maintains, the guiding force behind the

¹²Act of April 10, 1790, ch. 7, 1 Stat. 109.

¹³Cohen, *Science and the Founding Fathers*, p. 238.

¹⁴*Ibid.*

conflation.¹⁵ Furthermore, he asserts, the framers of the Constitution, fluent in Latin, understood the words translated “invention” and “discovery” to be interchangeable.¹⁶

On April 10, 1790, Congress enacted the first patent statute and on July 31, 1790, Philadelphian Samuel Hopkins was granted the first U. S. patent, “for an improvement in ‘the making of Pot ash and Pearl ash by a new Apparatus and Process.’”¹⁷ The patent was signed by President George Washington, Secretary of State Thomas Jefferson, and Attorney General Edmund Randolph. Interestingly, the patent statute remained intact for only three years. During that time fifty-five patents were granted.

We must not overlook at this point the contribution of Thomas Jefferson to the genesis and cultivation of patent protection for inventors.¹⁸ Jefferson was both the first superintendent of the U. S. patent office and the *de facto* first patent examiner. The official history of the PTO describes him as the “moving spirit” of the examining board.¹⁹ As is well known, Jefferson was a noted scientist and inventor himself.

¹⁵Ibid., p. 240.

¹⁶Ibid., p. 241.

¹⁷U. S. Department of Commerce, *The Story of the U. S. Patent and Trademark Office*, p. 2.

¹⁸In *Graham v. John Deere Co*, 383 U.S. 1, 5-6, 148 USPQ 459 (1966) the court recognized the contribution of Thomas Jefferson in the first two patent acts. “Thomas Jefferson, who as Secretary of State was a member of the group, was its moving spirit . . . He was not only an administrator of the patent system under the 1790 Act, but was also the author of the 1793 Patent Act.”

¹⁹U. S. Department of Commerce, *The Story of the U.S. Patent and Trademark Office*, p. 2.

Jefferson's interest in patents and inventions was that of a well educated, brilliant man. A mathematician, astronomer, architect, and student of languages, Jefferson was undoubtedly the most accomplished and versatile man in the public life of his time. Not only did he appreciate the value of patents from an intellectual viewpoint, but as an inventor himself he had first-hand knowledge of the problems of creative workers. Although he never took out a patent Jefferson made a number of inventions . . .²⁰

That Jefferson and the other founders were indebted to Lockean notions with respect to property rights will be seen in Chapter 4. Suffice to say here that Locke's influence on the protection of intellectual property through Jefferson and Madison cannot be overstated. The philosophical notions embedded in Article 1, Section 8 of the U. S. Constitution and in subsequent patent acts are decidedly Lockean.

In 1793, patent legislation was altered. *The Story of the U. S. Patent and Trademark Office* implies that the changes were necessary because no one had time to devote to the examination of patents.²¹ Thus, the adoption of the 1793 Act omitted the importance criteria (viz., that an invention be "sufficiently useful and important") and substituted a form of "registration" in place of "examination." Thus, patents were authorized for "any useful art, machine, manufacture, or composition of matter, or any new and useful improvement [thereon], not known or used before the application . . ."²² Furthermore, instead of a Patent Board issuing patents, the responsibility fell upon the Secretary of State.

²⁰Ibid.

²¹Ibid.

²²Cited in Donald S. Chism and Michael A. Jacobs, *Understanding Intellectual Property Law* (New York: Matthew Bender & Company, 1992), §2B[1].

Dr. William Thornton was appointed by James Madison as the first superintendent of the Patent Office, a newly-established division of the Department of State. Thornton served in this capacity from October 1802, until his death on March 28, 1828. During that time, the Patent Office was located in four rooms of the west wing of Blodgett's Hotel in Washington, D.C. When the British burned Washington on August 14, 1814, Thornton persuaded the Commander of the British army not to "burn what would be useful to mankind."²³

In 1836, through the encouragement of freshman Senator from Maine John Ruggles, Congress enacted major revisions of the patent laws. Ruggles reported to Congress that "For more than 40 years the Department of State has issued patents on every application, *without any examination into the merits or novelty of the invention.*"²⁴ The result of omitting the "importance" or "novelty" criterion was that, as Ruggles put it, "Many patents granted [were] worthless and void and conflict[ed] upon one another, and a great many law suits [arose] from this condition."²⁵ The provisions of the Patent Act of 1836 returned the examination process to its pre-1793 incarnation. Experts in patent law argue that the 1836 Act represented a momentous shift back to a successful system, one

²³U. S. Department of Commerce, *The Story of the U. S. Patent and Trademark Office*, p. 4.

²⁴*Ibid.*, p. 5 (emphasis in the original).

²⁵*Ibid.*

which survives to the present.²⁶ On December 15, 1836, the Patent Office was completely destroyed by fire.

The penultimate decade of the 19th century saw a monumental number of patents granted. From 1880 to 1891 patents were granted on Edison's incandescent light, the automobile, the pneumatic tire, electrical welding, the trolley car, the aluminum manufacturing process, and a host of additional inventions and processes. Also during this period, as the number of patent cases heard by the Supreme Court increased markedly, abuses of the patent system came under fire.

In *Atlantic Works*, Justice Bradley complained that "It was never the object of [the patent] laws to grant a monopoly for every trifling device, every shadow of a shade of an idea, which would naturally and spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures."²⁷

The Court was already beginning to wrestle with what would later become the criterion of "non-obviousness."

From 1892 to 1930, patents enjoyed a period of relative favor in the courts. During this era patents were granted to a number of noteworthies including Marconi, for "New and Useful Improvements in Transmitting Electrical Impulses and Signals . . ."

²⁶*The Story of the U. S. Patent and Trademark Office* avers, "With the exception of the original Act of 1790, this is the most important patent law ever enacted in the United States" (p. 6). Warshofsky opines that the patent law passed on July 4, 1836, "is the foundation of the modern patent system." *The Patent Wars*, p. 48. Also, as an interesting aside, it was under this Act that the requirement was made for inventors to submit models of their patented inventions. This was requisite until 1880. Many of these models became exhibits at the Smithsonian Institution Museum and may be seen there today.

²⁷Cited in Chisum and Jacobs, *Understanding Intellectual Property Law*, § 2B[4][a].

(1897); Zeppelin, for “Improvements in and Relating to Navigable Balloons” (1899); the Wright brothers, for “New and Useful Improvements in Flying-Machines” (1906); and Houdini, for a “Diver’s Suit” (1921). According to Chisum and Jacobs, this period of “receptiveness” was due both to improved economic conditions and the passage of the Evarts Act, “which created regional courts of appeal and relieved the Supreme Court of the burden of reviewing appeals in all patent infringement suits.”²⁸ Thus, the creation of Circuit Courts of Appeals meant that litigation could be handled more expeditiously. Nevertheless, with the increasing numbers of patents being sought, by 1930 the Patent Office was a year behind in processing applications for patent protection.

On May 23, 1930, the status of patentable subject matter was expanded to include plants, thereby making it possible to secure proprietary rights by anyone “who has invented or discovered and asexually reproduced any distinct and new variety of plant other than a tuber-propagated plant.”²⁹ Thomas Edison urged passage of the legislation and maintained that “nothing Congress could do to help the plant 3 [sic?] breeder the same status as the mechanical and chemical inventors now have through the patent law.”³⁰ In August of 1931 the first plant patent was awarded to Henry F. Bosenberg for his everblooming climbing rose.

²⁸Ibid., § 2B[4][b].

²⁹U. S. Department of Commerce, *The Story of the U. S. Patent and Trademark Office*, p. 23.

³⁰Ibid.

The period from 1930 to 1950 was both a period of growth of the Patent Office and a period which saw patents come under increasing scrutiny by the courts. In 1932, the Patent Office relocated to the Department of Commerce Building, occupying over eight acres of office space. In 1941, Supreme Court Justice Douglas raised the standard for patentability arguing in *Cuno Engineering* that for a product to be patentable it “must reveal the flash of creative genius.”³¹ As Chisum and Jacobs put it, “The Court’s anti-patent bias was so pronounced that Justice Jackson would complain [in 1949], in dissent, that the only valid patents were those the Court had not been able to get its hands on.”³²

On July 19, 1952, President Truman signed a new patent act. The Patent Act of 1952 was crafted largely by Judge Giles B. Rich, a patent attorney commissioned by the House Judiciary Committee to bring existing statutory provisions to bear on the patent process and offer a comprehensive rewrite of the law. The Act was codified as United States Code Title 35, still in effect today. While there were many modifications in the Act, most of the changes were noncontroversial.³³ The most important alteration is now codified in Section 103 as the criterion of nonobviousness.³⁴ Thereafter, an invention was

³¹Chisum and Jacobs, *Understanding Intellectual Property Law*, § 2B[4][c].

³²*Ibid.*, bracketed material added.

³³U. S. Department of Commerce, *The Story of the U. S. Patent and Trademark Office*, p. 28.

³⁴Addressing a meeting 1986 meeting of the San Francisco Patent and Trademark Law Association, Judge Rich reflected: “That statute requiring that a claimed invention be nonobvious had no counterpart in prior statutes.” Warshofsky, *The Patent Wars*, p. 50.

patentable only if, all things being equal, it was not obvious to any person skilled in the art pertinent to the relevant field of technology.

For nearly three decades patent law remained nearly unchanged, with only refinements being made in the 1960s and 1970s. With the advent of non-plant biotechnology and the consequent ascending importance of patent protection, however, major changes were almost inevitable. In 1980, in *Diamond v. Chakrabarty*, the Supreme Court ruled for the first time that a non-plant living organism was patentable. The reverberations of that decision are still being felt. Before we can understand properly the import of this decision, it is necessary to outline the criterion for patent protection as it existed up to the time of *Chakrabarty*.

2.2 The Criteria for Patent Protection

In essence, a patent consists of a written description of a process or product of invention. The patent document explains how to do or make the process or product and includes one or more “claims”—detailed descriptions of what is actually being protected under the patent. This protection excludes others from making, selling, or using a process or product for a period of twenty years from the original filing date.

Patent documents contain four distinct sections: Background of the Invention, Summary of the Invention, Detailed Description of Preferred Embodiments, and The Claims. The “Background of the Invention” section contains a concise statement of the motivation for applying for a patent. This section summarizes the nature of the invention and identifies the problem(s) the patented process or product is intended to solve.

Secondly, the "Summary of the Invention" section states the objectives of the invention in the light of the problems identified in the first section. Furthermore, the applicants must state in this section the language of the main claims of the patent. These claims will be set out again more formally in the final section of the patent application. Thirdly, the "Detailed Description of Preferred Embodiments" is divided into two parts. In the first, the insight(s) which led to the claimed invention are discussed. This discussion contains definitions and elucidations of the terminology used in the application and may include a description of the methodology used to make the invention. Patent specifications must describe the invention, enable one who is skilled in the art to make and use the invention, and describe the best mode for doing so. In the second part of this section, detailed working examples are provided. Tables, charts, graphs, and other visualizations are often included in this section of the patent application. Finally, the "Claims" section represents the heart of the patent document. Here, the inventors describe exactly what it is that others will be excluded from doing or making. Claims are similar to the metes and bounds description in a deed for land. Claims will be of varying scope and will stand alone.

According to the United States Patent and Trademark Office,

A patent for an invention is a grant of a property right by the Government to the inventor (or his heirs or assigns), acting through the Patent and Trademark Office. The term of the patent is 17 years from the date the patent is granted, subject to the payment of maintenance fees.³⁵

³⁵U. S. Department of Commerce, *General Information Concerning Patents* (Washington, DC: U. S. Department of Commerce, Patent and Trademark Office, 1994), p. 2. Under the provisions of the General Agreement on Tariffs and Trade (GATT), the lifetime of patents was extended from seventeen years from the date of the granting of the patent to twenty years from the original date of filing for the patent.

Since the Patent Act of 1952, the requirements of patentability have been fairly uniform. The patent statutes of the United States Code 35 provide for utility, design, and plant patents. For the purposes of the present study, utility patents will be the focus of attention. Section 101 of 35 U.S.C. defines what is eligible for a utility patent:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.³⁶

Thus, utility patents fall into four categories: process,³⁷ machine, manufacture, or composition of matter. (These four categories had their genesis in the Patent Act of 1793.) A process is a method of doing or making some novel entity or product. For instance, a process patent might be granted for a method of making synthetic yarns. A machine patent might be granted on the equipment for making that particular yarn. A manufacture or composition of matter patent might be granted on the yarn itself, the product resulting from the method or process.

In order for a process or product to be patentable, it must meet three conditions. First, a process or product must be novel. A novel invention is one which was not known or available to the public prior to the time when the patent applicant "invented" the

³⁶35 U.S.C. §101.

³⁷"Section 101 follows the wording of the existing statute as to the subject matter for patents, except that reference to plant patents has been omitted for incorporation in section 301 and the word 'art' has been replaced by 'process', which is defined in section 100. The word 'art' in the corresponding section of the existing statute has a different meaning than the same word as used in other places in the statute; it has been interpreted by the courts as being practically synonymous with process or method. 'Process' has been used as its meaning is more readily grasped than 'art' as interpreted, and the definition in section 100(b) makes it clear that 'process or method' is meant." "Historical Revision Notes," 35 U.S.C., Section 101.

process or product. U. S. Code 35, Section 102 states the novelty criteria in negative terms.

A person shall be entitled to a patent unless – (a) the invention was known or used by others in this country . . . , or (b) the invention was patented or described in a printed publication in this or a foreign country or on sale in this country, more than one year prior to the date of the application for patent in the United States, or © he has abandoned the invention, or (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate filed more than twelve months before the filing of the application in the United States, or (e) the invention was described in a patent granted on an application patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent, or (f) he did not himself invent the subject matter sought to be patented, or (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it.

Therefore, under current patent law, if an uninformed researcher were to invent penicillin today, a patent would not be awarded because isolated and purified penicillin is already widely known and in the public domain.

Second, any patentable process or product must have utility or usefulness.

According to Chism and Jacobs,

The patent laws impose three related utility conditions: (1) a claimed process must in fact be useful; (2) a person must have discovered the invention's utility to achieve a reduction to practice for the purposes of invention priority; and (3) the inventor's patent specification must disclose how to use the claimed invention.³⁸

That is to say, an invention must be demonstrated to provide some general benefit to humanity or be useful in specific laboratory situations. Unless an invention can be shown to be useful, it cannot be patented. In *Brenner*, the Supreme Court ruled that "The basic

³⁸Chisum and Jacobs, *Understanding Intellectual Property Law*, § 2C[2].

quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with substantial utility.”³⁹

Finally, the Patent Act requires that patentable subject matter be nonobvious.

Under the nonobviousness condition,

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.⁴⁰

This requirement entails that not all novel and useful inventions are necessarily patentable.

Thus, “Nonobviousness is the most important patentability requirement and the most difficult to apply.”⁴¹ However, as long as the process or invention would, on the whole, be unobvious to an ordinary worker in the pertinent field at the time the process was devised or the invention was made, then the claimed process or invention would be patentable. Hence, what is required by this criterion is that there be an “inventive step” involved. Furthermore, as specific technologies evolve, the nonobvious criterion may become more difficult to fulfill. What was previously nonobvious today may become highly obvious tomorrow.

³⁹Cited in Brian P. O’Shaughnessy, “Patentable Subject Matter,” in Kenneth D. Sibley (ed), *The Law and Strategy of Biotechnology Patents* (Boston: Butterworth-Heinemann, 1994), p. 69.

⁴⁰35 U.S.C., Section 103.

⁴¹Chisum and Jacobs, *Understanding Intellectual Property Law*, § 2C[4][a].

2.3 A History of Patenting Life

While the *Chakrabarty* decision was a landmark in the history of patenting life, nevertheless, living organisms, specifically plants, have been patentable since the Patent Act of 1930.⁴² The decision of Congress to include asexually reproduced plant varieties as patentable subject matter demonstrated a recognition that “the production of a new plant often requires more patience, skill, ingenuity, resourcefulness, knowledge, and observation than the making of mechanical invention.”⁴³

The United States Code asserts that,

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.⁴⁴

To qualify for a plant patent the subject matter of the patent must meet several statutory criteria: (1) it must be a plant; (2) it must be asexually reproduced, in order to preserve its unique genetic integrity; (3) it must be a “distinct new variety;” (4) it must be new; and (5) it must be nonobvious.⁴⁵ As with other patents, the plant patent excludes

⁴² Prior to 1930, plants were not deemed patentable subject matter because breeding techniques were not sufficiently inventive to warrant patent protection. Cf. Virginia C. Bennett, “Plant Biotechnology,” in Kenneth Sibley (ed), *The Law and Strategy of Biotechnology Patents* (Boston: Butterworth-Heinemann, 1994), pp. 171-185.

⁴³Cited in U. S. Department of Commerce, *The Story of the U. S. Patent and Trademark Office*, p. 23.

⁴⁴35 U.S.C., Section 161.

⁴⁵Chisum and Jacobs, *Understanding Intellectual Property Law*, § 6C[1][a].

others from asexually reproducing, selling, or using the plant while under patent protection.

Forty years later, Congress enacted companion legislation to the Plant Patent Act in the form of the Plant Variety Protection Act (PVPA) of 1970. The PVPA authorized patent-like protection to sexually reproduced plants "to encourage the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promoting progress in agriculture."⁴⁶ Instead of the Patent and Trademark Office granting a patent on sexually reproduced plants, however, the PVPA authorizes the Secretary of Agriculture to assign plant variety protection certificates to those which qualify. The subject matter of PVPA certification must, like other patentable material, be a novel variety. The nonobviousness criterion does not apply, however. Notably, the PVPA covers seed-bearing plants but excludes bacteria, fungi, and first generation hybrids. Plant Variety Protection Certificates are published in the *Plant Variety Protection Office Journal*.

From 1930 to 1980 the only living organisms which were patentable were plant varieties. According to Chief Justice Burger's majority opinion in *Diamond v. Chakrabarty*,

Prior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law. . . . The second obstacle to patent protection for plants was the fact that plants were thought not amenable to the "written description" requirement of the patent law. . . . Because new plants may differ

⁴⁶Pub. L. 91-577 (preamble).

from old only in color or perfume, differentiation by written description was often impossible.⁴⁷

Diamond v. Chakrabarty represents a seismic shift in United States patent law.

For the first time in the history of patent law a living animate object became subject matter for a patent.

In 1972, Ananda M. Chakrabarty, a microbiologist with General Electric Corporation used genetic engineering techniques to alter a *Pseudomonas* bacterium containing at least two energy-generating plasmids (as opposed to the single plasmid *Pseudomonas* which occurs naturally). This new bacterium possessed a unique property, namely, the ability to degrade crude oil. Realizing that this bacterium might have important commercial applications, Chakrabarty filed for a patent. Chakrabarty claimed the process for making the bacterium, an inoculum which enabled the bacterium to support the itself on a carrier material, and the bacterium itself. Thus, the controversy which followed revolved around the application of a composition of matter patent to a non-plant living organism.

Heretofore, patents were denied on naturally occurring living organisms; and, in fact, this remains the case to date. According to the Manual of Patent Examining Procedure, "... a thing occurring in nature, which is substantially unaltered, is not a 'manufacture.'"⁴⁸ There were several legal precedents which led to this position. For instance, in *Guaranty Trust Company of New York v. Union Solvents Company*, made a

⁴⁷*Diamond v. Chakrabarty*, 447 U. S. 303, 65 L Ed 2d 144, 100 S Ct 2204.

⁴⁸*Manual of Patent Examining Procedure*, Section 706.03(a).

clear distinction between a process for producing acetone and butyl alcohol through fermentation and the bacterium used in the process of fermentation.⁴⁹ The process was deemed patentable even though the process involved the life process of a living organism. In another important case, *Funk Brothers Seed Company v. Kalo Inoculant Company*, the United States Supreme Court ruled that a combination of six bacteria as they occur in nature are not patentable. The “qualities” of these bacteria were considered to be the “work of nature . . .” and were, therefore, “of course not patentable.”⁵⁰

When Ananda Chakrabarty applied for a patent on his novel *Pseudomonas*, a patent examiner initially rejected the composition of matter claim on the grounds that bacteria, as living things, were not patentable subject matter under the patent law. The PTO’s Board of Appeals agreed with the examiner, but the United States Court of Customs and Patent Appeals reversed the decision holding that the fact that the *Pseudomonas* was alive was without legal significance. Thus, the case was heard before the United States Supreme Court in March 17, 1980, and a decision was handed down on June 16th of the same year. In a 5-4 decision, the Supreme Court affirmed the Court of Customs and Patent Appeals’s decision and granted all three of Chakrabarty’s claims, including the claim on the novel *Pseudomonas* as a composition of matter. The argument of the majority, offered by Chief Justice Burger, was that Chakrabarty’s “discovery is not

⁴⁹*Guaranty Trust Company v. Union Solvent Company*, 54 F.2d 400, 12 USPQ 47 (D. Del. 1931).

⁵⁰*Funk Brothers Seed Company v. Kalo Inoculant Company*, 76 USPQ 280.

nature's handiwork, but his own; accordingly it is patentable subject matter under § 101."⁵¹

As the applications of biotechnology continued to expand, increasing numbers of patents were applied for on living organisms. Because these patents were controversial and because the interpretation of the patent statutes was still undergoing revision, many of these patents were rejected by the examiners and were, thereby, thrust into the domain of the courts or the Patent and Trademark Office's Board of Appeals and Interferences.

In *Ex parte Hibberd*⁵² (1985) the Plant Patent Act and the Plant Variety Protection Act came under closer scrutiny by the Board of Appeals and Interferences. As O'Shaughnessy opines, "In *Ex parte Hibberd*, the principle of *Chakrabarty* was extended to include plants."⁵³ Specifically, the patent examiner rejected patent claims on maize seeds, plants, and tissue cultures which were asserted to have increased free tryptophan levels or which were capable of producing seeds or plants with increased tryptophan content ("an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed"). The basis for the rejection was that Congress had authorized the Plant Variety Protection Act especially for plants and, therefore, plants were not patentable subject matter under 35 U.S.C., Section 101. The Board of Appeals made direct reference to *Chakrabarty* when it said,

⁵¹*Diamond v. Chakrabarty*, 447 US 303.

⁵²*Ex parte Hibberd*, 227 USPQ 443.

⁵³Brian O'Shaughnessy, "Patentable Subject Matter," in Sibley (ed), *The Law and Strategy of Biotechnology Patents*, p. 66.

The examiner acknowledges that an executive agreement cannot modify a federal statute, but urges, nevertheless, that the agreement can and should be considered "in interpreting a statute on which it bears." This argument overlooks the fact that the Supreme Court in *Diamond v Chakrabarty*, *supra*, has already interpreted the scope of section 101 to cover everything under the sun made by man. In our view, the examiner is asking for an implied partial repeal of Section 101 on the basis of an executive agreement. To do so would, in our opinion, elevate the agreement to a status superior to an Act of Congress, i.e., Section 101, contrary to the spirit of *United States v Capps, Inc.*, *supra*, and we decline to do so.

In 1988, in *Ex parte Allen*,⁵⁴ patent protection was extended to multicellular living organisms, namely, a variety of genetically engineered oyster. Arguing that polyploid oysters were, once again, "nonnaturally occurring manufactures or compositions of matter" the Board of Appeals and Patent Interferences granted the patent. Donald J. Quigg, at that time Assistant Secretary and Commissioner of Patents and Trademarks, issued a statement elucidating the Patent and Trademark Office's policy on patenting animals. According to the statement the PTO would, from that time forward, examine "claims directed to multicellular living organisms, including animals."⁵⁵ Also, the statement declared that "A claim directed to or including . . . a human being will not be considered to be patentable subject matter"⁵⁶ on the grounds that the right to own a human being was contrary to the Thirteenth Amendment to the U. S. Constitution. Quigg maintained that the Board of Appeals and Patent Interferences relied on the opinions in

⁵⁴*Ex parte Allen*, 2 USPQ 2d 1425.

⁵⁵Statement by Donald J. Quigg, "PTO Policy on Patenting of Animals," in U. S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Patenting Life—Special Report*, OTA-BA-370 (Washington, DC: U. S. Government Printing Office, April 1989), p. 93.

⁵⁶*Ibid.*

Diamond v. Chakrabarty and *Ex parte Hibberd*, “as controlling authority that the Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”⁵⁷ Importantly, the phrase, “anything under the sun that is made by man,” derives from the 1952 Committee Reports accompanying Congress’s recodification of the patent law in 35 U.S.C.

Less than a year after *Allen*, on 12 April 1988, U.S. Patent 4,736,866 was granted to Philip Leder and Timothy Stewart for a mouse whose genome had been altered to make it useful in cancer research. These Harvard scientists isolated a gene that causes cancer in mammals, including humans, and then injected the gene into fertilized mouse ova. One half of the resulting female mice developed cancer within ten months after their birth. By introducing the cancer gene into the animal’s germ cell, the cancer would be passed from the mother to her progeny.

With remarkably broad scope, the patent for the Harvard mouse covered any “transgenic nonhuman eukaryotic animal (preferably a rodent such as a mouse) whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal . . . which increases the probability of the development of neoplasms (particularly malignant tumors) in the animal.” In essence, then, Harvard received a patent on any mammal whose genome had been altered to produce cancerous neoplasms. On 29 December 1992, Harvard received a patent on a second mouse. This time the mouse had been altered genetically to develop an enlarged prostate gland.

⁵⁷Ibid.

Even though human beings are not patentable under existing protocols of the Patent and Trademark Office, human body parts may be. In an interesting state Supreme Court case, *Moore v. Regents of the University of California*,⁵⁸ John Moore brought suit against physicians who patented a cell line from his diseased spleen. In October 1976, shortly after learning that he had hairy-cell leukemia, Moore consulted physicians at the University of California at Los Angeles Medical Center. The attending physician, David W. Golde, informed Moore that his condition could be fatal and that a splenectomy was indicated. His spleen was removed 20 October 1976.

Either from Moore's diseased spleen or from tissues retrieved during follow-up treatment, Golde established a cell line from Moore's T-lymphocytes. Without the patient's knowledge or consent, Golde, and colleague Shirley G. Quan, applied for a patent on the cell line. Based upon University policy, any royalties or profits arising out of patents obtained by employees in their function as employees would be shared by the University. The patent issued on 20 March 1984, naming Golde and Quan as inventors.⁵⁹

Moore v. Regents of the University of California both demonstrates that patents are issued on human body parts and illustrates the ways the courts typically treat matters of biological ownership *vis-a-vis* patents. For these reasons the arguments in *Moore* will be more fully developed in the following chapter.

The history of patenting life was recently impacted by the effort of the National Institutes of Health, an agency of the United States government, to patent Expressed

⁵⁸*Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990).

⁵⁹U. S. Patent 4,438,032 (March 20, 1984).

Sequence Tags (ESTs). ESTs are clones of small segments of DNA. These copies, called cDNA (complementary DNA) may be useful in the production of therapeutic products such as human growth hormone and EPO (erythropoietin). In order to be used for therapeutic benefit, the particular cDNA must not only be identified but its function in the gene must be known. Once researchers have identified the function of cDNA they can determine if and how it may be used to treat illnesses.

NIH researchers developed a technique to rapidly sequence genes using cDNA, making it possible to identify thousands of ESTs in a very brief span of time. While the ESTs had been sequenced, their use remained unknown. That is, even though researchers at NIH had identified the ESTs they did not know how to use them to produce therapeutic tools.

Craig Venter and his colleagues at NIH filed for patents on several thousand ESTs in 1991.⁶⁰ In doing so, presumably NIH was hoping to protect their investment in developing the technology to identify ESTs. Once the attempt to patent ESTs became known, another cloud of controversy surrounded the United States Patent and Trademark Office and the patenting process. In November 1991, the American Society of Human Genetics, a professional society of over 4,500 U.S. and Canadian physicians, scientists, and genetic counselors, maintained that "the issuing of patents for ESTs is likely to do far

⁶⁰NIH had submitted patent applications on 347 fragments in 1991, another 2,375 fragments in early 1992, and 3,400 fragments later in the year. See Bernice Wuetrich, "All Rights Reserved: How the Gene-Patenting Race is Affecting Science," *Science News* 144 (4 September 1993), p. 155.

more harm than good . . .”⁶¹ Much of the controversy focused not so much on the fact that patenting ESTs of unknown biological function violated the utility requirement of the patent statutes, but on the patenting of human genes *qua* human genes. The debate made international headlines, leading to, for instance, an editorial in the *Financial Times of London*, calling for the NIH to cease and desist in their efforts to patent ESTs. In that editorial the French Minister of Science, Hubert Curien, is quoted as saying, “A patent should not be granted for something that is part of our universal heritage.”⁶² Bernadine Healy, at that time Director of the NIH said in response to Curien’s comments,

In fact, human and other genes have been patented by scientists of many countries. Indeed, most scientists and most governments of industrialized nations are arguing not against the patenting of genes, but rather against their being patented “prematurely”—that is, before their biologic function and commercial potential are adequately defined.⁶³

In December 1992, the Patent Office rejected the patent claims of NIH on ESTs. The PTO did so on the basis of the utility and nonobvious requirements of the patent statutes. Since, by definition, ESTs had unknown biological function, the usefulness of ESTs could not be known. Moreover, since ESTs were identified by what amounts to a mechanical process, the identification of ESTs was deemed obvious to anyone skilled in the art.

⁶¹*American Society of Human Genetics Position Paper on Patenting of Express Sequence Tags* (November 1991).

⁶²Cited in Bernadine Healy, “Special Report on Gene Patenting,” *The New England Journal of Medicine* 327 (27 August 1992), p. 666.

⁶³*Ibid.*

HUGO, The Human Genome Organisation, an international consortium of genetic scientists, issued its statement on patenting ESTs in January 1995. HUGO's position is that "the patenting of partial and uncharacterized cDNA sequences will reward those who make *routine* discoveries but penalize those who determine biological function or application."⁶⁴

The controversy over patenting ESTs is hardly over. At a recent meeting of the American Association for the Advancement of Science (AAAS), Lawrence J. Goffney, J.D., Assistant Commissioner of the Patent and Trademark Office, said that patents would be awarded by the PTO for ESTs.⁶⁵

Finally, in March 1995, the Patent and Trademark Office granted a patent on a cell line derived from a member of the Hagahai tribe of Papua, New Guinea.⁶⁶ The cell line was thought to be useful in a similar manner as John Moore's cell line. That is to say, the Hagahai cell line was derived from a person who was infected with human T-cell leukemia. The fact that the tribesman was not suffering from symptoms of leukemia gave researchers hope that his cell line would be helpful in treating the disease. The dispute over patenting the genetic materials of an indigenous tribe became so heated that on 24 October 1996, NIH filed paperwork to "disclaim" the patent.⁶⁷ Opponents of patenting

⁶⁴*HUGO Statement on the Patenting of DNA Sequences* (January 1995). Emphasis added.

⁶⁵"Notebook," *The Scientist* 11 (3 March 1997), p. 23.

⁶⁶"Patent Blather," *The Economist* (25 November 1995), p. 87.

⁶⁷"NIH Disclaims Patent After Policy Review," *GeneWATCH* 10 (February 1997), p. 7.

genetic materials of indigenous peoples worry over not only the patenting of human genes, but the commercial exploitation of people groups in the Southern Hemisphere by the industrialized nations of the Northern Hemisphere. The Rural Advancement Foundation International (RAFI) has labeled this an similar practices as a new form of "colonialism."⁶⁸ RAFI charged that,

Private ownership of human biological materials raises many profound social, ethical, and political issues. Industrialized nations are lobbying vigorously for "harmonization" of intellectual property laws worldwide with the ultimate goal of imposing patenting laws worldwide. In the South, issues of development and national sovereignty are at stake. Fundamental human rights are jeopardized everywhere.⁶⁹

2.4 Values Inherent in Patents

Obviously, the history of patents reveals that patents are enormously value-laden. From before the time of Thomas Jefferson, it has been recognized that the patenting process was considered necessary to protect and encourage important values in the advancement of civilization and technology. In 1930, the Patent Office Society urged that "National progress will not endure without invention, and invention will not endure without reward."⁷⁰ More recently, Arthur Kornberg has argued that "Without patent protection, there would be insufficient incentive for the enormous amounts of private

⁶⁸"Patent Blather," *The Economist*, p. 87.

⁶⁹"The Patenting of Human Genetic Material," *RAFI Communiqué* (Jan/Feb 1994), p. 1.

⁷⁰"Outline of the History of the United States Patent Office," p. 12.

investment required in biotech ventures.”⁷¹ It is widely perceived, then, that there is much at stake in patenting invention, and perhaps, especially in an age of exploding biotechnological growth and medical advancement, in patenting living organisms.

Patents focus exclusively on the value of fostering inventiveness. Thus, the values of living entities, including human genes, cells, tissues, and body parts in the form of composition of matter patents, are framed in economic values. In addition, some of the concerns raised by RAFI about the patenting of the cell lines of indigenous people groups likewise center around market values and the potential economic exploitation of those peoples.

Yet, there are competing values at stake in patenting living entities. We have traditionally valued living entities, especially human beings, in other than economic ways. Humans have located value in living entities in such nonmarket values as relationship, identity, community, beauty, companionship, sacredness, and others. Arguably, property discourse, the kind of discourse inherent in patents, tends to obscure other forms of discourse about living entities.

One question to be explored in following chapters is to what extent does the patenting of living entities and human biological materials obscure, erase, or marginalize noneconomic values? At least one way to answer to that question is to explore the discourse of patent law and the language the courts used to describe the rights thought to inhere in intellectual property.

⁷¹Arthur Kornberg, *The Golden Helix: Inside Biotech Ventures* (Sausalito, CA: University Science Books, 1995), p. 234.

In the next chapter, we will examine in greater detail the important cases in the history of patenting living entities. Beginning with *Diamond v. Chakrabarty*, we will attempt to tease out the value discourse about these entities, seeking to discover the types of value discourse endemic to disputes about intellectual property. Eventually, we will ask the question whether or not considering living entities and human biological materials in terms of market values is a sufficiently textured way to address values humans consider important to those forms of life.

