

Washington University Global Studies Law Review

Volume 3 | Issue 3

January 2004

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World Intellectual Property Organization (WIPO)

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Recommended Citation

Nuno Pires de Carvalho, *The Problem of Gene Patents*, 3 WASH. U. GLOBAL STUD. L. REV. 701 (2004), https://openscholarship.wustl.edu/law_globalstudies/vol3/iss3/2

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VOLUME 3

NUMBER 3

2004

THE PROBLEM OF GENE PATENTS

NUNO PIRES DE CARVALHO*

ABSTRACT

Genes are scientific discoveries and therefore they fail to meet the condition of alternativeness, which is the fourth substantive condition for patentability.¹ Hence, genes are not patentable subject matter even when they meet the three other conditions. The condition of alternativeness is an essential tool for the patent system to perform its metering function for, in its absence, the patentee's competitors cannot use existing technology or develop alternatives.² Competition with patented technology allows society to accurately meter inventions, and thus efficiently reduce transaction costs. Countries that grant gene patents undermine the patent system in the area of biotechnology; this will lead to serious problems of inefficiency and high transaction costs. This concern is eloquently illustrated by agrarian discontent in the United States in the late nineteenth century, which arose under the pressure of a malfunctioning patent system.

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1. The other substantive conditions of patentability that the Supreme Court has identified are novelty, non-obviousness, and utility. *LeRoy v. Tatham*, 55 U.S. 156 (1852). See discussion *infra* Part II.

2. See discussion *infra* Part III.

INTRODUCTION

This Article submits that the main problem with gene patents³ is the failure to meet the condition of alternativeness of inventions—a condition that embodies a core function of the patent system. As a result, gene patents conflict with the very rationale of the patent system. On the one hand, gene patents generate exclusive rights in discoveries, which does not necessarily pose a legal barrier to patentability, depending on the meaning of the word “discoveries.”⁴ However, when “discoveries” refers to products of nature or scientific truths, the patent system can, from a legal point of view, encompass discoveries as patentable subject matter only if the three substantive conditions of patentability are met: novelty, non-obviousness, and utility. The problem of gene patents, therefore, cannot be assessed from that perspective. At the same time, availability of patent protection for genes elicits criticism because of the restrictions that property rights place on downstream research and development of commercial products.⁵ One solution for this problem is to exclude gene-related technology from patentability without any scrutiny as to whether or not it has an inventive nature. Another proposal would establish certain exceptions to rights conferred by gene patents or would submit gene patent

3. For the purposes of this Article, the term “gene patents” means patent claims covering human genes or portions of human genes; the proteins for which they code in the human body (their natural environment); human genes as isolated, purified or synthetic molecules; and any combination thereof. For the purposes of this Article, “genes” includes the DNA fragment encoding the particular gene, expressed sequence tags (“ESTs”), and the messenger RNA (mRNA). “A gene is an ordered sequence of nucleotides [within a fragment of DNA] located in a particular position on a particular chromosome that encodes a specific functional product (i.e. a protein or RNA molecule).” National Plant Genome Initiative, *Glossary*, at http://www.ostp.gov/html/genome/genome_6.html (last visited Mar. 17, 2004). DNA is a double-stranded molecule held together by weak hydrogen bonds between nucleotide base pairs. These nucleotide bases, namely Adenine (A), Thymine (T), Guanine (G), and Cytosine (C), are the building blocks of DNA. Because of their particular chemical composition, A’s base pair only with T’s and G’s base pair only with C’s.

The mRNA is a single-stranded copy of a gene that carries the genetic information to the ribosomes. The ribosomes are the sites of protein synthesis in the cell. Proteins are made up of a chain of amino acids by deciphering the genetic code. Each set of three consecutive nucleotide bases in the mRNA codes for a single amino acid. Proteins are the building blocks and enzymes required for cell survival. A molecule of DNA or RNA is described by the specific order of nucleotide bases which is determined by “sequencing.” The number of base pairs or bases is used to describe the size of a DNA or RNA molecule. *See id.* Although this Article discusses the patentability, or lack thereof, of human genes, the analysis can be extended *mutatis mutandis* to plant and animal genes. Even though the ethical and economic pressure is not as high in these two fields, the condition of alternativeness is likewise applicable to non-human genomic inventions.

4. *See infra* note 84 and accompanying text.

