

ARTICLE

DOLLARS AND LIVES: FINDING BALANCE IN THE PATENT “GENE UTILITY” DOCTRINE

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The application of the patent utility requirement to genetic sequences has been a lightning rod of controversy. On the one hand, there is a perceived need for researchers to recoup expenses lost during gene discovery. On the other hand, there exists the real concern that allowing gene patents has a chilling effect on future research. The United States Patent and Trademark Office’s Utility Guidelines attempt to offer guidance for wading through the morass of the utility requirement and gene sequences. However, the Utility Guidelines clearly state that they are not making new law. Instead, utility should be interpreted as it has been in the courts and legislature. Thus, critics of gene patents must look elsewhere for reform. This Article presents a novel approach to the utility standard for gene sequence patents. An examination of the roots of patent law and the interests it attempts to serve sets the backdrop for discussing the tension between a system with a low utility standard and a system with a high utility standard. In doing so, this Article shows that adequate incentives exist for gene discovery and that research and development will survive a move to a patent regime more stringent than currently exists. This Article concludes with a legislative proposal for a “gene utility” standard—the “substantial similarity” utility test—that removes natural gene sequences from the realm of patentable subject matter.

TABLE OF CONTENTS

I.	INTRODUCTION	
II.	THE BASICS OF PATENT LAW	
	A. <i>The Roots of Patent Law</i>	
	B. <i>Defining the Interests Served By Patent Law</i>	
III.	THE STATE OF TECHNOLOGY	
	A. <i>Modern Uses</i>	
	B. <i>Modern Problems</i>	
	C. <i>Summary and Road Map</i>	

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IV.	GENES AND THE CURRENT UTILITY STANDARD.....	
A.	<i>Owning Life</i>	
B.	<i>The USPTO's Utility Guidelines</i>	
1.	The Background of the Utility Guidelines	
2.	The Current USPTO "Gene Utility" Standard.....	
V.	DEFINING AN APPROPRIATE UTILITY STANDARD IN A WORLD OF EXTREMES	
A.	<i>The Benefits of a Low Utility Standard</i>	
B.	<i>The Costs of a Low Utility Standard</i>	
C.	<i>The Benefits of a High Utility Standard</i>	
D.	<i>The Costs of a High Utility Standard</i>	
E.	<i>The Importance of Setting the Right Standard</i>	
VI.	CRAFTING A NEW DEFINITION OF "GENE UTILITY"	
A.	<i>A Real World Interlude</i>	
B.	<i>"Gene Utility" Reexamined</i>	
C.	<i>Real World Incentives</i>	
1.	The Current State of Basic Research.....	
2.	Incentives Reexamined.....	
3.	Secrecy and Little Genes	
D.	<i>A Call for Legislative Action</i>	
1.	A Basic Analytical Framework	
2.	Redefining "Gene Utility": The "Substantial Similarity" Utility Test.....	
a)	<i>The "Substantial Similarity" Utility Test Applied</i>	
b)	<i>Implementing the "Substantial Similarity" Utility Test</i>	
3.	Disclosure Costs of the "Substantial Similarity" Utility Test	
4.	Economic Costs of the "Substantial Similarity" Utility Test	
VII.	CONCLUSION	

Our body is a machine for living. It is organized for that, it is its nature. Let life go on in it unhindered and let it defend itself, it will do more than if you paralyze it by encumbering it with remedies.[†]

– Leo Tolstoy

Greed—for lack of a better word—is good. Greed is right. Greed works.[‡]

– Gordon Gekko

I. INTRODUCTION

Securing a patent involves the expenditure of significant economic

[†] LEO TOLSTOY, *WAR AND PEACE* 877 (Louise and Aylmer Maude, trans., Simon and Schuster 1942).

[‡] *WALL STREET* (Twentieth Century Fox, 1987).

resources.¹ The past twenty years has seen a dramatic increase in the number of patent applications for gene sequences.² Combine such factors with the potentially huge economic payoffs in the biotech industry and you have a recipe for contentious battles over gene patentability and patent ownership.³ In an industry where the stakes are so high, the current patent system, its rationales, and its standards are put to the test.

Caught in the middle of this high stakes game are the gene sequences themselves. Genes present a situation unique to the patent system because they require two layers of research and development: the genes must first be isolated before their function and use can be determined.⁴ There is a fundamental problem inherent in this two-tiered research process. If genes are allowed to be patented before they are attributed any function or use, “[e]ach upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.”⁵ It is one thing to decry theoretical possibilities but it is another thing altogether to observe theory play out in practice.

In the late spring of 1995, Human Genome Sciences (“HGS”) filed a patent application for a gene encoding a particular cell-surface receptor protein.⁶ HGS claimed that the receptor, encoded by a gene, was useful for “identifying [receptor] antagonists and agonists,”⁷ which are chemicals that either trigger or hinder a cellular response.⁸ However, at the time of filing, HGS had no idea

¹ See John H. Barton, *Reforming the Patent System*, 287 SCI., Mar. 17, 2000, at 1933 (noting that “lawyer’s costs alone approach \$10,000 to obtain a patent and \$1.5 million (per side) to litigate a patent”).

² Martin Ensernick, *Patent Office May Raise the Bar on Gene Claims*, 287 SCI., Feb. 18, 2000, at 1196, 1197.

³ See Tanya Wei, *Patenting Genomic Technology—2001 Utility Examination Guidelines: An Incomplete Remedy in Need of Prompt Reform*, 44 SANTA CLARA L. REV. 307, 309 (2003) (noting that biotechnology is a \$22 billion dollar per year industry); see also Eliot Marshall, *Patent Suit Pits Postdoc Against Former Mentor*, 287 SCI., Mar. 31, 2000, at 2399, 2401 (discussing a contentious lawsuit between a postdoc and her professor because the postdoc’s name was left off the patent application).

⁴ See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI., May 1, 1998, at 698, 699 (noting that “private firms have stepped in, . . . filing patent applications on newly identified DNA sequences, including gene fragments, *before* identifying a corresponding gene, protein, biological function, or potential commercial product”) (emphasis added).

⁵ *Id.*

⁶ U.S. Patent No. 6,025,154 (filed Jun. 6, 1995) [hereinafter AIDS Patent].

⁷ *Id.* (quoting Abstract).

⁸ Wei, *supra* note 3, at 325 n.195.

about the precise function of the protein the gene encoded.⁹ Scientists at the National Institutes of Health (“NIH”) later determined that the protein encoded by the gene was related to the mechanism by which the AIDS virus gained entry into human cells.¹⁰ HGS never thought that the protein played a role in such an important disease.¹¹ Due to serendipity alone, HGS now charges money through a licensing agreement with another pharmaceutical company to utilize the receptor in developing HIV medications.¹² Stated differently, HGS has the power to make companies interested in working with the gene “pay to play.” If the natural DNA sequence had not been included in the patent,¹³ this situation may have been avoided.

This Article proposes a solution to the problem posed by patenting “upstream” genetic discoveries and, in particular, the patentability of naturally occurring genes. Tightening the utility requirement for gene patents through legislative action allows “upstream” DNA sequences to be freely available for research. Moreover, this tightened “gene utility” requirement should not cause a massive shift of resources away from basic research and development, as some might predict. Part II introduces the basics of patent law. The current state of genetic technology is presented in Part III, followed by an explanation of the current “gene utility” standard in Part IV. Part V discusses the costs and benefits of adjusting the utility requirement in detail. Part VI reexamines the incentives that drive basic gene research and development and presents a legislative proposal for a tightened “gene utility” standard (namely, the “substantial similarity” utility test). Finally, Part VII concludes that the increased stringency of the proposed “substantial similarity” utility test benefits both researchers and society without imposing undue constraints on basic science.

II. THE BASICS OF PATENT LAW

In order to properly frame the discussion of the patent utility requirement and its application to gene patents, it is first necessary to examine the foundation on which modern patent law rests. Part A below introduces the constitutional and statutory underpinnings of modern-day patent law and Part B highlights the various interests that patent law seeks to serve. This general foundation provides the background principles essential for the remaining discussion of gene patents.

⁹ Teresa M. Summers, *The Scope of Utility in the Twenty-First Century: New Guidance For Gene-Related Patents*, 91 GEO. L.J. 475, 480 (2003).

¹⁰ Wei, *supra* note 3, at 325.

¹¹ See Summers, *supra* note 9, at 480.

¹² Wei, *supra* note 3, at 325.

¹³ AIDS Patent, *supra* note 6 (referencing Claims 1–11).

A. *The Roots of Patent Law*

According to the Constitution of the United States, Congress has the power to “promote the Progress of Science and useful Arts.”¹⁴ Patent law extends from this constitutional authority.¹⁵ Patent law is best understood as a *quid pro quo*: in exchange for disclosing innovations for the benefit of the public, the inventor is granted legal protection to “appropriate the full economic rewards of her invention.”¹⁶ Thus, patent law balances the general interests of society against the economic interests of the inventor.

An inventor of “any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent.”¹⁷ In order to qualify for patent protection for a new invention, an applicant must meet certain basic requirements, such as showing that the invention is useful¹⁸ and novel.¹⁹ To qualify as novel, an invention cannot previously have been invented.²⁰ In addition to requiring usefulness and novelty, patent law also requires that inventions are non-obvious.²¹ Generally, this means that an inventor cannot receive patent protection for slight and obvious improvements on existing technologies.²² Finally, the inventor must enable others to make and use the invention by providing an adequate description of the invention.²³ Once the inventor meets these requirements in a patent application, the inventor is generally entitled to patent his or her invention.

Patent protection lasts from the patent’s issue date to twenty years from the date the inventor filed the patent application.²⁴ During this time, the patent holder has the “right to exclude others from making, using, offering for sale, or selling” the invention.²⁵ The owner of the patented invention may sue another who infringes these rights for an injunction, damages, and, in “exceptional cases,” attorney fees.²⁶ Patent law justifies these powerful rights extended to

¹⁴ U.S. CONST. art I, § 8, cl. 8.

¹⁵ *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980).

¹⁶ ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 119 (3d ed. 2003).

¹⁷ 35 U.S.C. § 101 (2000).

¹⁸ *Id.*

¹⁹ *Id.* § 102.