CHAPTER 3

CASES IN BIOPATENTING

3.1 Biopatents, Cases, and Modes of Valuation

Patent regimes reflect a mode of valuing the subject matter of patents. Thus, the patent system is a socio-legal convention by means of which a particular mode or modes of valuation is/are assigned to the processes or objects which are patented. A mode of valuation is, according to University of Michigan professor of philosophy Elizabeth Anderson, a judgment that something is good or bad. Goods, for Anderson, are pluralistic. That is, there are different types of goods and, therefore, different modes of valuation. What one holds to be a good, one values. Goods may admit many and varied modes of valuation.¹ Furthermore, modes of valuation entail "certain ways of structuring deliberation concerned with what we value."²

In deciding the precedent-setting cases in biopatenting, courts invariably base their deliberations on modes of valuation. In every biopatenting case we will observe, the goods recognized by the courts are predominantly, if not exclusively, economic goods. Market values tend to shape the ways the courts deal with patenting living organisms. Some of the cases we will examine have not become matters of judicial deliberation.

¹Detailed attention will be given to Anderson's socially grounded, ideal-based, pluralistic theory of value in chapter 6. Cf. Elizabeth Anderson, *Value in Ethics and Economics* (Cambridge, MA: Harvard University Press, 1993).

²*Ibid.*, p. 5.

Nevertheless, discussion will reveal modes of valuation and the role they play in shaping policy related to the patenting of biological materials.

3.2 Oil-eating Microbes

The first significant debate concerning the patenting of living entities arose over the patenting of oil-eating microbes. Prior to 1980, non-plant living organisms were deemed unpatentable. As discussed in the previous chapter, these organisms were considered unacceptable subjects of patents because they were “products of nature.” With *Diamond v. Chakrabarty* a new era of biopatenting began in the United States.

The summary statement from the U. S. Supreme Court case highlights the essential elements of the controversy.

A microbiologist filed a patent application relating his invention of human-made, genetically engineered bacteria capable of breaking down multiple components of crude oil, a capability possessed by no naturally occurring bacteria. A patent examiner rejected the microbiologist's patent claim, ruling, among other things, that the bacteria, as living things, were not patentable subject matter under 35 USCS § 101, which provides for the issuance of a patent to a person who invents or discovers “any” new and useful “manufacture” or “composition of matter.” The United States Patent and Trademark Office Board of Appeals affirmed, but the United States Court of Customs and Patent Appeals ultimately reversed, holding that the fact that micro-organisms are alive is without legal significance for purposes of the patent law (596 F2d 952).³

While it is tempting to perform a *legal* analysis of *Chakrabarty*, the purpose here is to analyze the value discourse used by the Court, focusing on the ways which the Court understands (or constructs) the modes of valuing living microbes. We note again that the

³*Sidney A. Diamond, Commissioner of Patents and Trademarks, Petitioner, v. Ananada [sic] M. Chakrabarty, et al.*, 447 US 303, 65 L Ed 2d 144, 100 S Ct 2204.

case was decided on a five-to-four majority, with Justices Burger, Stewart, Blackmun, Rehnquist, and Stevens finding in favor of Chakrabarty. Justices Brennan, White, Marshall, and Powell dissented. Chief Justice Burger wrote the majority opinion while Justice Brennan wrote the minority opinion.

At issue is whether or not, in the words of Burger, Chakrabarty's "live, human-made micro-organism is patentable subject matter."⁴ Chakrabarty, we recall, had genetically altered *Pseudomonas* bacteria in such a way as to improve its usefulness in degrading oil spills. Prior to Chakrabarty's alteration of *Pseudomonas*, biological control of oil spills could only be accomplished by using a mixture of naturally occurring bacteria, each capable of decomposing various elements of crude oil. By altering *Pseudomonas* (which in its naturally occurring form has no capacity for degrading oil) to contain "at least two stable energy-generating plasmids," Chakrabarty produced an efficacious and efficient organism for degrading oil.

Justice Burger had already tilted the decision in favor of Chakrabarty by adopting the phrase "human-made" to describe the engineer's "invention." Words and their connotations carry enormous weight, not only in the law, but in the culture. For the sake of existing patent regimes, it is critical that the subject matter of a patent be able to be described accurately as "human-made," not naturally occurring. Moreover, the language of "invention" clearly shifts the weight of the argument in favor of patenting.

⁴Ibid. 447 US 305.

Furthermore, Justice Burger opined that “[Chakrabarty’s] discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”⁵ Thus, even though Chakrabarty’s alteration of *Pseudomonas* represented a relatively minor manipulation of a naturally occurring bacterium, Burger maintained that the “composition of matter” which Chakrabarty had claimed in the patent was of human invention.

Here I must disagree with Leon Kass who said that,

The Court’s opinion, and the dissent, were largely technical. Thus, readers of the opinion, who looked for large philosophical dicta about man’s art and living nature or about genetic engineering came away disappointed. Alas, it looked as if the Court was, for a change, being simply judicious, doing no more than its proper work.⁶

While I will not dispute that those who analyzed the case at the time saw the Court as deciding the case on very narrow grounds, in fact the majority opinion used inherently value-laden language to characterize Chakrabarty’s work. In describing the subject matter of the patent as “human-made” and as an “invention,” the Court adopted a mechanistic interpretation of living entities and perpetuated the “machine” metaphor characteristic of the biotechnik age (see Chapter 1).

It is true that the minority opinion responds to a very narrow question. Justice Brennan appears to have been focusing specifically on whether or not “Congress, exercising its authority under Art I, § 8, of the Constitution, intended that [Chakrabarty] be able to secure a monopoly on the living organism itself, no matter how produced or

⁵Ibid., 447 US 309.

⁶Leon Kass, *Toward a More Natural Science: Biology and Human Affairs* (New York: The Free Press, 1985), p. 129.

used.”⁷ Relying on the legislative history of the various patent acts, Brennan maintained that “. . . the Acts evidence Congress’ understanding, at least since 1930, that § 101 does not include living organisms.”⁸ Appealing to the Plant Patent Act and the Plant Variety Protection Act, Brennan averred that “Those plants, like the bacteria involved in this case, were new varieties not naturally occurring.”⁹ Brennan concluded that in authorizing the plant patent acts Congress, by providing for patents on plants, implicitly rejected the patenting of non-plant living organisms. He said pointedly, “. . . the 1970 Act clearly indicates that Congress has included bacteria within the focus of its legislative concern, but not within the scope of patent protection. Congress specifically excluded bacteria from the coverage of the 1970 Act.”¹⁰

The first mode of valuation apparent in the *Chakrabarty* case then is the value assigned to an inventor *qua* inventor and the invention *qua* invention he or she produces. That is to say, the Court assigned value to inventive-ness. This seems to be the value prized by Thomas Jefferson when he asserted that “ingenuity should receive a liberal encouragement.”¹¹ As Mark Sagoff, Fellow of the School of Public Affairs at the

⁷*Diamond v. Chakrabarty*, 447 US 318.

⁸*Ibid.*, 447 US 320.

⁹*Ibid.*

¹⁰*Ibid.*, 447 US 321. It is also important to note that Brennan did not dispute that *Chakrabarty* had a legitimate claim on the process of altering *Pseudomonas*. In fact, he stated explicitly that “Patents on the processes by which he has produced and employed the new living organism are not contested.” *Ibid.*, 447 US 318.

¹¹Cited by Chief Justice Burger, *Diamond v. Chakrabarty*, 447 US 308.

University of Maryland has said, "Whether the organisms should be patentable turns, in part, on how we construe the activity of their producers: do biotechnologists create these organisms, or do they serve merely as 'the occasions of their being'?"¹² We will return to this point in later chapters. Suffice to say here that what is at stake is the value attached to living entities and the way we understand or characterize the activity of those who manipulate or otherwise alter those entities.

Probably the most pervasive and supervening mode of valuation embedded in patent regimes is found in *Diamond v. Chakrabarty* when Justice Burger observed,

The Constitution grants Congress broad power to legislate 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." Art 1, § 8, cl 8. The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts. . . . The authority of Congress is exercised in the hope that "[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives of our citizens."¹³

Here we note a candid appeal to an economic mode of valuation. Indeed, the previous mode of valuation (viz., ingenuity) may be said to collapse into the economic mode of valuation if one considers both the genesis and more recent history of the U. S. patent system. The Court also acknowledged that a patent is a limited monopoly right which permits the holder of the patent to restrict the sale, use, or manufacture of the patented subject matter by others—again focusing on economic valuation.

¹²Mark Sagoff, "Animals as Inventions: Biotechnology and Intellectual Property Rights," *Report from the Institute of Philosophy & Public Policy* 16, p. 16.

¹³*Diamond v. Chakrabarty*, 447 US 307.

3.3 Polyploid Oysters

In April 1987, the U. S. Patent and Trademark Office's Board of Patent Appeals and Interferences held that "claimed polyploid oysters are nonnaturally occurring manufacture or compositions of matter within the meaning of 35 U.S.C. 101."¹⁴ In other words, the PTO decided, on the basis of, *Ex parte Allen*,¹⁵ a case heard by the Board of Patent Appeals and Interferences, that polyploid oysters were, in principle, patentable subject matter. With this announcement, the PTO—or more accurately, biotechnologists—revealed that research scientists were moving up the levels of complexity of living entities (or "man-made life forms") in the effort to patent animals as compositions of matter. In *Ex parte Allen*, the Board of Appeals and Interferences reversed the decision that patent examiner who maintained that Polyploid Pacific oysters were not patentable because they were "living entities."

Standish K. Allen, Jonathan A. Chaiton, and Sandra L. Downing, researchers at the University of Washington, Seattle, filed a patent application on 6 September 1984 for Pacific oysters of the species *Crassostrea gigas* modified through the use of hydrostatic pressure. By applying 6,000 to 10,000 psi of pressure to oyster ova for 15 minutes before and after fertilization, triploidy can be induced in the ova during meiosis.¹⁶

¹⁴Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks, "PTO Policy on Patenting Animals," in Office of Technology Assessment, *Patenting Life*, p. 93.

¹⁵*Ex parte Allen*, 2 USPQ 2d, pp. 1425-1428.

¹⁶See "Background of the Invention" in U. S. Patent 4,834,024.

At stake in *Ex parte Allen* was whether or not polyploid oysters qualify as patentable subject matter. According to the background section of the patent, inducing polyploidy in *Crassostrea gigas* results ultimately in oysters “characterized by high levels of glycogen, which add texture and flavor to the meat.”¹⁷ The original patent examiner held that “polyploid oysters are held to be living entities and do not fall within the statutory subject matter of 35 USC 101.”¹⁸ Furthermore, the examiner maintained that “the animal produced by the method claimed is ‘controlled by laws of nature and not a manufacture by man that is patentable.’”¹⁹

The examiner relied on two earlier court decisions for his rejection of the patent, viz., *In re Merat* and *In re Bergy*. Nevertheless, the Board of Patent Appeals and Interferences opined that:

We shall not sustain this rejection. As we have previously noted in our decision in *Ex parte Hibberd*, 227 USPQ 442 (BPAI 1985), the Supreme Court has interpreted the scope of 35 USC 101 in the recent case of *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The Court noted that the use of the expansive terms “manufacture” and “composition of matter” modified by the comprehensive “any” indicated that Congress “plainly contemplated that the patent laws would be given wide scope.” The Supreme Court also noted that the legislative history of Section 101 supports a broad construction and concluded from the Committee Reports accompanying the 1952 Act that Congress intended statutory subject matter to “include anything under the sun that is made by man.” Thus, the Court held at 447 U.S. 309, 206 USPQ 197, that the involved microorganism plainly qualified as patentable subject matter.²⁰

¹⁷U.S. Patent 4,834,024.

¹⁸*Ex parte Allen*, p. 1426.

¹⁹*Ibid.*

²⁰*Ex parte Allen*, p. 1426.

Thus, the Board of Patent Appeals and Interferences held that even though polyploid oysters were, as the examiner had argued, produced by a method “controlled” by the laws of nature, the fact that such oysters do not occur naturally and, therefore, require “the intervention of man”²¹ in order to exist, makes them patentable subject matter.

In a very interesting twist in this case, the Board of Patent Appeals and Interferences decided to affirm the patent examiner’s refusal of the *composition of matter* patent on polyploid oysters on grounds other than that they were “living entities.” The examiner maintained that the oysters were not patentable not only because they were not patentable subject matter, but because they were obvious to anyone skilled in the art. It will be recalled that “nonobviousness” is one of the established criterion for patentability. In a lengthy section of *Ex parte Allen*, the Board of Patent Appeals and Interferences argued that earlier publications by the researchers, Stanley, et al., had already revealed in the scientific literature the method for producing polyploidy in one species of oyster (the American oyster, *Crassostrea virginica*. The Board agree finally with the examiner that “in view of the express recommendation by Stanley et al., experts in the art who have successfully induced polyploidy in one species of oysters, it would have been obvious to one of ordinary skill in the art to induce polyploidy in Pacific *Crassostrea gigas*.”²² Thus, the decision of the patent examiner was affirmed.

Ex parte Allen was handed down on 3 April 1987. Four days later, Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks issued a

²¹Ibid., p. 1427.

²²Ibid.

statement explicating the Patent and Trademark Office's position on the patenting of animals.

A decision by the Board of Appeals and Patent Interferences in *Ex parte Allen* (Bd. App. & Int. April 3, 1987) held that claimed polyploid oysters are nonnaturally occurring manufacture or compositions of matter within the meaning of 35 U.S.C. 101. The Board relied upon the opinion of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980) as it had done in *Ex parte Hibberd*, 227 USPQ 443 (bd. App. & Int. 1985), as controlling authority that the Congress intended statutory subject matter to "include anything under the sun that is made by man." The Patent and Trademark Office now considers nonnaturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

The Board's decision does not affect the principle and practice that products found in nature will not be considered patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties, or combination not present in the original article existing in nature in accordance with existing law. See e.g., *Funk Bros., Seed Co. V. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948); *American Fruit Growers v. Brogdex*, 283 U.S. 1, 8 USPQ 131 (1931); *Ex parte Grayson*, 51 USPQ 413 (Bd. App. 1941).

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a nonplant multicellular organism which would include a human being within its scope include the limitation "nonhuman" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. In *re Wakefield*, 422 F2d 897, 164 USPQ 636 (CCPA 1970).

Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a nonhuman "nonnaturally occurring manufacture or composition of matter--a product of human ingenuity" (*Diamond v. Chakrabarty*), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter.²³

²³U. S. Patent and Trademark Office, 1987. Cited in *Patenting Life*, p. 93

Quigg's announcement was met with disapproval by both animal rights groups and farmers rights groups. Suit was filed with a United States District Court against the Commissioner of the United States Patent and Trademark Office and the Secretary of Commerce by the Animal Legal Defense Fund, the American Society for the Prevention of Cruelty to Animals (ASPCA), the Marin Humane Society, the Wisconsin Family Farm Defense Fund, and others.²⁴ The plaintiffs charged that Quigg had overreached his authority by issuing the new rule on patenting without holding a public hearing. Under the requirements of the Administrative Procedure Act, federal agencies may issue interpretative statements concerning existing laws or policies without public notice or opportunity for comment. The District Court held that due to the Supreme Court's decision in *Chakrabarty*, the Patent and Trademark Office's statement did not constitute a new policy, but only a clarification of existing law.²⁵ While recognizing other questions as important—viz., whether "animal" patents exceeded the Patent and Trademark Office's authority—the court decided on narrow grounds that Commissioner Quigg's interpretation did not violate his purview.

Undaunted by the District Court's judgment, the Animal Legal Defense Fund, et al., appealed the case to the Ninth Circuit Court of Appeals which transferred the case to the Federal Circuit Court. The Federal Circuit Court affirmed the decision of the District Court and held that (1) Quigg's "interpretative rule" did not violate the Administrative

²⁴*Animal Legal Defense Fund, et al., v. Donald J. Quigg, et al.*, 710 F. Supp. 728 (N.D. Cal. 1989).

²⁵*Ibid.*, 731.

Procedure Act, and (2) that the Animal Legal Defense Fund and the individuals and groups who joined the suit “did not have standing to seek a declaration that animals are not patentable subject matter and an injunction against the issuance of animal patents.”²⁶

In order to establish legal standing to sue, a plaintiff must show

(1) “that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct” (personal injury), (2) that “the injury ‘fairly can be traced to the challenged action’” (causation), and (3) that the injury is likely to be redressed by a favorable decision” (effective relief).²⁷

Both the Animal Legal Defense Fund and People for the Ethical Treatment of Animals claimed injury alleging that they “will have to devote significant financial resources to counteract the Defendants’ unlawful actions.”²⁸ Similarly, the Wisconsin Family Farm Defense Fund claimed on behalf of its members that economic harm would result to them by “forcing them to purchase high priced ‘patented’ animals or lose profits producing genetically inferior ‘unpatented’ animals.”²⁹ We note, therefore, in this case that those who argued against animal patenting appealed to economic values to make their claim. Yet, their appeal was not to the mode of valuing living entities, but to the consequences of Commissioner Quigg’s interpretative rule on their livelihood. The court

²⁶*Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991).

²⁷*Ibid.*, 925.

²⁸*Ibid.*, 926.

²⁹*Ibid.*, 932.

decided that any economic injury to the farmers was not, in fact, traceable to the Commissioner's action.³⁰

The decision of the Patent and Trademark Office to patent animals also evoked commentary by Boston University law professor George Annas. Writing in the *Hastings Center Report*, Annas observed,

The Commissioner drew the patenting line between animals and humans because the "grant of a limited, but exclusive property right in a human being is prohibited by the Constitution." This brief statement only raises the question, it does not begin to answer it. Since cloned human embryos are not persons protected by the Constitution and theoretically at least could be as 'immortal' as cloned cell lines, could a particularly "novel" or "useful" human embryo be patented, cloned, and sold? The logic of the Patent Office would seem to say "yes." Anything "under the sun" should be patentable (and used to make a profit for its "maker/inventor") as long as it does not run afoul of the Thirteenth Amendment (which forbids slavery and the "badges of slavery").³¹ While the question of patenting human beings will be taken up below, most

apropos to the present discussion is the way the Board of Patent Appeals and Interferences and the Patent Office construe the value of polyploid oysters. Not only does Annas point out that profit is inherent in patent regimes, but he goes on to say, "All that can be said at this point is that as long as there is the potential to make money from merchandising new life forms, the quest for profits rather than any well articulated and principled policy will continue to rule Washington."³² Interestingly, *Ex parte Allen* does not itself invoke the discourse of valuation *per se*. The decision of the Board of Patent

³⁰Ibid., 933.

³¹George J. Annas, "Of Monkeys, Man, and Oysters," *Hastings Center Report* (August 1987), p. 22.

³²Ibid.

Appeals and Interferences seems focused specifically upon the nuances of patent law.

Annas is correct, however, that patents, as constructed under U. S. law, inherently subsume economic modes of valuation (i.e. profitability). Moreover, eventually a *process patent* was granted to Allen, Chaiton, and Downing for a method of inducing polyploidy in oysters through the use of hydrostatic pressure.³³ As has already been observed, the process patent makes explicit appeal to modes of valuation:

In general, quality oysters are characterized by high levels of glycogen, which add texture and flavor to the meat. During the breeding season, the market quality of the oyster deteriorates because glycogen is diverted into gamete production instead of being stored. . . . Consequently, there exists a need in the art for a method of inducing polyploidy in oysters on a consistent and cost effective basis.³⁴

Thus, the patent makes clear that the exclusive value at stake in polyploid oysters is economic value.³⁵ Cost-effectiveness appears to have trumped other values.

In a statement issued by twenty-four religious leaders on July 22, 1987, criticism of the Patent and Trademark Office's decision to patent genetically modified animals reached a crescendo. These religious leaders opined that,

The decision of the U.S. Patent Office to allow the patenting of genetically engineered animals presents fundamental dangers to humanity's relationship with the natural world. Reverence for all life created by God may be eroded by subtle

³³U. S. Patent 4,834,024.

³⁴*Ibid.*

³⁵One might argue that something similar to gastronomic value (a form of aesthetics?) was also invoked with the polyploid oysters; however, gastronomic values collapse, in this instance, into the market value of oysters with induced polyploidy.

economic pressures to view animal life as if it were an industrial product invented and manufactured by humans.³⁶

Quite apart from the question of the merits of the statement, those who authored it were asserting that living entities should be subject to modes of valuation other than economic valuation. Apparently they saw the Patent and Trademark Office's policy as a threat to these modes of valuation. In an editorial counterpoint to the statement of the religious leaders, the *New York Times* rebutted by saying: "Life is special, and humans even more so, but biological machines are still machines that now can be altered, cloned, and patented."³⁷ Here, it should be pointed out, is another explicit appeal to the machine metaphor prevalent since the genesis of the biotechnic age.

Even though polyploid oysters would not exist apart from human manipulation of their environment during meiosis, should polyploid oysters be valued only in the market? Are there other values which should supervene? Attempts to answer these questions will be reserved for later chapters.

3.4 The Harvard Mouse

Applying patent regimes to animals, especially mammals, has been contentious in North America, Europe, and Japan. While it may be difficult to imagine valuing micro-

³⁶"Statement of Religious Leaders Against Animal Patenting to the Committee on the Judiciary Subcommittee on Courts, Civil Liberties, and the Administration of Justice," U. S. House of Representatives, July 22, 1987, cited in Andrew Kimbrell, *The Human Body Shop: The Engineering and Marketing of Life* (San Francisco: HarperSan Francisco, 1993), p. 201.

³⁷ Editorial, "Life Industrialized," *New York Times* (22 February 1988), cited in *Ibid.*

organisms or oysters in other than economic ways, certainly mammals and mammalian species are valued in a diverse ways. This seems especially the case since mammals are, without exception, sentient beings which are able to experience pleasure and pain.

What has become one of the most controversial cases in animal patenting involved the patenting of a genetically altered mouse by Philip Leder and Timothy Stewart, and assigned to Harvard University.³⁸ The announcement of the patenting of the so-called "Harvard mouse" provoked responses in the *Wall Street Journal*,³⁹ *Scientific American*,⁴⁰ and other news journals. Yet, Sheldon Krimsky has said, "Public reaction to the announcement of the patent was relatively mild."⁴¹

Filed 22 June 1984 and issued on 12 April 1988, the patent covers "A transgenic non-human eukaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal, or an ancestor of the animal, at an embryonic stage."⁴² In actuality, the patent was unusually broad in scope and covered all

³⁸It should be noted that Robert Proctor mistakenly attributes the patent to Walter Gilbert of Harvard. He correctly points out, however, that E. I. du Pont is licensed to practice the patent and markets the Harvard mouse under the trade name "Oncomouse" to cancer researchers at about \$50 each. See Robert N. Proctor, "Genomics and Eugenics: How Fair Is the Comparison?" in George J. Annas and Sherman Elias (eds.), *Gene Mapping: Using Law and Ethics as Guides* (New York: Oxford University Press, 1992), p. 69.

³⁹"Patents for Genetically Altered Mouse Opens Era for Research," *Wall Street Journal* (13 April 1988), p. 26.

⁴⁰Elizabeth Corcoran, "A Tiny Mouse Came Forth," *Scientific American* (February 1989), p. 73.

⁴¹Krimsky, *Biotechnics and Society*, p. 44.

⁴²U. S. Patent 4,736,866.

transgenic non-human mammals "whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal, or ancestor of the animal, at an embryonic stage."⁴³ The patent also states that "a primate such as a rhesus monkey, which is evolutionarily closer to humans than mice" is covered under the claims of the patent.⁴⁴ Oncomammals may be used, according to the patent, to test a suspected carcinogen, to test a proposed treatment modality, or as a source of cells for cell culture.

It is not possible to determine from the patent itself what mode or modes of valuation informed the decision to patent oncomammals. Unlike previous patents on living entities, the oncomammal patent did not result in litigation or new legislation. The Patent and Trademark Office's policy on patenting nonhuman, multicellular living organisms was by then firmly ensconced. While there were protests, no court case erupted. As Stephen Crespi, former Patents Controller for the British Technology Group observed: "Following the approval given by the Supreme Court to the patenting of bacteria modified from their natural form by the hand of man and the acceptance of this view in other industrialized countries, the extension of this principle to the patenting of other organisms of higher biological classification proceeded fairly smoothly."⁴⁵

⁴³Ibid.

⁴⁴Ibid.

⁴⁵R. Stephen Crespi, "The Patenting of Genetic Resources," *Impact of Science on Society* 158, pp. 177. By 1991, John Barton, professor of law and director of the Law and High Technology Program at Stanford Law School, could write, "The patenting of life-forms is rapidly expanding in the U.S., which now provides intellectual property protection in microbes, plants and animals." John H. Barton, "Patenting Life," *Scientific American* 264 (March 1991), p. 40.

Other controversy related to oncomammals which might illuminate the debate about modes of valuation.

3.5 John Moore's Spleen Cells

In 1976, while working on the Trans-Alaska pipeline, John Moore was diagnosed with hairy-cell leukemia. His spleen was over forty times the normal size. Following a brief hospitalization, Dr. David W. Golde confirmed the diagnosis at the UCLA Medical Center. Golde recommended that Moore undergo a splenectomy.

Sometime prior to the surgery, Moore and a colleague, Shirley Quan, determined to obtain portions of the patient's spleen for the purposes of research and possible commercialization of products derived from the tissues. According to the court record, "At this time all defendants, including Golde, were aware that 'certain blood products and blood components were of great value in a number of commercial and scientific efforts' and that access to a patient whose blood contained these substances would provide 'competitive, commercial, and scientific advantages.'"⁴⁶ Though he did sign a standard surgical consent form which included provision for the postoperative disposition of the excised tissues, Moore remained unaware of the potential commercial value of his cells.⁴⁷

⁴⁶*Moore v. Regents of the University of California*, 793 P.2d 481.

⁴⁷U. S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells—Special Report*, OTA-BA-337 (Washington, DC: U.S. Government Printing Office, March 1987), p. 26. (Hereafter: *Ownership of Human Tissues and Cells*.)

Between November 1976 and September 1983, Moore, a resident of Seattle, Washington, returned to UCLA Medical Center for follow-up tests. He was led to believe "that such visits were necessary and required for his health and well-being . . ."⁴⁸ Furthermore, the patient was told he needed to return to UCLA Medical Center because "the procedures were to be performed only there and only under Golde's direction."⁴⁹ On each visit, samples of Moore's blood, blood serum, skin, bone marrow aspirate, and sperm were retrieved.

During the period of time Moore was being treated at UCLA, Golde and Quan were conducting research on Moore's cells and "planned to 'benefit financially and competitively . . . [by exploiting the cells] and [their] exclusive access to [the cells] by virtue of [Golde's] on-going physician-patient relationship . . .'"⁵⁰ Sometime prior to August 1979, Golde and Quan established a cell line (called "Mo") from the patient's T-lymphocytes (a type of white blood cell). In 1981, the university began a 4-year collaborative research project with two biotechnology and pharmaceutical firms for exclusive use of the Mo cell line⁵¹ and on 30 January 1981, the Regents of the University of California applied for a patent on a human T-lymphoblast cell line and products resulting from that cell line. The claims of the patent were for both the composition of matter and the methods for maintaining a continuous culture for an indefinite period of

⁴⁸*Moore v. Regents of the University of California*, 793 P.2d 481.

⁴⁹*Ibid.*

⁵⁰*Ibid.*

⁵¹OTA Report, *Ownership of Human Tissues and Cells*, p. 26.

time.⁵² The patent, listing David W. Golde and Shirley G. Quan as inventors, was issued on 20 March 1984.

According to his own testimony, on his last visit to Dr. Golde, in September 1983, Moore was presented with a consent form which was substantially different from those he had signed before. Said Moore:

It was a legal-sized sheet. At the bottom was a paragraph that started out in parenthesis: (I do/I do not). And then it went on to say things like "give away all my rights and my heirs' and assigns' rights and blah, blah, blah to cell lines and anything else derived from this research." Well, I'd never seen that before so I said, well, why should I give up anything? So I circled "I do not". And apparently nobody noticed I had done that. They just assumed I would be happy to circle "I do." And even before I got back to my parents' house . . . Dr. Golde had called and talked to my mother and said I had missigned the consent form and what the heck was going on here?⁵³

After being telephoned by Dr. Golde and after having received another identical consent form from him in the mail, Moore consulted an attorney. In September 1984 he initiated litigation against Dr. Golde. The case went through a lengthy appeal process and was finally decided by the California Supreme Court on 9 July 1990. Moore charged his physician with breach of fiduciary responsibility, violation of the canons of informed consent, and sued for "conversion"⁵⁴ or the right of ownership of the cells which were

⁵² U. S. Patent 4,438,032.

⁵³Interview with John Moore in Beth Burrows, "' . . .to promote the Progress of Science . . .'" (Second Thoughts About U. S. Patent #4,438,032)," *The Boycott Quarterly* (Winter 1995), p. 6. Also reprinted in *GeneWATCH* 10 (October 1996), pp. 4-7.

⁵⁴George Annas, Professor of Health Law at Boston University Schools of Medicine, Public Health, and Law, says: "Conversion is a strict liability tort that under California law is committed against a person if the person can prove (1) ownership or the right to possession of property at the time of conversion, (2) the wrongful conversion or disposal of the property, and (3) damages. As a strict liability tort, conversion requires

removed from his body and which were likely to result in significant financial reward to Dr. Golde and the Regents of the University of California. In sum, the court held that Moore had cause of action for breach of fiduciary duty and lack of informed consent, but he did not have cause of action for conversion.⁵⁵

The relevant matters for the discussion of modes of valuation occur under the section of *Moore v. Regents of the University of California* treating the subject of conversion. Moore's attorneys argued that the "defendants' unauthorized use of his cells constitutes a conversion. As a result of the alleged conversion, Moore claims a proprietary interest in each of the products that any of the defendants might ever create from his cells or patented cell line."⁵⁶

The court made several crucial observations about Moore's argument. First, Moore attempted "to characterize the invasion of his rights as a conversion—a tort that protects against interference with possessory and ownership interests in personal property."⁵⁷ This legal argument would have an important consequence when applied to biotechnology. According to the majority opinion in the case, the invocation of tort

neither knowledge or intent of the defendant, but instead 'rests upon the unwarranted interference by the defendant with the dominion over the property of the plaintiff from which injury to the latter results.'" George J. Annas, "Outrageous Fortune: Selling Other People's Cells," in George J. Annas, *Standard of Care: The Law of American Bioethics* (New York: Oxford University Press, 1993), p. 168.

⁵⁵The justices split on this decision. Chief Justice Arabian and justices Lucas, Eagleson, and Kennard concurred. Justice Broussard both concurred and dissented. Justice Mosk dissented.

⁵⁶*Moore v. Regents of the University of California*, p. 487.

⁵⁷*Ibid.*

theory was originally used to determine whether the loser or finder of a horse had a better title to ownership. Yet, if Moore had been successful in finding a conversion liability against Golde, essentially a tort duty to investigate the “consensual pedigree” of each human cell used in research would have been imposed on scientists.⁵⁸ Also, Moore did not expect to retain possession of his cells following their removal. In fact, California law “drastically limits” any continuing interest of a patient in excised cells.⁵⁹ The court specifically noted that, under the law, the disposition of such things as human tissues, transplantable organs, blood, fetuses, pituitary glands, corneal tissue, and cadavers was a matter of public policy rather than personal property law. Since only property can be converted, and since Moore’s excised cells are not regarded as property in the law, then he could not have had a property right in his spleen cells after their removal. Curiously, however, Golde may have a property right in those same cells through the patent process. This is because it was deemed that “the patented cell line is both factually and legally distinct from the cells taken from Moore’s body.”⁶⁰ Following this remark, the court appealed to *Diamond v. Chakrabarty* for the legal precedent permitting the patenting of “organisms that represent the product of ‘human ingenuity,’ but not naturally occurring organisms.”⁶¹ Moreover, the court said,

⁵⁸Ibid.

⁵⁹Ibid., p. 488.

⁶⁰Ibid., p. 492.

⁶¹Ibid.

Human cell lines are patentable because “[l]ong-term adaptation and growth of human tissues and cells in culture is difficult—often considered an art . . .,” and the probability of success is low. (OTA Rep., *supra*, at p. 33; see fn 2, *ante*). It is this *inventive effort* that patent law rewards, not the discovery of naturally occurring raw materials. Thus, Moore’s allegations that he owns the cell line and the products derived from it are inconsistent with the patent, which constitutes an authoritative determination that the cell line is the product of invention.⁶²

In a lengthy commentary on the theory of conversion and its impact on biotechnology, the court offered the following argument: (1) research on human cells plays a critical role in medical research; (2) the extension of conversion law into biotechnology would restrict access to necessary “raw materials;” (3) such a restriction would have broad negative impact on the development of biotechnological research; (4) “. . . the theory of liability that Moore urges us to endorse threatens to destroy the economic incentive to conduct important medical research;”⁶³ (5) such a broad ranging impact is beyond the purview of the courts; therefore, (6) any liability accruing to researchers for failing to investigate the consensual pedigree of their raw materials ought to be determined by the Legislature, not by the Judiciary. Furthermore, the court judged that existing canons of informed consent and disclosure obligations were sufficient to protect patients against their physicians’ conflicts of interest.

Justice Broussard concurred with the majority with respect to the requirement of informed consent. At the same time, however, the justice dissented from the majority regarding conversion as a cause of action. Broussard acknowledged that the majority’s position entails that “a patient may *never* maintain a conversion action for the

⁶²*Ibid.*, pp. 492-493.

⁶³*Ibid.*, p. 495.

unauthorized use of his excised organ or cells . . .”⁶⁴ Although the majority opinion appears to admit a very expansive interpretation, Broussard maintains that they cannot actually intend “such a broad or dubious position”⁶⁵ and he presents a counter example to demonstrate his point.

If, for example, another medical center had stolen all the cells in question from the UCLA Medical Center laboratory and had used them for its own benefit, there would be no question but that a cause of action for conversion would properly lie against the thief, and the majority opinion does not suggest otherwise. Thus, the majority’s analysis cannot rest on the broad proposition that a removed body part is not property, but that *a patient* retains no ownership interest in a body part once the part has been removed from his or her body.