5. *See infra* Part I.C.

applications to a heightened scrutiny regarding conditions of patentability, in particular, utility.⁶

Part I looks briefly at the aforementioned criticisms and explains why they fail to address the real problem of gene patents. The laws of several countries exclude genes from patentability in very broad terms by identifying them as scientific discoveries.⁷ Such a legalistic approach does not provide an answer regarding the *appropriateness*, or lack thereof, of the policy of excluding genes from patentability. This solution thus does not help those countries to assess whether they should change or continue their legal policy.

Applying the criteria of patentability to the field of DNA recombinant technology, which differs from those used in other areas of technology, is not only inconvenient, it also infringes the non-discrimination rule of article 27.1 of the TRIPs Agreement.⁸ Under this provision, once national law establishes that gene-related technology is patentable subject matter, no exceptions to the confirmed rights or the conditions of patentability can be imposed on that technology that are not also imposed in other fields of technology.

This Article does not intend to scrutinize the products of nature doctrine from a legal or a technical standpoint. Instead, this Article discusses the rationale of the products of nature doctrine and does not include within its scope the relevance of the products of nature doctrine to individual patent applications.

6. See generally Ng-Loy Wee Loon, *Patenting of Genes—A Closer Look at the Concepts of Utility and Industrial Applicability*, 33 IIC-INT'L REV. OF IND. PROP. & COPYRIGHT L. 393 (2002); John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101 (2001). Utility, for patent purposes, means the invention is susceptible to use in producing services and goods. It does not mean that the invention is particularly appreciated by society, but simply that it works.

Utility does not mean a useful technical advance in respect of the prior art. Patents are not certificates of merit. It is for the market to decide whether the patented invention is useful or not. The utility requirement emphasizes the technical aspect of inventions. It means that inventions, in order to be patentable, must be capable of being used in the production of goods and services.

NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF PATENT RIGHTS* 146 (2002).

7. See *infra* notes 16–17 and accompanying text.

8. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994 Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO], Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND Vol. 31, 33 I.L.M. 81 (1994) [hereinafter “the TRIPs Agreement” or “TRIPs”]. See *infra* note 18 for the text of article 27.1. Despite this article, it is possible to apply the same criteria of patentability with a certain level of adaptation to the specific nature of the technology, according to the practices of each country. See *infra* note 110 and accompanying text.

Part II analyzes the patentability of genes from a more conceptual and fundamental perspective. This part, based on a consistent line of United States Supreme Court opinions, explains that the core rationale of the product of nature doctrine lies in the condition of alternativeness of inventions. This condition requires that patents can only be granted for inventions that are susceptible to being alternated by competing technology (i.e., technology that exists in the public domain, proprietary technology that lies within the exclusive control of certain individuals, or technology yet to be developed).

Part III revisits the primary rationale of the patent system: the metering function of inventions. Part III explains that the condition of alternativeness is an essential tool for the patent system because it permits patentees' competitors to develop and use alternative technology (both technology that is in the public domain and propriety technology). In this vein, the condition of alternativeness has already been invoked to refuse the application of the essential facility doctrine in the field of patents.⁹ Due to the susceptibility of inventions to being alter-invented (referring to the creation of alternative technical solutions for the same problem using the same natural principles), they do not constitute essential facilities. Furthermore, Part III emphasizes the economic risks arising from an incorrect use of the patent system, which distorts its function and makes it work less efficiently. The agrarian discontent that arose in the last decades of the nineteenth century in the United States illustrates this assertion.

This Article argues that the solution to problems posed by gene patents does not lie in diminishing patent rights, but rather in accepting that genes are non-statutory patentable subject matter. Genes, as products of nature, are not susceptible to "alter-invention." Because genes are not prone to alter-invention, the patents granted on DNA sequences, their fragments, or the proteins that these sequences are coded for, do not permit market forces to compete interactively, which otherwise would allow society to evaluate or meter inventions in a relatively accurate fashion. Because this metering is the primary function of patents, gene patents, as well as all patents for natural products, run counter to the very rationale of the patent system.

Part III carefully avoids discussion of the ethical and environmental issues that frequently arise in the context of gene patents. Similar to the scope of patentable subject matter, ethical and environmental concerns also depend on national perceptions, thus making it very difficult to take a

9. See discussion *infra* Part III.C.

position that encompasses the wide variety of views and, thus, issues of ethics and environmental safety are beyond the scope of this Article. The rationale of the patent system itself is at issue here, not the limits of patent protection.

This Article concludes that gene patents are contrary to the economic rationale of the patent system and therefore should not be patentable subject matter as a matter of law.