²⁰ *See id.*

²¹ *Id.* § 103.

²² *See MERGES ET AL.*, *supra* note 16, at 112 (noting that the patent application must represent “a nontrivial extension of what was known”).

²³ 35 U.S.C. § 112 (2000).

²⁴ *Id.* § 154(a)(2).

²⁵ *Id.* § 154(a)(1).

²⁶ *Id.* §§ 283–285; *See generally MERGES ET AL.*, *supra* note 16, at 118.

inventors within the context of the public interests that patent law attempts to promote.

B. Defining the Interests Served By Patent Law

Patent law attempts to answer a simple question: how can we as a society best stimulate innovation and invention? To understand how patent law approaches this question, it is first necessary to define the interests served by the patent system. On the one hand, technological progress benefits society in general. Technological developments not only enrich peoples' lives by making available new products, but also enable industries to produce goods for less money, making it easier on the consumer's pocketbook.²⁷ Since patent law requires the inventor to disclose the invention to the public, society also benefits through an increase in public information that can lead to further innovation.²⁸

Similarly, inventors also benefit from the current patent regime. Congress created patent laws to provide incentives for inventors to make the potentially costly investments required by research and development.²⁹ Generally speaking, the concern was that innovation would be hindered in a system that did not enable inventors to recoup the costs required to make the invention in the first place.³⁰ Without the proper incentives, innovation would diminish, resulting in less technological advancement and less public disclosure of new ideas.³¹

In the realm of genetic science, the need to find the proper investment incentives is an ongoing concern. The following examination of the current status of gene technology helps frame both the problems that bioscience attempts to solve as well as the legal tension surrounding gene patents.

III. THE STATE OF TECHNOLOGY

With the basics of patent law sufficiently outlined, it is now necessary to orient ourselves to where genes fit into the larger scheme of biotechnology. Genes are a set of instructions which a cell uses to build proteins.³² Genes

²⁷ JOHN W. SCHLICHER, 1 PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 1:1 (2d ed. 2003 & Supp. Nov. 2005).

²⁸ *Id.*

²⁹ *See id.*

³⁰ *See id.* (stating that “[i]nventors who anticipate being unable to capture enough of the value of their inventions will invest too little effort and other resources in creating new inventions”).

³¹ *See id.* (noting that patents provide inventors incentives to create as well as disclose); Wei, *supra* note 3, at 313 (discussing the incentives patent law offers inventors).

³² ELDRA PEARL SOLOMON ET AL., BIOLOGY 82 (5th ed. 1999).

consist of a polymer of four varieties of DNA bases: adenine, guanine, cytosine, and thymine.³³ Proteins are encoded by genes that consist of DNA bases. The order of the bases—the genetic code—dictates the protein that is ultimately made.³⁴ Genes are first transcribed into another polymer of bases, ribonucleic acid (RNA), by RNA polymerase.³⁵ The RNA is finally translated into protein by a ribosome.³⁶

This is of course an oversimplified explanation of how genes are translated into protein.³⁷ The important point is that genes are the foundation upon which the machinery of the cell is built. More importantly, the isolation of genes has enabled researchers to develop many useful medical treatments.³⁸ The ramifications of who, if anyone, has the right to patent genes may have far-reaching implications in the biomedical industry. Therefore, this Article surveys current genetic technology. Part A below discusses some of the current uses of genetic technology, while Part B introduces some of the basic problems that gene patents present, and with this understanding, Part C presents a road map for the rest of our analysis.

A. *Modern Uses*

It has almost become a cliché that biotechnology stands to revolutionize the way we practice medicine and the way we may come to view ourselves.³⁹ Genes and gene-technology hold incredible potential for a wide range of applications from agriculture to genetically modified designer babies.⁴⁰ However, the promises of genetic research are based not merely on what might happen in the future. Genetic technology is shaping society right now.

DNA and gene technology have already provided many benefits to society. Diabetics have benefited from pure insulin produced by bacteria that contain the gene for human insulin.⁴¹ Therapies for many human ailments may be on the brink of discovery because of the Human Genome Project.⁴² Moreover, as

³³ *See id.* at 267.

³⁴ *See id.*

³⁵ *Id.* at 269.

³⁶ *Id.* at 273–74.

³⁷ For a more detailed explanation of the basics of molecular biology see Rebecca M. Bratspies, *Biotechnology Primer for Lawyers*, SJ033 A.L.I.-A.B.A. 1 (2003).

³⁸ Linda R. Judge, *Biotechnology: Highlights of the Science and Law Shaping the Industry*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 79, 81 (2003).

³⁹ JEREMY RIFKIN, *THE BIOTECH CENTURY* 1 (1998).

⁴⁰ *See id.* at 2–4 (discussing the future of biotechnology and its applications).

⁴¹ Judge, *supra* note 38, at 81.

⁴² *See id.* at 83 (noting that the Human Genome Project has already led to the identification of genes involved in cystic fibrosis and sickle cell anemia, among others).

gene-based technology advances, it appears that such discoveries will only become more commonplace.⁴³ The potential applications appear limitless.

Nor are the fruits of genetic research limited to medical therapies for human disease. Genetic innovation also produces tools that are useful to researchers.⁴⁴ Research tools are products that “are used to test the efficacy or functionality of a pharmaceutical end product in a pre-clinical setting.”⁴⁵ Some examples include devices such as DNA sequencing machines and polymerase chain reaction (“PCR”) technology.⁴⁶ DNA sequences can be classified as research tools, depending on what they are used for.⁴⁷ For example, researchers have discovered that certain DNA molecules are useful as reaction catalysts in organic chemistry.⁴⁸ DNA can likewise be used in the research of drug and antibiotic function.⁴⁹ DNA has also proven useful in the study of enzyme kinetics, structure, and function.⁵⁰

It is useful to imagine a spectrum of DNA sequence research tools. At the most basic level there are naturally occurring genes, with a sequence unaltered by the human hand. At the other end of the spectrum are non-naturally occurring gene sequences engineered by humans.⁵¹ Assuming that each sequence along this spectrum has potential use as a research tool, the question then becomes: which gene research tools should be extended patent protection

⁴³ See *id.*

⁴⁴ See generally, Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising From Patenting Biomedical Research Tools*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 347 (2003).

⁴⁵ *Id.* at 348.

⁴⁶ See *id.* at 348–49. For an in depth discussion of the legal ramifications of PCR, see Kamarin T. MacKnight, *The Polymerase Chain Reaction (PCR): The Second Generation of DNA Analysis Methods Takes the Stand*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 95 (2003).

⁴⁷ Derzko, *supra* note 44, at 351.

⁴⁸ Andrew L. Feig & Olke C. Uhlenbeck, *The Role of Metal Ions in RNA Biochemistry*, in *THE RNA WORLD* 325 (Cold Spring Harbor Laboratory Press, 2d ed. 1999)

⁴⁹ See STEPHEN NEIDLE, *NUCLEIC ACID STRUCTURE AND RECOGNITION* 99 (2002) (noting that “[a] large number of clinically important drugs and antibiotics are believed to exert their primary biological action by means of DNA non-covalent interaction and subsequent inhibition of template function”).

⁵⁰ See Amy Martin et. Al., *Divalent Metal Dependence of Site-Specific DNA Binding by EcoRV Endonuclease*, 38 *BIOCHEMISTRY* 8430 (1999), available at <http://pubs.acs.org/cgi-bin/article.cgi/bichaw/1999/38/i26/pdf/bi9905359.pdf>.

⁵¹ See, e.g., DONALD VOET & JUDITH G. VOET, *BIOCHEMISTRY* 119 (3d ed. 2004) (discussing green fluorescent protein from jellyfish, the fusion of the green fluorescent protein gene with other genes for use as a reporter gene, and other genetically engineered variants).

and which should be freely available? As discussed below, the dividing line must be drawn through a thicket of difficult scientific, medical, and economic considerations.

B. Modern Problems

The biomedical industry is separated into three general sub-industries: traditional pharmaceutical companies, biotechnology companies, and genomics companies.⁵² Genomics companies are unique because while pharmaceutical and biotech companies produce commercial products, genomics companies attempt to build a market for genes that *may* be useful in the future development of commercial products.⁵³ For example, by attaining patent protection on DNA sequences, a genomics company “would control the downstream product’s production through . . . possession of the upstream patent.”⁵⁴ Such a scenario presents a host of potential problems to those interested in conducting basic research.

The specter of patents protecting many “upstream” genetic discoveries has been labeled the tragedy of the “anti-commons.”⁵⁵ By allowing basic genetic discoveries—for example, gene sequences—to be patented, the public empowers patent holders to exclude other prospective users to the point where the discovery becomes underutilized.⁵⁶ The more “upstream” gene sequences that are patented, the more a prospective researcher will spend on licensing and negotiating for the right to use those sequences.⁵⁷

A simple example illustrates this situation. Consider the basic model of a hypothetical cell signal transduction pathway.⁵⁸ This hypothetical pathway involves the interaction of many different proteins, each encoded by different genes. First, a cell surface receptor is activated by a hormone, for example.⁵⁹ Once the receptor is activated, it in turn activates a number of other different proteins. Each of these activated proteins may trigger a number of different

⁵² Alexander K. Haas, *The Wellcome Trust’s Disclosures of Gene Sequence Data Into the Public Domain & the Potential for Proprietary Rights in the Human Genome*, 16 BERKELEY TECH. L.J. 145, 147–50 (2001).

⁵³ *See id.* at 150.

⁵⁴ *Id.*

⁵⁵ *See generally*, Heller & Eisenberg, *supra* note 4 (presenting the theory of the anti-commons).

⁵⁶ Haas, *supra* note 50, at 156.

⁵⁷ *See id.* at 160.

⁵⁸ *See generally*, SOLOMON ET AL., *supra* note 32, at 1024–26 (discussing signal transduction).

⁵⁹ *See id.* at 1024.

cellular processes.⁶⁰ In sum, the activation of a single surface receptor may cause many different cell actions through various protein messengers.