. . . Although the majority opinion suggests that there are “reasons to doubt” that a patient retains “any” ownership interest in his organs or cells after removal, the opinion fails to identify any statutory provision or common law authority that indicates that a patient does not generally have the right, before a body part is removed, to choose among the permissible uses to which the part may be put after removal.⁶⁶

Boussard appealed to the Uniform Anatomical Gift Act, adopted in California in 1970 and revised in 1988, to demonstrate that patients have authority to designate the use of their organs or body parts prior to removal. The principle of “donor control,” therefore, is embodied in the law. Moreover, argued Broussard, under traditional common law principles, the right of patients to control the future use of their organs is protected by the law of conversion. Under these principles, the fact that Golde intentionally withheld material information from Moore—information which was

⁶⁴*Moore v. Regents of the University of California*, p. 501-502. Emphasis in original.

⁶⁵*Ibid.*, p. 502.

⁶⁶*Ibid.*

necessary for Moore's exercise of control over his body parts, at a time when Moore could have made decisions with respect to the disposition of those parts—constitutes a violation of the patient's right of control. Thus, argued Broussard, Moore did, in fact, have a justified conversion cause of action against Golde.

In a blistering attack on the majority opinion, Broussard observed that Justice Arabian suggested that the majority's conclusion was based on the principle that "it is immoral to sell human body parts for profit."⁶⁷ Broussard had a slightly different perspective.

Far from elevating these biological materials above the marketplace, the majority's holding simply bars *plaintiff*, the source of the cells, from obtaining the benefit of the cells' value, but permits *defendants*, who allegedly obtained the cells from plaintiff by improper means, to retain and exploit the full economic value of their ill-gotten gains free of their ordinary common law liability for conversion.⁶⁸

Dissenting in the Moore decision was Justice Stanley Mosk. Mosk opined that the majority opinion was flawed on a number of counts. First, he thought that the majority had misconstrued the California statute limiting a patient's control over his or her excised body parts. Mosk held that the law "does not authorize the principal use that defendants claim the right to make of Moore's tissue, i.e., its commercial exploitation."⁶⁹ According to Mosk, the statute only permits "scientific use" of excised body parts and tissue (which is reasonably assumed to include pathological examination, verification of diagnosis, and use in making a prognosis). Mosk also observed that "scientific use" might include

⁶⁷Ibid., p. 506.

⁶⁸Ibid.

⁶⁹Ibid., p. 508.

scientific research “by a disinterested researcher for the purpose of advancing medical knowledge—provided of course that the patient gave timely and informed consent to that use.”⁷⁰ Instead, on his characterization of the case, Golde and Quan “were not only scientists, they were also full-fledged entrepreneurs.”⁷¹

Additionally, Mosk said the majority erred in its understanding of property rights. Moore never relinquished his property rights in his own tissues. Mosk said, “. . . Moore nevertheless retained valuable rights in that tissue. Above all, at the time of its excision he at least had *the right to do with his own tissue whatever the defendants did with it*: i.e., he could have contracted with researchers and pharmaceutical companies to develop and exploit the vast commercial potential of his tissue and its products.”⁷²

Third, Mosk claims that the majority misunderstood the nature of the alteration made to Moore’s cells.

For present purposes no distinction can be drawn between Moore’s cells and the Mo cell line. It appears that the principal reason for establishing a cell line is not to “improve” the quality of the parent cells but simply to extend their life indefinitely, in order to permit long-term study and/or exploitation of the qualities already present in such cells. The complaint alleges that Moore’s cells naturally produced certain valuable proteins in larger than normal quantities; indeed, that was why the defendants were eager to culture them in the first place. Defendants do not claim that the cells of the Mo cell line are in any degree more productive of such proteins than were Moore’s own cells.⁷³

⁷⁰Ibid.

⁷¹Ibid., p. 509.

⁷²Ibid., p. 510. Emphasis in the original.

⁷³Ibid., p. 511.

Mosk, in fact, disdained what he called "the amateur biology lecture" included in the majority opinion. He maintained that, among other things, the material focused on whether or not Moore's genetic material was unique. That issue was irrelevant to the case, according to Justice Mosk.

Commenting on this case, George Annas contends that the *Moore* decision is important for two reasons. Clearly it draws attention to the physician-patient dyad as a fiduciary relationship, "and part of that trust is the assumption that anything not disclosed to the patient is withheld because the information could not affect the patient's decision, or the withheld information concerns something done for the patient's benefit."⁷⁴ In this case, information was withheld for the benefit of the physician.

Annas says *Moore* also points to the need for either new patent legislation or a revised consent policy. He says on the one hand, "My preference is to discourage increasing commercialization of the body and its tissues by amending the Patent Act explicitly to prohibit the patenting of human cells (including genes and gene fragments), and the Organ Transplant Act to include a prohibition on the sale of human tissue and cells for any purpose (not just when they are intended for transplantation)."⁷⁵ Barring legislative remedies, Annas recommends that patients should be fully informed that their organs, tissues, cells, or genes may be commercially exploited, and should have a right to accept or reject such a use. Should they accept, patients should be provided just compensation for the use of their biological materials.

⁷⁴Annas, "Outrageous Fortune," p. 176.

⁷⁵Ibid.

3.6 The NIH and Expressed Sequence Tags

In June 1991, the National Institutes of Health filed for patents on 315 human genetic sequences known as Expressed Sequence Tags (ESTs). An EST is a fragment of a genomic sequence (some only eight bases long) from a cloned portion of DNA known as complementary DNA (cDNA). ESTs can be used "to identify an expressed gene, and can also be used as a sequence-tagged site maker to locate that gene on a physical map of the genome" (HUGO Statement on the Patenting of DNA Sequences, see Appendix B). By the fall of 1992, the NIH had patents pending on 6,122 ESTs.⁷⁶

J. Craig Venter, then a researcher for the NIH, developed an automated method for sequencing genes using a machine developed by Applied Biosystems, Inc.⁷⁷ Venter and his group identified the ESTs using the automated gene sequencer and filed for patents in order "to encourage the rapid development of products for disease treatment," according to Bernadine Healey, at that time director of the National Institutes of Health.⁷⁸ The use of the gene sequencer, says Venter, "allows a single scientist to isolate and partially sequence, and hence uniquely identify, human genes at a rate of several hundred per week."⁷⁹

⁷⁶Bernice Wuethrich, "All Rights Reserved: How the Gene-Patenting Race is Affecting Science," *Science News* 144 (4 September 1993), p. 154.

⁷⁷John Carey, Joan O'C. Hamilton, Julia Flynn, and Geoffrey Smith, "The Gene Kings," *Business Week* (8 May 1995), p. 76.

⁷⁸Wuethrich, "All Rights Reserved," p. 155.

⁷⁹Ann Gibbons, "Genome Patent Fight Erupts," *Science* 11 (October 1991), cited in Fred Warshofsky, *The Patent Wars: The Battle to Own the World's Technology* (New York: John Wiley and Sons, 1994), p. 236.

On the one hand, the ESTs had no known function. That is, researchers had no idea what role these gene fragments play in the genome. On the other hand, no alteration was made in the ESTs. Patent law requires that the subject matter of patents meet the commercial utility and novelty criteria (see Chapter 2). ESTs meet neither criteria.

In November 1991, the American Society of Human Genetics (ASHG) issued a position paper on the patenting of expressed sequence tags (see Appendix A). The ASHG represents over 4,500 North American physicians, scientists, and genetic counselors. It was the view of the society that patenting ESTs was likely to prove harmful to genetic science, particularly to the Human Genome Project. "The ASHG does not support the concept of patenting a short sequence from a randomly isolated portion of a gene encoding a protein of unknown function." Failure to meet the canons of patent law was not the primary concern of the ASHG, however. The society worried that patenting ESTs would negatively impact the Human Genome Project by introducing "a competition between laboratories and countries to see who can 'own' the largest portion of the human genome."⁸⁰

Nobel laureate and co-discoverer of the double helical structure of DNA, James Watson, called the filing of the patents "sheer lunacy" and said, "virtually any monkey can

⁸⁰That this was a genuine concern was legitimated by the international response to the announcement of NIH's patent applications. Universities, researchers, and governments in Japan and Britain rushed to file their own patents on cDNA fragments. Wuethrich, "All Rights Reserved," pp., 155-156. For a commentary by British researchers and policy analysts see S. M. Thomas, A.R.W. Davies, N. J. Birtwistle, S. M. Crowther, and J. F. Burke, "Ownership of the Human Genome," *Nature* 380 (4 April 1996), pp. 387-388.

do what Venter's group is doing."⁸¹ Francis Collins, director of the National Center for Human Genome Research said, "ESTs without known function are not and never should be patented."⁸² In December 1992, the Patent and Trademark Office rejected the NIH's patent applications, questioning both the novelty and usefulness of ESTs.

The issue appeared to be resolved, or at least dormant, until February 14, 1997, when Lawrence J. Goffney, Assistant Commission for the U. S. Patent and Trademark Office, announced at a meeting of the American Association for the Advancement of Science, that ESTs would now be patentable.⁸³ Following the announcement by Goffney, University of Washington geneticist Leroy Hood chided, "It's an appallingly bad thing to have happened."⁸⁴ By mid-March, the National Institutes of Health responded to the PTO's new policy with a series of letters protesting the decision to patent ESTs. Jack Spiegel, director of the Division of Technology Development and Transfer for the NIH sent a letter to Goffney detailing NIH's objections to patenting ESTs (see Appendix C). Two days later, Harold Varmus, director of the NIH, noted in a letter to Bruce Lehman, Assistant Secretary of Commerce and Commission of the PTO, that ESTs do not meet the PTO's own definition of practical utility and a decision to patent gene fragments of unknown biological function "will adversely affect the commercialization of new therapeutic technologies arising from these findings" (see Appendix D).

⁸¹Warshofsky, *The Patent Wars*, p. 236.

⁸²Weuthrich, "All Rights Reserved," p. 155.

⁸³"ESTs Again," *The Scientist* 11 (3 March 1997), p. 23.

⁸⁴*Ibid.*

Finally, in April 1996, the National Center for Human Genome Research published a policy directive prohibiting research institutions receiving NCHGR grants from patenting gene fragments sequenced by those institutions (see Appendix E). Again, the policy was premised on the view that raw human genomic DNA sequences lack utility. Furthermore, the NCHGR policy requires that all funded institutions publish their data "as rapidly as possible" and place their data "in the public domain where it will be freely available." Thus, a number of institutions upload to the Internet the results of their research at the end of each day. This makes raw human genomic DNA sequences available to everyone.

It is difficult to characterize the modes of valuation which might apply to ESTs based on the extant documents. From Venter's and Healy's statements, it appears that ESTs are valuable instrumentally as an impetus to settle the question of patentability or as a step in the dissemination of information. Not everyone agrees, however, that the motivation of Venter and colleagues is one of economic disinterestedness. Venter presently directs The Institute for Genomic Research (TIGR), a non-profit research group in Gaithersburg, Maryland. TIGR has assigned the rights to commercialize its findings to Human Genome Sciences (HGS), a for-profit group headed by William A. Haseltine. In turn, HGS provided a ten-year grant of \$70 million to fund TIGR's research.⁸⁵ One

⁸⁵Weuthrich, "All Rights Reserved," p. 156. In an interesting development, TIGR and HGS dissolved their relationship in June 1997. According to Venter, TIGR was "feeling more and more constrained by our rights going to this one biotech company." He also said the relationship "inhibited our ability to publish data as quickly as we wanted to." "Split Genes," *The Scientist* 11 (7 July 1997), p. 23.

pharmaceutical executive has said of Venter and Haseltine, "They want to be the gatekeeper of the genome."⁸⁶

No one can predict where this debate will end. If ESTs are deemed patentable by the Patent and Trademark Office, the PTO's justification for granting the patents will no doubt reveal much about how ESTs are valued.

3.7 Patents on Indigenous People Groups

The latest chapter in the story of patenting human genes is remarkable. The details remain somewhat sketchy, but the implications of the case are profound. In March 1995, the National Institutes of Health received a patent⁸⁷ on a cell line derived from the blood of an unidentified 21-year-old male member of the Hagahai people, an indigenous people group in Papua, New Guinea.⁸⁸ The man's cells are thought to contain qualities making them resistant to malaria and to carry a human T-cell leukemia virus, without being affected by the disease.⁸⁹ The patent claims included: (1) a cell line, designated papua New Guinea-1 (pNG-1) ATCC CRL 10528; (2) a viral preparation comprising the HTLV-I-variant in the cell line; and (3) a number of bioassays for diagnostic purposes.⁹⁰

⁸⁶Carey, Hamilton, Flynn, and Smith, "The Gene Kings," p. 74.

⁸⁷U. S. Patent 5,387,696.

⁸⁸"Patent Blather," *The Economist* (25 November 1995), p. 87.

⁸⁹Charles J. Hanley, "Can U.S. Patent Blood of Tribesman?" *The Tennessean* (21 April 1996).

⁹⁰U. S. Patent 5,387,696.

The patent lists Carol Jenkins and four government researchers as inventors. The United States of America as represented by the U. S. Department of Health and Human Services is listed as the "assignee." The NIH allegedly claimed that the cell lines were not likely to result in useful products. Jenkins is said to have promised to relinquish to the Hagahai people any royalties she might receive as a result of using the cell line.⁹¹

The decision of the PTO to patent the cell line of an indigenous people group sparked international controversy. Charges of "genetic colonialism" were made by the government of New Guinea and a Canadian environmental group, the Rural Advancement Foundation International (RAFI). According to a statement from the National Institutes of Health, NIH entered into discussions with representatives of the New Guinea government in May 1996.⁹² On October 25, 1996, the National Institutes of Health filed the necessary documents to "disclaim" the Hagahai patent. No explanation was given for NIH's rationale in disclaiming the patent.

⁹¹"Patent Blather," p. 87.

⁹²Statement of the NIH, "NIH Disclaims Patent After Policy Review," reprinted in *GeneWATCH* 10 (February 1997), p. 7.

3.8 Summary and Conclusion

This brief survey of the major cases in biopatenting demonstrates that the courts have, almost exclusively, adjudicated patenting disputes on the basis of economic modes of valuation. The principal questions addressed by the courts have related to the commercial value of patented subject matter.

Similarly, even those cases not adjudicated by the courts but determined by policy decisions of governmental agencies have, for the most part, revolved around questions of commercial value. E. Richard Gold has said,

The impact of biotechnology on the way we value the human body is not limited to simply causing us to recalibrate the ways which we value the body; the advent of biotechnology creates a setting in which to value the body and its components as commodities. The products of biotechnology from genetic therapies, to hormones, to pharmaceuticals are things that we buy, sell, and trade. The body itself, when understood as the mine from which we extract these products, is similarly valuable as a commodity. There is a tension, however, between valuing them in terms of warmth, identity, and comfort. Unlike pharmaceuticals, we cannot buy or sell warmth and friendship without doing serious injury to what we mean by those terms.⁹³

This tension is no less evident when it comes to modes of valuing animals (or at least animal species) than it is when valuing human beings and the human body. It is this tension which must be addressed if there is any hope for resolving the legal, ethical, and cultural upheaval which has resulted from a burgeoning biotechnology industry and an arguably over broad patenting regime.

In subsequent chapters we will examine the historical origin of property rights to determine how helpful it may be in ameliorating these disputes. We shall also examine the

⁹³E. Richard Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, DC: Georgetown University Press, 1996), p. 2.

arguments for and against patenting. Each of these arguments are grounded in a moral theory and we will examine how helpful traditional ethical categories are in solving the conflict which seems to be inherent in patenting biological materials.

CHAPTER 4

LOCKEAN PROPERTY RIGHTS AND BIOPATENTS

4.1 The Origin of Modern Property Rights

Lockean notions of property rights, it is argued, have informed the discourse on patenting in profound ways. Of all the previous theories of property, John Locke's theory of property became the classical liberal theory. The liberal theory of property has been preeminent in the West for centuries. There is general agreement among legal scholars and philosophers that "The Lockean system was dominant at the time when the Constitution was adopted"¹ and we have already noted the influence of the "twin luminaries" of the Augustan age,² John Locke and Isaac Newton, on the views of America's Founders.³ Paschal Larkin puts it very well when he says, "Locke's individualism, his glorification of property rights and his love of conscience have been interwoven into the economic and social texture of American life."⁴

¹Richard A. Epstein, *Takings: Private Property and the Power of Eminent Domain* (Cambridge, MA: Harvard University Press, 1985), p. 16. Hastings Rashdall said that Locke's theory of property had "become the basis of almost all attempts of modern philosophers to base the justification of private property upon some *a priori* principle, and not upon the ground of general utility and convenience." Hastings Rashdall, "The Philosophical Theory of Property," in C. Gore (ed.), *Property: Its Duties and Rights* (London: Macmillan, 1913), p. 40. Cf. also Richard Schlatter, *Private Property: The History of an Idea* (New Brunswick, NJ: Rutgers University Press, 1951), p. 151.

²I. Bernard Cohen, *Science and the Founding Fathers*, p. 59.

³See Chapter 2.

⁴Cited in the introduction to the Peardon edition of Locke's *Second Treatise*. John Locke, *The Second Treatise of Government*, ed. Thomas P. Peardon (New York: Bobbs-

The idea that individuals are entitled to own whatever they mix with their labor is a Lockean notion which persists to the present. Lawrence Becker maintains that Locke made a unique and lasting contribution to property rights theory by arguing that labor entitles one to property.⁵ “Once enunciated in the context of natural rights theories of the seventeenth century,” says Becker, the idea “has seemed nearly inescapable and self-evident.”⁶

Furthermore, contemporary understandings of intellectual property rights, including patent regimes, are said to owe their conceptual framework largely to Locke. With respect to the debate on biopatents, in 1979, Irving Holtzman argued in favor of patent protection for certain forms of life noting that “Efforts have been made to justify the grant of a patent under the theory that an inventor has the ‘moral right’ to reap the fruits of his labor or to control what he has created. This amounts to a reward theory for granting patents and originates in John Locke’s theory of property.”⁷ When the Office of Technology Assessment report sought a ground for so-called forward looking arguments for patenting biological entities, it observed that such arguments “. . . justify property

Merrill Company, 1952), p. xx.

⁵Lawrence Becker, *Property Rights: Philosophic Foundations* (Boston: Routledge and Kegan Paul, 1977), p. 32.

⁶Ibid.

⁷Irving Holtzman, “Patenting Certain Forms of Life: A Moral Justification,” *Hastings Center Report* 9 (June 1979), p. 11.

rights as entitlements to the fruits of one's labor and draw upon themes derived from John Locke's seminal discussion of property rights."⁸

While discourse on property rights began in Greece and Rome with Plato, Aristotle, Cicero, and others, for modern and contemporary discourse, Locke's influence cannot be overstated. Thus, it is important if one is to understand contemporary property rights and their application to biopatents that one understand Lockean theory. Furthermore, an analysis of Lockean property rights may prove very telling when it comes to evaluating just how well his theory supports patenting biological materials.

Locke's theory of property rights is contained almost exclusively in his *Two Treatises of Government*⁹ of 1698, though scholars dispute whether, and to what extent, Locke's *Essay on Human Understanding* is connected with the *Two Treatises*.¹⁰ Moreover, most of what Locke has to say about property rights *per se* is contained in chapter five of the *Second Treatise*. In the following discussion I will give attention primarily to the interpretation of property rights advanced by Locke in the latter of those works.

⁸*Patenting Life*, p. 130.

⁹John Locke, *Two Treatises of Government*, ed. Peter Laslett (Cambridge: Cambridge University Press, 1988).

¹⁰For the purposes of the present study it is not necessary to entertain this dispute. Those wishing to explore this debate should compare Laslett's introduction to the *Two Treatises on Government* with James Tully's *A Discourse on Property: John Locke and His Adversaries* (Cambridge: Cambridge University Press, 1980), pp. 3-34.

4.2 The Commons and the Right to Property

The literature on Locke's theory of property rights is vast and much of it recent. In addition to the standard commentaries, including Laslett's "Introduction" to the *Two Treatises of Government*; Lawrence Becker's chapter on Locke in *Property Rights: Philosophic Foundations*; Dunn's exploration in *The Political Thought of John Locke*; Nozick's treatment of Locke in *Anarchy, State and Utopia*;¹¹ Jeremy Waldron's examination in *The Right to Private Property*,¹² and Tully's *A Discourse on Property*; D. A. Lloyd Thomas,¹³ A. John Simmons,¹⁴ and Gopal Sreenivasan¹⁵ have made new contributions to the literature. It is unlikely that I will contribute, in the space of a chapter, any novel understanding of Locke's views. I will, however, be able to explicate Locke's general view of property rights and demonstrate how this has been applied to the discourse on patenting, particularly biopatenting. In the end, I will argue that Lockean property rights are insufficient to ground the contemporary convention of patenting of biological materials.

¹¹Robert Nozick, *Anarchy, State, and Utopia* (New York: Basic Books, 1974).

¹²Jeremy Waldron, *The Right to Private Property* (Oxford: Clarendon Press, 1988).

¹³D. A. Lloyd Thomas, *Locke on Government* (New York: Routledge Press, 1995).

¹⁴A. John Simmons, *The Lockean Theory of Rights* (Princeton, NJ: Princeton University Press, 1992).

¹⁵Gopal Sreenivasan, *The Limits of Lockean Property Rights* (New York: Oxford University Press, 1995).

In chapter five of the *Second Treatise* it is clearly Locke's intention to give an account of how persons may acquire individual property from that which belongs in common to all humanity. That is, Locke gives a justification for private property, defining how the property held in common among all persons may be privatized. At the outset of the chapter Locke says, "... I shall endeavour to shew, how Men might come to have a *property* in several parts of that which God gave to Mankind in common, and that without any express Compact of all the Commoners" (II, §25, 16-19).¹⁶ Or, as he puts it in the next section, "... all the Fruits [the Earth] naturally produces, and the Beasts it feeds, belong to Mankind in common ... and no body has originally a private Dominion ... yet ... there must of necessity be a means *to appropriate* them some way or other before they can be of any use, or at all beneficial to any particular Man" (II, §27, 3-12). Explaining his theory of acquisition is the goal of Locke's exposition.

This apparently simple goal is fraught with several hermeneutical difficulties for those who wish to understand Locke's view. The first problem is defining the nature of the original community which holds all things in common. Simmons suggests four possible interpretations of the original community in Locke: negative community, joint positive community, inclusive positive community, and divisible positive community. In a negative community, "all persons are at liberty (morally) to use the world and its products, but none has a protected liberty or exclusive right to anything (hence, there is no property,

¹⁶I shall follow the convention in which the first number refers to the book, the second to the section, and the third to the line in the Laslett edition of *Two Treatises of Government*. Unless otherwise specified I will retain the spelling and emphasis of the original.

which requires at least an inclusive right).¹⁷ If this were Locke's view then he would be saying that individuals do not really possess any property exclusively (no one owns anything), but only enjoy the liberty to *use* of the commons. This view seems to contradict what Locke himself avers when he states that "every Man has a *Property* in his own *Person*. This no Body has any Right to but himself. The *Labour* of his Body, and the *Work* of his Hands, we may say, are properly his" (II, §27, 1-4). So it seems that, for Locke, individuals have a positive right to property in their own bodies (or persons). Furthermore, Locke argues that whatever is taken from the commons and joined with a individual's labor may be said to be "his *Property*" (II, §27, 7). Finally, the very problem Locke wants to solve is the negative community interpretation of his opponents who have "a very great difficulty, how any one should ever come to have a *Property* in anything . . ." (II, §25, 9-10). The negative community view seems not to be what Locke had in mind.

The joint positive community perspective is the notion that "all persons jointly own the world, each holding an undivided proportional share (as instances of contemporary 'concurrent estate,' such as 'joint tenancy')." ¹⁸ On this view, there is no individual ownership of anything. Rather, this view represents a fairly straightforward form of communism in which everyone *qua* community owns everything.¹⁹ In joint positive

¹⁷Simmons, *The Lockean Theory of Rights*, p. 238.

¹⁸Simmons, *The Lockean Theory of Rights*, p. 238.

¹⁹Says Laslett, "Locke and his fellows were in some difficulty in accounting for the fact that this original communism had given way to private property. They could and did argue from occupancy, 'findings and keepings,' but in the end this must imply consent. In fact, as Filmer had argued with ingenuity and force, the only way out of original communism was to assume that in some way or other every individual in the world had

community, everyone has a right to use all resources in common with others, but no one could be excluded from the use of the items held in common. Again, this view violates Locke's principle of individuals having a property in themselves and their labor. On Locke's view property may be particularized.

Inclusive positive community entails that "each person holds an inclusive use right to the common; the common belongs to all only in the sense that each has a protected right (a claim right) to free use of the common for support and comfort."²⁰ Against the negative community idea, where no one has a protected liberty or exclusive right to anything, here each person may make a positive claim to use that which is common to all. That is to say, each individual is *entitled* to just the portion of the common necessary to sustenance and comfort. Tully argues that this view represents Locke's attempt to "redefine positive community."²¹ He characterizes Locke's notion of the commons in the following way:

Although the common belongs to everyone in the same manner, it belongs to them to use for the duty of acquiring the means necessary for support and comfort. Their inclusive rights refer to these means which are due to each. Thus, each right does not refer to every item on the common. Indeed, it does not refer to any item on the common but, rather, to items made from the common. 'Things necessary for support and comfort' is a natural definition of the share which ought to belong to each. Since each man has a right to his due share and no more, acquisition of it cannot be robbery.²²

consented to every act of property acquisition." Locke, *Two Treatises of Government*, p. 101.

²⁰Simmons, *The Lockean Theory of Rights*, p. 238.

²¹Tully, *A Discourse on Property*, p. 127.

²²*Ibid.*

This may well be Locke's position. It is consistent with what he says throughout the *Two Treatises*. A notable feature of the inclusive positive community perspective is that appropriation does not require the consent of the commoners. While the consent problem has engendered significant commentary,²³ nearly all agree that Locke does not hold that consent of the original community is requisite to appropriation of private property. He explicitly says that his project is to show how individuals come to acquire property from the commons, "and that without any express Compact of all the Commoners" (II, §25, 18-19). In fact, Locke himself argues fairly straightforwardly that were universal mutual consent required before one may take from the commons, "Man had starved, notwithstanding the Plenty God had given him" (II, §28, 15-16).²⁴

Nevertheless, Simmons believes the divisible positive community perspective is closer to Locke's own position. On the divisible positive community model "each person has a (claim) right to a share of the earth and its products equal to that of every other person. Each may take an equal share independent of the decisions of the other commoners . . ." ²⁵ Simmons interprets Locke's view to be that "mankind's common right is only a *power* to take property."²⁶ Individuals are born with a "right to property"

²³See Sreenivasan, *The Limits of Lockean Rights in Property*, pp. 24-28; Tully, *Discourse on Property*, pp. 128-130; Simmons, *The Lockean Theory of Rights*, pp. 222-225, and Waldron, *The Right to Private Property*, pp. 149-153.

²⁴In this respect Locke is no doubt arguing against Grotius and Pufendorf, both of whom maintained that the origin of property was generated by mutual consent or original compact. See Laslett's comments in *Two Treatises*, pp. 288, fn.

²⁵Simmons, *The Lockean Theory of Rights*, p. 238.

²⁶*Ibid.* Emphasis in the original.

because they are born with a property in themselves (i.e., in their bodies). Property rights to *this* or *that* particular arise only from labor or by right of transfer.

4.3 The Labor Theory of Property Acquisition

Once the common is established, Locke then addresses the means by which private property emerges. First, every individual has a property “in his own *Person*” (II, §26, 17). And what proceeds from the body, namely, “The Labour of his Body and the Work of his Hands” (II, §27, 3-4) belongs to the individual as her property. To illustrate this point, Locke uses a thought experiment (§28). Suppose a man picks up apples in woods which are part of the commons. The apples he appropriates are said to be his. The nourishment he receives from the apple is said to be his. “When did they begin to be his? When he digested? Or when he eat? Or when he boiled? Or when he brought them home? Or when he pickt them up?” (II, §28, 4-6). Locke’s reply is, “if the first gathering made them not his, nothing else could” (II, §28, 7-8). The labor is what distinguished the apples in the commons from the apples which became the private property of the picker. “That added something to them more than Nature, the common Mother of all, had done; and so they became his private right” (II, §28, 9-11). Locke follows this thought experiment with a series of additional examples which illuminates his argument (cf. §§29-30). Locke’s argument, then, is:

1. Every person has a property right in his or her body.²⁷

²⁷D. A. Lloyd Thomas points out that it is slightly inaccurate to state the case this baldly. In fact, Locke held that individuals are God’s property because God created them. “For Men being all the Workmanship of the one Omnipotent, and infinitely wise Maker;

2. The labor of the body is part of the body and is, therefore, an extension of one's property.
3. That from the commons upon which one exerts his or her labor becomes his or her private property.

So Locke says of hunting a hare, "whoever has imploy'd so much labour about any of that kind, as to find and pursue her, has thereby removed her from the state of Nature, wherein she was common, and hath *begun a Property*" (II, §30, 15-18). Mixing one's labor with something found in the commons thereby makes that thing one's private property. This has been called the labor-added, value-added, or labor-mixing theory of property.

Individuals may not take from the common indiscriminately or gluttonously.

Persons do not have title to unlimited individual appropriation. Property rights are limited by two provisos, the spoilage limitation and the sufficiency limitation.²⁸ The spoilage limitation entails that one may take only as much as one may make use of legitimately. "As much as any one can make use of to any advantage of life before it spoils; so much he may by labour fix a Property in. Whatever is beyond this, is more than his share, and belongs to others" (II, §31, 7-11). The sufficiency limitation entails that one leave as

All the Servants of one Sovereign Master, sent into the World by his order and about his business, they are his Property, whose Workmanship they are, made to last during his, not one anothers Pleasure" (*Two Treatises of Government*, II, §6, 10-14). Nevertheless, "as no other *persons* have the right to control us (except with our consent, and then only in particular respects and for a certain time), we might as well be said to own ourselves from the point of view of other human beings," says Thomas. *Locke on Government*, p. 107.

²⁸Tully calls these provisos "quantitative (enough) and qualitative (as good)," in his *A Discourse on Property Rights*, p. 129. I prefer the more descriptive terms used by Sreenivasan. See Sreenivasan, *The Limits of Lockean Rights in Property*, p. 34, and Nozick, *Anarchy, State, and Utopia*, p. 175ff.

much and as good in the common as that on which one has labored. "For this *Labour* being the unquestionable Property of the Labourer, no Man but he can have a right to what that is once joyned to, at least where there is enough, and as good left in common for others" (II, §27, 10-13). Nozick states that the sufficiency limitation "is meant to ensure that the situation of others is not worsened."²⁹ But this should not be taken in an altruistic sense. Instead, a very strong case may be made that the reason for the sufficiency proviso is because it is consistent with Locke's general theory of community and property. The divisible positive community perspective requires that each person have an equal claim on the common. If any one person takes too much of the common to herself, the claim of others is thereby violated. This claim is endemic to Locke's natural rights perspective. Thus we may add a fourth point to Locke's argument:

4. Property may be acquired as one wishes, as long as (1) no one takes more than he or she can use without spoilage and (2) as long as there is enough and as good for others.

4.4 Transfer of Property

For Locke, once property has been appropriated from the common by labor, there are a variety of legitimate means by which property may be transferred from one person to another. Simmons maintains, *contra* Tully, that there are at least four ways property may

²⁹Nozick, *Anarchy, State, and Utopia*, p. 175.

be transferred: inheritance, need, reparation for injuries, and alienation of property rights.³⁰

We shall see that the latter right, viz., to forfeiture, is not so clear. In his chapter on “Paternal Power” Locke says that the “Power Men generally have to *bestow their Estates* on those, who please them best” is constitutive of what he calls “*Paternal Jurisdiction*” (II, §72, 10-12). Locke continues, “The Possession of the Father being the Expectation and Inheritance of the Children ordinarily in certain proportions . . .” (II, §72, 12-13).

When treating the Monarchy in the First Treatise, Locke attests, “But if any one had began, and made himself a Property in any particular thing (which how he, or any one else, could do, shall be shewn in another place) that thing, that possession, if he dispos’d not otherwise of it by his positive Grant, descended Naturally to his Children, and they had a right to succeed to it, and possess it” (I, §87, 12-17). Then Locke imagines the question, “but why does the property not revert to the commons?” He suggest that some might answer that the property does not revert to the commons in virtue of the consent of the community (I, §88, 1-7). Locke does not, however, think consent properly answers the question. Rather, “if common tacit Consent hath establish’d it, it would make but a positive and not Natural Right of Children to Inherit the Goods of their Parents: But where the Practice is Universal, ’tis reasonable to think the Cause is Natural” (I, §88, 10-

³⁰In Chapter 6 of *A Discourse on Property*, Tully cites only “charity” and “inheritance” (in addition to labor, of course) as means of gaining natural title to individual property, relying on something Locke says in I, §42): “As *Justice* gives every Man a Title to the product of his honest Industry, and the fair Acquisitions of his Ancestors descended to him; so *Charity* gives every man a Title to so much out of another’s Plenty, as will keep him from extream want . . .” See Tully, pp. 131-135.

13). Thus, for Locke, inheritance is a natural right and a legitimate means of appropriating property.

Transfer of property may also be required and appropriated by need.

But we know God hath not left one Man so to the Mercy of another, that he may starve him if he please: God the Lord and Father of all, has given no one of his Children such a Property, in his peculiar Portion of the things of this World, but that he has given his needy Brother a Right to the Surplusage of his Goods; so that it cannot justly be denied him, when his pressing Wants call for it. . . . *Charity* gives every Man a Title to so much out of another's Plenty, as will keep him from extremum want, where he has no means to subsist otherwise (I, §42, 1-7).

Genuine need is a positive and natural right against which others have a corresponding duty to supply charity. This duty of charity is an extension of Locke's general theory of property since the putative purpose of property is to preserve oneself and others (II, §6).

Interestingly, Tully maintains that the natural right to charity is consistent with the fact that, on Locke's scheme, property may only be transferred by consent. Says Tully, "If a case of need arises then, *ipso facto*, one man's individual right is overridden by another's claim, and the goods become his property. By failing to hand over the goods, the proprietor invades the share now belonging to the needy and is liable to punishment."³¹

The need of one member of the community constitutes the consent of one who possesses property. If the proprietor does not exercise charity, she has violated the claim right of the poverty-stricken.