I. TAMPERING WITH THE PATENT SYSTEM TO ADDRESS PARTICULAR CONCERNS STEMMING FROM GENE PATENTS

The idea persists that gene patents harm scientific and commercial research. As the building blocks of life, genes form the raw material for all processes and products that originate, or are originated from, genetic engineering. Genetic engineering is the technology that consists of transferring genes between organisms, including diagnostic tests for detecting diseases, therapeutic methods, and biological products. Thus, once a patent is issued on a certain gene, all commercial applications of that gene require an authorization from the patent holder. Furthermore, gene patents are particularly controversial because they are upstream of a largely unexplored field, both scientifically and commercially. A patent owner may block any future use of a certain gene, regardless of whether the proposed use seeks to clarify the gene's particular role in the human cell or to develop the gene for commercial applications. The cases demonstrating this problem have been widely publicized.

For example, the Miami Children's Hospital, which owns a patent for a gene responsible for Canavan Disease (a neurological disorder), prevents doctors from testing or examining patients for the gene without paying a fixed royalty fee.¹⁰ In another example, several European laboratories have refused to recognize, and are actually challenging the validity of, a patent held by Myriad Genetics, a U.S. company, on a gene "that is strongly linked to breast and ovarian cancer."¹¹ These breast cancer genes, BRCA1 and BRCA2, have become the subject of a resolution by the European Parliament, which recalled that the patent owner licensed U.S. genetic

10. 148 CONG. REC. E 355 (daily ed. Mar. 14, 2002) (statement of Hon. Lynn N. Rivers, Member, House) (introducing the "Genomic Research and Diagnostic Accessibility Act of 2002," H.R. 3967, 107th Cong. (2002), and the "Genomic Science and Technology Innovation Act of 2002" H.R. 3966, 107th Cong. (2002)), available at http://www.house.gov/science_democrats/member/lr031402.htm (last visited Apr. 18, 2004).

11. *Id.* See Matthew Rimmer, *Myriad Genetics: Patent Law and Genetic Testing*, 25 EUR. INTEL. PROP. REV. 20 (2003).

laboratories to test for a very limited number of mutations of BRCA1 and BRCA2, and that corresponding patent applications had been filed with the European Patent Office (EPO).¹² The European Parliament expressed “its dismay at the possible consequences of the granting by the European Patent Office of a patent on a human gene” and, among other recommendations, stated that the European Council, the European Commission and the Member States should “adopt the measures required to ensure that the human genetic code is freely available for research throughout the world and that medical applications of certain human genes are not impeded by means of monopolies based on patents.”¹³ Similarly, the American College of Medical Genetics stated its concern over current patterns of gene patent enforcement.¹⁴

In order to avoid, or at least reduce, the negative impact on downstream research and product development, some have sought either to change the law or the process of granting patents in the field of gene technology. These proposals may be classified in three categories: (a) those that would exclude genes from patentability regardless of their potentially inventive nature; (b) those that accept their patentability but impose limitations or exceptions to rights conferred; and (c) those that accept patentability of genes without modifying the standards of protection, but adopt a different approach to the conditions of patentability, in particular, with regard to utility.

A. *Excluding Genes From Patentability*

The European Parliament, among others, purports to exclude human genes from patentability in order to facilitate genetic research.¹⁵ The new

12. Text of the European Parliament Resolution on the patenting of BRCA1 and BRCA2 (“breast cancer”) genes, *available at* <http://www.cptech.org/ip/health/biotech/eu-brca.html> (last visited Aug. 12, 2003) [hereinafter European Parliament Resolution]. *See also* Steve Bunk, *Researchers Feel Threatened by Disease Gene Patents*, 13[20] THE SCIENTIST 7 (1999), *available at* http://www.the-scientist.com/yr1999/oct/bunk_p7_991011.html (by free registration only) (last visited Aug. 4, 2003).

13. *Id.*

14. American College of Medical Genetics, *Position Statement on Gene Patents and Accessibility of Gene Testing*, (Aug. 2, 1999), <http://genetics.faseb.org/genetics/acmg/pol-34.htm> (last visited Aug. 13, 2003). Their concern is

monopolistic licensing that limits a given genetic test to a single laboratory, royalty-based licensing agreements with exorbitant up-front fees and per-test fees, and licensing agreements that seek proportions of reimbursements from testing services. These limit the accessibility of competitively priced genetic testing services and hinder test-specific development of national programs for quality assurance. They also limit the number of knowledgeable individuals who can assist physicians, laboratory geneticists and counselors in the diagnosis, management and care of at-risk patients.