Imagine that such a signal transduction pathway was implicated in some form of cancer and that several biotech firms owned patents on different genes involved in the pathway. In this scenario, a scientist interested in researching this form of cancer would have to contend with the patents on all of the patented genes. One might be willing to accept this scenario by reasoning that wealthy biotech companies have the means to pay. However, such restricted access to “upstream” genes is of particular concern in the realm of university research.⁶¹ The threat of the “anti-commons” should not be written off as the theoretical musings of academics.

When a company patents “upstream” research tools, the company has tremendous power, under patent law, to force new researchers to license the tool before being able to conduct any research.⁶² This is not an idle concern. Although not specifically related to gene sequences, the stem cell research community is worried that a single patent covers not only the method for isolating stem cells, but the stem cells themselves.⁶³ This patent, combined with President Bush’s restrictions on the creation of new stem cell lines, has led to “overwhelming concern that [researchers] will not be able to gain access to stem cell lines that are patented by private companies.”⁶⁴

The implications of such “upstream” patents go beyond the mere frustration of researchers. Great Britain has fewer legal restrictions on stem cell research,⁶⁵ and the United States, with its “complicated legal and regulatory burdens,” has created incentives for companies interested in conducting stem cell research to move overseas.⁶⁶ More restrictions thus result in both loss of innovation as well as loss of domestic jobs. The stem cell patent does not exactly mirror the situation with the human genome. However, stem cells provide a stark example of the potentially adverse consequences of a regulatory scheme that ties up information and innovation. We must proceed

⁶⁰ *See id.* at 1026.

⁶¹ *Cf. Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (limiting the ability of the university to use inventions experimentally without infringing the underlying patent—the “experimental use” exception—because university research helps “to increase the status of the institution and lure lucrative research grants, students and faculty”).

⁶² *See Keala Chan & Dennis Fernandez, Patents in Proteomics: Possibilities and Precautions*, 22 BIOTECHNOLOGY L. REP. 273, 275–76 (2003) (discussing the potential areas in proteomic research susceptible to such “tollbooth” patents).

⁶³ Stacy Kincaid, *Oh, the Places You’ll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research*, 30 PEPP. L. REV. 553, 571–73 (2003).

⁶⁴ *Id.* at 573.

⁶⁵ *See id.* at 571.

⁶⁶ *Id.*

2006]

DOLLARS AND LIVES

with caution.

C. Summary and Road Map

This Part introduced the fundamental role human genes play in scientific research. As gene technology advances, we can expect to see more uses of genetic material in the lab. However, the patentability of “upstream” innovation poses serious threats both in terms of innovation as well as negative economic fallout. Professor Rebecca Eisenberg has noted that the patent regime and its application to genetic innovation are in flux.⁶⁷ As a result, the patentability of DNA is fraught with “profound uncertainty.”⁶⁸ The remainder of this Article attempts to bring certainty to the question of gene patentability. Before we can propose meaningful changes to the current patent regime, we must ascertain exactly where patent law currently stands with respect to human genes.

IV. GENES AND THE CURRENT UTILITY STANDARD

The utility of an invention must be determined before or at the time of filing the patent application.⁶⁹ But what exactly does a determination of utility require? This Part answers this question by examining how DNA—a substance fundamental to all life on Earth—came within the scope of patentable subject matter, and by discussing the United States Patent and Trademark Office’s (“USPTO”) current utility requirements and their history.

A. Owning Life

Can we devise a method of cleaning up oil spills? When one microbiologist posed this question, he could not have foreseen the legal ramifications of his query.⁷⁰ Ultimately, however, the legal spillover from his invention to clean up oil slicks forced the United States Supreme Court to grapple with the “ownership” of life. In *Diamond v. Chakrabarty*,⁷¹ Mr. Chakrabarty created genetically engineered bacteria that could break down oil.⁷² It was thought that this microbe held incredible potential for the cleanup of oil spills.⁷³ Whatever

⁶⁷ See Rebecca S. Eisenberg, *How Can You Patent Genes?*, in WHO OWNS LIFE? 117, 128–29 (David Magnus et al. eds., 2002) (noting that the current patent regime may not address the informational aspect of genetic innovation).

⁶⁸ *Id.* at 118.

⁶⁹ ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY* 255 (3d ed. 2002).

⁷⁰ See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

⁷¹ *Id.*

⁷² *Id.* at 305.

⁷³ *Id.*

the scientific merits of his discovery were, the patentability of genetically modified living organisms was, at the time, an undecided issue.

The Supreme Court had previously determined that natural laws and phenomena were not patentable subject matter.⁷⁴ Nevertheless, the Supreme Court ruled that Mr. Chakrabarty's genetically engineered bacteria were patentable because they were not "a hitherto unknown natural phenomenon" but rather a "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity."⁷⁵ There was no ambiguity in the statute—the court believed that a broad definition of patentable subject matter, including manmade living organisms, would best achieve the purpose of patent law.⁷⁶ As discussed earlier, that purpose is the economic security for the inventor in exchange for public dissemination of the innovation.⁷⁷

This broad net of patentability has been cast over DNA sequences as well.⁷⁸ However, the patentability of gene sequences is by no means a closed subject. On the contrary, technological advances, for example, "may render the successful identification of the DNA sequence in a gene of interest routine and predictable."⁷⁹ Thus, we must be wary in concluding that patent trends of today will repeat indefinitely into the future.⁸⁰ Nevertheless, some twenty years later, the reverberations of *Chakrabarty* still resonate deep within the USPTO's patentability requirements.

B. *The USPTO's Utility Guidelines*

While *Chakrabarty* stands for the proposition that living organisms are patentable provided that they are manmade, it also presents the more general rule that "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity" is patentable.⁸¹ Relying on this exact language from *Chakrabarty*, the Utility Guidelines make clear that the USPTO does not

⁷⁴ See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (determining that a mixture of bacteria was not patentable because "these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men"); *Parker v. Flook*, 437 U.S. 584, 593 (1978) ("The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect").

⁷⁵ *Chakrabarty*, 447 U.S. at 309.

⁷⁶ *Id.* at 315.

⁷⁷ See discussion *supra* Part II.B (discussing the *quid pro quo* of the patent system).

⁷⁸ See Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 722–36 (1990) (discussing patent case law and its applicability to DNA sequences).

⁷⁹ *Id.* at 730.

⁸⁰ *Id.*

⁸¹ *Chakrabarty*, 447 U.S. at 309.

need not to wait for Congress to determine the patentability of genes.⁸² Rather, as the USPTO notes, *Chakrabarty* already clarified that the intended scope of patentable subject matter includes gene sequences when they are a product of human ingenuity.⁸³ As long as they meet the statutory requirements, DNA “sequences are eligible for patenting when isolated from their natural state and purified.”⁸⁴

Critics of gene patenting may overlook the importance of this conclusion in the Utility Guidelines.⁸⁵ By making the above declarations, the USPTO clarifies that it will not be the source of special criteria for gene patents. The Utility Guidelines reject the idea of limiting patent protection to the uses of the gene rather than the sequence itself.⁸⁶ The Utility Guidelines note that “[p]atent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter.”⁸⁷ Therefore, the lens through which the USPTO views gene patents is already established. To present this standard, this Part next (1) turns to the background of the Utility Guidelines, and (2) outlines the current utility standard.

1. The Background of the Utility Guidelines

Initially, a compound met the utility requirement if it had “practical” utility,⁸⁸ which meant that it could be used by other researchers.⁸⁹ In this context, practical utility merely reflects the ordinary understanding of utility—the ability of the invention to be used by someone.⁹⁰ Utility depended less on judicial definition than on common sense.⁹¹ This liberal utility requirement did not last.

⁸² Utility Examination Guidelines, U.S. Patent and Trademark Office, 66 Fed. Reg. 1092-02, 1093 (Jan. 5, 2001) (Discussion of Public Comments) [hereinafter Utility Guidelines].

⁸³ See *Chakrabarty*, 447 U.S. at 309 (noting that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man’”) (quoting S. REP. NO. 82-1979, at 5 (1952)).

⁸⁴ Utility Guidelines, *supra* note 82, at 1093.

⁸⁵ See, e.g., Summers, *supra* note 9, at 509 (concluding that “the PTO and the courts should make clear that the law recognizes the differences between chemical compounds and biotech research tools”).

⁸⁶ Utility Guidelines, *supra* note 82, at 1095–96.

⁸⁷ *Id.* at 1095.

⁸⁸ *In re Nelson*, 280 F.2d 172, 180 (C.C.P.A. 1960).

⁸⁹ *Id.* at 180–81.

⁹⁰ Eric P. Mirabel, “Practical Utility” is a Useless Concept, 36 AM. U. L. REV. 811, 818 (1987) (quoting WEBSTER’S NINTH COLLEGIATE DICTIONARY 1299 (9th ed. 1984)).

⁹¹ See *id.* at 817 (stating that, following *Nelson*, “‘practical’ use does not mean ‘carrying judicial imprimatur,’ but is equivalent to ‘useful’ in the lay sense”).

The seminal case of *Brenner v. Manson* planted the seeds for the current utility standard for chemical compound patents.⁹² At issue in *Brenner* was the patentability of a chemical process that produced steroids.⁹³ The USPTO rejected the patent application because the applicant did not state any utility for the steroids.⁹⁴ However, the Court of Customs and Patent Appeals (“CCPA”) reversed the decision, reasoning that a patent for a chemical process that produces an already-known product need not assert the utility of the final product.⁹⁵

The United State Supreme Court reversed the CCPA, with its oft-quoted proclamation that “a patent is not a hunting license.”⁹⁶ Because the applicant was unable to define a use for the resulting steroids, the Court was concerned that awarding patent protection for the process for making the steroids would grant monopoly control over “a vast, unknown, and perhaps unknowable area . . . [block]ing off whole areas of scientific development, without compensating benefit to the public.”⁹⁷ The Court narrowed the idea of practical utility by requiring “substantial utility” that derives “specific benefit.”⁹⁸ The Supreme Court has not revisited the concept of utility since *Brenner*.⁹⁹

At first glance, one might question the applicability of *Brenner* to gene sequences. While genes perhaps hold a special position in our hearts and minds because of their centrality to human existence, they are still chemical compounds.¹⁰⁰ This fact has not been lost on the courts either. One court noted, “[a] gene is a *chemical compound*, albeit a complex one” that may be patented “after the gene has been isolated.”¹⁰¹ This fundamental principle—genes as chemical compounds—is crucial to our understanding of the current utility standard for gene sequences.