Transfer of property may also be required as reparation for injuries done to another. Under the rubric of "The Right to Punish," Locke avers that "he who has suffered the damage has a Right to demand in his own name, and he alone can *remit*: The

³¹Ibid., p. 132.

damnified Person has this Power of appropriating to himself, the Goods or Service of the Offender, by *Right of Self-Preservation* . . .” (II, §11, 10-13). We should note again that the right to reparation is ineluctably connected to the more general right to self-preservation.

Finally, Simmons argues that property may also be transferred legitimately through forfeiture, that is, by free gift, sale, or trade. While a father may not, according to Locke, “give away the liberty of the Son,” the father may, of his own estate, “dispose or settle it as he pleases” (II, §116, 18-25). The gift of inheritance to a child is a sub-category of the alienability of property. Simmons states that “alienation of property rights (by gift, sale or trade, for example) can also give subsequent title to what was first acquired by labor.”³² This interpretation of Locke is not without problems, however.

In an extended discussion, Sreenivasan opines that the right of bequest should not be understood to be consistent with Lockean property rights.³³ The general theory of property transfer includes the idea that the present owner of a property has a right to transfer that property and that the potential owner of the property has a right to receive that property. Both of these rights must remain intact if property is to be transferrable according to Sreenivasan. “A’s giving a gift to B is as much a case of B’s acquiring a property as it is one of A’s relinquishing one.”³⁴ A’s right to transfer property, then, is correlated to B’s right to acquire property. If and only if B has a right to acquire property

³²Simmons, *The Lockean Theory of Rights*, p. 225.

³³Gopal Sreenivasan, *The Limits of Lockean Rights in Property*, pp. 106-110.

³⁴*Ibid.*, p. 108.

does A have a right to transfer property to B. On the Lockean formulation, however, labor alone entitles one to acquire private property (except in cases of need or through inheritance). So, free gifts are not a legitimate means of transfer.

With gifts and bequests, however, it is difficult to imagine on what the potential owner's right of acquisition might be grounded. There does not seem to be any sense in which labour could so entitle her, for these are cases of unilateral transfer. Nor can recourse be made to the rights of charity or maintenance as alternative grounds, for these actually entitle their bearer to much more than a right of acquisition subject to the consent of the previous owner. As we have seen, the title to subsistence which dependent children and the disabled needy possess in virtue of these rights is enforceable against the surplus holdings of property owners, who have no right to refuse it. It would thus be misleading to describe this sort of transfer as a gift or bequest.³⁵

Since the right to acquire a gift is not consistent with Lockean property rights, Sreenivasan concludes that the right to transfer property via a gift is not consistent with those rights. "Hence, the rights of gift and bequest are not permissible incidents of Lockean ownership."³⁶

The right to transfer property by sale or trade is more clearly stated by Locke. Accordingly, "No Mans Labour could subdue, or appropriate all: nor could this Enjoyment consume more than a small part; so that it was impossible for any Man, this way, to intrench upon the right of another, or acquire to himself, a Property, to the Prejudice of his Neighbor, who would still have room, for as good, and as large a Possession (after the other had taken out his) as before it was appropriated" (II, §36, 1-8). The limits of labor, the abundance of goods (in this case land), and the spoilage limitation

³⁵Ibid., p. 110.

³⁶Ibid.

entail that, in the original commons, there is more than enough for all. In the "first Ages of the World" individuals were "more in danger to be lost . . . than to be straitned for want of room to plant in" (II, §36, 11-14).³⁷ Nevertheless, "the *Invention of Money*, and the tacit Agreement of Men to put a value on it, introduced (by Consent) larger Possessions, and a Right to them" (II, §36, 36-39). Money was invented, according to Locke, to accommodate the desire of individuals to possess more than they need (II, §37, 1-3). Thus, money makes possible, through mutual consent, the "disproportionate and unequal Possession of the Earth" (II, §50, 5), a method of transfer which Locke grudgingly allows.

4.5 The Mixing Argument

Labor, according to Locke, gives one title to property. This notion is established on at least three grounds. First, labor represents pain (which I take to mean something like "work," "effort," or even "activity").³⁸ So, Locke says, "Before the Appropriation of Land, he who gathered as much of the wild Fruit, killed, caught, or tamed, as many of the Beasts as he could; he that so employed his Pains about any of the spontaneous Products of Nature, as any way to alter them, from the state which Nature put them in, by placing

³⁷Interestingly, Locke judges that "there is Land enough in the World to suffice double the Inhabitants" (II, §36, 36-37) had not money been invented. On what basis such a judgment is made, viz., that there was double the land necessary for the inhabitants of the earth, we are not told.

³⁸Simmons argues persuasively that "labor" entails "a kind of purposive activity aimed at satisfying needs or supplying the conveniences of life." Simmons, *The Lockean Theory of Rights*, p. 273. Waldron, however, challenges the entire Lockean labor mixing argument as incoherent. How does labor "join," "mix," or "annex" itself to anything? Waldron claims that Locke has made a category mistake which is devastating to his general argument. Cf. Waldon, *The Right to Private Property*, 184-191.

any of his Labour on them, did thereby *acquire a Propriety in them*" (II, §37, 30-35).

The sheer effort required to acquire property through labor warrants appropriation as a form of just desert. Second, and perhaps more importantly, labor is an extension of one's property rights in one's body. Locke uses vivid language to describe the means of "annexing" something to one's property in himself. "He that . . . subdued, tilled and sowed any part of [the commons] thereby annexed to it something that was his *Property*, which another had no Title to, nor could without injury be taken from him" (II, §32, 15-18). "For this *Labour* being the unquestionable Property of the Labourer, no Man but he can have a right to what that is once joyned to" (II, §27, 10-12). Third, labor implies improvement. "The *labour* that was mine, removing them out of that common state they were in, hath *fixed my Property* in them" (II, §28, 24-26). This "common state" is not only the state of the commons, but the state of the unimproved commons. Locke makes a rather elaborate argument to demonstrate that labor improves the commons. "For 'tis *Labour* indeed that *puts the difference of value* on everything; and let any one consider, what the difference is between an Acre of Land planted with Tobacco, or Sugar, sown with Wheat or Barley; and an Acre of the same Land lying in common, without any Husbandry upon it, and he will find, that the improvement of *labour makes* the far greater part of the *value*" (II, §40, 3-9).

It is still unclear exactly how mixing one's labor with some item in the commons warrants a right to property in that item. In fact, the question itself has several species, depending on where one puts the emphasis. First, *how* is it that mixing one's labor with some item warrants a property right in that item? Second, how is it that mixing one's

labor with some item warrants a property right *in that item*? We shall take the latter question first.

Why is it that mixing one's labor with some item in the commons warrants a property in that particular item and not another? Why not a property right in something relevantly equal in value to the item mixed with labor? Why that particular item? The answer would seem to be that labor makes items useful and apart from the labor they are unusable. When Locke computes the value of the improved commons, he concludes that labor is the primary constituent of value. "I think it will be but a very modest Computation to say, that of the *Products* of the Earth useful to the Life of Man 9/10 are the *effects of labour*: nay, if we rightly estimate things as they come to our use, and cast up the several Expences about them, what in this is purely owing to *Nature*, and what to labour, we shall find, that in most of them 99/100 are wholly to be put on the account of *labour*" (II, §40, 9-15). The "improvement" which is the result of labor is the usefulness an item from the commons obtains when mixed with labor. "For whatever *Bread* is more than Acorns, *Wine* more than Water, and *Cloth* or *Silk* than Leaves, Skins, or Moss, that is wholly *owing to labour* or industry" (II, §42, 8-10). The laborer has, therefore, made an improvement to the goods in the commons. Furthermore, since there are no other improved goods lying around other than those which have already been the object of labor and therefore belong to the laborer, what would be the reward to the laborer if not the goods which is or she has improved?³⁹ Hence, the laborer has a property in the item

³⁹See Simmons, *The Lockean Theory of Rights*, p. 248.

which has been improved just because (1) she was the one who improved the item and (2) there are no other items by which to reward labor than those which she has improved.

Why is it that mixing one's labor with some item in the commons warrants property in that item? Of this question Robert Nozick famously asks, "Why isn't mixing what I own (viz., my own labor) with what I don't own a way of losing what I own rather than a way of gaining what I don't?"⁴⁰ To borrow Nozick's thought experiment, if one owns a can of tomato juice and pours it into the sea, thereby mixing one's labor with the sea, does one come to own the sea, or has one "foolishly dissipated" her tomato juice?⁴¹

There are at least two reasons why mixing labor with the sea does not warrant a property right to the entire thing. First, the Lockean spoilage proviso and the sufficiency proviso limit ownership of the sea. One may own a part of the sea, in a bucket or in a bay, but only as much as one may make use of without spoilage and as long as one leaves enough and as good for others. Second, it is unclear what improvement would be made or what value would be added by pouring one's tomato juice in the sea. Locke's theory requires that something which was previously unimproved or unusable be improved or be made useable by one's labor if property rights are to obtain.

4.6 Are Lockean Property Rights Right?

Having provided a rudimentary exposition of Lockean property rights, it is now appropriate to ask whether Lockean property rights are right. That is, do Locke's notions

⁴⁰Nozick, *Anarchy, State, and Utopia*, p. 175 (parenthesis added).

⁴¹*Ibid.*

do the work he hopes they do and, furthermore, do Lockean property rights provide a sufficient grounding for property rights in biological materials? Since Lockean notions are appealed to in the system of property rights embedded in patent law, if Lockean principles are substantively challengeable, patent law should search for other foundations on which to erect a system of exclusive right to property.

Quite apart from questioning the entire schema of natural rights,⁴² there are several points at which Lockean property rights are challengeable. Simmons examines six critiques of Lockean property rights, each with a rejoinder.

(1) "The idea of the mixing of labour is fundamentally incoherent"; some sort of category mistake is involved in speaking of literally mixing one's labor with an object. Actions (labor) cannot be mixed with objects.

(2) "Why isn't mixing what I own [my labor] with what I don't own a way of losing what I own rather than a way of gaining what I don't?" Locke cannot just assume that ownership of our labor continues after we employ that labor. Mightn't our property in it simply end once with use it? . . .

(3) Why shouldn't the *second* labor on an object ground property in it as reliably as the *first* labor? Locke seems to limit property to the first laborer, but subsequent laborers on the same object may labor more or more productively than the first. . . .

(4) Why should mixing one's labor with an object be thought to give one *full* ownership of the object (including the rights to exclude and alienate, say), rather than some more limited rights over the object (e.g., just a right of usufruct)? If others are also denied full title to the object, the laborer's labor will not be "taken" or given to another as a "right" or "title" (II, 27,32).

(5) Locke's mixing argument also faces what we can call the "boundary problem." It is not obvious that labor can ground a clear right to *anything* if it is not possible

⁴²For a classic critique of natural rights, see H. L. A. Hart, "Are There Any Natural Rights?" in David Lyons (ed.), *Rights* (Belmont, CA: Wadsworth Publishing Company, 1979, pp. 14-25.

to specify the boundaries of what is acquired by labor. But exactly what does labor get mixed with when one labors on what is common? . . .

(6) Locke himself uses examples (e.g., in II, 43) that point to the social nature of production. But if the skills, tools, or inventions (etc.) That are used in laboring are not simply the product of the individual's effort, but are instead the product of a culture or a society, should not the group have some claim on what individual laborers produce. For the labor the individual invests includes the prior labor of many others.⁴³

I will grant, *argumendum*, that Simmons solves successfully the difficulties of each of the traditional arguments against Lockean property rights. There are, nevertheless, at least two problems which seem beyond the ability to resolve so neatly. First, Becker raises the issue of "transfer" of property rights to one's body to "property in the products of one's labor."⁴⁴ Recall that Locke's argument is that (1) everyone has a property right in her own body, (2) the labor of one's body is part of the body, therefore, (3) mixing one's labor with the commons yields a right to the product of one's labor. So, property extends or is transferred from the body to one's activity (labor) and from one's labor to the object of labor. As Becker observes, it is relatively easy to understand how the first extension is warranted. One's labor is, by definition, inseparable from one's body. But the second extension—"from ownership of the labor to ownership of labor's products"—seems unwarranted since the products of labor are clearly separable from the body. The locution

⁴³Simmons, *The Lockean Theory of Rights*, pp. 267-269.

⁴⁴Becker, *Property Rights*, p. 40.

“it is mine” is appropriate of one’s labor, but not necessarily (logically) of the products of one’s labor. Thus, the second extension is problematic.⁴⁵

Becker does not think Lockean property rights theorists can extricate themselves from this dilemma.

What reason is there to conclude that this altered relationship constitutes, or warrants, or gives any support at all to the claim that you have ownership rights in the thing? Why does it not just mean that you are entitled to public admiration? Or the gratitude of your fellows? Or perhaps nothing more than the appropriate change in the great book which describes the world? It is labor theorists who are making the assertion here—that changes produced by their labors entitle them to property rights. The burden of proof is on them to show how it is so, and they have not done so. I see no reason to think that they can.⁴⁶

The upshot of this challenge is to demonstrate that in some cases property is clearly warranted by one’s labor, but in other cases it is not. Sometimes property is warranted and sometimes “recognition, admiration, or gratitude of other people”⁴⁷ is warranted. Laborers may deserve something, be it a fee or an award, for their labor, but not necessarily a property right.

A second challenge to Locke’s theory is directed at the assumption that the unimproved commons are “useless” or “waste” (II, §37, 16; §42, 19; *et passim*). Even if we agree that Locke is being hyperbolic here (after all, he does say in §40 that nature

⁴⁵Thomas says, in fact, that the extension results in an absurdity. “On Locke’s view your bodily secretions are part of you (and hence yours in the ownership sense) before they leave your body. But it is absurd to suppose that if they leave your body and mingle with the earth which is still in common, then that which is in common becomes yours. You do not own the sod on which you shed a tear.” D. A. Lloyd Thomas, *Locke on Government*, p. 108.

⁴⁶Becker, *Property Rights*, p. 40.

⁴⁷*Ibid.*, p. 47.

produces *some* value, even if it is as little as 1/100th of the part that labor adds), he still seems not only to understate the case greatly, but seems to be just wrong. Recent environmental and animal rights ethics repudiate such a diminished view of the value of the natural order. First, he is mistaken in the anthropocentric bias of his argument. For Locke claims that “the intrinsic value of things . . . depends only on their usefulness to the Life of Man” (II, §37, 2-4). Anthropocentrism, it may be argued, is the legacy of the Enlightenment, of which Locke was one of the chief architects.

Second, though Locke may not be blamed for his naiveté at this point, he nevertheless ignores the interconnectedness of the commons, or at least the biological commons. Today we recognize that we are living in a biosystem or ecosystem and that the living things of the earth are not disposable commodities. This is not a trivial challenge to Lockean property rights, especially when applied to biotechnology.

A final challenge to Lockean property rights is that identification of what constitutes the commons is problematic from the Lockean perspective. When applying Lockean property rights theory, the first step must be to identify the commons. In the case of previously unowned land, the commons seem identifiable enough. In what we might call the “primitive” state, all vacant and unused land is part of the common. Individual labor on the land or in the items of the land (e.g., herbs, nuts, berries, and animals), creates a property right in the land (or in those items of the land). Appropriation of the commons continues without consent. Says Locke of this primitive condition, “there could be no doubt of Right, no room for quarrel” (II, §39, 7).

Likewise, Locke asserts that in his own day any one could appropriate land in America without the consent of others:

For supposing a Man, or Family, in the state they were, at first peopling the World of the children of *Adam*, or *Noah*; let him plant in some in-land, vacant places of *America*, we shall find that the Possessions he could make himself upon the *measures* we have given, would not be very large, nor, even to this day, prejudice the rest of Mankind, or give them reason to complain, or think themselves injured by this Man's Incroachment, though the Race of Men have now spread themselves to all the corners of the World, and do infinitely exceed the small number [which] was at the beginning (II, §36, 16-25).

In fact, however, we know that most of America was not unused or uninhabited at the time Locke wrote. Like many of his contemporaries, Locke found no difficulty arguing that the Native Americans living on the land at the time he penned the *Two Treatises* were not legitimate property owners. In a recent work,⁴⁸ James Tully describes the justification for "taking" from the American commons. First, settlement and defense were warrants for European appropriation of property. By charter, European international law, permitted the settlement of the primitive land of America.⁴⁹ Second, justification for taking aboriginal America required that Europe "ignore the Amerindians and . . . characterize America as terra nullius, a vacant land (a condition the principle of occupation and long usage requires)."⁵⁰ Third, Europe had to "downgrade the status of the aboriginal peoples to that of beasts or savages so no juridical recognition was

⁴⁸James Tully, *An Approach to Political Philosophy: Locke in Contexts* (Cambridge: Cambridge University Press, 1993).

⁴⁹*Ibid.*, p. 147.

⁵⁰*Ibid.*

required.”⁵¹ Locke provided an argument for disregarding Native American property rights and, therefore, viewing America as a *vacuum domicilium*. Others, like Roger Williams, were quick to point out that Native Americans had met the prerequisites for having property rights in the land.

Williams argued that hunting and land-clearing certainly constitute use and occupation and, therefore, Amerindians have title to their traditional lands: they ‘hunted all the Country over’, he wrote, ‘and for the expedition of their hunting voyages, they burnt up all underwoods in the countrey, once or twice a yeare’.⁵²

The point I wish to make here, following Tully, is that even in the case of property in the form of land, it is not always so easy to identify the commons. Further, very different intuitions and political theories inform this identification. Native Americans, no doubt had very different notions about the land and property. Tully reminds us that for many native peoples, the land “is inalienable and the identity of the nation as a distinct people is inseparable from their relation to and use of the land, animals, and entire ecosystem. Although the land belongs to them, it is more accurate to say, as the Inuit stress, that they belong to the land.”⁵³ Lockean theory does not account for these notions of property.

When it comes to applying Lockean property rights to the commons in biotechnology, the problem of identification is encountered with a vengeance. Just what constitutes the commons from which biotechnology may appropriate legitimately? As we

⁵¹Ibid.

⁵²Cited in Tully, Ibid., p. 150.

⁵³Ibid., pp. 153-154.

have seen, the position of the U. S. Patent and Trademark Office is that the statutory subject matter of patents (read “intellectual property rights”) includes “anything under the sun that is made by man” including “nonnaturally occurring nonhuman multicellular living organisms, including animals.”⁵⁴ In addition, human cell lines, as in the case of John Moore, are patentable. No one yet knows what the Patent Office’s final position will be on ESTs and the cell lines of indigenous people groups. Are these biological materials, prior to the addition of labor, part of the commons? Or, are they preowned in some way? Or, do they constitute the common heritage of humankind in such a way that they may not be forfeited legitimately by any property regime?

Moreover, in this section, I argued that Lockean property rights were insufficient for grounding exclusive rights to all property. It is unclear why, for instance, laborers who make “improvements” to the commons should not receive praise instead of property rights. Further, the commons are not common in the Lockean sense. That is, it has not been shown that the unaltered materials of biology should be deemed of no use or waste. In fact, a strong case is being made that altering the ecosystem is what is destructive and wasteful, not lack of ownership. Now, the fact that the items in the biological commons are part of a larger system does not by itself argue that they may not be altered. Nevertheless, the fact that they may not be understood accurately as “waste” or “unused” mitigates against Lockean property rights in those items. Thus, any appeal to Lockean property rights as a sufficient foundation for biopatents seems doomed.

⁵⁴Donald J. Quigg, “PTO Policy on Patenting of Animals,” U.S. Patent and Trademark Office, 7 April 1987.

4.7 Alternative Grounds for Property Rights in Biopatents

Rather than appealing to Lockean property rights theory as a justification for patenting biological materials, it is more likely that patent law relies on utilitarian concerns for its justificatory grounds. Instead of relying on so-called backward-looking views of property (as with Lockean desert notions), patent law in the American context, especially since *Diamond v. Chakrabarty*, has rested on a forward-looking defense of property rights. Arthur Kuflik, Associate Professor of Philosophy at the University of Vermont, has argued: "The most plausible argument for the special authority that is vested in patent holders turns on the long-term effects of the patent system on research and development efforts."⁵⁵ We may recall from Chapter 2 that Article I, Section 8 of the U. S. Constitution says that Congress has been given authority "... [t]o promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." This article does not ground property rights to writings and discoveries in a theory of natural rights. Instead, a limited property right is granted with a view toward encouraging invention (i.e., to promote progress in science and the arts). This point is underscored by the Supreme Court in *Graham v. John Deere Co.*:

The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society—at odds with the inherent free nature of disclosed ideas—and was not to be freely given. Only inventions and discoveries which furthered human

⁵⁵Arthur Kuflik, "Moral Foundations of Intellectual Property Rights," in Vivian Weil and John W. Snapper (eds.), *Owning Scientific and Technical Information: Value and Ethical Issues* (New Brunswick, NJ: Rutgers University Press, 1989), p. 228.

knowledge, and were new and useful, justified the special inducement of a limited private monopoly.⁵⁶

Legal analyst David Korn concurs with this understanding of patent law. Says Korn, "The patent system is the main legal tool Congress has created for promoting innovation in the technological sciences."⁵⁷ The patent system encourages invention in two ways, argues Korn. First, it serves as an "inducement" for inventors to market their products. Second, through the disclosure requirement, patents relieve fear of commercial competition while at the same time making information available to the scientific community.

Nevertheless, others expand the goals of forward-looking property rights embedded in the patenting system beyond simply encouraging invention and disclosing information. At a conference on intellectual property convened by the National Science Foundation in 1985, participants were divided on what they saw as the ends for which intellectual property rights exist. Gerald Dworkin, reflecting on the papers delivered at the conference, suggests "that technological innovation is only one possible end in which

⁵⁶*Graham v. John Deere Co.*, 383 U. S. 1,9 (1966), cited in Kuflik, *Ibid.*, p. 229.

⁵⁷David E. Korn, "Patent and Trade Secret Protection in University-Industry Research Relationships in Biotechnology," *Harvard Journal on Legislation* 24 (Winter 1987), p. 209. See also Rebecca Dresser, "Ethical and Legal Issues in Patenting New Animal Life," *Jurimetrics Journal* (Summer 1988), p. 403, where Dresser says, "By granting inventors a limited monopoly on the patented invention, the law creates an economic incentive for inventors and their employers to bear the financial risks entailed in developing and commercializing an invention. The incentive, it is hoped, will ultimately benefit the public by stimulating advancements in knowledge and technology that would otherwise be delayed or never occur."

people are interested.”⁵⁸ Other goals of patenting include: (1) more money for universities, (2) improvements in public health, (3) securing openness of communication within the scientific community, (4) preserving the values of the academy, (5) maximizing wealth, (6) keeping options open, (7) strengthening the public sector, (8) promoting a sense of social responsibility among scientists for the consequences of their research, (9) ensuring quality control for new products, particularly drugs, and (10) supporting the development of an information society.⁵⁹

While many of these issues will be dealt with in later chapters, the important point to note now is that, at least in U.S. patent law, private property is not predicated on natural rights theory, but on the encouragement of invention, the dissemination of knowledge, and notions of the public good.

⁵⁸Gerald Dworkin, “Commentary: Legal and Ethical Issues,” in Weil and Snapper, *Owning Scientific and Technical Information*, p. 251.

⁵⁹*Ibid.*, pp. 251-252.

CHAPTER 5

ARGUMENTS FOR AND AGAINST PATENTING LIVING ORGANISMS

5.1 The Debate Over Biopatents

As we have already seen, the debate over patenting biological materials, especially the patenting of animals and human cells, has been anything but sedate. That biotechnology is controversial is a commonplace. As the industry continues to expand into the twenty-first century, there is every reason to believe that the arguments for and against biopatents will be rejoined. Having traversed some of the legal terrain, it is important to analyze the philosophical arguments provided both to support and oppose "the patenting of life." The purpose of this chapter is to examine, as comprehensively as possible, the justification for and against biopatents.

I will trace the arguments cited by the Office of Technology Assessment in two of its reports. These arguments are the most common in the biopatenting debate. Next I will rehearse the arguments offered by others who have addressed the controversy, including one who appeals to a form of intuitionism (Kass) and one who appeals to a form of environmental ethic or biocentrism (Hettinger). I will also discuss the Constitutional prohibition against owning persons and the way it might be understood in order to permit patenting human beings. Finally, I will suggest that the arguments for biopatents essentially fall into two traditional categories: utilitarian arguments and nonutilitarian arguments. Since we are a society of moral strangers, I will argue that we must look beyond these ethical theories for a resolution to the patenting debate.

5.2 Biopatents and the Role of the Office of Technology Assessment

Fortunately, helpful sources exist for these arguments in the reports from the Congressional Office of Technology Assessment (OTA). The OTA had its genesis in 1972 through The Technology Assessment Act.¹ Established by the U. S. Congress, the OTA was assigned the responsibility of being “an aid in the identification and consideration of existing and probable impacts of technological application.”² In accordance with its function the OTA was to:

1. identify existing or probable impacts of technology or technological programs;
2. where possible, ascertain cause-and-effect relationships;
3. identify alternative technological methods for implementing specific programs;
4. identify alternative programs for achieving requisite goals;
5. make estimates and comparisons of the impacts of alternative methods and programs;
6. present findings of completed analyses to the appropriate legislative authorities;
7. identify areas where additional research or data collection is required to provide adequate support for the assessments and estimates described in paragraph (1) through (5) of this subsection; and
8. undertake such additional associated activities as the appropriate authorities specified under subsection (d) may direct.³

Over a period of twenty-three years the OTA produced hundreds of reports on topics as diverse as mass transit, offshore energy systems, computerized tomography, solar technology, disaster assistance, and the whole range of biotechnology. In 1995

¹Public Law 92-484, 92d Congress, H.R. 10243, October 13, 1972.

²Ibid.

³Ibid.

alone the OTA produced well over fifty reports for Congress.⁴ Due to budget cuts the OTA was defunded in 1995 and closed its doors on September 30th of that year.

Though there were over 200 persons employed by OTA, much of its research work was performed by outside contractors, individuals who were recognized as having expertise in the areas under examination. The OTA also held workshops and convened panels to discuss the items under review for a particular report. In addition, the OTA worked with other congressional agencies, including the Congressional Budget Office, the Congressional Research Service of the Library of Congress, and the General Accounting Office.

Several OTA reports touched on issues related to intellectual property and biotechnology. Two reports are especially *apropos* to the subject of biopatents: *New Developments in Biotechnology: Patenting Life—Special Report*⁵ and *New Developments of Biotechnology: Ownership of Human Tissues and Cells—Special Report*.⁶ As the debate heated up over the patenting of DNA sequences, the OTA also began work on a

⁴The entire corpus of the Office of Technology Assessment is now available on CD-ROM. The set of five CDS contains all of the formal reports and many of the background and contractor papers. This library contains over 100,000 pages of material. *OTA Legacy*, Stock Number 052-003-01457-2 (Washington, DC: Government Printing Office).

⁵U. S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Patenting Life—Special Report*, OTA-BA-370 (Washington, DC: U.S. Government Printing Office, April 1989). Hereafter *Patenting Life*.

⁶U. S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells—Special Report*, OTA-BA-337 (Washington, DC: U.S. Government Printing Office, March 1987). Hereafter, *Ownership of Human Tissues and Cells*.

report which was never published. While the entire document is not available, the section dealing with "Ethical Considerations" of *The Human Genome Project and Patenting DNA Sequences* includes helpful information for analyzing the direction of the proposed OTA report.⁷ Taken together, these sources contain a veritable catalog of the arguments for and against biopatents.

5.3 Patenting Animals

The 1989 report of the OTA, *New Developments in Biotechnology: Patenting Life—Special Report*, focuses specifically on the question of whether or not transgenic animals should be patented. The report acknowledges that "The ability to patent animals introduces a new legal conception in the notion of ownership of animals—a limited, exclusive, intangible property right—that did not exist previously."⁸ At the same time the chapter on "Ethical Considerations" is predicated on the premise that there are not only legal issues, but also moral concerns to be adjudicated. There is a symmetry about the chapter in that it presents five arguments *for* patenting transgenic animals and five arguments *against* patenting transgenic animals. Below is a summary of those arguments.

The arguments for patenting animals revolve around pragmatic concerns which, it is observed, may be rooted in consequentialist moral theory. The first argument is that patent law regulates inventiveness, not commercial uses of patented materials. As we

⁷While the entire report was never published, I have obtained the section dealing with the ethical issues on the subject. Draft of Chapter 4, "Ethical Considerations," *The Human Genome Project and Patenting DNA Sequences* (April 1994).

⁸*Patenting Life*, p. 127.

have noted previously, patents were inaugurated in the U. S. Constitution "to Promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."⁹ That is, the purpose of granting patents was to encourage inventiveness. Inventiveness, it is implied, requires that inventors be able to secure limited, exclusionary property rights in the objects of their invention. Furthermore, the OTA report observes that there is no provision in patent law for questioning the ethical appropriateness or inappropriateness of a given invention, except for the very narrow restrictions of the Inventions Secrecy Act¹⁰ which disallows patents on any invention which could be shown to be a threat to national security.

The second argument favoring patenting of transgenic animals is that patenting promotes useful consequences. Again, the most apparent fact about this argument is its indebtedness to consequentialist/pragmatic concerns. The report acknowledges that,

By their nature, consequentialist arguments provide greater or lesser support for a social policy depending upon the probability of the outcome (the higher the probability, the stronger the support) and upon the perceived desirability of the outcome (the more desirable the outcome, the stronger the support). This feature makes their support difficult to assess in particular cases, since it is often difficult to predict how desirable the outcomes will be and how likely they are to occur.¹¹

In the third place, proponents of patenting argue that patenting is necessary to assure U.S. competitiveness in the global marketplace. Clearly, biotechnology is a global

⁹U. S. Constitution, Art. I, §8, clause 8.

¹⁰35 U.S.C. 181-188.

¹¹*Patenting Life*, p. 128.

enterprise, Japan being the United States's chief competitor. Fourth, some who support biopatents point to the desirability and social utility of patents over trade secrecy. Since patents require disclosure, it is argued that patents perform a critical function in making information available to those who are doing research in biotechnology. If the only alternative to patenting is trade secrecy, dissemination of knowledge would be severely limited if not entirely terminated.

Finally, supporters of patenting biological materials argue that patenting rewards innovation and entrepreneurship. This argument combines both a consequentialist and nonconsequentialist premise. The former sees patents as a contract between the inventor and the government. The reward of a patent is a *quid pro quo* for disclosing the patent holder's invention. The latter sees patents as a reward for labor and is a form of the desert argument (see next chapter).

Opposition to "patenting life" is rooted in five arguments, according to the OTA report. First, there are metaphysical and theological arguments against patenting animals. Some religious opponents to biopatents see the Patent and Trademark Office's decision to patent animals as "compositions of matter" as an untenable form of philosophical materialism which is neither consistent with the nature of living things nor with religious dogma. Transgenic manipulation and, *mutatis mutanda*, patenting is especially problematic for some religious persons and groups. Mixing animal and human genes violates what the OTA report calls "the sanctity of human worth"—"a fundamental moral

principle of society, standing behind society's beliefs, for example, that humans cannot be killed or mistreated and are entitled to freedom from enslavement."¹²

Another important metaphysical/philosophical issue addressed by the OTA report is human responsibility toward nature and, especially, the importance of protecting species integrity. Those who oppose patenting sometimes argue that humans are stewards over the natural order and that conservation of nature, not re-engineering nature, is consistent with that stewardship responsibility.

The second set of arguments offered against animal patenting in the OTA report involves the potential of animal harms. Three arguments are set forth in this section of the report: (1) developing transgenic animals, encouraged by patenting, will lead to more animal suffering than changes produced through selective breeding and crossbreeding; (2) patenting reflects an inappropriate sense of human control over animal life and an underestimation of the value of nonhuman life; and (3) patenting animal life is the first step towards a decline in the belief in the sanctity and dignity of human life.¹³ Each of these arguments are based on the larger issues at stake in the animal rights debate.

Opposition to patenting based on international concerns forms the third set of arguments traced by the OTA report. First, it is observed that "most countries in the developed world do not permit animal patents, especially members of the European Patent Convention."¹⁴ While efforts are under way to address patenting in the global context, it

¹²Ibid., p. 132.

¹³Ibid., pp. 133-135.

¹⁴Ibid., p. 135.

is unlikely that there will be universal acceptance of the practice. Yet as the OTA report acknowledges, cultural uniformity has never been a sufficient test for moral acceptability of a practice. Second, opponents of animal patents point to the potential adverse economic implications for Third World countries. Social justice issues are at stake in this argument. Will underdeveloped countries have access to biotechnology? What will be the health-related costs to those who cannot afford that technology? Also, does patenting encourage "imperialistic exploitation" of the less developed countries since many of the potentially patentable resources exist in the poorer Southern Hemisphere?

The environmental impact of patenting forms the fourth reason opponents disfavor patenting animals. These concerns include not only the potential risks which attend the release of transgenic animals into the environment, but also the threat to genetic diversity posed by transgenic science encouraged by patenting.

Finally, opposition to biopatents is grounded in the ways patenting might burden American agriculture. Specifically, opponents of patenting argue that animal patents will result in increased consumer costs as producers are forced to pay royalties to owners of animal patents. Owners of small farms might be disproportionately affected by these increased costs. Furthermore, as patented animals reproduce, patent holders will reap unfair benefits from farmers who must pay royalties on succeeding generations of patented animals.

The concluding summary of the OTA report does not offer to resolve the debate. The report does point out that consequentialist arguments are testable by empirical data (e.g., whether patenting results in harms to animals). Nevertheless, since such data are

unavailable, "these consequentialist arguments are speculative."¹⁵ The report also observes that many of the arguments for and against animal patents depend on presuppositions regarding animal rights, social justice, and environmental ethics.