2. The Current USPTO “Gene Utility” Standard

So what, then, *is* the current utility standard? A genetic invention will pass the utility threshold “(1) if a person of ordinary skill in the art would

⁹² 383 U.S. 519 (1966).

⁹³ *Id.* at 520–21.

⁹⁴ *Id.* at 521.

⁹⁵ *Id.* at 522.

⁹⁶ *Id.* at 536.

⁹⁷ *Id.* at 534-35.

⁹⁸ *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966).

⁹⁹ MERGES & DUFFY, *supra* note 69, at 250.

¹⁰⁰ See VOET & VOET, *supra* note 51, at 80–82 (discussing the basic chemical properties of DNA).

¹⁰¹ *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (emphasis added).

immediately appreciate why the invention is useful . . . and (2) the utility is specific, substantial, and credible.”¹⁰² The Utility Guidelines, however, do not provide tremendous guidance because they define specific and substantial utility, not by what they are, but by what they are not: “This requirement excludes ‘throw-away,’ ‘insubstantial,’ or ‘nonspecific’ utilities, such as the use of a complex invention as landfill”¹⁰³ Credibility determinations are to be made by a person of ordinary skill in the art based on “evidence of record . . . that is probative of the applicant’s assertions.”¹⁰⁴ Landfill, we know now, is out. But how does this help us determine what is in?

At this stage, it may be helpful to consider a spectrum of possible gene inventions.¹⁰⁵ Assume that it is possible to use any gene along this spectrum, whether natural or human-made, as a research tool. The issue, then, is how to distinguish between those tools that are patentable and those that are not. On one end, there are purified and isolated naturally occurring genes. The Utility Guidelines make clear that isolated genes are not patentable if the researcher cannot identify a utility.¹⁰⁶ At the other end of the spectrum are genetic inventions—such as genes that have been modified or created by humans—with defined, specific and substantial uses easily recognizable by one skilled in the art. These, as we know, are patentable.¹⁰⁷ For example, a researcher could create a protein, useful for research, by mutating or altering the genetic code of a natural gene to such an extent that the protein encoded by the gene is substantially different from what occurs in nature.¹⁰⁸

We may assume that the debate about gene patentability is not over the two extremes on the utility spectrum but over what lies in between. What the Utility Guidelines have not done and, by the USPTO’s own admission, will not do, is clarify where the dividing line between useful and non-useful gene inventions should be drawn.¹⁰⁹ This Article now proposes an answer to this question. What follows is not a debate over the ethics of owning “life” or a philosophical discussion of property rights. Rather, this Article suggests a practical solution based on a synthesis of the economic, intellectual, and social incentives that drive genetic research.

¹⁰² Utility Guidelines, *supra* note 82, at 1098.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ See David B. Resnik, *Discoveries, Inventions, and Gene Patents*, in *WHO OWNS LIFE?* 135, 150 (David Magnus et al. eds., 2002) (presenting a similar spectrum for the purpose of discussing the distinction between discoveries and inventions).

¹⁰⁶ See Utility Guidelines, *supra* note 82, at 1098.

¹⁰⁷ See *id.*; Resnik, *supra* note 105, at 135.

¹⁰⁸ See discussion *infra* Part VI.D.1 (discussing genetically engineered variations of Green Fluorescent Protein).

¹⁰⁹ See Utility Guidelines, *supra* note 82, at 1096.

V. DEFINING AN APPROPRIATE UTILITY STANDARD IN A WORLD OF
EXTREMES

This Article proposes a new strategy for establishing the utility of genetic inventions. With an understanding of the goals of patent law and the current utility requirement, we must discuss the effects of changing the utility standard. In so doing, we examine two extremes: a world with a low utility threshold and a world with a high utility threshold. This Part presents a survey of (A) the benefits of a low utility standard, (B) the costs of a low utility standard, (C) the benefits of a high utility standard, and (D) the costs of a high utility standard. This Part concludes with a brief discussion of (E) the reasons supporting the importance of setting the utility standard at the proper level.

A. *The Benefits of a Low Utility Standard*

Generally, the lower the patent utility standard, the easier it will be obtain a patent, and thus the incentive to file early will be increased.¹¹⁰ It stands to reason that the earlier one files, the more likely that inventor can beat the competition to the patent, thus gaining all the advantages of owning the patent. According to Professor Edmund Kitch, the patent system has built-in mechanisms that encourage early patent filing.¹¹¹ First, Kitch notes that certain inventions may have multiple uses.¹¹² There is an incentive to file under the rubric of one use with the intention of conducting further research on other uses.¹¹³ Second, there is incentive to file early because “the patent is awarded to the first inventor, a technical status almost always obtained by the first to file.”¹¹⁴ Professor Kitch concludes that the patent system is essentially a “prospect system” that forces inventors to file as early as possible.¹¹⁵

There are benefits to a patent regime that encourages early filing. For example, Kitch notes that early filing leads to early disclosure, which reduces duplicative efforts on the part of competitors.¹¹⁶ Also, early filing gives inventors security when advertising potential uses for the product because competitors will not be able to wait for the first inventor to create the market and then simply copy the product.¹¹⁷

Inventors are not the only beneficiaries of a low utility standard; society, in

¹¹⁰ MERGES & DUFFY, *supra* note 69, at 255.

¹¹¹ Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 267 (1977).

¹¹² *Id.* at 269.

¹¹³ *See id.* (noting that this is an important part of the patent system in the drug industry).

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 276.

¹¹⁷ *Id.* at 277.

theory, also benefits from early disclosure.¹¹⁸ Since public disclosure of the patented invention is part of the patent bargain, the greater the number of patents, the more information will be publicly available for further innovation.¹¹⁹ This is the “bricks-and-mortar” view of the patent system.¹²⁰ In this paradigm, “[t]he traditional patent bargain ensures that patenting enriches the information base, even as it slows down commercial imitation.”¹²¹ Patenting provides inventors protection while deepening the existing pool of knowledge from which future inventors may draw.¹²² It follows that the more patents issued under a liberal utility standard, the more information disclosed for the benefit of society. However, a low utility standard does not come without costs.

B. The Costs of a Low Utility Standard

As discussed above, a low utility standard may lessen research costs by reducing duplicative efforts in identifying and isolating genes. However, this is a simplistic conclusion because the benefits of gene discovery are not the genes themselves, but rather the fruits of the research that inevitably follow.¹²³ Moreover, under this conclusion, a low utility standard for DNA sequences is only justifiable insofar as discovered genes would not be disclosed in the absence of patent protection. As explained later in this Article, lack of disclosure, and the concomitant rise in duplicative gene discovery, is a dubious assumption.¹²⁴

Despite the potential benefits, a lower utility threshold has economic drawbacks as well. By making it easier to obtain a patent on a gene sequence, it is likely that more of these patents will be pursued and issued. For example, consider the situation in which ten different biotech firms each own a patent to a separate gene, all of which are related to a certain form of cancer. Any company that wishes to put these genes to use in developing cancer medication will need to negotiate with those patent holding firms. These negotiations are costly and will ultimately increase the costs of drug development.¹²⁵ The

¹¹⁸ See *id.* at 276-77.

¹¹⁹ Eisenberg, *supra* note 67, at 126-27.

¹²⁰ *Id.*

¹²¹ *Id.* at 126.

¹²² See *id.*

¹²³ See Summers, *supra* note 9, at 491-93 n.137 (refuting the application to gene research of Kitch’s argument that reducing duplicative research justifies a low utility requirement).

¹²⁴ See discussion *infra* Part VI.C.2 (discussing incentives for basic genetic research in the absence of patent protection for gene sequences).

¹²⁵ See R. H. COASE, *THE FIRM, THE MARKET, AND THE LAW* 114 (1988) (stating that

higher the costs, the greater the impediment to beginning the research needed to develop the drug.¹²⁶ Similarly, the more “upstream” patents are allowed—protecting the natural, unaltered, gene sequences rather than concrete inventions—the greater the costs of “downstream” drug development will be.¹²⁷ Even when these costs are not insurmountable, the costs are ultimately passed on to the consumer in the form of higher drug prices.¹²⁸

Further, the costs are not the only problems in a liberal patent regime. Calabresi and Melamed note that whether legal entitlements may be bought and sold implicates how wealth is distributed in society.¹²⁹ Assuming that there is a price at which any gene patent can be licensed, it follows that allowing the grant of gene patents causes wealth to funnel into firms that hold those patents and, therefore, away from those firms that do not hold those patents.¹³⁰ This situation, in turn, limits the access that society has to patented gene inventions.¹³¹ Determining patentability standards reflects whether society deems accessibility to patented gene sequences as something socially valuable.¹³²

The economic costs of a low patentability requirement are a limit, via high entry costs, to the access other researchers have to basic genetic innovations. Limited access, through high licensing and transactional costs, may detrimentally affect the ability of future researchers to build upon what is already known. By increasing these entry costs to genetic research, it logically follows that such costs will be passed on to the consumer in the form of higher

entering a transaction requires the costly expenditure of resources to locate others with which to do business, inform those parties you want to do business with them, enter negotiations with those parties, draft the necessary contracts, and monitor the performance of those contracts).

¹²⁶ *Id.*

¹²⁷ Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Informational Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 *FORDHAM L. REV.* 477, 481 (2003) [hereinafter Eisenberg (*FORDHAM L. REV.*)].

¹²⁸ *See id.* at 487 (noting that “[w]hen new product development uses many prior patented inventions, strengthening patents adds to the costs of drug development as well as the profits from selling new drugs”).

¹²⁹ Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 *HARV. L. REV.* 1089, 1098–1101 (1972).

¹³⁰ *See id.* at 1114 (noting that “[w]hether an entitlement may be sold or not often affects directly who is richer and who is poorer”).

¹³¹ *See id.* at 1100 (discussing “merit goods” and stating that when “society wishes to maximize the chances that individuals will have at least a minimum endowment of certain particular goods . . . the society is likely to begin by giving the individuals an entitlement to them.”).

¹³² *Id.* at 1101.

drug prices. As Calabresi and Melamed state, the “entitlement that society wishes to sell, and which it decides to give away, will likely depend in part on which determination promotes the wealth distribution that society favors.”¹³³ A lenient patent utility requirement shifts an undue amount of wealth from the consumer into the pockets of the scientific firms. However, before hastily concluding that the world would be a better place with a stringent “gene utility” requirement, it is important to first take a closer look at the benefits and costs of a high utility standard.

C. *The Benefits of High Utility Standard*

In a patent regime with a low utility requirement, duplicative research efforts are minimized by early disclosure of the patented invention, informing competitors to either make arrangements with the patent owner or cease development.¹³⁴ However, this cuts both ways. Certain situations may arise in which an inventor knows that the benefits of the patent greatly exceed the costs of innovation.¹³⁵ When such circumstances arise, “inventors will often compete with each other to be the first and only inventor to win the patent.”¹³⁶ As such, duplicative research is not eliminated by a system granting patents early in the invention process. Rather, duplicative efforts may merely be shifted to the period before the first patent issues.

Duplicative waste due to a patent race might not be, in and of itself, a bad thing. However, the costs of duplicative research are potentially exacerbated—to the detriment of useful drug development—by the behavior of the patent holder once the race ends. After the “winner” of the patent race receives patent protection, the patent holder could hypothetically block access to the gene by prohibiting access to others unless they pay a fee. A low utility standard would enable researchers to patent genes without fully understanding their specific functions. The holders of these patents would then be able to extract a premium from subsequent researchers who wish to develop the drug.¹³⁷ Not only does a low utility standard create an incentive to engage in such exclusionary behavior, it arguably tempts researchers to enter the wasteful duplicative race in the first place. A high utility requirement helps to alleviate this possibility by forcing researchers to invest in further research and development before acquiring patent protection.

¹³³ *Id.* at 1099.

¹³⁴ See Kitch, *supra* note 111, at 276.

¹³⁵ Matthew Erramouspe, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 976 (1996).

¹³⁶ *Id.*

¹³⁷ See Summers, *supra* note 9, at 480–81 (discussing an actual example in which HGS held the patent for a gene important for HIV/AIDS therapy).

Similarly, allowing natural genes to be patented—possible under a regime with a liberal utility requirement—hinders post-patent races to generate improvements on the gene.¹³⁸ Specifically, gene discovery and subsequent patenting will not induce a race to improve the gene because purified genes cannot be improved.¹³⁹ Therefore, the issue is not whether disclosure enables subsequent researchers to refine genes. Instead, the gene must be modified or developed into a useful product, a process only made more difficult if a blocking patent ties up the natural sequence.¹⁴⁰ A more stringent “gene utility” requirement keeps the sequence free and forces firms to develop useful products before marching off to the USPTO. It is debatable what society gains from the mere disclosure of a gene sequence.

There is a dark side to the prospect patent system espoused by Professor Kitch. The easier it is to get a patent, the more likely subsequent inventors will attempt to invent around the patent.¹⁴¹ Setting the proper patent utility standard helps prevent wasteful races to generate trivial modifications.¹⁴² But as noted above, one cannot practically improve on naturally occurring genes, refined through millennia of evolution. As a result, the actual payoff to getting a gene patent comes from simply being the first to discover the sequence. Like a gold rush, such a prospect system imposes heavy costs on society:

In a gold rush . . . a single lucky prospector wins big, and then society loses as follow-on prospectors bid resources from higher valued uses outside the prospecting industry to lower valued ones inside it. This overbidding means more gold will be found earlier, but the value to society of finding the gold this week rather than next is less than the loss to society caused by the prospectors’ overinvestment, resulting in a net loss to society.¹⁴³

In gene patenting, the analogy to a gold rush is quite useful. If the possibility of generating wealth from a gene patent exists through licensing and the control of “downstream” development, companies have an incentive to invest resources in finding and patenting genes. However, because one cannot know if a particular gene will be valuable in the future, the risk is that firms will invest heavily in discovering and patenting genes simply with the hope that the gene will have some future undetermined value. The cost to society is a squandering of resources and a corresponding tying up of genes for research

¹³⁸ Erramouspe, *supra* note 135, at 976.

¹³⁹ *Id.* at 992.

¹⁴⁰ See discussion *supra* Part V.B (discussing the costs of a liberal patent regime).

¹⁴¹ Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 318 (1992).

¹⁴² *Id.*

¹⁴³ *Id.* at 314–15.

purposes. A high utility standard helps avoid this sort of behavior.

Considering the complexities in human disease, a high utility requirement for gene patents makes a great deal of sense. Even in a situation where a researcher discovers the function of a particular gene, the potential exists for that same gene to have another different, but equally important, function.¹⁴⁴ And as patent law currently stands, a researcher who discovers such a secondary function can receive a patent, if at all, only on the newly discovered function; and this second patent, limited to the new use, is entirely dominated by the patent on the gene itself, which covers all uses.¹⁴⁵ Gene patents—issued in a regime with a low utility standard—undermine the necessity of allowing many avenues of gene research to be explored.¹⁴⁶ The more basic the level of utility at which gene patents are issued, the more progress may be hindered.¹⁴⁷

D. The Costs of a High Utility Standard

Despite the benefits of a high utility standard, such a system is not without its costs. Recall the *quid pro quo* of the patent system: in exchange for public disclosure, the inventor receives a limited monopoly over the invention.¹⁴⁸ In the absence of other incentives, it seems clear that disclosure of gene sequences would be inhibited. This could occur if researchers simply refused to invest in discovery or continued to do so while keeping their discoveries secret.

Making it more difficult to attain patent protection for gene sequences may have other effects as well. Patents are important, especially for smaller companies, for the influx of investment money necessary for research.¹⁴⁹ As Professor Rebecca Eisenberg noted, patentability is a major factor in decisions to invest in research and development in the biotech industry.¹⁵⁰ As private funding plays a larger role in biological research and development, a toughened patent utility requirement could threaten the influx of dollars spent on basic research.¹⁵¹

¹⁴⁴ See SOLOMON ET AL., *supra* note 32, at 1035–36 (noting that the hormone insulin stimulates some cells to take in sugar while inhibiting liver cells from releasing sugar).

¹⁴⁵ Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1667 (2001).

¹⁴⁶ Summers, *supra* note 9, at 493.

¹⁴⁷ *Id.*

¹⁴⁸ See discussion *supra* Part II.B (discussing the interests served by the patent system).

¹⁴⁹ Gitter, *supra* note 1455, at 1671.

¹⁵⁰ Eisenberg, *supra* note 1277, at 480.

¹⁵¹ See *id.* at 480 (noting that “despite steady increases in National Institutes of Health . . . funding aimed at doubling the NIH budget, private funding has overtaken public

Higher patentability standards may impose even further costs on the biotech industry. Unable to protect gene discoveries, firms might be forced to invest in secrecy measures.¹⁵² Decreased levels of protection could trigger an exodus of the biotech industry to regions where patent standards are more liberal.¹⁵³ Proposals to adjust the utility standard for genes must attempt to account for less public disclosure of genetic information as well as the possibility of a massive withdrawal of private funding.

A high utility requirement implicates Calabresi's and Melamed's notions that legal entitlements help determine how we choose to properly balance wealth distribution in society.¹⁵⁴ Patents, enabling the patent holder to exclude others from using the invention, help make medical drugs profitable.¹⁵⁵ The possibility of economic payoff, especially for private firms, is no small consideration. Concern that both the United States and Great Britain would tighten patentability requirements resulted in a multi-billion dollar decrease in the stock market value of biotech firms.¹⁵⁶ Shifting to a more stringent regime may therefore redistribute wealth away from medical innovators, potentially resulting in less beneficial innovation. As a result, tightening the utility requirement for gene patents in a cavalier and unprincipled way will not yield a simple solution to the gene utility conundrum.

E. The Importance of Setting the Right Standard

After understanding the theoretical implications of setting the utility standard, one can determine, in the proper context, whether the Utility Guidelines set the utility bar appropriately. Gene patents push the balance involved in the quid pro quo nature of patents to the brink.¹⁵⁷ The potential for creating pharmaceuticals spurs private investment in biomedical research and development projects.¹⁵⁸ Furthermore, the patents issued for new pharmaceuticals—unlike patents in other fields where “patented products face significant competition from patented or unpatented substitutes”¹⁵⁹ confer an actual monopoly to the patentee. As a result, further incentives exist for

funding”).

¹⁵² Gitter, *supra* note 1455, at 1671.

¹⁵³ *Id.*

¹⁵⁴ Calabresi & Melamed, *supra* note 129, at 1099.

¹⁵⁵ Eisenberg, *supra* note 1277, at 480.

¹⁵⁶ Gitter, *supra* note 1455, at 1629.

¹⁵⁷ See discussion *supra* Part II.B (discussing the *quid pro quo* nature of the patent system).

¹⁵⁸ Eisenberg, *supra* note 1277, at 477.

¹⁵⁹ *Id.* at 479.

continued investment by the private sector.¹⁶⁰

Unfortunately, the very health of our society is trapped in the middle of this economic balancing act. No one can reasonably argue that people do not benefit from the new medicines. These benefits, however, must be weighed against the costs individuals pay when they have their prescriptions filled.¹⁶¹ Furthermore, a lower utility requirement, as discussed above, opens the door for an increased number of patents on natural gene sequences.¹⁶² A large number of such “upstream” patents may increase the costs of “downstream” research and development of new medicines and treatments.

This utility standard balancing act has generated concern within the medical community. The American College of Medical Genetics (“ACMG”), recognizing the importance of genetic research in medicine, states that current patent enforcement trends are “restricting the availability of gene testing . . . [with] long-term implications.”¹⁶³ The ACMG concludes that genes are natural products and should not be patentable.¹⁶⁴ Similarly, the American Medical Association (“AMA”) notes that some “physicians fear [that] if too many genes receive patents, genetic testing of patients could become prohibitively expensive . . . [and] may never be used effectively to help patients.”¹⁶⁵ Yet, the AMA also recognizes that the elimination of gene patents could have a detrimental impact on research and development investment.¹⁶⁶

Although these critiques do not provide much by way of an answer to the gene utility puzzle, they do highlight the importance of the issue underlying this debate. Arguing that the very health of society is at stake is by no means an understatement. The consequences of setting the correct utility standard will be measured in dollars and lives. The remainder of this Article attempts to strike the proper balance in this seemingly unpredictable and unstable situation.