In keeping with its assignment as an advisory agency to Congress, the Office of Technology Assessment rarely, if ever, offered specific recommendations. On the matter of patenting transgenic animals, the OTA suggested a series of eleven options revolving around three specific issues: (1) should the patenting of animals be permitted by the Federal Government?; (2) is the current statutory framework of intellectual property protection for plants appropriate?; and (3) is the current system of patent enablement adequate for biological material?¹⁶ The options included taking no action, enacting a moratorium on animal patents, amending patent law, and enacting a legal prohibition against animal patenting. To date, Congress has opted to take no action on the patenting of transgenic animals.

5.4 Patenting Human DNA Sequences

In 1994 the Office of Technology Assessment reviewed the text of a report entitled, *The Human Genome Project and Patenting DNA Sequences*.¹⁷ Though this report was never published because the OTA was cut from the Congressional budget,

¹⁵Ibid., p. 137.

¹⁶Ibid., pp. 22-26.

¹⁷Draft report, *The Human Genome Project and Patenting DNA Sequences* (April 11, 1994). Hereafter *Patenting DNA Sequences*.

portions of the text are available. Since the report was never printed, the exact language of the report remains unknown. It is safe to say, however, that the chapter on the "ethical considerations" was in near final form by April 1994. The author of the draft was Baruch Brody of the Baylor College of Medicine in Houston, Texas, who also had served as a contractor for the *Patenting Life* project.¹⁸ Brody's analysis of the ethics of patenting transgenic animals appeared in a number of sources prior to and following the demise of the Office of Technology Assessment.¹⁹ This chapter of the report no doubt grew out of his contract document, "Ethical Considerations in Patenting Human DNA Sequences," prepared for the OTA.²⁰

The impetus behind the 1994 study was the National Institutes of Health's effort to patent expressed sequence tags or ESTs (see Chapter 3), an action which continues to elicit debate. The report attempts to examine even larger questions than merely those involving ESTs. Is it appropriate to patent human DNA sequences if they are viewed as part of humanity's common heritage and so should be in society's custody? Is patenting human DNA sequences compatible with respect for the dignity of human beings and human life? Will patents unfairly affect research and commercial efforts in developing

¹⁸Per private conversation with Dr. Brody at the Hastings Center.

¹⁹Cf. Baruch Brody, "An Evaluation of the Ethical Arguments Commonly Raised Against the Patenting of Transgenic Animals," in Lesser (ed.), *Animal Patents: The Legal, Economic, and Social Issues* (New York: Stockton Press, 1989), pp. 141-153; and "Should We Allow The Patenting of Life?" *Ag Bioethics Forum* 3 (August 1991), p. 4.

²⁰Brody himself cites this document in *Patenting DNA Sequences*, p. 4-29.

nations?²¹ The report marks these as questions which are “fundamentally moral in nature” as opposed to those questions which merely deal with policy-related issues. Indeed these questions encompass profound moral concerns.

The report takes up these issues one at a time in the “analysis” section of the document. Under “Issues Related to Common Heritage Concerns” the report asks: “Are there moral justifications for intellectual property rights? And, why should anyone be allowed to patent something that they isolated, but that already existed in nature and is therefore not new?”²² According to the report, intellectual property is justified morally either as an incentive for individuals or companies to invest in the process of invention or as a reward for discovery. Even if this is so, should anyone be able to monopolize through a patent those substances which are at once both a part of nature and the common heritage of humanity?²³ The analysis proceeds to show how, through the history of property rights discourse from Locke forward, private property has been justified. It is suggested that patenting naturally occurring human DNA sequences might be analogous to owning land or possessing mining rights.

²¹*Patenting DNA Sequences*, p. 4-7.

²²*Ibid.*, p. 4-11.

²³In this regard, Daniel Kevles and Leroy Hood have said: “If anything is literally a common birthright of human beings, it is the human genome. It would thus seem that if anything should be avoided in the genomic political economy, it is a war of patents and commerce over the operational elements of that birthright.” Daniel Kevles and Leroy Hood (eds.), *The Code of Codes* (Cambridge, MA: Harvard University Press, 1992), pp. 313-314.

The report warns, however, that the analogy is inexact at best. Human DNA is not the exact analogue of land since on the one hand land is external to us and on the other hand DNA is internal to us. Further, the report argues that proprietary rights in DNA might harm future research: "If researchers are excluded from working on certain problems because relevant stretches of DNA have been patented by another party, the granting of that intellectual property right might be viewed as having unfairly harmed the new researchers."²⁴ Since the DNA fragment exists in nature and is, as it were, waiting to be used freely without restriction, researchers are actually harmed when someone identifies and patents any given stretch of DNA.

This section concludes by referring to an "experimental use doctrine" which "could be viewed as a balance between moral justifications of private property ownership of common heritage and public access to that same heritage."²⁵ The experimental use doctrine permits researchers to use a patented invention without threat of infringement as long as the researcher does not attempt to market a product based on the patented invention.²⁶

As one might imagine, the most lengthy section of the chapter on ethical concerns of patenting human DNA involves issues related to human dignity. Here a number of themes are analyzed. First, is patenting human DNA tantamount to owning human

²⁴*Patenting DNA Sequences*, p. 4-14.

²⁵*Ibid.*, p. 4-15.

²⁶Rebecca S. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," *The Yale Law Journal* 97 (December 1987), pp. 177-231.

beings? Interestingly, the report observes that the Patent and Trademark Office has no means by which to adjudicate moral concerns such as the intuition that owning human beings is immoral. Nevertheless, since there is a Constitutional prohibition in the Thirteenth Amendment against owning slaves, the PTO is not without guidance on that matter. The Constitution prohibits owning a human being, however, and not human body parts or DNA.

Appeal is made to the Commission of the European Community's (EC) draft discussion document. The report says:

The draft concluded that "in light of the general principle that the ownership of human beings is prohibited, the human body or parts of the human body *per se* much be excluded from patentability (Commission, 1992; Commission, 1994)." However, "parts of the human body *per se*" encompasses those "found inside the human body. It is important that this be spelled out so as to remove all possible ambiguity with respect to the position of certain products or parts of the human body which are already covered by patents granted in connection with the development of medicinal products" (Commission, 1992; Commission 1994).²⁷

Following this summary of the EC's position, the report takes up several of the conundrums which are endemic to discussions of patenting DNA. First, it is observed that the EC does not provide moral justification for extending a prohibition on owning human beings to owning human body parts. Second, "because the basis for the extension is undefined, it is difficult to ascertain whether extending the prohibition to encompass body parts as long as they are within humans is morally justified."²⁸ Third, the EC's statement

²⁷Cited in *Patenting DNA Sequences*, p. 4-16.

²⁸*Ibid.*

does not extend to prohibiting the patenting of *ex vivo* DNA sequences.²⁹ This discussion leads to the next section of the report.

The next issue taken up by the OTA report is the issue of commercialization of human beings. The report points out that the history of philosophical and moral thought about this issue has resulted in an emphasis on altruism and gift relationships where human tissues and fluids are concerned (e.g., with respect to blood and organ donation). However, the report laments that "It would be easier to assess philosophical issues related to commercialization of human DNA sequences if a good general theory existed about

²⁹A more recent opinion by the Group of Advisors to the European Commission on the Ethical Implications of Biotechnology (GAEIB) says, "2.2 The traditional distinction between discovery (not patentable) and invention (patentable) involves, in the field of biotechnology, a particular ethical dimension. It follows from this distinction that the knowledge related to the human body or its elements is relevant to scientific discovery and cannot be patented. It has to be clearly specified that the simple knowledge of the complete or partial structure of a gene cannot be patented. 2.3 The human body, at different stages of its constitution and development, as well as its elements, do not constitute patentable inventions. Such an exclusion does not come only from the usual conditions of patentability, but it is also inspired by the ethical principle of non-commercialisation of the human body. Therefore no patent can be given on the human body or its elements. Also, it follows that no remuneration to the person from whom the samples are retrieved, or to his/her eligible party, can be allotted. . . . 2.4 Concerning the inventions issued from the knowledge of a human gene or a partial human gene sequence, the granting of a patent is acceptable only if, on the one hand, the identification of the function attached to a human gene or partial gene sequence allows new possibilities (for instance the production of new drugs), and, on the other hand, if the intended use of the patent is sufficiently specific and identified." European Commission, Group of Advisors on the Ethical Implications of Biotechnology of the European Commission, *Ethical Aspects of Patenting Inventions Involving Elements of Human Origin* (25 September 1996), p. 119. To date the European Commission does not permit the composition of matter patents on either animal or human genes. "Animal and plant varieties" are expressly excluded from patentability under Article 53(b) of the European Patent Convention (EPC).

what sorts of things should or should not be treated as commodities.”³⁰ One problem with comparing DNA and organs is the disanalogy between the use of DNA and transplant organs. On the one hand, in the case of transplant organs, an organ is transferred from one person to another. On the other hand, in the case of ESTs, sequence donors provide some tissue or fluids, and these are used to isolate specific gene sequences. The sequences are then produced for commercialization through biotechnological processes. “That is, blood or kidneys are useful without added effort, whereas commercialization of human DNA needs both financial and intellectual investment. This subtle difference affects the moral arguments.”³¹

Furthermore, one of the principal arguments against commercialization of human organs has been that the poor would be tempted to sell their body parts for the necessities of life—which, it is argued, is a clear affront to human dignity. In the case of DNA sequences, only a very small portion of renewable resources is necessary; in fact, sequences may be retrieved from biological materials already discarded (e.g., hair or body fluids).

The report then mentions a number of efforts to find a principle which could ground a moral prohibition against the sale of human biological materials.

One attempt offered is that it is wrong to sell something ‘intimate’ (Nelson, 1991). Another possible argument posits that it is wrong to commercialize something with which individuality and personhood are intertwined (Radin, 1991). This theme appears to provide a moral objection to commercialization of human DNA

³⁰*Patenting DNA Sequences*, p. 4-17.

³¹*Ibid.*, p. 4-18.

sequences, since they do seem to be connected with human identity and, in part, with personal identity.³²

This consideration segues to the third area of concern with respect to human dignity, namely, patenting human DNA sequences is wrong because doing so commodifies that which in some important ways defines human and personal identity. This objection is problematic because it appears to be reductionistic. That is, it implies that human and personal identity are in the genes alone. Furthermore, it ignores the fact that “the human genome shares significant homology with animal genomes—i.e., most human DNA sequences are not, in fact, truly unique to humans.”³³ The philosophical discourse on human and personal identity is far from univocal. Thus it is unlikely that any help in resolving the issue will be found there.

Finally, of the central issues with respect to human dignity, the last involves preserving human genetic integrity. Not only might religious and metaphysical arguments substantiate a concern to preserve human genetic integrity, but concerns about the implications of eugenics mitigate against patenting human DNA sequences.

Again, appeal is made to the European Commission’s debates about patenting. “‘Processes for modifying the genetic identity of the human body for nontherapeutic purpose, which is contrary to the dignity of man, is [sic] not patentable’ (Commission, 1992; Commission 1994).”³⁴ The European Commission, does not, however, define what

³²Ibid., p. 4-19.

³³Ibid., p. 4-20.

³⁴Cited in Ibid., p. 4-22.

constitutes "therapeutic" procedures, nor does it define that which is "contrary to the dignity of man."

The final core concern analyzed by the OTA report revolves around issues of social justice, particularly questions about the economic gap between developed and developing nations. Do patents in DNA sequences widen the gap? Do patents result in inordinate benefits accruing to biotechnologically developed countries and too few going to countries without a large biotechnology industry?

In seeking to address these questions, one strategy is to appeal to market forces. On the surface, developing nations would be free to purchase or refuse to purchase biotechnological products based upon their judgment of their value. Nevertheless, the report acknowledges that due to economic weakness, developing nations might not be genuinely free to make such purchases. Thus, "Such a limitation could be viewed as unjust for patented products comprised of material viewed as part of humanity's common heritage."³⁵ The notion that genetic sequences comprise a common heritage was found to be problematic in the first section of the report, however, so, it is argued, restricting free market exchanges on the basis of this argument is equally problematic.

Just distribution of wealth between the industrialized and nonindustrialized countries is acknowledged to be a crucial issue. Nevertheless, the OTA report opines that empirical data would be required to make the argument successful—a task which is acknowledged to be beyond the scope of the report.

³⁵Ibid., p. 4-24.

The OTA report concludes that there are no extant arguments which present necessary and sufficient reasons to prohibit the patenting of human DNA sequences. The conclusion of the document recapitulates the arguments given in the body of the text. There are no recommendations given in the chapter.

5.5 Kass and a More Natural Science

University of Chicago physician and social philosopher Leon Kass argues against biopatents in his trenchant volume, *Toward a More Natural Science*.³⁶ After tracing the historical/philosophical legacy of science and law in the American context, Kass launches into his argument against "patenting life." He questions, first, whether the rewarding of patents on living entities serves the public good, one putative justification for patent regimes. The answer to this question depends on the potential danger of a given technology.

Genetic engineering is regarded by many as just such a dangerous technology, and one posing no ordinary dangers. For in human genetic engineering, the previous beneficiary of the power to alter nature becomes himself subject to that power and those alterations. The power to engineer sharply raises questions about the meaning and limits of progress.³⁷

This criticism seems to be analogous to one of the traditional arguments against voluntary slavery. One may not use her freedom to give up her freedom. Similarly, Kass

³⁶Leon R. Kass, *Toward a Moral Natural Science: Biology and Human Affairs* (New York: Free Press, 1985).

³⁷*Ibid.*, p. 139.

seems to imply, one may not express her human power of inventiveness to alter her humanness.

Moreover, Kass points to the fact that the potential harms of genetic engineering are extraordinarily difficult to assess. Clearly, potentially burdensome risks are endemic to the manipulation of human, animal, and plant genomes. Regardless, neither the Courts nor the Patent and Trademark Office are equipped to assess such hazards. Congress is charged with the responsibility of assessing the potential risks of a given technology and may make laws prohibiting research and its application in areas which it thinks are sufficiently dangerous. Nevertheless, Kass argues, "patent laws assume that innovations proposed by inventors are, because innovative and useful to some, simply good for the community at large. Instituted well before many people recognized the communal price everyone pays for certain kinds of technological change, they reflect one little-questioned faith in progress."³⁸ While patents may be efficient conventions to reward invention, they are ill-suited to regulate it.

Kass also finds the patent system's "usefulness" criterion problematic. Usefulness supports innovation, but at what costs? Kass asks:

How should [the Patent Office] judge the usefulness of a manufacture that has obvious and likely misuses and abuses, along with some clear and well-defined use? For example, how should it judge the usefulness of a perfected pleasure drug, admittedly beneficial in the treatment of depression, but almost certainly subject to widespread social or political abuse? What about improved devices for subliminal advertising? Or new and improved miniature recording and photographic devices that would no doubt increase snooping and invasions of privacy? Should the

³⁸Ibid.

inventor of selective spermicides and his financial backers be able to decide by patenting that our society should be able to practice sex-selection of offspring?³⁹

Nevertheless, Kass agrees that harms should be assessed by the legislature, not by the patent systems. Patent regimes, in general, are helpful. Congress and its regulatory agencies (e.g., the Food and Drug Administration) must scrutinize questions about health, safety, and morality. Kass is aware that the "task of inventing suitable braking mechanisms" to analyze unfettered development will not be easy. Presumably, the risks of biotechnology require attention to the task.

Kass next critiques the Supreme Court in its decision in *Diamond v. Chakrabarty*. While the Court refused ostensibly to encroach on Congresses' responsibility to determine if microorganisms *should* have been patented, it nevertheless, made the decision in the affirmative by declaring that Chakrabarty's organisms were a composition of matter. Says Kass,

Though the majority opinion does not directly *argue* that the microorganism in question, is, say, a composition (i.e., a putting together) of matter, it treats its aliveness as irrelevant to its patentability. It ignores altogether the nature of the

³⁹Ibid, p. 140. Bernard Rollin has recently offered a similar critique: "... the Patent Office rushed in where angels fear to tread ... the issuing of patents begs these questions or ignores them. It was a bureaucratic decision made in a value-free context (or value-ignoring context) by an agency that has notoriously avoided engaging the ethical and social issues raised by inventions like switchblades, assault rifles, shock collars, and devices for sadomasochists, and agency that judges applications only by the formal criteria of novelty, usefulness, and nonobviousness. It disavows concern with issues of safety; danger to humans, animals, or environment; or welfare of animals. The decision is, as it were, a punch line without a joke, and ending without a story. The decision to patent or not to patent should follow in the wake of a democratic social examination of the concerns discussed here, and in the wake of establishing a democratic regulatory mechanism for all aspects of genetic engineering of animals." Bernard E. Rollin, *The Frankenstein Syndrome: Ethical and Social Issues in the Genetic Engineering of Animals* (Cambridge: Cambridge University Press, 1995), p. 207.

object, arguing: "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." Finally, the Court argues that novelty, utility, and the fact of Chakrabarty's discovery "is not nature's handiwork but his own" renders the bacterium patentable subject matter and Chakrabarty and General Electric the proud owners of "his" new species.⁴⁰

Arguing that neither Jefferson nor the other framers of the U. S. Constitution envisioned living entities as "compositions of matter," Kass rebukes the Court for its failure to conserve distinctions contained in the patent statutes. After all, there is no need for the distinction between "processes, machines, manufactures, and compositions of matter" if "anything under the sun," as long as it was modified by human ingenuity, were intended to be patentable. In other words, Kass argues that the Supreme Court overstepped its role by granting Chakarabarty's patent.

Second, Kass asks, "If patenting and the patent laws do not always serve the public or political good, are they simply good for science?"⁴¹ This section of his argument focuses on the ways patenting has transformed research. Federal funding for research in the biological sciences was funneled through university research centers in the past. In some cases, philanthropic foundations supported university-based research in specialized arenas. Kass argues that this system for research funding "thrived on free and cooperative exchange of information and materials."⁴² With the growth of contemporary industrialized biotechnology—fueled by competition, market forces, and profit motives—research

⁴⁰Ibid., p. 143.

⁴¹Ibid., p. 144.

⁴²Ibid., p. 145.

dynamics have been altered in significant ways. Now secrecy, deception, and restriction of information characterizes research. An entrepreneurial spirit reigns in the applied sciences. Patenting is lauded as an incentive to publish research and to disseminate knowledge. Nevertheless, argues Kass, there is reason to worry. Commercialization of the patented products of science has changed the nature of scientific research itself. Today research is rarely done for its own sake (i.e., for the sake of knowledge alone). Pure science is largely a thing of the past. Relevance and utility are the themes of the day. Research must have the potential to yield practical (read marketable) results or it will not be funded. The union of the academic sciences and the industrial community, Kass thinks, threatens the *raison d'être* of university science departments.

American universities are, for all their faults, precious and precarious institutions. In fact, the present balance within them between the busy and the deliberate, the clever and the wise, the useful and the true, is already tipped so far toward the former that we must be cautious about all further changes that tend to diminish the latter. It should now be evident that my concern for universities and for theory and fundamental thought goes beyond my concern for the so-called pure science. The earlier discussion should have made clear the importance of careful and thorough thinking about the relationship between science and the American polity and about the implications of our new forays into genetic engineering. Indeed, especially now, when the goal and direction of the scientific project for the mastery of nature seems less clear than ever, and when, despite this confusion about the end, the means are being amassed to directly and deliberately affect all forms of life on the planet, we stand in urgent need of the far-seeking and high-minded reflection about science, ethics, and society that the patent laws, industry, and even such fine institutions as the National Institutes of Health cannot encourage or foster.⁴³

Thus is Kass concerned that liberal learning, philosophical reflection, and science for science's sake have been co-opted by the impetus to turn a profit or produce a marketable

⁴³Ibid., p. 148.

product.⁴⁴ Though Kass himself does not mention it, one problem he is addressing tangentially is the potential of biotechnology to steer scientific research away from the “big questions” toward application. Historians of science remind us that often the most revolutionary scientific discoveries have been made serendipitously, not intentionally. One may only wonder about what we may not discover because of industrial biotechnologies tendency to skew research.

Last, Kass examines the *Chakrabarty* decision and its implications for “owning life.”⁴⁵ Kass’s main concern is that *Chakrabarty* proffers a reductionist form of materialism. Kass states,

Consider first the implicit teaching of our wise men, that a living organism is no more than a composition of matter, no different from the latest perfume or insecticide. What about other living organisms—goldfish, bald eagles, horses? What about human beings? Just compositions of matter? Here arise deep philosophical questions to which the Court has given little thought; but in its eagerness to serve innovation, it has, perhaps unwittingly, become the teacher of philosophical materialism—the view that all forms are but accidents of underlying matter, that matter is what truly is—and therewith, the teacher also of the homogeneity of the given world, and, at least in principle, of the absence of any special dignity in all of living nature, our own included.⁴⁶

Taking issue with the Court’s decision to classify living organisms as compositions of matter, Kass wonders if and where lines are to be drawn. Might the artificially engineered combination of a human and chimpanzee (“humanzee”) be patentable?

⁴⁴Kass is not alone in his concern. See Kai Nielsen, “On Being Skeptical About Applied Ethics,” in Terrence F. Ackerman, Glenn C. Graber, Charles H. Reynolds, and David C. Thomasma (eds.), *Clinical Medical Ethics: Exploration and Assessment* (Lanham, MD: University Press of America, 1987), pp. 95-109.

⁴⁵*Ibid.*, p. 149.

⁴⁶*Ibid.*, pp. 149-150.

Furthermore, Kass is troubled by the scope of the patents awarded on transgenic species. *Chakrabarty* granted property rights in an entire species of microorganism. The patent on the Harvard mouse granted proprietary rights to all oncomammals. The Court clearly over-reached in these cases, according to Kass.

Here Kass appeals to an intuition he calls "repugnance."⁴⁷ The idea of owning entire species, he says, evokes a sense of repugnance. "The thought of a man buying up and collecting all the world's camels or giraffes or horses is repulsive, though nothing in the law prevents it."⁴⁸ In a now somewhat famous line, Kass asserts, "It is one thing to own *a* mule; it is another to own *mule*."⁴⁹

Moreover, since most agree that life is a continuum from more primitive to more sophisticated forms, and one form is patentable, there is no justification for limits on patentability, says Kass. If a microorganism is patentable then the inventor of the microorganism would be patentable if he were the object of some form of human, biotechnological manipulation. "If a genetically engineered organism may be owned because it was genetically engineered, what would we conclude about a genetically altered or engineered human being?"⁵⁰

⁴⁷Ibid., p. 150. This is a theme he develops more fully in the aftermath of the announcement that researchers at the Roslin Institute in Edinburgh, Scotland had successfully cloned a sheep named Dolly. See Leon R. Kass, "The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans," *The New Republic* (2 June 1997), p. 18.

⁴⁸Kass, *Toward a Moral Natural Science*, p. 150.

⁴⁹Ibid.

⁵⁰Ibid., p. 151.

Kass's final argument against patenting living organisms relates to the distinction he sees between "invention" qua human art and living entities qua "compositions of matter."

In the present case, our inventor even had nature's active assistance; for it is not strictly true, as the Court claims, that "his discovery is not nature's handiwork, but his own." Chakrabarty did not himself *create* the new bacterium. Rather, he played the matchmaker for a shotgun wedding and the selector of its progeny, while the living organisms did the work. . . . Though the process was, in many senses, creative and his own, the novel organisms was not *his creature*.⁵¹

Kass is reacting to what he must surely think is hubris. That humans think they can do anything without cooperation from nature Kass finds ludicrous. Even inventiveness itself is not a human invention, but a product of the mind and its interaction with the nature it discovers.⁵²

5.6 Hettinger and Biocentrism

Edwin C. (Ned) Hettinger is Associate Professor of Philosophy at the College of Charleston and has written widely on intellectual property and patenting of living organisms.⁵³ Hettinger grounds his argument against biopatents in a brand of

⁵¹Ibid., p. 152.

⁵²Ibid.

⁵³See Edwin C. Hettinger, "Justifying Intellectual Property," *Philosophy and Public Affairs* 18 (Winter 1989), pp. 31-52; "Owning Varieties of Life: Biotechnology, Intellectual Property, and Environmental Ethics," a paper delivered at the Symposium on Ethics and Patenting of Transgenic Organisms, Center for Biotechnology Policy and Ethics, Texas A&M University, College Station, Texas (April 1994), pp. 1-26; and "Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics," *Environmental Affairs Law Review* 22 (1995), pp. 267-305. Hereafter *Biotech Patents* to distinguish this work from the OTA document.

environmental ethic he calls "biocentrism," following Albert Schweitzer's "reverence for life" philosophy.⁵⁴ As Hettinger frames it, biocentrism entails that: (1) all living organisms have welfares which are served by their physical features; (2) the proper functioning of the organism is a good for that organism; (3) these welfare interests do not depend on any preferences or desires of the organism, but on the good of the organism itself; and (4) "because all organisms—including genetically-altered ones—possess morally-considerable interests, organisms are not mere resources that people are naturally entitled to own in the way people own their bodies or own artifacts."⁵⁵ Hettinger concludes that biocentrism will not support a natural entitlement to ownership of genetically engineered organisms.

Environmental holism is the view that preservation of species is more important than preservation of individuals. This holistic approach proscribes species ownership according to Hettinger. Echoing Kass, but for obviously different reasons, he says, "There is no inconsistency in being comfortable with people owning individual blue spruce trees, for example, and being appalled by the idea of a person owning or monopolizing all blue spruces."⁵⁶

⁵⁴*Biotech Patents*, p. 281. For a historical sketch of environmental ethics, including Schwieterian theory, see Roderick Frazier Nash, *The Rights of Nature: A History of Environmental Ethics* (Madison, WI: The University of Wisconsin Press, 1989).

⁵⁵*Biotech Patents*, p. 283. Hettinger does not accept an egalitarian form of biocentrism in virtue of which all living organisms have the same moral standing. Instead, he believes that organisms deserve varying degrees of moral significance. Thus, he says, "I find animal patents to be more troubling than either plant or microbe patents." *Ibid.*, p. 285.

⁵⁶*Ibid.*, p. 284.

Hettinger also maintains that patenting explicitly affirms that the patentable item is a tool or machine and that patenting is a legal convention which was originally intended to apply to inanimate devices or artifacts. By permitting the patenting of organisms, living things are "inappropriately conceptualized as tools."⁵⁷

While the patenting of whole organisms is untenable in Hettinger's version of biocentrism, he acknowledges that his argument does not hold for, say, genes or cell lines. Genes, he observes, are not living things with welfare interests of their own. It would be, therefore, inappropriate to extrapolate a prohibition against patenting whole organisms to a prohibition against patenting genes; nevertheless, gene patenting is problematic for other reasons. Naturally occurring genes, like the laws of nature, should be unpatentable, Hettinger says, not because they are organisms with welfare interests, but because they are part of the common heritage of humanity. "As previously existing, nonexclusive objects that may be used beneficially by everyone at once, no one should possess the right to monopolize gene-types with patents or to 'lock up' genes through any other property arrangements."⁵⁸

When organisms, genes, or cell lines are classified as compositions of matter, an interesting ambiguity in the patenting statutes arise. Recall that patent law allows for patents for "whoever *invents or discovers* any new and useful process, machine, manufacture, or composition of matter."⁵⁹ While technically the Patent and Trademark

⁵⁷Ibid.

⁵⁸Ibid., p. 286.

⁵⁹35 U.S.C. §101. Italics added.

Office does not grant patents on substances “as they are found in nature,” genes are patentable when they are isolated from their “impure form” and either “substantially altered,” purified, or concentrated. According to Hettinger’s view, however, altering, purifying, or concentrating a gene should not be seen as the same thing as inventing it. So Hettinger argues,

There is a substantial disanalogy between biopatents and the traditional subject matter of patents. Edison really did *invent* the light bulb. The Wright brothers *did create* a flying machine. But Harvard biotechnicians did not *invent or create* the oncomouse. Biotechnicians alter, modify, assist, or manipulate nature. Biotechnicians are not inventors of organisms or genes that could be appropriate objects of patents.⁶⁰

Next, Hettinger takes up the desert rationale for patents. The desert argument for property rights (see Chapter 5) entails that labor invested in an object warrants the reward of property rights in that object. “But,” asserts Hettinger, “patents are likely to give biotechnicians far more than they deserve.”⁶¹ Suppose that biotechnicians genetically alter a variety of legume so that they require only twenty percent of the water other legumes require. These altered legumes would be highly valuable. Yet the effort to modify the legumes might be relatively modest. “Valuable biotechnologies can result from flashes of genius and years of diligent effort can prove fruitless. Thus, awarding patents in biotechnological innovations to those who produce them is likely to be a highly imprecise way of proportioning rewards to the effort biotechnicians expend.”⁶² Not only so, but

⁶⁰*Biotech Patents*, p. 289. Emphasis his.

⁶¹*Ibid.*, p. 290.

⁶²*Ibid.*

one must acknowledge that most of the value of these genetically altered legumes originated in the legumes themselves. Patents awarded on genetically modified organisms awards biotechnicians disproportionately, according to Hettinger. Moreover, Hettinger argues that innovation builds upon previous knowledge. Patents on living organisms fail to account for the contributions of the intellectual predecessors to those who obtain the patents. "To claim that the biotechnician is responsible for the entire value of the modified organism or gene is like saying that the last person needed to lift a car should get full credit for lifting it."⁶³

Probably the most ubiquitous rationale for biopatents is the consequentialist argument. Incentive to patent living organisms is found in the social utility of biotechnological invention. New pharmaceuticals, advances in genetic therapy, and innovation in agricultural biotechnology all depend, it is argued, on the reward of patents. Hettinger argues that the consequentialist argument is paradoxical in that it "involves trying to maximize social benefits from innovation by putting constraints on society's ability to use and thus benefit from innovation."⁶⁴ In fact, however, biopatents may undermine innovation.

Privatization of biological knowledge inhibits the scientific sharing of ideas and thus slows innovation. University-business joint ventures result in secrecy in university laboratories. One commentator notes a growing reluctance among researchers to freely exchange plasmids and cell lines. Furthermore, publication of

⁶³Ibid., p. 291.

⁶⁴Ibid., p. 292.

scientific results is delayed until after the application for and receipt of patents, a process that takes years to complete.⁶⁵

In addition, patents, Hettinger argues, may "crush" innovation: (1) by diverting resources from invention to patent development and defense, (2) by suppressing competition as larger biotechnology firms purchase patents from smaller firms, and (3) by encouraging a litigious business environment which discourages smaller firms from entering the marketplace.⁶⁶ The point Hettinger is making is that there are non-patenting responses to all of the consequentialist arguments for patenting.⁶⁷ This is a problem to which we shall return.

Finally, Hettinger focuses on what he perceives as patenting's costs and risks. He observes that patents do not, in themselves, permit the patent holder to produce or market a patented organism; rather, patents exclude others from using patented organisms.

⁶⁵Ibid., p. 293.

⁶⁶Ibid., p. 294.

⁶⁷This point is frequently made. For instance, Arthur Caplan and Jon Merz have said of the NIH effort to patent ESTs, "If there is no persuasive reason to forbid the patenting of human genes, the argument must turn to consequences. The issue is no longer whether genes can be patented on principle, but what sort of patents on what sort of genetic information will most encourage the development of useful inventions and products for promoting human health and wellbeing. While a convincing case can be made for the value of patents in securing investment and attention from those who hold them, limiting access to portions of the human genome to a small set of scientists simply because they identified the sequences first is unlikely to lead to the maximal intellectual exploitation of this resource. Nor does it make moral sense. If government funds have been used to map and sequence the human genome, why should the fruits of that effort be turned over to a single owner? Permitting patents of simple segments of the genome, rather than for products and inventions, would seem to be contrary to the public interest." Arthur L. Caplan and Jon Merz, "Patenting Gene Sequences: Not in the Best Interest of Science or Society," *British Medical Journal* 312 (13 April 1996), p. 926.

Patenting proponents, therefore, conclude that regulatory control will harness the potential harms of biopatents. Hettinger suggests that this conclusion leads to a false sense of security. If, as proponents maintain, patents are such powerful incentives, then "biopatents are likely to contribute to biotechnologies being introduced and exploited before their negative impacts can be properly assessed."⁶⁸ Once biopatents proliferate, regulatory bodies will have considerable difficulty disciplining the biotechnology industry. Commercial interests become powerful countervailing forces against regulation, according to Hettinger.⁶⁹

Furthermore, consideration of the costs of biopatents usually focuses on monetary costs and market values. Nevertheless, Hettinger argues that there are other costs to be measured with respect to patenting living organisms. First, he says, nature is devalued by human manipulation. "Modern biotechnology is a significant change in, as well as enhancement of, humankind's ability to manipulate nature 'from the inside out.' In many people's eyes, too much of the world is already domesticated and manipulated by humans."⁷⁰ Second, biopatents increase harms to animals. Since one major purpose of biopatents is to protect investments in animals which have been altered to produce certain forms of disease, biopatents contribute to animal suffering. Another use of animals in biotechnology is to increase production. Genetic alteration leads to anomalies such as the Beltsville pig, a porcine species into which human growth hormone was injected. These

⁶⁸Ibid., p. 296.

⁶⁹Ibid.

⁷⁰Ibid., p. 297.

pigs suffered bowleggedness, were cross-eyed, became arthritic, and, because of a compromised immune system became overly susceptible to pneumonia.⁷¹ While Hettinger is aware that animal harm may result from biotechnological manipulation quite apart from patenting, he argues that biopatents exacerbate the situation, encouraging human manipulation and consequent animal suffering. Third, the risks of biotechnology have been underestimated according to Hettinger. Alteration of ecosystems and the risks associated with genetically engineered animals escaping or being set free in the environment are potential hazards resulting from biotechnology.⁷² Again, patents, he argues, increase the likelihood that these problems will become realities. Fourth, there are direct costs to farmers resulting from biopatents. Small farmers will be forced to go out of

⁷¹See Gary Comstock, "What Obligations Have Scientists to Transgenic Animals?," a paper delivered at a symposium at the Center for Biotechnology Policy and Ethics, Texas A&M University, College Station, Texas (May 1992), p. 4. Cf., Michael W. Fox, *Superpigs and Wondercorn: The Brave New World of Biotechnology . . . and Where it May Lead* (New York: Lyons and Burford, 1992), pp. 114-123; Michael W. Fox, "The New Creation: An Update on Animal Gene Engineering," in June Fessenden MacDonald (ed.), *Animal Biotechnology: Opportunities and Challenges*, NABC Report 4 (New York: National Agricultural Biotechnology Council, 1992), pp. 49-61; and Dorothy Nelkin, "Living Inventions: Biotechnology and the Public," in *Ibid.*, pp. 63-72.