¹⁶⁰ *Id.*

¹⁶¹ *See id.* at 486 (noting, in her discussion of the interaction between patent law and FDA regulation that “[a]s the population ages and becomes more concerned about health care, and as public and private payors struggle to control rising health care costs, the laws that set the ground rules for biomedical innovation are receiving closer and more skeptical scrutiny . . .”).

¹⁶² *See* discussion *supra* Part V.B (discussing the costs of a liberal patent regime).

¹⁶³ American College of Medical Genetics, *Position Statement on Gene Patents and Accessibility of Gene Testing*, <http://genetics.faseb.org/genetics/acmg/pol-34.htm> (last visited Feb. 9, 2006).

¹⁶⁴ *Id.*

¹⁶⁵ American Medical Association, *Gene Patenting*, <http://www.ama-assn.org/ama/pub/category/print/2314.html> (last visited Feb. 9, 2006).

¹⁶⁶ *Id.*

VI. CRAFTING A NEW DEFINITION OF “GENE UTILITY”

Part V addressed how changes in the utility standard may impact patent behavior. With these economic consequences in mind, this Part presents a change in the current utility standard that restricts the patentability of naturally occurring gene sequences. Part VI.A discusses a recently patented cancer gene, Part VI.B reexamines the idea of “gene utility” to clarify what sort of behavior we are trying to encourage with the utility standard, Part VI.C investigates the incentives that already exist—outside the patent regime—in the world of gene research, and Part VI.D presents model legislation redefining “gene utility.” Part VI demonstrates that a heightened standard, inquiring whether the utility derived from a sequence is substantially similar to the natural function of the gene, will not have the dire consequences that many fear.

A. *A Real World Interlude*

A patent application has met the utility requirements necessary to receive a patent when the USPTO finds that the stated use does not cause “one of skill in the art to reasonably doubt the asserted usefulness.”¹⁶⁷ It seems logical to infer from this language that utility is defined at a very basic level. The USPTO slightly tightened the standard by requiring that a person of ordinary skill in the art realize the utility without “undue experimentation”¹⁶⁸ and that the claimed utility be “specific, substantial and credible.”¹⁶⁹ The question remains as to which gene sequences will meet this threshold. The current utility requirements clearly show that the USPTO will deny a patent to, for example, a researcher who purifies a gene for use as a paperweight. But what level of utility actually suffices?

The USPTO recently issued a patent for a human gene that acts as an oncogene (“Oncogene Patent”).¹⁷⁰ The researcher-inventor first applied for this patent in November 1996.¹⁷¹ The Oncogene Patent is assigned, on its face, to Chiron Corporation, a biotechnology company in Emeryville, California. Oncogenes are essentially genes that lead to the formation of cancer.¹⁷² According to the patent applicant, the oncogene and its protein products are useful as “diagnostic, prognostic, and therapeutic tools for neoplastic disorders.”¹⁷³

Society clearly gains from the discovery and disclosure of genes implicated

¹⁶⁷ *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

¹⁶⁸ *Id.* at 1564.

¹⁶⁹ Utility Guidelines, *supra* note 82, at 1098.

¹⁷⁰ U.S. Patent No. 6,673,911 (filed Apr. 11, 2000) [hereinafter Oncogene Patent].

¹⁷¹ *Id.* (referencing Related U.S. Application Data).

¹⁷² SOLOMON ET AL., *supra* note 32, at G-28.

¹⁷³ Oncogene Patent, *supra* note 17070 (quoting the Abstract).

in cancer. However, the Oncogene Patent states that although “not wanting to be bound by any particular theory, it is believed that there are lethal [forms of the gene] . . . which are involved” in various cancers.¹⁷⁴ The Oncogene Patent claims the isolated DNA sequence of the oncogene.¹⁷⁵ It also suggests that all naturally occurring variations of the gene sequence, as well as some non-natural forms, “are within the scope of this invention.”¹⁷⁶ Importantly, because the claims of the patent cover compositions, and because a patent gives its owner the power to exclude others from, among other things, using the claimed invention, this patent covers *all* uses that might be made of the claimed genes. Consequently, this patent implicates a number of concerns regarding the patentability of human genes.

For example, the patent states that one of the uses for the gene is for comparison when attempting to identify cancerous tissue.¹⁷⁷ At first, this appears reasonable. It is worthwhile to consider the potential research implications. A drug company seeking to compare expression patterns or a university research lab studying the gene would likely infringe this patent by using the gene sequence. The potential infringer may need to expend resources searching out the patent holder and working out a license agreement.

It would be disingenuous to state that this patent only covers the sequence of the oncogene. For example, one of the embodiments of the patent is antibodies which bind to the protein the oncogene encodes.¹⁷⁸ These antibodies, the patent notes, can be used to detect the presence of the cancerous oncogene.¹⁷⁹ Assuming that the medical community needs such a diagnostic tool, the antibodies themselves may well serve the interests of society, justifying the issuance of a patent. The question, however, is whether the sequence *itself* need be included in that patent.

A patent on these antibodies need not include a patent on the gene sequence itself. If the sequence were not part of the patent, the gene would still be available for future research and the patent holder would still benefit from being able to sell the diagnostic antibodies. This brief example introduces the idea—presented in greater detail later in this Article—that patents on genetic inventions should not extend protection to the natural DNA sequences that those inventions are based on. But before a new utility standard is proposed,

¹⁷⁴ *Id.* at col.4 1.1-4.

¹⁷⁵ *Id.* at col.18 1.27-28.

¹⁷⁶ *Id.* at col.4 1.20-29.

¹⁷⁷ *See id.* at col.2 1.44-51 (stating that one can compare the expression of the gene in sample tissue with the expression of the gene in normal tissue).

¹⁷⁸ *Id.* at col.2 1.15-17.

¹⁷⁹ *See id.* at col.6 1.41-45 (stating that the “antibodies can be . . . used to detect the presence of mutations in the . . . gene”).

we must take a closer look at what we really mean by “gene utility.”

B. “Gene Utility” Reexamined

It is important to recognize that genes, isolated and purified from the genome, do not do anything.¹⁸⁰ Purified genes are akin to other laboratory chemicals. Their utility derives from how researchers apply them to scientific and medical problems. As such, the utility of a gene invention is best understood, not in terms of what the gene itself does, but rather the actual uses to which human beings put those genes. Still, it has been argued that genes are fundamentally different from other bio-chemicals.¹⁸¹

The perceived distinction between genes and other bio-chemicals seems to be based more on moral or ethical value judgments than on sound patent policy. Perhaps, because genes are considered so basic to what we are as a species, genes are somehow “more important” than other chemical compositions. However, by stating that “[p]atent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter,” the Utility Guidelines reject any notion of a policy distinction between DNA and chemicals.¹⁸² Other proposed revisions to the Utility Guidelines are equally inadequate because they operate under the same assumption that there is some inherent quality separating genes from other chemicals.

The first comment that the Utility Guidelines address and reject is that genes should not be patentable because they are more like natural discoveries than inventions.¹⁸³ Other literature has suggested that genes should be patentable provided that the function of the gene—what the protein it encodes does—is disclosed as well.¹⁸⁴ One might also suggest the implementation of a “morality requirement” to heighten the utility standard.¹⁸⁵ However, these sorts of solutions, focused on the utility of the genes themselves rather than on what

¹⁸⁰ See Summers, *supra* note 9, at 503 (stating the basic point that “DNA sequences are things that, standing alone, provide no added value to society beyond their mere existence”).

¹⁸¹ See *id.* at 509.

¹⁸² Utility Guidelines, *supra* note 82, at 1095.

¹⁸³ *Id.* at 1092–93.

¹⁸⁴ Summers, *supra* note 9, at 506–7.

¹⁸⁵ See *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (D. Mass. 1817) (No. 8,568) (stating that an “invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society”). See also Nathan Machin, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CAL. L. REV. 421, 450–51 (1999) (noting that moral utility questions are best resolved by allowing the person of ordinary skill in the art to make such determinations). Cf. Wei, *supra* note 3, at 332 (concluding that there is a need for a morality requirement separate from a more stringent utility standard).

can be *done* with them, do not provide a concrete solution to the “gene utility” problem.

Putting aside morality, which would be a rather nebulous requirement, heightening the “gene utility” standard, with reference only to the genes themselves, implicates a debate over when a gene invention becomes a patentable product of human innovation rather than a non-patentable natural curiosity. This distinction, while perhaps intellectually obvious, is far more difficult when actually applied to gene inventions.¹⁸⁶ This is not to say that genes have no use, but rather to argue that a proper utility definition must constantly refer to the goals that the patenting of genes is supposed to achieve. Therefore, “gene utility” is best contextualized in the economic, social, and intellectual incentives that motivate genetic research.

Alexander Flemming discovered penicillin in 1928.¹⁸⁷ However, it was not until after a patent issued—to Andrew Moyer, not Alexander Flemming—that people began mass producing penicillin.¹⁸⁸ The discovery and dissemination of penicillin has been extremely beneficial to society; penicillin has become one of the most used and effective medicines.¹⁸⁹ However, referring to the penicillin revolution as support for gene patents is an oversimplification.

Allowing gene patents, so the argument goes, enables medical innovation by encouraging investment in medicines and tests that are useful in providing medical care.¹⁹⁰ The problem with this argument is that there is a wide research gap between the isolation of a gene and the discovery of a useful pharmaceutical product. A gene, unlike penicillin, is not medication in and of itself. Rather than the destination, a gene is the beginning. Comparing the economic incentives behind drug manufacture and gene discovery is of little value when attempting to craft appropriate “gene utility” legislation. A purified and isolated gene is not the same thing as a pharmaceutical. Since medicine may be based on gene sequence information, we need to create incentives for disclosure of genes and allow researchers access to those genes. In order to propose valuable changes to the current patent utility requirement, we must outline the various incentives at play within basic research and how they can drive disclosure of gene sequences in the absence of patent protection.