⁷²Many have commented on the potential risks of releasing genetically engineered organisms into the environment. But how are these risks different from risks associated with natural mutation or with breeding programs? One International expert says, "The real risks of deliberate release today arise from three causes. (1) The short timescale on which the genes are shuffled, compared with traditional breeding methods, allowing time for testing or ecological adjustment. (2) The breadth of the gene pool which is being and will be shuffled, widening the range of 'farmers' experiments'. (3) The exotic mechanisms used to do the work—laboratory gene splicing and cloning—which inevitably separates researchers from the real conditions where their discoveries and products will be used." Robert Walgate, "Making Biotechnology Appropriate and Environmentally Sound," in E. J. Da Silva, C. Ratledge, and A. Sasson (eds.), *Biotechnology: Economic and Social Aspects* (New York: Cambridge University Press, 1992), p. 302.

business, unable to compete with gargantuan agribusinesses. One Congressman even suggests that "major chemical, biotechnological, and pharmaceutical companies [will be] in the position to virtually take over animal husbandry in America."⁷³ Fifth, biopatents stimulate "genetic prospecting"⁷⁴ of the Southern Hemisphere by large biotechnology firms in the Northern Hemisphere. In addition to the problem Hettinger finds generally in justifying intellectual property rights in biopatents, these concerns mitigate against the consequentialist arguments favoring biopatents. Thus, Hettinger claims that biopatents cannot be justified. Further, he suggests that: (1) we explore alternatives to patenting, (2) increase public funding to stimulate biotechnological research without resort to profit motives, and (3) where that might be impossible, develop appropriate incentives for the biotech industry.⁷⁵

⁷³Statement by Rep. Charles Rose (D-North Carolina) cited in *Biotech Patents*, p. 301.

⁷⁴Of course genetic prospecting impacts the United States as well. A recent article in the University of California at Berkeley's *Ecology Law Quarterly*, argues that the U. S. government should charge biotechnology companies for extracting valuable "wild" genetic resources from federally-owned land. The author asserts that intellectual property law is one of the major developments contributing to the rise of domestic biotechnology. The other contribution is the ability to manipulate DNA through genetic engineering. John R. Adair, "The Bioprospecting Question: Should the United States Charge Biotechnology Companies for the Commercial Use of Public Wild Genetic Resources?" *Ecology Law Quarterly* 24 (1997), pp. 131-171.

⁷⁵*Biotech Patents*, p. 305. A more fully developed argument, similar to Hettinger's, is found in Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (Boston: South End Press, 1997). Shiva is a physicist and ecologist who directs the Research Foundation for Science, Technology, and Natural Research Policy, and is an Associate Editor of the journal *The Ecologist*. Her argument may be characterized as a biocentrist/feminist argument against biopatents.

5.7 Human Biopatents and the Thirteenth Amendment

The present position of the Patent Office is that a whole human being may not be owned because the Thirteenth Amendment disallows slavery. Kevin D. DeBré, writing in the *Hastings Constitutional Law Quarterly*,⁷⁶ challenges this widely held judgment.

DeBré correctly summarizes the Patent and Trademark Office's current stance,

Given the Supreme Court's statement that statutory subject matter includes "anything under the sun that is made by man," human inventions would seem to be patentable subject matter. The PTO, however, has stated that "a human being will not be considered patentable subject matter under 35 U.S.C. 101" because "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution."⁷⁷

DeBré proceeds to argue, however, that the PTO's position is not consistent with either the role of the PTO or Constitutional law. "Given the Supreme Court's statement that statutory subject matter includes 'anything under the sun that is made by man,' human inventions would seem to be patentable subject matter."⁷⁸ Thus, if it can be shown that patenting human genotypes does not result in the subjugation proscribed by the Thirteenth Amendment, it might well be the case that human genotypes are, legally speaking, patentable.

The Thirteen Amendment provided Congress with broad enforcement powers to prohibit subjugation of one person by another, including the elimination of private and

⁷⁶ Kevin D. DeBré, "Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?" *Hastings Constitutional Law Quarterly* 16 (Winter 1989), pp. 221-259.

⁷⁷*Ibid.*, p. 221.

⁷⁸*Ibid.*

state actions that constitute “badges of slavery.” “Under the Thirteenth Amendment, Congress is empowered to secure freedom, which may be described as the absence of restrictions, whether imposed by governments, by private individuals, or by environmental conditions.”⁷⁹

According to DeBré, subjugation would result through genetic engineering, “when the manufacture of a patented genotype creates inferiority in the resultant being.”⁸⁰

Furthermore, subjugation of an individual with a manufactured genotype would include “disabling conditions ranging from highly visible restrictions on external autonomy (e.g., genetically engineering a person to be born of low intelligence) to subtle intrusions upon internal autonomy (e.g., mass producing the same genotype throughout the population, leading to an erosion of the sense of individuality in one possessing the genotype).”⁸¹

Additionally, a patent on a human life form can be a badge of slavery where subjugation is a direct result of the patent. “For example, the property rights conveyed in a patent may give rise to constraints in the patented individual’s external or internal autonomy.”⁸²

“Property rights granted under a patent,” maintains DeBré,

are limited to those rights prescribed by Congress. The patentee may recover damages from infringers of the patent. And although the patentee may manufacture, use, or sell the patented product, or assign or license others to do so, patents do not confer possessory rights in the article in which the inventor has patent rights.

⁷⁹Ibid., p. 230.

⁸⁰Ibid.

⁸¹Ibid.

⁸²Ibid., p. 231.

Therefore, a holder of a patent in a human invention does not have rights in the physical manifestation of the patented genotype, in the trait expressed by the genetic manipulation, nor in any altered genotypes possessed by the recipient of the patented gene. An inventor holding a patent on a new form of human genotype would have an exclusive right only to practice the patent—that is, to make, use, or sell the patented genotype himself. The inventor would have the right only to enforce actions to exclude others from manufacturing, using, or selling the patented genotype. Once the patented genotype is sold and implanted, the patentee impliedly licenses the recipient to use the product.⁸³

Since the patent holder does not have “possessory rights” over the genetically altered life form—in this case, a human life form—DeBré maintains that there is no necessary violation of the Thirteenth Amendment. “The patent holder’s exercise of his right to exclude others from manufacturing, using or selling the human invention would not by itself give rise to socially imposed inferiority in patients of genetic therapy.”⁸⁴

While that may be the case, one wonders if DeBré’s legal distinction is a distinction without a moral difference. That is to say, even though the patent holder is not entitled to possessory rights, does not the exclusive right to practice the patent and, thereby, exclude others from doing so, impose substantial limitations on the person whose genome has been altered? For instance, the person with the altered genome is, as DeBré seems to grant, a “human invention” and thus, a sub-species—namely, *Homo sapiens* plus the modified genome. Will this not negatively impact the psychology of either the modified individual or the culture in which they live? Furthermore, if it were germ cell manipulation which took place, would the person’s reproductive rights be threatened by

⁸³Ibid., p. 232.

⁸⁴Ibid.

the competing entitlements of the patent holder?⁸⁵ To the first question, DeBré answers, "One possessing the patented gene would feel no less human in relation to others than would one possessing an artificial limb or a transplanted organ."⁸⁶ DeBré may underestimate the psychosocial impact of amputation and organ failure. Women who have mastectomies, for instance, often complain of "feeling less than whole." To the second question DeBré responds that "It is unlikely. . . that any court would impose infringement liability under these circumstances, since the Supreme Court has recognized a fundamental right of privacy in certain personal decisions" and ". . . has recognized procreation as 'a basic liberty.'"⁸⁷ Of course, few would have imagined that the Supreme Court would have granted a patent to Harvard for all oncomammals or that all the profits from the use of John Moore's splenic cell lines would accrue to someone other than the person whose spleen it was.

5.8 Synthesis and Conclusion

The arguments for and against patenting living organisms are many and varied. One helpful means of classifying the arguments is to separate the utilitarian arguments from the non-utilitarian arguments. Arguments which stress benefits or harms are based on certain types of claims, many of which can be empirically tested. Non-utilitarian

⁸⁵Linguist Noam Chomsky cites one cynical researcher who "remarked that as government-industry efforts are proceeding, some day parents might have to pay royalties for having children." Noam Chomsky, *Year 501* (Boston: South End Press, 1995), p. 113.

⁸⁶*Ibid.*, p. 235.

⁸⁷*Ibid.*, p. 239.

arguments are grounded in varied metaphysical or theological commitments. The problem is that neither of these types of arguments seems to be resolvable. The utilitarian arguments, at least those which are empirically verifiable, cannot be tested unless the practice of patenting living organisms goes forward. If patenting proponents are correct, then that the benefits of patenting outweigh the harms will be evident. Needless to say, opponents of patenting contend that the potential for harm is so great that if patenting continues to proliferate, it will be too late to reverse the harmful consequences of patenting once the harms are obvious. Thus, when David Resnik says, "the extension of patent laws to human genetics at this point in time is on sound moral ground, provided that we are willing to revise our laws in light of scientific, technological, and social changes and consequences,"⁸⁸ opponents of patenting are likely to remain unpersuaded.

Those who are committed to non-utilitarian claims are not swayed by the utilitarian arguments. Adjudication of non-utilitarian arguments must be done on other than cost-benefit analysis. Generally speaking, Westerners have had only limited success in developing moral consensus on policy related to bioethical issues, including genetic engineering. Add to this the fact that now biotechnology is a global enterprise, involving cultures which have extraordinarily diverse moralities, and the hope for resolution seems improbable at best. Nevertheless, the next chapter explicates a moral theory which offers a way beyond the impasse.

⁸⁸David Resnik, "The Morality of Human Gene Patents," *Kennedy Institute of Ethics Journal* 7 (March 1997), p. 53.

CHAPTER 6

PATENTING AND MODES OF VALUATION

6.1 Valuing and Modes of Valuation

The biotechnology industry is a powerful and important institution both domestically and internationally. No one can deny the wonderful and valuable contributions biotechnology has made to the quality of life for most in the world. We have traced the expansion of biotechnology and its vigorous embrace by Western culture from the turn of the century forward. Especially in recent decades the biotechnology industry and the products it offers have been ensconced in health care, food production, and pharmaceutical manufacturing. The advent of the recombinant DNA era has energized the biotechnology industry and promises to usher biotechnology into the next millennium and beyond.

Two concomitant phenomena have accompanied the biotechnological explosion. First, the biotechnic age has witnessed the marriage of medicine, engineering, and agriculture. The machine metaphor and the application of engineering to biology has resulted in a seismic shift in the ways living organisms are conceptualized in the culture in general and in industry in particular (Chapter 1). Secondly, along with an increasingly mechanistic and materialistic view of biology, patenting regimes have enjoyed a remarkable period of growth. As competitiveness in biotechnology has become more intense, so have the incentives for patent protection.

Patents have a long history. Dating back to the Romans and imported to the New World through Enlightenment philosophy and the natural law tradition, the American patent regime is arguably among the most highly developed and broadly applied in the world. The American founders, especially Thomas Jefferson, believed patents were a potent incentive to innovation and invention. Patents are social constructs and preservers of value. There are, however, competing values at stake in patenting living entities and biological materials (Chapter 2).

The controversy over patenting biological materials has been brewing for several decades. Especially since *Diamond v. Chakrabarty*, the patent process has expanded in scope. Not only have Chakrabarty's oil-eating microbes been patented, but so have mammalian species, cell lines derived from human spleens, and even human DNA fragments. With a rapidly advancing global biotechnology industry and the revolution in genetic engineering, there are few reasons to think that the controversy will abate (Chapter 3).

When one examines the putative foundation for intellectual property rights, namely, the theory of Lockean property rights, one finds a less than sufficient ground for patenting biological materials. The labor-added theory of value and the desert theory of property rights are not only internally suspect, but lead to as many conundrums as they purport to solve. Despite what some persons may think, American patent law is rooted less in Lockean property rights than in consequentialist claims that patenting will stimulate innovation. Quite apart from Lockean theory, intellectual property is granted in biological materials on the view that in so doing society is encouraging invention (Chapter 4).

The debate over patenting biological materials has been engaged on a variety of levels, the most comprehensive of which has been in the arena of public policy. Government agencies, such as the Office of Technology Assessment, have been the venue for recording the manifold voices which have spoken to the morality of biopatents. Yet the arguments for and against biopatents are not unlike other arguments in the culture; they are diverse and grounded in competing moral visions. In a society of moral strangers is there any hope of resolving the debate about patenting biological materials? Or, are we destined to wrangle incessantly over the appropriateness of biopatents (Chapter 5)?

This chapter will explicate and apply a pluralistic theory of value to the controversial issues in the debate over patenting biological materials. The hope is that through this process some resolution(s) may be found to diminish the otherwise intractable difficulties associated with biopatents. Part of the task will be to explicate what Elizabeth Anderson calls an ideal-based pluralistic theory of value.

6.2 Elizabeth Anderson's Theory of Modes of Valuation

Elizabeth Anderson is Associate Professor of Philosophy at the University of Michigan. Her pluralistic theory of valuation is expounded in her volume, *Value in Ethics and Economics*.¹ Anderson's theory provides a very useful schema for understanding the ways we might appropriately value biological materials—including human body parts, whole animal organisms, and genetic materials—in relation to property rights.

¹Elizabeth Anderson, *Value in Ethics and Economics* (Cambridge, MA: Harvard University Press, 1993), p. 14. Hereafter *VE&E*.

A *pluralistic theory* of value recognizes that goods are diverse, differing in kind and quality. Our evaluative judgments are likewise manifestly pluralistic. While, as we have argued, biopatents rest essentially on only one mode of valuation (viz., market values), it may be appropriate for us to value biological materials in ways other than commercially. At least, this is the case I will argue.

To value something is to be positively disposed toward it. That is, when we value a thing we possess one or more positive attitudes about it. Parents love their children, observers appreciate a lovely sunset, and homeowners find their houses comfortable. Since there are a variety of ways of being positively disposed toward a thing, values are not monistic but pluralistic. Furthermore, as Anderson says,

... to judge that something is good is to judge that it is properly valued. And to judge that it is bad is to judge that it is properly disvalued. Often people judge that something is good in some particular respect, as in being charming, or inventive. I suggest that the proposition "x is F," where F is a respect in which something is judged to be genuinely valuable, entails that x meets a particular standard F, and that x merits valuation in virtue of meeting F.²

Anderson's pluralistic theory of value is a version of *rational attitude theory* in that Anderson holds that it is "correct" to value a thing if and only if it is rational to value it. Attitudes involve not just feelings, as with forms of emotivism, but with "judgment, conduct, sensitivities to qualities in what we value, and certain ways of structuring deliberation concerned with what we value."³ Moreover, there are a variety of correct ways to value things. For instance, love admits different forms: parental, romantic,

²VE&E, p. 2.

³Ibid., p. 5.

fraternal, etc. Admiration and respect are also various ways of being positively disposed toward an object. Anderson calls these diverse ways of valuing objects "modes of valuation."⁴

In addition, Anderson's ethical theory may be called an *ideal-based theory*.

The core of an ideal consists in a conception of qualities of character or characteristics of the community, which the holders regard as excellent and as central to their identities. Associated with this core is a conception of admirable conduct or worthy practices and projects that demand the cultivation, exercise, and expression of these qualities. An ideal is constitutive of a person's identity if it governs her self-assessments and her responses to her achievement and failure and if she uses it to discipline her desires and frame her choices. Failure to live up to one's ideals will prompt shame, guilt, self-contempt, or other negative self-assessing emotions. Circumstances which prevent a person from realizing her ideals are likely to be experienced as humiliating and degrading, not just as frustrating.⁵

Thus, one's ideals enable her to distinguish among goods which are more or less important to her goals, and therefore goods which are weakly or strongly valued.

This ideal-based, pluralistic theory of value admits many and varied modes of value and disvalue. Anderson illustrates the way her theory contrasts with, say, Kantian theory which admits a very narrow range of value.⁶ Her moral theory, unlike Kantian deontology, supports appropriate treatment of animals as sentient beings. "The ideal of a

⁴Ibid., p. 6.

⁵Ibid., pp. 6-7.

⁶Kant only admits two modes of valuation: intrinsic value and instrumental value. As he says, "In the kingdom of ends everything has either a price or a dignity. Whatever has a price can be replaced by something else as its equivalent; . . . whatever is above all price, and therefore admits of no equivalent, has a dignity." Immanuel Kant, *Groundwork of the Metaphysics of Morals*, Translated and analyzed by H. J. Paton (New York: Harper and Row Publishers, 1958), p. 102.

pet owner includes much more than even the avoidance of cruelty and the provision of basic necessities—we criticize an owner for failing to show proper affection for her pet. Although we make fewer demands for our treatment of animals in the wild, there is a baseline of care which we should show for all animals,”⁷ says Anderson. This mode of valuation Anderson calls “consideration.” Despite the fact that animals are not rational, consideration entails a way of caring for them which attends to their interests as sentient beings.

Furthermore, Kantian moral theory views inanimate nature instrumentally, merely as a means to an end. Today we “recognize ideals expressed in environmental movements to preserve ecosystems and natural wonders which express a deeper concern for nature.”⁸ Anderson calls this mode of valuing inanimate nature, “appreciation.”

In sum, “Use, respect, appreciation, consideration, and love are five different ways of valuing things.”⁹ There are also many other modes of valuation, such as admiration, honor, reverence, etc. Modes and expressions of disvaluation include disrespect, humiliation, mockery, despising something, and hatred. These modes of valuation are supported by the variety of ideals a person possesses. Goods differ in kind if they are properly valued in different ways.

Ideals tell individuals how they should value different things, depending on their value and personal importance. Some goods merit a particular mode of valuation because they meet a standard of value: beautiful things are worthy of appreciation,

⁷*VE&E*, p. 9.

⁸*Ibid.*, p. 10.

⁹*Ibid.*

rational beings of respect, sentient beings of consideration, virtuous ones of admiration, convenient things of use. Here the pluralism of values or standards underwrites the pluralism of kinds of goods. Other goods are appropriately valued in a particular way because of their relation to the valuing agent, which makes them important to him.¹⁰

Anderson's theory is also an *expressive theory* in that modes of valuation involve a complex of emotion, desire, perception, deliberation, and conduct that expresses one's valuation of the object's importance. For instance, to love another person entails the performance of those actions which express that love, which show the special importance of the loved one to the lover.

Finally, Anderson's theory is *socially based theory*. That is to say, "I am capable of valuing something in a particular way only in a social setting that upholds norms for that mode of valuation."¹¹ Respecting another person entails expressing that respect in ways (through certain actions, gestures, manners of speaking, etc.) which are commonly understood to express honor in one's cultural context. "To care about something in a distinctive way, one must participate in a social practice of valuation governed by norms for its sensible expression."¹² Thus, Anderson summarizes her view: "The following shall be my primary account of the heterogeneity of goods: goods differ in kind if people properly enter into different sorts of social relations governed by distinct norms in relation

¹⁰Ibid., p. 11.

¹¹Ibid., p. 12.

¹²Ibid.

to these goods. It is proper for them to do so if it makes sense to value the goods in the ways expressed by these norms.”¹³

Anderson is aware that her socially grounded, ideal-based, pluralistic theory of value runs counter to those philosophical traditions which seek to establish a monistic theory of value. Monistic theories of value are, according to Anderson, “drastically reductionistic.”¹⁴ Monistic theories of value assume that just one attitude or desire, for instance, is normative. The bulk of her work in *Value in Ethics and Economics* is a defense of her view against monistic theories of valuation. I will not rehearse these arguments here. Instead, I will seek to apply Anderson’s theory to the problem of valuing biological materials. I will explicate additional features of Anderson’s theory as they are necessary to the discussion which follows.

6.3 Valuing the Human Body

As we have seen in Chapters 2 and 3, patenting regimes and property discourse encourage economic modes of valuation. Since *Chakrabarty*, the U. S. Patent and Trademark Office has been issuing utility (composition of matter) patents on living organisms. Utility patents establish an exclusive, exclusionary property right in the object of the patent. Courts have adjudicated cases involving these patents in terms of market values and economic modes of valuation.

¹³Ibid.

¹⁴Ibid., p. 15.

Property, ownership, transfer, and inheritance are the moral-legal categories of property discourse. Yet Western culture, especially American culture, has a long tradition of treating the human body and the human person with special respect.¹⁵ Even after death the human body is accorded special respect.¹⁶ Thomas Murray has argued that the value of human bodies should be conceived in terms of "gift" relationships instead of contractual relationships.¹⁷ Contracts rely on market mechanisms or legal remedies to resolve disputes about property. Gift relationships, he says, "are better for initiating and sustaining more rounded relationships, where future expectations are unknown, and where exchange of goods is secondary in importance to expressing the relationship itself."¹⁸ This gift relationship and the special respect for the body it entails, result in special community obligations.

... the evidence of charitable practices in general and gifts of the body in particular affirm the belief that there *are* human needs—biological and cultural; that the body, especially in its health-giving and life-saving manifestations, should not be treated as a mere commodity; and that we are bound together by our often needy bodies (and by our other, nonphysiological needs) into a community of needs. In this community—really multiple communities, sometimes overlapping, some like ripples extending wider and wider around a core—we can recognize the

¹⁵Of course, there have been notable exceptions to this rule. Human chattel slavery and the Holocaust are infamous examples. Nevertheless, in recent history our moral sentiments have excluded these practices from the realm of acceptability.

¹⁶For an interesting discussion of the ways the human body is treated after death see Kenneth V. Iserson, *Death to Dust: What Happens to Dead Bodies?* (Tucson, AZ: Galen Press, 1994).

¹⁷Thomas H. Murray, "Gifts of the Body and the Needs of Strangers," *Hastings Center Report* (April 1987), pp. 30-38.

¹⁸*Ibid.*, p. 31.

needs of others through our shared embodiment. And we can minister to those needs by sharing the fruits, the very living tissues of the body.¹⁹

Several points should be observed with respect to Murray's argument. First, Murray's conceptualization of the body as gift is more consistent with Elizabeth Anderson's moral theory than the monistic theory which informs property discourse. We value the body in a variety of noneconomic ways: with respect and appreciation, for instance. Second, the values of the human body are rooted in the ideals of the community. In this case, the community is not only defined locally but globally. Murray provides an impressive survey of cultures whose ideals about the body demonstrate decidedly noneconomical modes of valuation. Third, economic modes of valuation are forms of commodification. Commodification is problematic when applied to the human body or to human body parts.

6.4 Commodification and the Human Body

Many items are commodified in contemporary society. There is even a "commodities exchange." But commodification becomes problematic when it becomes a universal practice. By commodification I mean applying economic modes of valuation to items which have been traditionally the objects of noneconomic modes of valuation. Commodification is based upon two assumptions of market value: (1) "that there exists some scale into which every value inhering in a good can be translated" and (2) "that this

¹⁹Ibid., p. 38.

scale is money."²⁰ That is, commodification entails that all modes of valuation are commensurate with economic valuation.

Margaret Jane Radin, Stanford University professor of law, has done seminal work on commodification theory. Both in her work *Reinterpreting Property*²¹ and her more recent volume *Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts, and Other Things*,²² Radin examines what she calls "commodification as a worldview."²³

In universal commodification, the value of a commodity (from the social point of view) is defined as its exchange value, often referred to as market value, when it is traded in a laissez-faire market—or hypothetically traded in a hypothetical laissez-faire market. Valuation in terms of dollars implies that all commodities are fungible and commensurable—capable of being reduced to money without changing in value, and completely interchangeable with every other commodity in terms of exchange value.²⁴

Radin denies that all values or modes of valuation are commensurable with market values.

In fact, the burden of her work is to demonstrate that some forms of commodification are

²⁰E. Richard Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, DC: Georgetown University Press, 1996), p. 148.

²¹Margaret Jane Radin, *Reinterpreting Property* (Chicago: The University of Chicago Press, 1993).

²²Margaret Jane Radin, *Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts, and Other Things* (Cambridge, MA: Harvard University Press, 1996).

²³*Ibid.*, pp. 1-14.

²⁴*Ibid.*, p. 3.

clearly wrong. For instance, a market in babies is immoral in Radin's view.²⁵ When a baby is bought and sold in the marketplace—i.e., becomes a commodity—her personal traits or attributes (sex, eye color, I.Q., predicted height, etc.) also become commodified.²⁶ Furthermore, commodification of the infant is *ipso facto* a form of commodification of the future person (e.g., the academic, the homemaker, the career woman, etc.) the baby will become, according to Radin. Baby giving (adoption) is nonproblematic for Radin (for similar reasons as giving the gifts of the body is unproblematic for Murray). In fact, giving up a child for adoption may be seen as a commendable form of altruism in those cases where the adoption results in good to the child and contributes to the adoptive parents' lives.

A socially grounded, ideal-based pluralistic theory of value will not countenance selling babies either. The most fundamental mode of valuation between parents and children is love. According to Elizabeth Anderson, "Parental love can be understood as a passionate, unconditional commitment to nurture one's child by providing her with the care, affection, and guidance she needs to develop her capacities to maturity."²⁷ This seems to be an uncontested definition of parental love. Buying and selling children would seem, then, to alter radically our understanding of parental love and the correlative rights of parents with respect to their children. Instead of love as a mode of valuation,

²⁵For the purposes of her argument, Radin distinguishes between surrogacy and a woman selling her own baby, though it is clear that Radin finds paid surrogacy unethical. See *Ibid.*, p. 142ff.

²⁶*Ibid.*, p. 137.

²⁷Elizabeth Anderson, *VE&E*, p. 170.

something more similar to (if not, in fact) property rights would result. Rights of ownership and transfer would govern the relationship between parent and child rather than obligations of love and trust.

What remains to be examined is whether and to what extent these inferences about buying and selling children (or adults for that matter) may be transferable to buying and selling human body parts. In the case of John Moore and his splenic cells, Justices Arabian and Mosk were concerned about the implications of subjecting Moore's organs to market discourse (see Chapter 3). Justice Arabian opined that, "The ramifications of recognizing and enforcing a property interest in body tissues are not known, but are greatly feared—the effect on human dignity of a marketplace in human body parts, the impact on research and development of competitive bidding for such materials, and the exposure of researchers to potentially limitless and uncharted tort liability."²⁸

Should we reduce John Moore's spleen cells to market values? If the body in general and the spleen in particular are merely biological machines, then there seems to be no good reasons for discouraging the patenting of the body and its cellular parts. Nevertheless, the body is valued in Western societies in other than market values. Not only is this evident in American culture, but in others as well. The body *qua* body is the subject of a variety of modes of valuation, but none of them are economic.

The human body, for example, is part of our self-definition. Our self-identity is intractably connected to our embodiment. In another work, Radin says that

²⁸*Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990), p. 498.

commodification of the body creates two kinds of alienation. The first kind of alienation is an alienation from the body itself.²⁹ This kind of alienation inclines one to disassociate herself from her own body. For example, the surrogate mother who agrees to sell the child she is carrying is alienated from the daily experience of pregnancy in remarkable ways, including the sense that the pregnancy is "her" pregnancy and that the child she is carrying is "her" child. The second kind of alienation, Radin argues, is alienation from the community. For instance, those who contract with the surrogate regard some relationship to the child she is carrying as important to their future, while at the same time encouraging the surrogate mother to regard her relationship with the child as trivial or reductionistic (i.e., reduced to market value).

There are, of course, many other ways we value the body *qua* body. We value the body as the seat or extension of our autonomy. Thus, the experience of physical disability is often accompanied by a sense of having lost one's self-determination. We value the body as a boundary between us and the world around us. Interestingly, we even create a space around the body which may not be violated except in rare circumstances. We, therefore, often feel discomfort when we must sit or stand too close to another. Yet among all the ways we value the body *qua* body, we do not value it in terms of market values.

Someone might object and claim that we value the body in economic ways when we award financial compensation for personal bodily injury. But when a court awards

²⁹Margaret Jane Radin, "Market Inalienability," in K. D. Alpern (ed.), *The Ethics of Reproductive Technology* (New York: Oxford University Press, 1992), p. 180.

\$100,000 for the loss of an arm in an accident, the court is not equating the arm with a certain dollar amount. Radin argues, correctly I think, that in these cases "compensation is understood not as a commensurable quid pro quo for harm, but rather as a form of redress: affirming public respect for the existence of rights and public recognition of the transgressor's fault with regard to disrespecting rights."³⁰ Some might argue with Radin's characterization of the law, but, it seems too incredible to imagine that a jury which awards compensation for personal injury believes it is assigning a market value to a lost or injured body part. In fact, juries probably award sometimes inordinantly high monetary penalties just because they know that a market value cannot be put on the loss of life or limb. As one court put it:

An economic loss can be compensated in kind by an economic gain; but recovery for non-economic losses such as pain and suffering and loss of enjoyment of life rests on "the legal fiction that money damages can compensate for a victim's injury." We accept this fiction, knowing that although money will neither ease the pain nor restore the victim's abilities, this device is as close as the law can come in its effort to right the wrong. We have no hope of evaluating what has been lost, but a monetary award may provide a measure of solace for the condition created.³¹

It seems clear then that the human body and its parts are not commensurable with economic modes of valuation. When legal conventions, such as patent regimes, attempt to assign market values, through the extension of exclusionary property rights, to objects which are not appropriately valued economically, they commodify those objects. As Richard Gold says, "The market has no mechanism by which to compare the values of autonomy, dignity, and increased health or to decide whether a holistic or reductionalist

³⁰Radin, *Contested Commodities*, p. 185.

³¹Cited in *Ibid.*, p. 193.

approach to medicine is most beneficial.”³² Commodification may be appropriate to nuts and bolts, but it is not appropriate to the human body or human body parts..

6.5 Human Genes

What about patenting human genes? Unlike many human body parts, the human gene seems less a constitutive part of the human body than solid organs. Furthermore, like blood and other bodily fluids, genes are replenishable. Yet there seem to be at least several reasons human genes should not be deemed patentable. First and most obviously, unaltered human genes are not patentable because items as they are found in nature are not patentable (see Chapter 2). The identification or sequencing of a human gene does not meet the novelty requirement of patent law. Without alteration there is no legally legitimate claim to ownership of a human gene or genetic sequence.

Second, as with expressed sequence tags (ESTs) of unknown biological function, some gene sequences do not have utility. Unless utility can be demonstrated, objects are not patentable.

Quite apart from these first two objections to patenting human genes, an ideal-based, pluralistic theory of value will not support gene patenting. Human genes are not patentable *qua* genes. Patents, it will be recalled from chapter 2, are a form of intellectual property protection. But ideas themselves are not patentable. Only ideas instantiated in patentable objects are patentable. No one can prevent another person from sharing their own idea. Intellectual property protection does not prevent others from thinking one's

³²E. Richard Gold, *Body Parts*, p. 157.

thoughts. Rather, intellectual property protection prevents others from *using* one's ideas. A patent is a form of property right which restricts the sale, use, or manufacture of a patented object. Even copyrights do not protect a person's ideas *per se*. Again, anyone may think another person's thoughts after them. Copyrights protect one's thoughts as they are instantiated in a piece of written material. Similarly, patents on intellectual property protect one's idea as it is instantiated in a patentable object.

If the problem of commodification is properly understood, any human gene which is instantiated in another human body, and is therefore the potential object of patent protection, suffers the same fate as a bodily organ. That is, if the human body and its organs are not the appropriate subject matter of patents, then neither would human genes inserted into the human body be appropriate subject matter for patents. The human body and its parts, including those parts which have been altered by genetic manipulation, would not be the appropriate subject matter of patent protection. Patented human genes inserted into the human body would be subject to modes of valuation not appropriate to the human body or its parts.

6.6 Animals and Modes of Valuation

Of course, some living things are commodities. Not only is livestock bought and sold every day on the commodities exchange, but also, dogs, cats, fish, and exotic animals are sold in pet shops and kennels. Animals have been the objects of economic modes of valuation for centuries. Thus, it may be more difficult to establish a prohibition against patenting animals than against patenting the human body and human body parts.

Traditionally, animals have been valued in the West as instrumental goods. That is, animals have been valued for their contribution to human happiness, welfare, desires, etc. Only more recently have theories of animal interests and animal rights become sophisticated and popular.³³ Many of these arguments focus almost exclusively on animal harms. An example of the way these arguments are used against patenting is found in the following statement by philosopher Bernard Rollin. In his argument against animal patenting Rollin asks rhetorically,

Will society accept a proliferation of defective disease-modeling animals who live lives of constant suffering for human benefit? Will it accept, to take an example actually suggested by a genetic engineer, a ten-thousand-pound cow? Will it accept animals that are nakedly designed to be nothing but factories at a time when it is rejecting, or at least questioning, confinement agriculture?³⁴

Indeed, biotechnology poses great potential harm to animals. Transgenic animals, animals whose genomes have been altered by the insertion of a human or other foreign gene, may well suffer due to genetic manipulation. We have already mentioned the Beltsville pig (Chapter 5) and the complications of introducing human growth hormone

³³See for example, Tom Regan, *The Case for Animal Rights* (Berkeley, CA: University of California Press, 1983); Mary Midgley, *Animals and Why They Matter* (Athens, GA: University of Georgia Press, 1984); Peter Singer, *Animal Liberation: A New Ethics for Our Treatment of Animals* (New York: New York Times Publications, 1975); Bernard Rollin, *Animal Rights and Human Morality*, second edition (Buffalo, NY: Prometheus Books, 1992); and Tom Regan and Peter Singer (eds), *Animal Rights and Human Obligations* (Englewood Cliffs, NJ: Prentice Hall, 1976).

³⁴Bernard Rollin, *The Frankenstein Syndrome: Ethical and Social Issues in the Genetic Engineering of Animals* (New York: Cambridge University Press, 1995), p. 208.

into animals. Michael Fox, officer of The Humane Society of the United States, rehearses a litany of harms to transgenic animals in *Superpigs and Wondercorn*.³⁵

While it may be argued that patenting regimes exacerbate the potential for harms to animals by providing incentives to genetically manipulate those animals, it is not the case that all genetic engineering necessarily results in animal suffering. In fact, genetics have been used to relieve animal suffering in some cases (as in veterinary science). Animal suffering, then, is not necessarily endemic to biotechnology. At the same time, animal suffering may result through biotechnology even without patenting. Biotechnologists may, without the benefit of patent protection, manipulate animal genes in ways which cause suffering. Therefore, patenting transgenic species does not necessarily result in animal harms, if harms are defined as suffering and pain.