¹⁸⁶ See Resnik, *supra* note 105, at 148–151 (discussing the difficulties with the invention/discovery division and concluding that its resolution will come only when we “weigh and assess the values, norms, and purposes that have some bearing on the issue”).

¹⁸⁷ SOLOMON ET AL., *supra* note 32, at 544.

¹⁸⁸ Gitter, *supra* note 1455, at 1659–60.

¹⁸⁹ SOLOMON ET AL., *supra* note 32, at 544.

¹⁹⁰ See Gitter, *supra* note 1455, at 1659 (discussing the “utilitarian” justifications for gene patents).

C. *Real World Incentives*

Congress enacted the Bayh-Dole Act¹⁹¹ in order “to use the patent system to promote the utilization of inventions arising from federally supported research or development.”¹⁹² One aspect of this objective is the promotion of cooperation between private research firms and public non-profit firms, such as universities.¹⁹³ A nuanced analysis of the Bayh-Dole Act and its effects on research and development is beyond the scope of this Article. Nonetheless, it has been noted that, as a result of the Bayh-Dole Act, universities are now asserting patent rights for biomedical innovations at an ever-increasing rate.¹⁹⁴ Consequently, the distinction between public and private research has blurred.¹⁹⁵ This Section demonstrates that, despite the blurring of the division between public and private research, different incentives drive research in each sphere. Section 1 below briefly illustrates the current state of university research, Section 2 examines the incentives that can drive basic genetic research in the absence of patent protection for gene sequences, and Section 3 presents the issue of keeping genes secret in a world without patent protection.

1. The Current State of Basic Research

This Article considered the concerns that “upstream” patents have on research and development.¹⁹⁶ The problem has been exacerbated because the Bayh-Dole Act does not differentiate between basic discoveries and “downstream” commercial innovations.¹⁹⁷ As a result of this failure to differentiate, a new sort of competition has emerged, pitting the private sector against the public university.¹⁹⁸ Science has traditionally been based on openness and “relatively unfettered access to fundamental knowledge developed by prior researchers.”¹⁹⁹ Basic biological discoveries are crucial to “downstream” drug development. A patent regime that allows patents to issue for gene sequences can only be justified insofar as it is necessary to promote the discovery and disclosure of gene sequences. As the following Section

¹⁹¹ Act of Dec. 12, 1980, Pub. L. No. 96-517, § 6(a), 94 Stat. 3019 (1980) (codified as amended at 35 U.S.C. §§ 200–212 (2000)).

¹⁹² 35 U.S.C. § 200 (2000).

¹⁹³ *Id.*

¹⁹⁴ Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 291–92 (2003).

¹⁹⁵ *Id.* at 294.

¹⁹⁶ See discussion *supra* Part V.A–B (discussing the costs and benefits of a liberal patent regime).

¹⁹⁷ Rai & Eisenberg, *supra* note 185, at 290–91.

¹⁹⁸ *Id.* at 294.

¹⁹⁹ *Id.* at 289.

demonstrates, there are ample incentives outside the realm of patents that ensure that gene discovery shall continue even under a more stringent patent utility standard.

2. Incentives Reexamined

If we assume that a more stringent patent utility requirement results in a decrease in research motivated by the promise of economic reward, then the question becomes whether other existing incentives sufficiently motivate basic research. A good place to start looking for the answer is in the university. Professor Risa Lieberwitz notes that universities—both public and private—are founded on principles quite different from their private sector counterparts:

Universities have a public mission to engage in teaching and research for the social good, independent from any private interests To fulfill this public mission . . . the faculty[] have been provided unique rights of academic freedom to engage in an open exchange of ideas in their teaching, research, and public speech Faculty academic freedom includes significant autonomy and self-governance over academic matters of research The tenure system provides job security and due process rights to protect faculty from retaliation for exercising their academic freedom.²⁰⁰

Accepting this description as the model for the basic idea of the university, it is clear that there are many non-monetary benefits to joining the faculty of a university that are generally not available in the private sector. The university, at least in theory, provides a prestigious forum for research to take place for reasons beyond mere economics.²⁰¹

The university is not only a forum for research, it also allows dissemination of information by promoting publication.²⁰² Recall that in exchange for a patent, the inventor is required to disclose the invention to the public.²⁰³ The university may enable society to benefit from the fruits of disclosure without the cost of tying up basic research in a tangle of patents. However, just because the university pushes researchers to publish their findings, it does not necessarily follow that there is any overriding incentive to publish. For publication to meet the public disclosure motives behind the patent regime, there must be sufficient incentives for researchers to publish their results.

²⁰⁰ Risa L. Lieberwitz, *The Corporatization of the University: Distance Learning at the Cost of Academic Freedom?*, 12 B.U. PUB. INT. L.J. 73, 75 (2002).

²⁰¹ See generally *id.* at 77–85 (discussing the history and principles of academic freedom).

²⁰² Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 181 (1987).

²⁰³ See discussion *supra* Part II.B (discussing disclosure in exchange for innovation).

In the world of the biosciences a lack of publication is not a concern. Rather, publication is the currency researchers use to gain prestige and notoriety in the field. Similar to the quid pro quo duality of the patent system, publication is exchanged for professional advancement. Although the discoverer loses her exclusive rights to innovation, she is rewarded with “recognition and esteem” for her contribution.²⁰⁴ This system not only enables researchers and society to gain from disclosure through publication, but also furthers the general pursuit of science.

Publication benefits the development of scientific theory and innovation in two main ways. First, when a scientist’s work is published, the dissemination of the work enables the results to be verified by other researchers.²⁰⁵ Not only does this enable the field to confirm scientific data, but it also allows subsequent scientists to use the disclosed information as a foundation for further useful research. Second, in a world where prestige is a function of who manages to publish first (colloquially known as “publish or perish”), researchers are unlikely to resort to secrecy. The prospect that another researcher will publish the discovery first will generally override any inclinations to withhold a discovery for fear that it will be competitively used by others.²⁰⁶ Therefore, at least for certain forms of discovery, the patent system may not be needed.

It would be irresponsible to suggest that patents play no role in driving biological innovation. It would also be a stretch to rely on the perks of university life and the incentives to publish to stimulate the development of medications. However, in a system where notoriety is based on publication, it is safe to assume that not all publications are created equal. Some publications are better than others, some more revolutionary than others. There is a mechanism driving researchers to focus on making important discoveries. When it comes to genes, there is likely more prestige to be gained from being the one who discovers *the* gene of importance in a certain form of cancer or AIDS than from discovering the gene that encodes cheek dimples. In this sense, the publication system further aligns the interests of scientists with the greater public welfare.²⁰⁷

3. Secrecy and Little Genes

What are scientists—more likely, profit driven private firms—to do in the

²⁰⁴ Eisenberg, *supra* note 2022, at 183–84.

²⁰⁵ *Id.* at 184, 197.

²⁰⁶ *Id.* at 197–98.

²⁰⁷ *See id.* at 183–84 (noting that in “offering recognition and esteem to those who contribute to its shared body of knowledge, the scientific community insures that scientists’ self-interest will coincide with the public good”).

absence of patent protection for gene sequences? If patents are unavailable, scientists seeking to retain control over the genes they discover and “downstream” developments are likely to rely on secrecy measures.²⁰⁸ The problem is, of course, that genes are very small and if successfully isolated and purified, would likely be very easy to steal.

Genetically engineered bacteria, for example, are very easy to preserve in small quantities. Similarly, purified DNA samples need only be kept in minute amounts to be useful in a lab.²⁰⁹ Therefore, at least hypothetically, it would be very easy for someone who knew what to look for to steal a sample of a purified gene for use by a competitor. There is really no question that this is the case. While secrecy measures are always available, there will always be someone who will know where to look and who could thus misappropriate purified DNA samples. However, it is important to understand exactly what would be gained from stealing a newly discovered gene sequence.

For comparison, consider again the facts of *Diamond v. Chakrabarty*.²¹⁰ Mr. Chakrabarty developed genetically modified bacteria which had the ability to break down oil.²¹¹ These bacteria had potential to be used as a tool to clean up oil spills.²¹² Now, assume that the bacteria actually worked as hypothesized. It is safe to conclude that there may well have been significant market potential for the bacteria. In a sense, Mr. Chakrabarty created a viable commercial product that, if stolen by a competitor, could very easily have been put to use immediately. Noting that the bacteria were “the result of human ingenuity and research,”²¹³ the Court held that the bacteria could be protected with a patent.²¹⁴ The situation is quite different with natural gene sequences.

As discussed above, a naturally occurring gene does not do anything on its own.²¹⁵ While it is true that stealing a purified gene that is implicated in cancer may save a competitor time and money, it is not the same thing as stealing a polished product, such as genetically engineered bacteria. Certainly, theft of a gene sequence—especially one in which a researcher invested time and money developing into a useful product—is a serious problem. The question is how much should patent policy be driven by the possibility of the theft of

²⁰⁸ *Id.* at 206.

²⁰⁹ This is based on the author’s experience with DNA purification and cloning at the Memorial Sloan-Kettering Cancer Center in New York City.

²¹⁰ 447 U.S. 303 (1980).

²¹¹ *Id.* at 305.

²¹² *Id.*

²¹³ *Id.* at 313.

²¹⁴ *Id.* at 318.

²¹⁵ See discussion *supra* Part VI.B (discussing the fact that genes alone do not do anything).

unchanged, naturally occurring genes. The next section presents a solution to this problem and proposes a new definition of utility as it applies to gene patents by distinguishing between uses based exclusively on the naturally occurring sequence and “gene utility” based in human ingenuity.

D. A Call for Legislative Action

We live in a world where research institutions, such as universities, and the private sector are pursuing patents. Since both private firms that fund research and development and the universities are entrenched in the current system, a solution to the proper utility standard will have to come from legislative action.²¹⁶ Section 1 provides a useful framework by presenting a simple spectrum of gene sequences, Section 2 proposes a new definition of “gene utility,” Section 3 discusses the implications this definition will have on disclosure of gene sequences, and Section 4 considers the economic fallout of this proposed definition. This analysis shows that the proposed change in the definition of “gene utility,” to the “substantial similarity” utility test, yields beneficial results.

1. A Basic Analytical Framework

Before proposing a new definition of “gene utility,” we must first consider, once again, a spectrum of gene sequences. Green fluorescent protein (“GFP”), from a species of jellyfish (*Aequorea victoria*), illustrates this spectrum perfectly.²¹⁷ At the most basic level is the naturally occurring, isolated, and purified GFP gene sequences, which are unpatentable under the definition of utility proposed below. Moving along the spectrum towards patentability are gene sequences that are mutated to have specific uses, divorced from the normal function of the naturally occurring sequence.

For example, GFP mutants have been developed that are useful in monitoring intracellular pH levels.²¹⁸ At the far end of the spectrum are GFP mutants where the GFP gene, or some variation of it, is fused to another gene. Used in this manner, “the GFP gene is placed under control of the gene expressing the particular protein . . . [and] the protein’s expressional activity can be readily determined.”²¹⁹ This is just one example of the possible utility of fusion proteins. In any event, the utility of these mutants is not based solely on the function of the natural GFP gene.

GFP provides a useful model because it demonstrates the importance of

²¹⁶ See Rai & Eisenberg, *supra* note 1944, at 304–5 (noting that both public and private firms are taking full advantage of the patent system).

²¹⁷ See VOET & VOET, *supra* note 51, at 119 (discussing GFP).

²¹⁸ *Id.*

²¹⁹ *Id.*

keeping the basic sequence freely available. Once the naturally occurring gene was discovered, subsequent researchers were able to modify it into useful research tools.²²⁰ The tools that were developed created non-naturally occurring variations of the gene sequence.²²¹ Moreover, their utility had nothing to do with the natural sequence: GFP did not exist in nature as a pH sensor or as a reporter gene for a certain unrelated protein.²²² Such tools have utilities that do not rely on the naturally occurring sequences or functions. With this in mind, we can now turn to a possible legislative redefinition of “gene utility.”²²³

2. Redefining “Gene Utility”: The “Substantial Similarity” Utility Test

The USPTO requires that, in order to obtain a patent for a gene, the gene must have specific, substantial, and credible utility.²²⁴ This guideline need not be altered. Rather, this Article proposes that the “gene utility” requirement be defined in such a way that excludes the patentability of any naturally occurring gene, even if purified and isolated, when its utility is based on the natural genetic sequence. The following analytical framework should prove useful in redefining “gene utility.”

Determinations of whether the DNA sequence itself is essential to the claim of “gene utility” can be determined by the “substantial similarity” utility test. When determining utility, the following question should be asked: Is the utility of the gene in question “substantially similar” to the function of the naturally occurring DNA sequence? If the answer to this question is “yes,” then the sequence does not have the requisite utility to qualify for patent protection. If the answer to this questions is “no,” then the sequence itself would be eligible for patent protection. At this stage, it might prove useful to evaluate this test by reconsidering the Oncogene Patent²²⁵ and GFP.²²⁶

²²⁰ See Gilbert Chin, ed., *Editors’ Choice: Highlights of the Recent Literature*, 306 SCI., Nov. 26, 2004, at 1439 (noting that synthetic GFP constructs have now become a “workhorse of the cell biologist.”).

²²¹ See, e.g., *id.* (pointing out that researchers “have spliced GFP into well-characterized protein constructs.”)

²²² See Martin Chalfie et al., *Green Fluorescent Protein as A Marker for Gene Expression*, 263 SCI., Feb. 11, 1994, at 802 (discussing that, because its stability when expressed in cells, natural GFP can be modified to monitor gene activity and other cellular behavior).

²²³ Legislative action directed at the patentability requirements for a specific type of invention has occurred before. See, e.g., 35 U.S.C. § 103(b) (2000) (setting forth non-obviousness criteria for “a biotechnological process using or resulting in a composition of matter”).

²²⁴ Utility Guidelines, *supra* note 82, at 1098.

²²⁵ Oncogene Patent, *supra* note 170.

a) *The “Substantial Similarity” Utility Test Applied*

The “substantial similarity” utility test seems initially to be a rather trivial or obvious inquiry. However, the purpose of this test is to make a threshold distinction between isolated, natural genes and those genes that have been developed and refined by the human hand. A purified oncogene, such as the gene at issue in the Oncogene Patent, has not been altered.²²⁷ Any utility derived from the DNA sequence is integrally linked to the function of that gene in nature, not to human ingenuity. Stated differently, the sequence itself has not been “substantially altered” and thus, the utility derived from the sequence is “substantially similar” to the natural function of the gene. As noted earlier, because of the possibility that a gene may have multiple functions—and thus, many potential uses—keeping the naked sequence free for research and development is crucial to the advancement of the biosciences.

On the other hand, a gene encoding GFP, modified by substantial human-induced mutations to such a degree that the utility of the gene is no longer based in the natural GFP sequence, would be a patentable sequence.²²⁸ In this instance, a researcher has taken a protein with a natural function—emitting green fluorescent light—and modified it into a tool useful to measure pH or some other cellular process. In terms of our new test, the natural sequence has been “substantially altered” such that its function is “substantially different” from the natural, unchanged, GFP gene. These genes created in a laboratory do not trigger the concern over locking up natural genes for further research.

b) *Implementing the “Substantial Similarity” Utility Test*

This proposed “substantial similarity” utility test does not eliminate any of the existing inquiries into the utility of a particular gene. It simply adds a preliminary layer to the utility analysis. For example, a gene that passes the “substantial similarity” utility test would still need to satisfy the USPTO’s requirement that the claimed utility be “specific, substantial, and credible.”²²⁹ This framework preserves the current utility requirements while taking naturally occurring genes out of the body of patentable subject matter. It forces researchers to create something different than what the machinery of evolution has already provided.

²²⁶ See discussion *supra* Part VI.D.1 (examining GFP in detail).

²²⁷ See Oncogene Patent, *supra* note 17070 (stating in the Abstract that the gene in the patent is merely a “human oncogene”).

²²⁸ See VOET & VOET, *supra* note 51, at 119 (discussing, for example, GFP molecules that sense pH changes).

²²⁹ Utility Guidelines, *supra* note 82, at 1098.

3. Disclosure Costs of the “Substantial Similarity” Utility Test

It has been noted that weakening patent protection might result in researchers resorting to secrecy.²³⁰ While it would be naïve to suggest that firms would not rely on secrecy, there is reason to believe that this would not pose a substantial problem. First, fear of disclosure to competitors, at least in the university setting, will be minimal because the academic research achieves recognition through publication. The academic system pushes discoveries into the open rather than keeping them secret.²³¹ It is thus reasonable to expect a steady flow of important gene sequences from the university laboratory.²³²

It may also be argued that society could be harmed if private industry, knowing that it has no patent rights in naturally occurring gene sequences, withheld sequences. Even assuming that this is true, this is only a concern insofar as it harms society. As we saw with the gold rush example, quick exploitation of the resource does not necessarily provide a net gain to society.²³³ Disclosure of genes that are tied up with patent rights may provide intellectual stimulation but because it is a long process from gene to medication, it is unlikely that less disclosure will lead to less medicine.

4. Economic Costs of the “Substantial Similarity” Test

Above, we examined the costs and the benefits of a tightened patent utility standard.²³⁴ By implementing the “substantial similarity” utility test, and thus excluding from patent protection naturally occurring gene sequences, we can expect research costs to decrease because parties will not have to enter into negotiations and expensive licensing agreements. Freeing up these costs spent on getting around “upstream” patents on natural genes will, in turn, help stimulate basic research for the benefit of society as a whole.²³⁵

Secrecy costs will be felt most prominently in the private sector because

²³⁰ See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1032 (1989) (citing research suggesting “that weakening patent protection by providing compulsory licensing . . . would lead to greater reliance by firms on secrecy instead of patent protection”).

²³¹ See Eisenberg, *supra* note 2022, at 206.

²³² See *id.* at 207 (noting that disclosure through the patent process generally takes longer than disclosure through other means).

²³³ See Grady & Alexander, *supra* note 1411, at 314–15.

²³⁴ See discussion *supra* Part V.A–D (discussing the costs of high and low utility thresholds).

²³⁵ See Rai & Eisenberg, *supra* note 1944, at 302 (stating that “upstream patents issued to academic institutions serve as a tax on innovation, diluting rather than fortifying incentives for product development”).

firms will need to invest funds to keep their discovered genes secret.²³⁶ This concern, however, is mitigated by two considerations. First, as noted above, disclosure of a gene to a competitor is not the same as disclosure of a finished product. Simply gaining access to a gene—through surreptitious or other means—does not mean that a competing firm will be able to develop the gene. It is reasonable to conclude that gene theft will not be a substantial concern.

Second, perhaps the biggest concern posed by the “substantial similarity” utility test—a heightened utility standard—is a potential decrease in the amount of money spent on research and development.²³⁷ For this argument to be convincing, we must assume that “upstream” patents on natural genes have particular value. However, there is reason to doubt this conclusion. Rather than basing investment decisions on “upstream” patents, “downstream patents are generally far more important in motivating private firms to develop end products than upstream patents on prior discoveries owned by a university.”²³⁸ Concerns over a mass economic exodus from basic research and development, triggered by a tightened “substantial similarity” utility requirement for gene sequences alone, are unfounded.

VII. CONCLUSION

The patentability of naturally occurring gene sequences has provoked much discourse and controversy. Instead of attempting to define utility based on morality, this Article addressed the issue in economic and practical terms.²³⁹ After outlining the basics of patent law and some of the pressing concerns in the realm of biotechnology, this Article discussed the economic and practical fallout of tightening or loosening the utility requirement. The potential ramifications of legislative action provided a backdrop for the conclusion that stiffening the “gene utility” requirement—excluding the patentability of naturally occurring gene sequences through the “substantial similarity” utility test—enables further research without imposing adverse consequences on research and development. Not only will industry survive the transition to the “substantial similarity” utility test, but ultimately science and medicine will also better serve humanity.

²³⁶ See Eisenberg, *supra* note 2307, at 1028–30 (discussing the pros and cons of secrecy).

²³⁷ See Rai & Eisenberg, *supra* note 1944, at 295.

²³⁸ *Id.* at 296.

²³⁹ See Resnik, *supra* note 105, at 151 (suggesting a “goal oriented and pragmatic” examination of gene patents).