A pluralistic theory of value might be, nonetheless, appropriately applied to animals in such a way as to prohibit patents on transgenic species. While individual animals may be valued in economic ways, it is unclear that market values ought to apply to entire animal species. Individual animals may be owned, but animal species are valued in ways other than fungible property.

Anderson's view is that "we value some environmental goods in higher ways than we value pure commodities."³⁶ For instance, we value environmental goods aesthetically

³⁵Michael W. Fox, *Superpigs and Wondercorn: The Brave New World of Biotechnology . . . and Where it All May Lead* (New York: Lyons & Burford, 1992). See also his "The New Creation: An Update on Animal Gene Engineering," in June Fessenden MacDonald (ed), *Animal Biotechnology: Opportunities and Challenges* (Ithaca, NY: National Agricultural Biotechnology Council, 1992), pp. 49-61.

³⁶Anderson, *VE&E*, p. 208.

or because of their ecological significance. We do not preserve the wilds on the basis of an economic cost-benefit analysis. Furthermore, we do not offer environmental goods for purchase to the highest bidder. Mt. Everest does not have a cash value. Interestingly, the United Nations Convention on the Law of the Sea proclaims that the seabed and the ocean floor and its resources may not be owned. These resources are reserved for all humankind and are not to be reduced to market values. Similarly, animal species are subject to modes of valuation that might include appreciation, aesthetic enjoyment, and biodiversity. Animal species do not admit to cash values. What is the value that one would put on mammals, or even arachnids? Modes of valuation applied to animal species are incommensurable with market values.

This view does not entail that animals may not be used in experimentation (provided that they are not subjected to unnecessary harm). But it does mean that entire animal species are not to be exhausted or driven to extinction to serve human ends. The Endangered Species Act and similar laws against species extinction are expressions of society's ideals with respect to animal species.

Transgenic animals are species or subspecies of animal life. The patent on the Harvard oncomouse is an example of an inappropriate mode of valuation applied to an animal species. Through the patenting process, an entire species (viz., all mammals with a human cancer gene inserted) is reduced to market values. This is the intuition to which Kass appeals when he says, "It is one thing to own *a* mule; it is another to own *mule*."³⁷ Furthermore, he says, "We do not endorse possession for the sake of possession: The

³⁷Kass, *Toward a More Natural Science*, p. 151.

thought of a man buying up and collecting all the world's camels or giraffes or horses is repulsive, though nothing in the law prevents it."³⁸

Another reason a ideal-based pluralistic theory of value might forbid patenting of transgenic animals is that most transgenic animals produced by introducing human genetic material into animals. In these cases, the problem of commodification of human genes comes into view. If our understanding of commodification is accurate, then it is wrong to submit human genes inserted in animals to patenting regimes. To have an intellectual property right in the instantiation of the idea (in the form of an animal species) is morally problematic for the reasons we have already explained. Not only may animal species not become the objects of commodification themselves, but since the human genome or its parts should not be commodified, neither should animals which are altered to include portions of the genome become the objects of commodification.

Finally, transgenic animals should not be the objects of intellectual property rights because it is clear that they are not inventions. Mark Sagoff has argued that even though Chakrabarty altered or manipulated bacteria, it is not accurate to say he "invented" it.³⁹ Thus the Chakrabarty patent on oil-eating microbes confuses invention with the production of a new bacterial strain. Says Sagoff, "To cross strains of plants or microinject genes into embryos is not to invent, design, or create living things."⁴⁰ Sagoff

³⁸Ibid., p. 150.

³⁹Mark Sagoff, "Animals as Inventions: Biotechnology and Intellectual Property Rights," *Report from the Institute of Philosophy and Public Policy* 16, p. 17.

⁴⁰Ibid., p. 19.

is not denying that effort or labor is involved in the manipulation of living entities, but that manipulation is not relevantly similar to creation. As he points out, in *Funk Brothers Seed Company v. Kalo Inoculant*, the Supreme Court found that merely combining bacterial strains found in nature did not constitute "an invention or discovery within the mean of the patent statutes."⁴¹

According to the Court, "a product must be more than new and useful to be patented; it must also satisfy the requirements of invention." The Court regarded the repackaging of genetic information taken from nature as a commercial not a scientific advance: "Even though it may have been the product of skill, it certainly was not a product of invention."⁴²

6.7 Alternatives to Patenting Biological Materials

If patents are inappropriate means by which to protect biological materials, are there alternative ways to provide incentives for scientific research and, at the same time, reward those who are responsible for a new idea or improvement on an existing idea? This question is, in my view, of extraordinary import. Many of the products of biotechnology are tremendous boons to human health and flourishing. Proponents of patents, in fact, point to this as the primary reason for preserving biopatents. Without patents in living organisms, will significant research continue? The first part of this chapter will focus on possible alternatives to biopatents. The second part of this chapter suggests areas for additional research.

⁴¹*Funk Brothers Seed Company v. Kalo Inoculant*, 75 USPQ 280.

⁴²Sagoff, p. 16.

It must be pointed out that the argument against utility patents in biological materials does not preclude process patents on the methods for altering organisms, cell lines, cells, genes, or body parts. "Processes," say Chisum and Jacobs, "are methods and procedures (roughly speaking: how to do something)."⁴³ A process patent is a form of intellectual property protection on a method of making something. In the case of biological materials, the patent might be granted on the method for altering an existing organism. Interestingly, the Chakrabarty patent on oil-eating microorganisms included claims on both the process and the composition of matter. A process patent, protecting Chakrabarty's right to exclude others from using his method to produce those microorganisms is unproblematic. Industrial methods are the kinds of things we value in economic ways. Processes may be valued economically without becoming reductionistic and process patents do not subject biological materials to commodification.

Another alternative to composition of matter patents in biological materials is the Statutory Invention Registration (SIR). A SIR is a form of patent protection which protects a persons research without conferring monopoly rights. Thus, the SIR "does not protect the claimed invention from unauthorized use but is a way of making the application's disclosures prior art against other person's subsequently filed applications because the SIR's disclosures are effective as prior art as of its effective United States filing date."⁴⁴ SIRs are established in U.S. law in 35 U.S.C. Section 157. SIRs contain

⁴³Donald S. Chisum and Michael A. Jacobs, *Understanding Intellectual Property Law* (New York: Matthew Bender & Co., 1992), § 2C[1][a].

⁴⁴*Ibid.*, § 2C[5][e][iv].

the same specifications, drawings, and claims sections of other forms of patent protection, but they do not confer limited ownership rights. Through SIRs, researchers may be acknowledged for the ingenuity of their manipulation while, at the same time, the subjects of their manipulation are not commodified. If Harvard had a SIR on the oncomouse, Leder and Stewart would receive the professional honor of having manipulated a mouse which is useful in cancer research, yet oncomammals would not be the exclusive property of Harvard University. An article in *The Scientist* observes,

Publication of important results often leads to additional grant support, career promotions, invitations to speak at important gatherings, and many other benefits that accompany a boost in scientific status. And it is in this area that competition among scientists is sharpest, researchers contend, rather than for patents. More than financial rewards, researchers want to be credited with discoveries.⁴⁵

Another alternative to applying patent regimes to animal species, human body parts and other biological materials would be a significant increase in government funding for biotechnological research. Caplan and Merz observe that there is something intuitively amiss in a system in which tax-payers fund research which later makes fortunes for private entrepreneurs. With respect to the debate of patenting ESTs, they ask: "If government funds have been used to map and sequence the human genome, why should the fruits of that effort be turned over to a single owner?"⁴⁶ Hettinger has argued that if biopatents

⁴⁵Franklin Hoke, "Gene Patenting On the Rise, But Scientists Are Unimpressed," *The Scientist* 9 (17 April 1995), p. 7.

⁴⁶Arthur Caplan and Jon Merz, "Patenting Gene Sequences: Not in the Best Interests of Science or Society," *British Medical Journal* 312 (13 April 1996), p. 926.

were prohibited, "Increased public funding for biotechnical research should be used to offset unwanted decreases in incentives to innovate, should they result."⁴⁷

There is no empirical data to demonstrate that patenting, in fact, stimulates research and bringing biotechnological products to market.⁴⁸ It is largely assumed that patenting has provided incentives for research which otherwise would not have been done. Nevertheless, reports of patenting as an incentive to research are anecdotal. At the anecdotal level testimonies like that of University of Utah scientist Mark Keating must be taken into account: "My science is not driven by wanting to get patent applications. Nobody goes into science because they think they're going to get rich. Some patents are world-beaters, but most don't amount to a hill of beans."⁴⁹

The Council for Responsible Genetics (CRG) is an scientific watch-dog group committed to raising public awareness about the potentials for abuse of genetic technologies. Their document entitled, *No Patents on Life!*, asks whether or not a prohibition on patenting biological materials would obstruct the development of life-saving drugs. CRG answers,

Important drugs and vaccines have been produced and successfully distributed in the absence of patents, such as a recent vaccine for malaria and the Salk polio vaccine. The patenting process allows the speedier development of some drugs

⁴⁷Ned Hettinger, "Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics," *Boston College Environmental Affairs Law Review* 22 (1995), p. 305.

⁴⁸This conclusion has been reached both through an extensive survey of the literature and in private conversations with Sheldon Krimsky of Tufts University and Gillian Woolett of the Biotechnology Industry Organization (BIO).

⁴⁹Hoke, "Gene Patenting on the Rise," p. 7.

through the promise of large profits; however, patents are also used to suppress competition and prevent other institutions from conducting beneficial research. Patents serve the interests of the investors who are looking for rapid return on their investment. The interests of those in need of medicines are often not of primary importance. Both India and Brazil prohibit the patenting of pharmaceuticals and food crops. As a result, quality products are available to everyone at a more affordable price.⁵⁰

Increased levels of public funding for biotechnological research and Statutory Invention Registration might be combined to both finance useful needed research and reward researchers and institutions professionally. Sufficient government funding and immediate disclosure of information might be a way to maintain incentives to research and avoid the commodification of animal species, human beings, and their body parts. Furthermore, since patenting tends to skew research by rewarding only marketable inventions, excluding biological materials from the patent protection might serve as a means to broaden research to areas which might be useful but which might not lead immediately to marketable products.⁵¹

Admittedly, this alternative seems more unworkable than others. In an era of pervasive government downsizing and budgetary cutbacks and burgeoning biotechnological industrialization, it is unlikely that Congress will fund public research at

⁵⁰The Council for Responsible Genetics, *No Patents on Life! DNA Patents Create Corporate Monopolies on Living Organisms*, nd., p. 2.

⁵¹For instance, Laura Meagher, Associate Dean of Research, Cook College, Rutgers University, told a meeting of the National Agricultural Biotechnology Council, that "with the incentive of ownership and patenting, and with pressure on land-grant institutions to apply for ownership and make money," she "is concerned that profit-minded researchers will only research big money items to the exclusion of less profitable projects which help provide the knowledge base which has fueled recent innovation." "Genes for the Future: Discovery, Ownership, Access," *NABC News* 11 (Fall 1995), p. 7.

sufficient levels. However, a system of government funded biotechnological research might well test society's commitment to these technologies. Just as health care has come under public scrutiny and theories of social justice have been brought to bear on access to scarce medical resources, public funding of biotechnological research might cause society to make important choices about what it is willing to fund. How such an experiment might work out is a matter of conjecture.

Clearly, as with other issues arising from the new genetics, the proliferation of biopatents requires public scrutiny and deliberation. Decisions about what should be patentable subject matter should not be made via bureaucratic fiat. As the biotechnology industry continues to grow and perceived incentives for patent protection of biological materials continues to expand, the potential for biopatents to violate society's considered moral judgments increases. Legislators should be sensitized to the ethical issues involved in patenting biological materials so that they may inform and consult their constituencies on these matters. Alternatives to biopatents should be likewise addressed and the public informed about these alternatives.

6.8 Suggestions for Further Research

In a market economy commodification is a commonplace. With an increasingly competitive marketplace in biotechnology, the potential problems which may attend commodification become more real and pressing. Not only does the ascendancy of the biotechnology industry raise important questions with respect to commodification, so do the expanding varieties of reproductive technologies. Surrogate motherhood, for instance,

risks commodifying a woman's reproductive organs. Radin has said, "commodification threatens the personhood of everyone."⁵² Additional exploration of the ethical implications of commodification will be increasingly important for the future. Along with Radin, Allen Verhey has begun to address some of these implications in his recent article "Commodification, Commercialization, and Embodiment."⁵³ Likewise, John A. Robertson has addressed some implications of commodification in his provocative volume *Children of Choice: Freedom and the New Reproductive Technologies*.⁵⁴ Much more needs to be done.

A perennial issue in bioethics is exacerbated in the debate over biopatents, namely, how is public policy developed in a pluralistic society? Since biotechnology is a global enterprise, the problem becomes more complicated: how are international policies developed in a wildly diverse world? Again, this is not a new problem, but the stakes seem to be as great in biotechnology as in any other arena. On the one hand, life-saving and health-giving technologies are being developed. On the other hand, these technologies may either violate the moral or religious beliefs of certain cultures or may be developed at the expense of certain cultures. When industrial biotechnology firms in the North exploit the resources of indigenous peoples in the Southern Hemisphere,

⁵²Margaret Jane Radin, *Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts, and Other Things* (Cambridge, MA: Harvard University Press, 1996), p. 125.

⁵³Allen Verhey, "Commodification, Commercialization, and Embodiment," *Women's Health Issues* 7 (May/ June 1997), pp. 132-142.

⁵⁴John A. Robertson, *Children of Choice: Freedom and the New Reproductive Technologies* (Princeton, NJ: Princeton University Press, 1994).

distributive justice issues come to the fore. Should remuneration be made to those people groups? How much should be given? What form should the remuneration take? Should money be exchanged for goods harvested from the South or should other social goods, such as educational benefits or the like, be exchanged for those goods?

Furthermore, since we are living in an increasingly pluralistic culture, how do we adequately attend to all the moral voices? In American bioethics, we often rely on special commissions, like the National Bioethics Advisory Commission (NBAC) to be the sounding board for various interest groups.⁵⁵ Similarly, organizations like the American Association for the Advancement of Science or the Institutes of Medicine often become the venue for discussions among scientists, ethicists, philosophers, and theologians. Typically, some form of consensus is sought. But what does this consensus mean? Is this the best way to frame public policy related to sometimes highly technical issues like genetics? Moreover, as the culture becomes more fragmented and pluralistic, will consensus on these issues remain a possibility?

In my own experience of participating in several dialogues on gene patenting, I have found this problem to be very perplexing at times. Many science and industry representatives have a very reductionistic view of patenting biological materials. For them, human genes are merely bits of biological information. Human tissues are merely

⁵⁵The National Bioethics Advisory Commission was established by President Clinton and operates under the Federal Advisory Committee Act. On May 13-14, 1997, NBAC convened a meeting in Washington, DC to hear from representatives of moral and religious communities concerning cloning. Those two days of testimony generated over 500 pages of transcripts. NBAC issued a report to the President which included recommendations for public policy.

the stuff of research and commerce. For others, genes and tissues have a highly symbolic value and represent something much more intimate and personal than biological information. For still others, such as some Native American groups, there is no way to distinguish human genes and tissues from the other facets of the grand scheme of Life. Devising policy which respects these diverse viewpoints may be an impossibility. Yet, in a representative democracy efforts must continue to be made to do so. While this task is part of an on-going project to frame a theory of distributive and social justice, some of the issues which arise from the new genetics, such as gene patenting, make the project more urgent.

Finally, a third area demanding additional research in a world of expanding biotechnology is the moral obligations owed to transgenic species. So-called animal ethics have focused, for the most part, on obligations to animals used in research and factory farming. In most cases these animals are used as they are found in nature. They are bred through natural breeding techniques or through the use of reproductive technologies. But as we continue to manipulate animal species, making, in some cases, radical alterations to their biology, questions abound as to what special obligations, if any, we might have to animals which come to exist through human manipulation. As participants in a discussion at the Hastings Center put it, "As with many moral issues, the fashioning of transgenic organisms present us with treacherous slippery slopes and moral ambiguities. Such

organisms pose questions about our moral obligations to both our fellow humans as well as the other living beings with whom we share this planet.”⁵⁶

These questions have begun to be explored by ethicists such as Bernard Rollin and Gary Comstock.⁵⁷ These discussion must continue. Recent developments in biotechnology and genetics require that our ethical deliberation catch up with our technical abilities. For instance, British scientists at Bath University announced in October 1997 that they had produced a frog embryo which develops without a head.⁵⁸ Initially, the use of such technologies seem grotesque and evoke what bioethicists have called the “yuck factor.” However, in light of the fact that it is speculated that this technology might be used to produce headless human embryos which might be the source of transplantable organs and tissues, the ethical issues become both profound and urgent. Does biotechnology raise new ethical issues in animal ethics? Or, does biotechnology simply reframe existing questions? How do we measure and account for potential animal harms resulting from transgenic and other forms of manipulation? These questions are bound to nag us for decades.

⁵⁶Strachan Donnelley, Charles R. McCarthy, and Rivers Singleton, Jr., “The Brave New World of Animal Biotechnology,” Special Supplement, *Hastings Center Report* (January-February 1994), p. S14.

⁵⁷See, for instance, Bernard E. Rollin, *The Frankenstein Syndrome: Ethical and Social Issues in Genetic Engineering of Animals* (Cambridge: Cambridge University Press, 1995) and Gary Comstock, “What Obligations Have Scientists to Transgenic Animals?” discussion paper, Center for Biotechnology Policy and Ethics (College Station, TX: Texas A&M University, 1992).

⁵⁸“Technique Creating Headless Embryos May Aid Transplants,” *The (Nashville) Tennessean* (19 October 1997).

6.9 Summary

The problem with patenting the human body, body parts, and animals is that patenting results in commodification. Human beings are valued in many and varied ways. A pluralistic theory of value is consistent with these modes of valuation. Human beings are not, however, valued appropriately in terms of economic modes of valuation. To reduce human beings to market values is to commodify them. Commodification is problematic because the modes of valuation appropriate to human beings are not commensurate with case value or other economic modes of valuation.

Likewise, animal species are not to be reduced to economic modes of valuation. As species we value animals in many and varied ways. Commodification results when animal species are reduced to cash value. Further, when human genes are inserted into animals to form transgenic species, the problem of commodification appears. On the one hand, transgenic species become the objects of economic modes of valuation. On the other hand, human genetic material in transgenic species becomes the object of market values.

Patent regimes are designed to protect intellectual property rights—to exclude others from the sale, use, or manufacture of the subject matter of patents. Patent regimes are, by definition, modes of economic valuation, establishing boundaries in the marketplace. Patents are appropriate to goods which are appropriately commodified. As we have argued, human beings, human body parts (including genes), and animal species are not appropriately valued as commodities.

Biopatents should be the subject of greater public deliberation. Alternatives to composition of matter patents in human and animal biological materials exist and through collaborative efforts between science, industry, law, and public policy groups additional and workable alternatives may be discovered.

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APPENDICES

APPENDIX A

American Society of Human Genetics Position Paper on Patenting of Expressed Sequence Tags

November 1991

The American Society of Human Genetics (ASH), a society of over 4500 American and Canadian physicians, scientists and genetic counselors has followed the development of the human Genome Project with great interest, and considers it to be of great potential benefit to the field of medicine. In a statement strongly supportive of the Project (*Am. J. Hum. Genet.*, 687-691, 1991), the Society endorsed an emphasis on the cloning and sequencing of expressed sequences as one route to achieve greater potential relevance for human health. The ASH is now deeply concerned about the recent submission of patent applications for expressed sequence tags (ESTs) by scientists at the National Institute of Neurological Disorders and Stroke.

The issues relate to two questions, "can they be patented?" and "should they be patented?" (*Science*, 254 184-186, 1991; *Nature* 353 485-486, 1991). The Human Genome Committee of the ASH has taken the view that the issuing of patents for ESTs is likely to do far more harm than good, and that before any patents are issued the impact on the Human Genome Project and on the field of medicine should be carefully examined. This view is supported by the ASH Board of Directors.

First, it should be pointed out that the ASH has not opposed patenting of genetic information when that information had utility. This would include, for example, recombinant clones for the production of human proteins (e.g. factor VIII, growth hormone, erythropoietin) and disease gene probes for diagnostic testing, carrier identification and prenatal diagnosis (e.g. cystic fibrosis, muscular dystrophy, fragile X syndrome).

The attempt to patent ESTs, however, is another matter. The ASH does not support the concept of patenting a short sequence from a randomly isolated portion of a gene encoding a protein of unknown function. "How can you patent something when you don't know what it is, much less what it will be used for?" (*Science*, 254, 184-186, 1991).

Furthermore, the ASH does not consider that the three tenets of patentability (novelty, non-obviousness and utility) have been met. We wish to make two points in this regard. First, there is absolutely nothing novel about the identification of ESTs. An EST is simply a DNA sequence of a short segment of a cDNA clone that is picked more or less at random from a set of cDNA clones obtained by essentially standard published procedures. The idea of picking a large number of cDNA clones and using the sequence of a short piece of each as a genetic marker or tag is also an obvious approach that has been

extensively discussed in the human genetics community and it is currently the basis of on-going genome projects both within and outside the USA.

Second, the utility of ESTs can be seriously questioned. Scientific experience suggests that an EST itself is unlikely to have commercial utility. The anticipated utility of an EST is simply as a research tool to identify the remainder of the coding region of the gene. Additional research would allow the determination of its DNA sequence, the deduced amino acid sequence of the encoded protein, reagents to generate antibodies against the protein and clues to the protein's structure and function. Further, if the protein was defective in individuals with a genetic disease or genetic predisposition to disease, then the gene and its product might have utility in diagnostic or therapeutic applications for that disease. Thus, the utility would not be known until additional research was complete and the utility would almost certainly rest with the full cDNA, the genomic clones containing the gene or the protein product of the gene, and not with the EST itself. The EST is, at best, a starting point for further research, and should not be patentable.

With regard to the second question - should they be patented? - the ASH is concerned that patenting of ESTs may be quite detrimental to the interests of the Human Genome Project and to society. The issue is complex. Indeed, the genome project itself is a venture whose very nature, magnitude and scope is new to society, and the complex ethical, legal and social issues raised by the project are challenges worthy of careful and considered debate. At this time, the issue of patents for ESTs deserves particular attention.

The primary concern is that the Human Genome Project should be a project of international collaboration. It should not be a competition between laboratories and between countries to see who can "own" the largest portion of the human genome. HUGO, the international Human Genome Organization, has stated this principle since its inception in 1988. The patenting of ESTs clearly and unequivocally contradicts this principle. There is no question that the patenting of ESTs by the NIH group, or by anyone else, will precipitate a race to isolate ESTs in many countries, a race to patent throughout the world and a race to exploit the genome information for all its "worth". It is virtually certain that under such conditions the information would not be shared between the competing groups until after patents are secured, so that duplication of effort will be impossible to avoid.

A second concern is the morass of competing claims that will be created by allowing patents for ESTs. Since an EST is part of a gene it is clear that different ESTs from the same gene may be isolated by different groups. Furthermore, a gene is often part of a gene family so that one EST may recognize more than one gene. We anticipate major problems in dealing with patent claims when several research groups could end up with competing claims for the same gene or genes. In essence, an EST is not specific enough to be the only marker for a gene nor to be a marker for only one gene.

A third concern is the potential inhibitory effect of patenting ESTs on the scientific community, both academic and commercial. Normally, a patent ensures that a gene will be available for all researchers and for any company willing to license it. We fear that in the case of ESTs it may have quite the opposite effect. An EST patent, to be useful to the commercial sector, must make broad claims in regard to future use, including protection for the rest of the gene and its protein product, and their use for diagnostic and therapeutic applications. The academic community is unlikely to put major research effort into an EST-identified gene or its protein product if someone else already has the right to license its use based on the trivial effort required to sequence the original EST. In the commercial sector there may be reluctance to invest heavily in further research on EST-identified genes when a small but unknown fraction of them will turn out to have commercial utility, and when the useful ones may be contested by patents involving other ESTs from the same gene. Genome research could end at the level of ESTs.

Finally, we wish to make one point with regard to urgency in this matter. The ASH recognizes that the decision regarding patentability of ESTs in the US rests with the US Patent and Trademark Office. Given the high stakes of the decision on medical science, the biotechnology industry, the delivery of health care, and on the international cooperativeness in all these areas, the ASH urges the patent office to give high priority to the resolution of the EST patent issue.

Furthermore, we urge the patent office to take into account not only the current patent law, but to consider also the implications of the decision for the field of medical science and for the international community in which we live. One argument for patenting ESTs has been that if they were published without patenting this might compromise the patentability of a future diagnostic or therapeutic procedure based on a gene or gene product derived from an EST in the public domain. What is needed without delay is a statement from the US patent office with regard to this potential problem. If it is not a problem, then it takes away the main argument for patenting ESTs. If it is a problem, then perhaps the best course is to rethink current patent law and to amend it to insure that the genome effort is not thwarted by laws developed in simpler times to deal with simpler issues.

An international collaborative venture as bold as the Human Genome Project should not be jeopardized by the possibility of irrevocable damage inflicted by EST patents, the majority of which may never have any commercial utility. Let us strive to ensure that patents are obtainable at a stage in the process that will still allow commercial exploitation of genetic information, but not so early in the process that it will stifle individual scientific endeavour and lead to international chaos.

*The Human Genome Committee and The Board of Directors
The American Society of Human Genetics*

APPENDIX B

HUGO Statement on the Patenting of DNA Sequences

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Summary

HUGO (The Human Genome Organisation) is worried that the patenting of partial and uncharacterized cDNA sequences will reward those who make routine discoveries but penalize those who determine biological function or application. Such an outcome would impede the development of diagnostics and therapeutics, which is clearly not in the public interest. HUGO is also dedicated to the early release of genome information, thus accelerating widespread investigation of functional aspects of genes. This statement explains our concerns.

Background

HUGO is an international membership organization whose goal is to coordinate and enhance efforts in genome research. HUGO members include the leading scientists engaged in genome research, scientific advisors to biotechnology companies involved in genome research, and representatives from government agencies involved in genome research. The research efforts of these members exceed \$250 million per year. HUGO members helped to develop the key technologies and methodologies that led to the Human Genome Project and the development of the genomics industry. In particular, their inventions include DNA sequencing,[1,2] automated devices for DNA sequencing,[3,4] DNA-based genetic mapping,[5-10] genome-wide physical mapping,[11,12] techniques for mutation detection (reviewed in references 13 and 14), computer-based methods for the detection of gene function by sequence analysis,[15] and methods for the construction of high-quality cDNA libraries[16-18] and for the isolation of gene sequences based on partial functional and structural information.[19] In addition, HUGO members have taken leading initiatives in constructing most of the existing maps of the human,[10,12] mouse,[20] rat,[21] fruit fly,[22] nematode,[23] yeast,[24] and bacterial[25] genomes.

HUGO members are carefully following developments in the area of intellectual property protection for the results of genetics and genome research and wish to see these matters resolved in a way that considers the interests of researchers, private firms, and society. In particular, we want intellectual property rights to be allocated fairly, in a manner that appropriately weighs the contributions of different parties to the total research effort, and creates necessary incentives for the ongoing development of products without interfering unduly with scientific research.

Because our expertise is primarily scientific rather than legal, it is not our place to offer an opinion on questions of patentability as such. Nonetheless, we are concerned that public debates about these issues are sometimes based on misinformation concerning the underlying science, and we fear that similar misunderstandings may infect decisions about

patentability. In the hope of clarifying these issues, we wish to offer a scientific opinion on some of the underlying technical questions that may affect determinations of patentability.

Specific issues

An expressed sequence tag (EST) is part of a sequence from a cDNA clone that corresponds to an mRNA.[26] An EST can therefore be used to identify an expressed gene, and can also be used as a sequence-tagged site marker[11] to locate that gene on a physical map of the genome.

Among the issues that have emerged in the discussions to date are the nature and extent of scientific work involved in:

- (1) the generation of ESTs;
- (2) the use of ESTs to obtain full-length cDNA and gene sequences;
- (3) the use of ESTs or full-length sequences to obtain expression of proteins;
- (4) the use of ESTs or full-length gene sequences to determine their normal biological functions, association to disease(s) and their RNA and protein products; and
- (5) the use of genes or gene fragments for categorizing; mapping; tissue typing; individual or forensic identification; production of antibodies; antisense, triple helix, and ribozyme applications; or locating gene regions associated with genetic disease, etc.

We consider each of these issues in turn.

(1) The generation of ESTs

The scientific work involved in generating ESTs is straightforward and based on automated sequencing technology that has been well understood since the mid-1980s.[3] Advances in DNA sequencing technology since then have increased the speed of the operation without altering the approach in any fundamental respect.[27] Indeed, the sequencing of any gene involves the sequencing of individual small fragments. Moreover, the sequencing of fragments of genes has long been used as a rapid tool for the characterization of genes encountered in a variety of settings, including library screening.[28]

The current strategy of large-scale EST sequencing[27] represents a useful but straightforward extension of a technique that has been in use on a smaller scale for years. Since the mid-1970s, cDNA libraries have been constructed from many sources, including different organisms, different tissues, and different functional cellular states such as activated immune cells versus naive ones or malignant versus normal.[29] This has allowed cDNA libraries to be enriched for genes of interest. The idea of coupling DNA sequencing to cDNAs was discussed as early as 1986.[30] It has also been understood for

some time that considerable information can be gleaned from partial DNA sequences and that putative protein function can be inferred from sequence similarity to previously-characterized genes.[31,32] A laudable but not yet achieved objective of the Human Genome Project is the determination of full-length sequence of all mapped genes. Such information will accelerate (but cannot guarantee) disease gene associations and functional assignments.

(2) The use of ESTs to obtain full-length cDNA and gene sequences

The process from EST to full-length cDNA or genomic sequence is not straightforward. The full-length cDNA represents the entire sequence of the mRNA and the genomic sequence includes introns and other flanking regions. Using partial gene sequences to find full-length cDNA and genomic sequences is an important research activity, ongoing in many laboratories on a daily basis. It has been successfully accomplished in many cases, and many specific strategies have been developed over the years for approaching this task. Nonetheless, it remains a task that is fraught with uncertainty. In some cases known techniques such as specific primer extensions may be successful;[33] in others extraordinary skill will be required to overcome obstacles such as secondary structure.[34] Foreseeable obstacles include the difficulty or impossibility of cloning mRNAs that are large[35,36] or that encode poorly clonable sequences;[37] the problems posed by immature, or incorrectly or alternatively spliced messages;[38,39] the difficulties posed by cross-hybridization among members of gene families;[40,41] and the rare but extremely challenging problems posed by post-transcriptional alterations of RNA sequence.[42,43] Having an EST in hand does not guarantee insight into a practical or feasible strategy for overcoming these obstacles. The effort involved may range from a matter of weeks (in case of an extremely short, easily cloned gene) to more than a year. It may be necessary to screen multiple cDNA libraries and tissue sources or to use various cloning-based and polymerase chain reaction-based techniques.[19]

(3) The use of ESTs or full-length sequences to obtain expression of proteins

Getting correct expression of a gene sequence presents several obstacles that can complicate the generation of a useful product. For instance, it may be necessary to attempt cloning in multiple hosts, including bacterial, yeast, insect, and mammalian cells, to find a usable host.[44] There is no guarantee as to what expression vector and gene structure will be adequate for the task. Moreover, there is little way to know in advance what cell types will produce the appropriate post-translational modifications. Each expression construction must also allow for appropriate promoters, high affinity translation sequences, and often enhancers and splice junctions.[45]

- (4) The use of ESTs or full-length gene sequences to determine their normal biological functions, association to disease(s) and their RNA and protein products

The task of identifying biological functions of a gene is by far the most important step in terms of both its difficulty and its social benefit. It therefore merits the most incentive and protection. Because this step is the key to the development of useful products, we are concerned that it will not receive adequate protection under current law. Determining function for a sequence is a matter of tremendous complexity, requiring biological experiments of the highest order of creativity. Nevertheless, with only DNA sequence it is possible to execute a computer-based algorithm comparing the sequence to a database of previously-characterized genes.[31] In about 50% of cases, such a mechanical comparison will indicate a sufficient degree of similarity to suggest a putative enzymatic or structural function that might be possessed by the unknown gene.[46] This process involves straightforward analysis of private or public database information to provide an idea of potential function. In contrast to sequence analysis, the task of establishing actual biological functions requires specific experiments that are individually tailored to the particular gene. These may range from searching for the intracellular location of the gene product,[47,48] testing expressed proteins for a variety of potential enzymatic functions,[49,50] attempting to construct knockout mice,[51,52] attempting to identify human or animal disease states in which the gene is disrupted,[53-55] or attempting to interfere with the function of the gene through antisense,[56] ribozyme[57] or related technologies. In each case it is a major undertaking for which the likelihood of success is frequently unknown.

- (5) The use of genes or gene fragments for categorizing; mapping; tissue typing; individual or forensic identification; production of antibodies; antisense, triple helix, and ribozyme applications; or locating gene regions associated with genetic disease, etc.

Several uses have been suggested for genes and gene fragments to get past the utility requirement for patent protection. For any random gene, gene fragment, or collection of genes or gene fragments, it is easy to give a list of potential uses without knowledge of their true biological functions. These uses include categorizing genes according to their expression profile;[58] developing markers for mapping;[11] tissue typing;[59] individual or forensic identification;[60,61] production of antibodies;[62] antisense;[63] triple helix[64] and ribozyme [65] applications; and location of chromosomal regions associated with genetic disease.[66] In all important cases the development of a truly useful tool for these purposes will require the investment of considerable further effort and creativity, far more than that invested in finding the initial fragment. Furthermore, in disease gene mapping, the probes employed, knowledge of their localization, and physical and genetic distances have been determined by a collective scientific community and found in open databases. For example, in order to use DNA fragments for individual identification, one

must first find sites of polymorphic variation and identify the distribution of such polymorphisms in appropriate populations.[67] Similarly, to use DNA fragments for tissue typing, one must first establish that a particular fragment or set of fragments provides a sufficiently discriminating signature of a particular tissue type or state.[68-70] Mapping a sequence may sometimes be routine, but in other cases it may involve overcoming problems posed by gene families, pseudogenes, and repetitive elements which lead to mapping ambiguities due to signals from multiple locations.[41] Moreover, with antisense and triple helix applications, it is easy to postulate such uses, but scientists would not pursue them without specific and detailed knowledge of biological function. Each of these asserted uses may not be carried out without considerable further effort and additional biological information not apparent from the information inherent in the sequence alone.

Conclusion

The discovery process in molecular biology is rich and complicated. Technological advances in recent years have rendered some aspects of the procedure, such as sequencing, increasingly mechanical and straightforward, which has led to the generation of large quantities of DNA sequence for many organisms.[71,72] Continued developments promise to yield still greater quantities of sequence information, culminating in the complete genetic information of higher organisms.[73,74] Yet other steps in biological discovery, such as the understanding of biological function and the use of genes and gene products in the diagnosis and treatment of human disease, remain exceedingly challenging, uncertain, and needing great creativity.

It would be ironic and unfortunate if the patent system were to reward the routine while discouraging the innovative. Yet that could be the result of offering broad patent rights to those who undertake massive but routine sequencing efforts—whether for ESTs or for full genes—while granting more limited rights or no rights to those who make the far more difficult and significant discoveries of underlying biological functions. A second, equally unfortunate outcome would arise if a partial sequence publication or submission to a database precluded patenting of innovative disease gene discoveries leading to improved medical diagnostics and therapeutics. This could lead to inhibition of contributions to databases and lack of investment protection for the innovative. We hope that the system will find some way to adjust to the changing realities in this field to promote and protect this important and ongoing process of discovery in the public interest.

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APPENDIX C

Letter from Jack Spiegel to Lawrence Goffney

March 21, 1997

Mr. Lawrence J. Goffney
Deputy Assistant Secretary of Commerce and
Deputy Commissioner of Patents and Trademarks

Dear Mr. Goffney:

This communication follows our telephone conversation of February 17, 1997 confirming your comments on expressed sequence tag (EST) patenting at the February 14th AAAS meeting in Seattle. We spoke at length of our mutual concerns that patent claims issuing on partial cDNA ESTs be commensurate in scope with their enabling disclosures. At the conclusion of our conversation, you kindly invited continued dialog with appropriate Group 1800 staff to advance this common goal. While there has been no communication back to me from Group 1800, debate on this issue continues to ferment within the biotechnology community at the National Institutes of Health (NIH), academic institutions, and industry. Therefore, I submit these written comments, herein, for consideration by you and your managers within the Biotechnology Group in anticipation that this formally initiates dialog between our offices on these matters of common interest.

Background - NIH Involvement in ESTs:

As you undoubtedly know, EST technology originated in the NIH laboratory of Dr. Craig Venter at the National Institute of Neurological Diseases and Stroke (NINDS), and we believe the first patent applications in this field were filed on Dr. Venter's discoveries by NIH in June 1991. A serious concern, at the time, was that public disclosure of EST sequences could create a prior art effect against subsequent patenting of newly discovered complete gene sequences possessing important diagnostic or therapeutic utilities. EST patent applications were filed, in significant measure, to provide short term insurance against such potential prior art blockage of future gene discoveries.

Contemporaneous with our invention filings, and continuing through the period of patent examination, the Court of Appeals for the Federal Circuit (CAFC) rendered a series of opinions drawn to DNA/protein sequences, including *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed.Cir.1991); *Fiers v. Sugano*, 25 USPQ2d 1601 (Fed.Cir.1993); *In re Bell*, 26 USPQ2d 1529 (Fed.Cir.1993); and subsequently, *In re Deuel*, 34 USPQ2d 1210 (Fed.Cir.1995) which reduced significantly our prior art concerns. These court decisions, in conjunction with the evolution of our definitive Patent Policy that moves away from patenting research tools, led to the NIH abandoning all pending EST applications. However, the NIH continues to actively pursue varied aspects

of genomic research, including transferring the useful products of that endeavor to the private sector. Despite having no EST applications pending before your office, the NIH maintains an ongoing policy interest in these compositions as long as EST technologies potentially influence the development and availability of genomic inventions for the public health.

NIH Issues and Concerns:

Like many in the biotechnology research and intellectual property communities, the NIH is both surprised and disappointed by media reports indicating the USPTO now finds the use of ESTs as probes to be a specific utility in satisfaction of Section 101 requirements. Typically, the identity of the gene corresponding to an EST is not known. NIH scientists, as well as many in the academic community (i.e., those of ordinary skill in this art), view such bare EST sequence disclosures as providing little or no practical (real world) value toward advancing discovery in the human genome art. Potential value for EST sequences derives from future research relating EST sequences to genes or proteins of known function. At best, therefore, ESTs represent a poor research tool.

The relative merit of these discoveries as research tools should not militate against their public disclosure in any forum, including scientific literature, databases, or patents. The nature of such disclosures follows from the formats, policies, and statutes governing or established by each forum. We appreciate the unique character of the patent forum that balances the value of public disclosure against the right to exclude others from the claimed invention for a limited period of time. We appreciate also the mission of the USPTO to administer the patent statutes and rules to establish in each patent grant the appropriate quid pro quo between public disclosure and rights of exclusivity; thereby, advancing the constitutional mandate to promote the progress of science and the useful arts.

The interest of the NIH is to provide the PTO sufficient information to make appropriate and consistent decisions in establishing this quid pro quo relative to EST inventions. In this regard, NIH has concerns along two lines. First, we believe the utility of the typical EST invention may not meet the threshold criteria of utility set forth in 35 USC 101. Our second concern is more critical. If EST inventions do satisfy the specific utility requirements of patent law, we are concerned the PTO understands all the relevant issues to establish an appropriate balance between the value of EST disclosures and the scope of exclusionary claim protection. In other words, we are concerned how the PTO applies the enablement and description provisions of 35 USC 112 to establish a proper claim breadth for EST inventions.

As indicated previously, the NIH no longer has a proprietary position in patenting ESTs. Therefore, the NIH, similar to the PTO, has no interest in the commercial success or failure of any particular applicant or company in this arena. Rather, the NIH communicates our concerns in this regard, because we are sensitive to the possibility that prototypical ESTs with claim scope broad enough to encompass the corresponding

complete gene sequence may unduly shift the intended quid pro quo in favor of the patentee. The systematic promulgation of this imbalance may have serious chilling consequences to further research and commercial development of diagnostic and therapeutic products related to human genomics. Clearly, this situation could negatively affect the public health, and the advancement of the public health is the mandate of this agency.

Our primary interest, in this regard, is that a new species of "submarine" patent not be spawned by unduly broad patents routinely issued in the EST art. This may arise through the congruence of two conditions. The first involves the expectation in the art that the PTO will issue EST patents routinely, wherein the utility of the corresponding gene is not known; yet claim scope is broad enough to encompass the entire gene. The second condition may develop as a consequence of the new sequence restriction practice, whereby up to ten nucleic or amino acid sequences may be examined per application. The remaining sequences are withdrawn from consideration pending filing of a Divisional application. The net effect of this restriction process may be millions of confidential EST sequences lying in "limbo" within the PTO.

Upon subsequent and independent discovery of the complete gene, possessing a clinically and/or commercially significant utility, applicant resurrects the corresponding withdrawn EST species. The patent issuing on that Divisional potentially could block or retard development of the significant public health invention. The economics of this situation may be resolved within the marketplace for individual cases, and this should not be the preoccupation of the PTO; or the NIH. However, a health care issue is created if industry delays or refrains from investing in this important endeavor because of rampant uncertainty surrounding the existence of submarine ESTs lurking within the PTO. This should be a concern not only to the NIH mandate, but also to the mandate of the PTO.

Patent procedures should not encourage submarine patents that undermine the pursuit of invention. In particular, submarine ESTs portray a singularly unsatisfactory perception of a secret disclosure of de minimis utility, whose only real function is to lay in predatory wait and feed off later developed inventions with significant health care utility. While it may fall within the four corners of legal patent prosecution procedure, this scenario does not advance the progress of science and the useful arts. The means by which the PTO can affect this process is to circumvent the perception that useless parasitic inventions are hibernating in the Central Files of the PTO. The public must feel confident the PTO will issue patents only for inventions with claims commensurate in scope with their specific "real world" utilities.

We believe the PTO can foster this public confidence by practicing consistently the guidelines regarding Section 101 and 112 issues it has already promulgated. What follows is intended to be the constructive input of a sister government agency with a common interest in advancing the progress of science and useful public health arts.

Legal Considerations regarding the Patenting of ESTs

- I. The PTO should re-evaluate whether an asserted utility as a probe represents a "specific utility" for ESTs under 35 USC 101.

It is generally accepted that there is no practical utility in the use of a probe as an intermediate to analyze or make a final product gene of unknown function (utility). Indeed, most practitioners in this art believed the issue was resolved with release of the USPTO Utility Guidelines, along with its Legal Analysis Supporting Utility Examination Guidelines, and supporting documentation available through the USPTO Home Page.

One such supporting document, titled: "Synopsis of Application of Utility Guidelines With Examples" defines "Specific utility" in part as follows:

- a practical utility which defines a "real world" context of use. Utilities which require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not "specific utilities".

In the instant case, the context of use as a probe has no "real world" meaning until the gene for which the EST is a probe is identified; i.e., functionally characterized. A gene with no associated biological function has no "real world" meaning. Consequently, there can be no "specific utility" in probing a gene of unknown biological function. It requires further research to ascribe a biological function to an unknown gene probed by an EST in order to provide "real world" context. This deficiency in EST inventions follows from the fundamental Supreme Court ruling in *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." This theme was advanced also by the Federal Circuit in *In re Brana*, 34 USPQ2d 1436 (Fed.Cir.1995). Most recently, the Court of Appeals for the Federal Circuit in *Genentech v. Novo Nordisk*, Case 96-1440, decided March 13, 1997, invalidated a Genentech patent on cleavable fusion stating, "Genentech is attempting to bootstrap a vague statement of a problem into an enabling disclosure sufficient to dominate someone else's solution of the problem. This it cannot do."

The above indicated definition continues on to recite examples illustrating "specific utility", as well as examples illustrating the lack of "specific utility" resulting from a need for further research to identify or reasonably confirm a "real world" context of use. The instant EST scenario is consistent with three of the examples illustrating situations that do not define "specific utilities." One such example is "a method of assaying for or identifying a material that itself has no 'specific utility'". This is consistent with using an EST as a probe to assay or identify a gene that itself has no specific utility, because the gene has no known biological function. The second example is "a method of making a material that itself has no 'specific utility'". This is consistent with using an EST as a probe to make a gene that is itself has no specific utility, because the gene has no known

biological function. The last example is most cogent and defines "a claim to an intermediate product for use in making a final product that has no known utility". Indeed, an EST probe for an unknown gene may be considered an intermediate for use in making a final product. In this case, the final product (i.e., the unknown gene) is a product with no known utility.

The last example regarding failure of the intermediate product to establish a "specific utility" is in concert with the probative case law. See *In re Joly*, 153 USPQ 45 (CCPA 1967) wherein Judge Rich instructs

*** the conclusion is inescapable that, just as the practical utility of the compound produced by a chemical process "is an essential element" in establishing patentability of the process, [*Brenner v. Manson*] 383 U.S. 519, 148 USPQ 689, so the practical utility of the compound, or compounds, produced from a chemical "intermediate," the "starting material" in such a process, is an essential element in establishing patentability of that intermediate. It seems clear that, if a process of producing a product of only conjectural use is not itself "useful", within Section 101, it cannot be said that the starting materials for such a process—i.e., the presently claimed intermediates—are "useful". It is not enough that the specification disclose that the intermediate exists and that it "works," reacts, or can be used to produce some intended product of no known use. Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use.***

We conclude that appellants have not discharged their burden to show that the claimed subject matter is "useful" within the requirements of Section 101.

Finally, following the "Synopsis of Application of Utility Guidelines" are a set of 12 examples of common biotechnology invention scenarios designed to walk the examiner/reader through the disclosure fact pattern, claims, and analysis of relevant utility issues. Example 9 is particularly applicable in being drawn to a disclosure and claims to a large number of cDNA fragments (ESTs). The disclosed utility of each EST is as a probe to obtain the corresponding full length gene. The full length gene is used prophetically to make the corresponding protein via routine recombinant methodologies. The protein product then is used to study cellular mechanisms and activities associated with the protein. Each EST is claimed individually using closed ("consisting of") language, wherein the claim is limited to the exact disclosed Sequence ID Number. The asserted utility for each EST is identified as a method of making the corresponding protein. The example goes on to explain that the probative determination of "specific utility" is whether or not the protein product has a "specific utility". Since the asserted utility for the protein was a research utility (not a "real world" or "specific utility under *Brenner v. Manson* criteria), the method of making that protein (the asserted utility of the claimed EST)

necessarily could not define a "real world" context of use. The conclusion reached from the analysis was that no utility existed under 35 USC 101, and both Section 101 and Section 112, 1st paragraph enablement rejections are proper.

Therefore, the standard for "specific utility" of EST-probe intermediates is the objective factual determination whether the final gene or protein products themselves possess "real world" utility (i.e., known and defined biological function). Considerations regarding advances in the state of the art, the routine nature of hybridization and recombinant DNA techniques, or the relative efficiency of the probe-intermediate for its intended purpose are of little moment in this determination. Deviation from or failure to meet this standard leads invariably to a conclusion of no "specific utility" under 35 USC 101.

The NIH is not aware of any legislation or court decisions that negate or modify these reasoned guidelines recently developed by the PTO to analyze issues regarding "specific utility". It appears that a consistent application of those guidelines leads to the conclusion that EST probes have no "specific utility" under Section 101 if the corresponding gene is unknown or has no "specific utility."

II. If Deemed to Have Utility, The Scope of EST Claims Should Be Limited To The Specific EST Sequence.

It is well established that a deficiency under Section 101 creates also a deficiency under Section 112, first paragraph, since the specification cannot enable one skilled in the art to use an invention that is not useful. *Nelson v. Bowler*, 206 USPQ 881 (CCPA 1980). Therefore, ESTs failing the above "specific utility" test as probes to unknown genes should be considered not patentable also under the enablement provision of 35 USC 112. In the event the PTO deems any or all ESTs satisfy the utility requirements for patentability, the following arguments are set forth regarding breadth of claim scope.

A. General Considerations Regarding Scope of Claims

While monitoring polynucleotide composition claims issued recently, we observe regularly that polynucleotide claims are broader than the disclosed Sequence ID Number listings. NIH observed open "comprising" language in conjunction with claim constructions, as well as the following forms of structural (sequence) variability: allelic variants; a polynucleotide complementary to a polynucleotide in a Markush group; and less than 100% sequence identity expressed as—at least "X" % (e.g., 95%) identity to a Markush group of polynucleotides.. It is not our intent to question the propriety of claim breadth in the particular fact situations of those issued patents. However, NIH has serious concerns if EST claims will issue with similar broad open-ended claim constructions. For the reasons developed in the sections to follow, we submit it should be a rare disclosure that supports EST claim scope broader than the specific Sequence ID Number.

- B. PTO Guidelines/Training Materials for Examining Patent Applications With Respect to 35 USC Section 112, First Paragraph-Enablement Chemical/Biotechnical Applications support the proposition that ESTs should be limited in scope.

On November 5, 1996, training material and guidelines analogous to the utility guidelines were made available to the public on the PTO Home Page. Included in the materials are two examples (Examples A & B) presenting related fact patterns and claims drawn to hybridization probes and methods of using same. Claims in the first example recite open “comprising” language and Markush groups containing specific Sequence ID numbers corresponding to three disclosed nucleotide probe sequences, ranging between 30 and 35 nucleotides in length, which hybridize specifically to a defined target of known utility. The second example differs by eliminating the functional limitation drawn to the specificity of hybridization. Both examples cite a pair of literature references, *Sambrook et al.* and *Wallace et al.*, for their teaching that mismatches within an oligonucleotide probe impart unpredictability to the hybridization process.

In the analysis, both examples explain how the “comprising” language markedly broadens the scope of the probe embodiment by introducing random sequences of indeterminate length. In view of the teachings of *Sambrook et al.* and *Wallace et al.* regarding the effect of base mismatching on probe specificity, the introduction of random base sequences into a hybridization probe would require undue experimentation to identify or make all nucleic acid probes encompassed by and satisfying the functional (specificity) requirements of the claim. Therefore, hybridization-probe claims containing such open-ended “comprising” language would be subject to rejection under 35 USC 112, 1st paragraph. Both examples instruct replacing the open-ended “comprising” language with “consisting” language directed specifically to the disclosed probes in order to eliminate the undue breadth problem.

The second example indicates the need for functional claim limitations directed to the specificity and utility of the probe. The lack of such functional limitations exacerbates the Section 112, 1st paragraph deficiencies associated with “comprising” language by introducing additional enablement issues drawn to failure to teach how to use all the probes encompassed by the claim.

C. Application of Enablement Guidelines to EST Inventions

The hybridization-probe examples in the PTO Enablement Guidelines relate to EST cases asserting a probe utility. EST sequences, corresponding to unknown genes or genes of unknown function (specific utility), relate to at least Example 2, above. Regardless the breadth of claim language, we submit this scenario fails the “how to use” considerations of enablement under Section 112, 1st paragraph by teaching the use of an EST moiety to probe specifically for an unknown structure. If a probe does not bind specifically, how can

it be distinguished from other probes? If the EST does bind something, the person skilled in the art would not know if the probe bound the intended species. It is left to experimentation outside the teachings of the specification to define all the parameters of a successful hybridization and, thereby, the real use of the claimed probe. It is not routine in this art to require the user to discover new genes in order to use a patented hybridization probe. At the very least, this would fall into the category of requiring undue experimentation.

EST sequences related to genes of known function are not subject to the "specific utility" criticisms described previously, but do correspond to the scenario outlined in the first hybridization example, above. Consequently, EST product and method of use claims with closed "consisting of" language drawn to specific Sequence ID Numbers should be free of Section 112 enablement criticisms, assuming an adequate written disclosure setting forth how to make and use the invention, including the best mode. Introducing open "comprising" claim language, of course, would trigger the above indicated "Undue Breadth" rejection under Section 112, 1st paragraph. The introduction of more moderate claim broadening language, however, such as allelic variants, fragments thereof, having at least 90% identity, a polynucleotide complementary to, etc., should be analyzed for undue breadth on a claim by claim basis using standard *Ex parte Forman/In re Wands* considerations viewed from the perspectives elucidated in Example 1, above.

An additional factor to be considered when ESTs are used to probe genomic DNA is that peptide coding regions (exons) generally are interrupted by non-coding introns. EST probes, derived from cDNA, reflect only exon and regulatory sequences from the genomic polynucleotide population. Consequently, the nucleotide sequence of EST probes may not be contiguous with the corresponding genomic DNA. Indeed, an EST sequence may have homology to several discontinuous regions of genomic DNA separated by multiple exons. Under such circumstances, only a variable fraction of each EST sequence probe would actually hybridize to the gene. Depending on a number of factors, including the size of the EST, introducing variability into such EST structure via claim broadening language may compromise the ability of the EST to function as a probe in concert with the considerations set forth in the *Sambrook et al.* and *Wallace et al.* citations discussed in Example 1, above. It would be expected, therefore, that any claim broadening language would be supported by appropriate working examples addressing these issues. In this regard, information gained from one EST species does carry over to different EST species. This should necessitate different working examples for each claimed EST species.

D. Additional Considerations

As indicated previously, "comprising" claim language encompasses additional random DNA sequences different from those specifically disclosed in the application. Applicants cannot describe or envisage the structure of these additional sequences. Consequently, the specification must be defective under the "description" requirement of Section 112, 1st

paragraph. This interpretation is in concert with a line of Federal Circuit decisions involving nucleic acid and amino acid structures. See *Fiers v. Sugano*, 25 USPQ2d 1601 (Fed.Cir.1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed.Cir.1991). Also see *In re Bell*, 26 USPQ2d 1529 (Fed.Cir.1993) and *In re Deuel*, 34 USPQ2d 1210 (Fed.Cir.1995) regarding related issues drawn to treating nucleic acids as chemical structures. Furthermore, the Examiner cannot search the prior art to determine novelty and unobviousness without knowledge of which sequences are being claimed. A claim that does not define the invention with sufficient distinctness to permit a proper search of the prior art is invalid also under the second paragraph of 35 USC 112.

In summary, the NIH believes EST sequences for use as probes do not satisfy the utility requirements under Section 101 unless the EST sequences correspond to genes of known function. Furthermore, the scope of all EST probe claims should be limited to "consisting of" language consistent with the PTO guidelines for enablement issues. Indeed, we caution against any broadening of the scope of EST claims beyond the disclosed Sequence ID Number. We feel a consequence of issuing broad claims to EST sequences as probes to unknown genes could be the emergence of "submarine" patents having a chilling effect on development of genomic products for the public health. The solution to this potential health care problem merely requires the PTO to strictly and consistently adhere to existing utility and enablement examination guidelines established during the last two years.

I appreciate this opportunity to present the views of the NIH. I again hope this communication initiates ongoing dialog between our offices to advance these issues. Please feel free to contact me if I can be of any assistance.

Sincerely yours,

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cc: Dr. Harold E. Varmus
Dr. Michael M. Gottesman
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APPENDIX D

Correspondence Between Harold Varmus and Bruce Lehman

Letter from Harold Varmus to Bruce Lehman

National Institutes of Health
Bethesda, Maryland, 20892
March 23, 1997

The Honorable Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Commissioner Lehman:

I am writing to express concern about the position of the United States Patent and Trademark Office (PTO) on the patentability of Expressed Sequence Tags (ESTs), as presented by Acting Deputy Commissioner Laurence J. Goffney on February 14, 1997, at the meeting of the American Association for the Advancement of Science in Seattle.

From transcripts of his remarks and in follow-up discussions with my staff, it is our understanding that the PTO determined in October 1996 that ESTs could meet the statutory utility requirements based on their usefulness as probes for corresponding nucleotide sequences. On the basis of this determination, the PTO has begun the process of examining more than 300 applications currently pending related to ESTs.

As a scientist and public health official, I am deeply concerned about this decision. In February 1994, following extensive discussions with scientists, industry representatives, and experts in patent law, the NIH determined that it was not in the best interest of the public health or science to pursue patents on partial or full gene sequences for which function and practical utility are unknown. At that time, I personally communicated this decision to key leaders in the U.S. and the international scientific communities. I enlisted the help of these individuals in educating biomedical research scientists on the importance of publishing and freely disseminating the results of early sequencing work to ensure both a growing body of scientific knowledge and the availability of novel therapies and diagnostics through commercialization of that knowledge. Over the past three years, scientists in academia and industry have benefitted from an ever-growing public database due to their willingness to place their sequencing data in the public domain. The PTO decision, based on new utility guidelines, will affect this ongoing research as it will once

again call into question whether scientists can reasonably be asked to share early sequencing data.

Further, I am concerned that the ability to obtain a patent on a partial gene sequence, before the full sequence and substantive knowledge of biological function is obtained, will adversely affect the commercialization of new therapeutic technologies arising from these findings. We can expect few companies to embark on the massive expenditure of time and resources required to bring biomedical products to market if there is a high likelihood that claims could later issue from an EST or partial sequence patent application filed many years earlier. While the issues related to commercialization are within the purview of industry, a public health concern does arise if industry delays or refrains from developing and marketing these important technologies.

My staff has articulated these concerns in a letter to Mr. Goffney, which I have enclosed for your information and use. I am confident that the interaction between the PTO and the NIH on this important matter will ensure that the public investment in biomedical research will enhance the public health.

Sincerely,

Harold Varmus, M.D.
Director

Response from Bruce Lehman to Harold Varmus' Letter of March 23, 1997

US Department of Commerce
Patent and Trademark Office
Assistant Secretary of Commissioner
of Patents and Trademarks
Washington, DC 20231

April 2, 1997

Harold E. Varmus, MD
Director, National Institutes of Health
Bethesda, MD 20892-0148

Dear Dr. Varmus:

Thank you for your letter concerning a speech made by our Acting Deputy Commissioner, Lawrence J. Goffney Jr., at the annual meeting of the American Association for the Advancement of Science, regarding the patentability of Expressed Sequence Tags (ESTs).

I truly understand your concern regarding the perceived change in our policy and the impact that this has had on the investment and scientific communities. We are also aware of the considerable media attention these comments have produced and clearly understand the issues at the heart of this controversy. You can be assured that our policy regarding the patentability of small fragments of RNA and DNA, including ESTs, has not changed.

To address your concerns and briefly those expressed by Dr. Spiegel in his letter to Mr. Goffney, an EST may be patentable in the United States under appropriate circumstances (i.e., an EST, which meets all the criteria under applicable patent laws, including utility, enablement, novelty and unobviousness). Mere allegation of utility of an EST as a probe without further disclosure is not sufficient to meet the utility and enablement criteria. Example 9, in our training materials for the Patent Utility Guidelines, outlines a DNA probe, which lacks utility because no utility for the protein corresponding to the cDNA identified by the probe or for the cDNA itself, was disclosed. A copy of example 9, setting forth the Patent Utility Guidelines, has been enclosed for your convenience. [Note: He is referring to pages 88 to 91 of the 35 USC 101 Utility Guidelines Training Manual, 22 August 1995 edition which you can obtain from the PTO.]

The patentability of any EST application is meticulously analyzed to determine the sufficiency of the disclosure and the enabled utilities for the EST. For example, disclosures of the use of ESTs for forensic identification, tissue type or origin

identification, chromosome mapping, chromosome identification, and to tag a gene of known and useful function, may be enabled if supported by a sufficient disclosure. Examples of potentially non-enabled utilities include location of disease-associated genes, wherein the disease has no known genetic origin; use as an anti-sense reagent, wherein the corresponding protein to be suppressed is unknown; use as a triplex probe to inhibit expression of a protein, where the protein and its function are unknown; and, for location and identification of genes of unknown utility.

Patent claims, limited in scope to a specific novel and non-obvious EST, generally should not preclude the future patenting of the corresponding, latter discovered, full length gene of known function or of therapeutic technologies arising therefrom. Under appropriate and limited circumstances, claims of a perceived broad scope that are adequately supported by the disclosure under 35 USC 112 and the state of the art may be patentable, but such claims do not necessarily preclude future patenting of the full length gene.

We are continuously working with the biotechnology and investment communities to ensure that the patent system fulfills its constitutional mandate while enhancing the well-being and health of our Nation.

Again, thank you for informing me of your concerns and, as always, I welcome your comments and suggestions for improving and maintaining the public service of the Patent and Trademark Office.

Sincerely,

Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

APPENDIX E

POLICY ON AVAILABILITY AND PATENTING OF HUMAN GENOMIC DNA SEQUENCE PRODUCED BY NHGRI PILOT PROJECTS (FUNDED UNDER RFA HG-95-005)

April 9, 1996

This document describes the policy of the National Center for Human Genome Research with respect to availability and patenting of human genomic DNA sequence produced under grants funded as a result of RFA HG-95-005. In conformity with the existing spirit and philosophy of the Human Genome Project and in response to the recommendations of advisors and the expressed wishes of the community, NHGRI seeks to make DNA sequence information available as rapidly and freely as possible.

Background

The Human Genome Project (HGP) is an international research effort, begun in 1990, which has the scientific goals of generating maps of the human genome[1] and producing the complete sequence of the human DNA by the year 2005. The project was undertaken in the U.S. following the advice of several scientific committees that emphasized its importance in creating a resource that "will facilitate research in biochemistry, physiology and medicine"[2], "have a major impact on health care and disease prevention"[2] and provide "enormous scientific and technological advances..., having both basic and commercial applications"[3]. At NIH, the National Human Genome Research Institute (NHGRI) was founded to implement the HGP.

The HGP has progressed rapidly, even beyond optimistic expectations. The initial mapping goals are nearly completed and recent improvements in DNA sequencing technology and capacity have led many scientists, including NHGRI advisors, to conclude that complete sequencing of human genomic DNA should begin. Early in 1995, NHGRI issued RFA HG-95-005 to solicit grant applications for pilot projects to test strategies that can potentially scale up to sequence the human genome. The applications received in response to the RFA were peer reviewed in the fall of 1995 and approved by the National Advisory Council for Human Genome Research in January 1996. A set of grants will be funded by April 1996.

At the inception of the HGP, the planners emphasized that, in order to reap the maximum benefit from the HGP, human DNA sequence should be freely available in the public domain. The NIH Ad Hoc Program Advisory Committee on Complex Genomes stated that "Distribution of and free access to the databases (containing the sequence data) must be fully encouraged. Thus, the data must be in the public domain, and the redistribution of

the data should remain free of royalties.”[3] Similarly, the National Research Council stated: “...access to all sequences and material generated by these publicly funded projects should and even must be made freely available...”[2]. Most recently, an international group of scientists, from both the public and private sectors, who are already involved in genomic DNA sequencing, passed a unanimous resolution that “all human genomic DNA sequence information, generated by centers funded for large-scale human sequencing, should be freely available and in the public domain in order to encourage research and development and to maximize its benefit to society”[4].

There are very strong scientific arguments that human genomic DNA sequence should be freely available and in the public domain:

- The human genomic DNA sequence is unique. Although there are many other types of information that contribute to the understanding of human biology, e.g., DNA sequence of model organism genomes, in the end, the only source of definitive information about the human is the human sequence.
- The human genomic DNA sequence is a vast resource. It contains a very large number of genes and an enormous amount of additional biological information. It is anticipated that the sequence resource will be the basis for many useful inventions and patentable products. It will take many researchers years to find and characterize all of the genes and other functional elements within the sequence and to use that information to develop products and other approaches that will improve the health of the American people.
- The human genome is a bounded resource. Once the genome has been sequenced, few or no opportunities will exist for discovery of new information that will not make reference to, or be dependent on, that first sequence. Thus, it is important to ensure maximum access of a large number of parties to the initial genomic DNA sequence as it is generated, to provide a broad opportunity for development of new products.

Policy

It is therefore NHGRI's intent that human genomic DNA sequence data, generated by the projects funded under RFA HG-95-005, should be released as rapidly as possible and placed in the public domain where it will be freely available. In order to implement this policy, NHGRI will require that grantees under RFA HG-95-005 adopt a policy of rapid release of data to public databases. This policy will be made a condition of the award.

In NHGRI's opinion, raw human genomic DNA sequence, in the absence of additional demonstrated biological information, lacks demonstrated specific utility and therefore is an inappropriate material for patent filing. NIH is concerned that patent applications on large blocks of primary human genomic DNA sequence could have a chilling effect on the

development of future inventions of useful products. Companies are not likely to pursue projects where they believe it is unlikely that effective patent protection will be available. Patents on large blocks of primary sequence will make it difficult to protect the fruit of subsequent inventions resulting from real creative effort. However, according to the Bayh-Dole Act, the grantees have the right to elect to retain title to subject inventions and are free to choose to apply for patents should additional biological experiments reveal convincing evidence for utility. The grantees are reminded that the grantee institution is required to disclose each subject invention to the Federal Agency providing research funds within two months after the inventor discloses it in writing to grantee institution personnel responsible for patent matters. NHGRI will monitor grantee activity in this area to learn whether or not attempts are being made to patent large blocks of primary human genomic DNA sequence.

During this pilot period, NHGRI will be soliciting opinions and collecting evidence from the broad scientific and commercial sectors to allow an evaluation of whether the approach described above is sufficient to ensure that sequence generated by these grants is maximally useful to the research and commercial sectors. If not, NIH will consider a determination of exceptional circumstance to restrict or eliminate the right of parties, under future grants, to elect to retain title.

References

1. The human genome is the complete haploid set of human chromosomes, including the genes they contain.
2. Report of the Committee on Mapping and Sequencing the Human Genome, Board on Basic Biology, Commission on Life Sciences, National Research Council, National Academy Press, Washington, D.C., 1988.
3. Recommendations and Priorities Developed by the Ad Hoc Program Advisory Committee on Complex Genomes, National Institutes of Health, 1988.

VITA

Carl Benjamin Mitchell was born in Tampa, Florida, on January 22, 1955. Reared in a military family, he attended public schools in Tampa, Florida; Whiteman Air Force Base, Missouri; and Lompoc, California, where he graduated from Cabrillo High School in June 1973. In 1975, he attended Southern Technical Institute in Marietta, Georgia, and Covenant College in Lookout Mountain, Tennessee, in 1976-77. Between 1977 and 1980 he attended Mississippi State University in Starkville, Mississippi, and graduated in August of 1980 with the Bachelor of Science degree in Educational Psychology.

In 1980 he entered Southwestern Baptist Theological Seminary in Fort Worth, Texas, and graduated with the Master of Divinity degree in August of 1983.

Between 1983 and 1989 he pastored two Southern Baptist churches before moving to Knoxville, Tennessee, to begin course work at the University of Tennessee. In 1992, after completing the required course work and hospital practicums (at the University of Tennessee Medical Center at Knoxville and the East Tennessee Mental Health Institute) required for a Ph.D. in philosophy with a concentration in medical ethics, he moved to Nashville, Tennessee, to serve the Southern Baptist Convention as Director of Biomedical and Life Issues. In this position he had the opportunity to present testimony before congressional committees and the Institutes of Medicine as well as to attend several important conferences in the field of medical ethics. While in Nashville he was able to work with the department of clinical and research ethics at Vanderbilt University Medical Center and make regular rounds with the ethicists and physicians.

In August of 1994, he returned to Knoxville to teach at the University of Tennessee as a graduate teaching assistant and to complete his comprehensive exams and dissertation.

In August of 1996, he was appointed Visiting Professor of Christian Ethics at The Southern Baptist Theological Seminary in Louisville, Kentucky, and was appointed Assistant Professor of Christian Ethics in February 1997.

He received his Doctor of Philosophy degree from the University of Tennessee in December of 1997.