15. European Parliament Resolution, *supra* note 12. It is worth noting that four years earlier, the

position of the European Parliament conforms to the standards of patentability as adopted by a large number of countries, where genes are explicitly or implicitly identified as non-patentable subject matter. For example, article 2(5) of Egypt's recently-enacted Law No. 82/02 states that "organs, tissues, live cells, natural biological substances, nuclear acid and genome" shall be barred from patentability.¹⁶ The Patents Amendment Act of India likewise excludes "plants and animals in whole or any part thereof other than microorganisms, but including seeds, varieties and species" from patentability.¹⁷

The language of these two provisions seems to indicate that their particular exclusions are based on the language of article 27.3(b) of the TRIPs Agreement,¹⁸ which permits the exclusion of some inventions in the

same European Parliament reluctantly approved the European Directive on the legal protection of biotechnological inventions. Article 5.2 of the Directive states that, "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element." Council Directive 98/44, art. 5.2, On the Legal Protection of Biotechnological Inventions, 1998 O.J. (L213) 39.45, available at http://www.europa.eu.int/eur-lex/pri/en/oj/dat/1998/1_213/1_21319980730eu00130021.pdf (last visited Apr. 18, 2004). An intermediate solution was proposed by Philippe Jacobs and Geertrui Van Overwalle, *Gene Patents: A Different Approach*, 23 EUR. INTELL. PROP. REV. 505 (2001). These commentators suggested

Perhaps patents should no longer be granted for DNA, but only for new medicinal products, new vaccines and genetic tests that are developed on the basis of DNA. . . . In other words, only patents on the end products would be granted, while patents on the base product used to make these products would be refused. Expressed in technical terms, this means that there would be no more patents on DNA as a research tool (product claims), but there would be patents on the use of DNA to diagnose, prevent, or treat a specific disease (use claims) and on the resulting end product.

Id. This suggestion is plainly wrong because it is based on the misleading and erroneous idea that one can distinguish between inventions that are research tools and inventions that are end products. Actually, a stretch of DNA can be simultaneously a tool for research and a component of a commercial product. A microscope is undoubtedly a research tool, but it is also a commercial article. The legal regime governing the microscope does not vary according to its specific utility: if a scientist performs some acts covered by the patent in order to understand the microscope's architecture, the scientist will probably be covered by a research exemption (but in that event the microscope has no commercial utility). But if the scientist manufactures a microscope and uses it to investigate scientific activities that do not relate to the academic unveiling of any of microscopes' features and mode of operation, such activity would constitute an infringement. In this event, the scientist would be using the microscope as a research tool of a commercial nature. The commercial nature (and the end-product nature) of research tools is taken for granted by manufacturers and commercial distributors.

16. Law No. 82/02, art. 2(5), O.J. NO. 2 bis (June 2, 2002) (Egypt), available at <http://www.egypt.gov.eg/inner/english/PDFs/law2002e.pdf> (last visited Apr. 18, 2004).

17. The Patents (Amendment) Act, No. 38 § 4 (2002), (India), available at <http://www.patentoffice.nic.in/ipr/patent/patentg.pdf> (last visited Apr. 18, 2004).

18. Article 27 of the TRIPs agreement provides:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application [footnote omitted]. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this

field of biotechnology from patentability. They do not appear to be based on the language of article 27.1, which does not require WTO members to make patents available for discoveries or products of nature.

The Egyptian and Indian statutory provisions contrast to some extent with the language adopted by the patent statutes of Brazil and the Andean Community. Brazil's patent law establishes that "all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes" are "not considered to be inventions or utility models."¹⁹ Similarly, the decision of the Andean Community on the common regime of industrial property states that "any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing" shall not be considered inventions.²⁰ The contrast lies in the qualification of the excluded matter as not being inventions. Thus, in the cases of Brazil and the Andean Community, article 27.1 of the TRIPS Agreement controls.

There are two principal arguments for excluding genomic technology from patentability. The first is that patents should not cover genes because they offend morality. The second argument excludes patents for genes because the patents on genes are inconvenient.

Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *order public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

TRIPs, *supra* note 8, art. 27.

19. Brazilian Industrial Property Act, LAW NO. 9.279, art. 10 IX (1996).

20. Decision 486, art. 15(b) (Sept. 14, 2000) (Andean Community). The Andean Community of Nations is formed by Bolivia, Colombia, Ecuador, Peru and Venezuela. The decision has the force of national law in the community member states.

The European Parliament strongly advocated the former argument.²¹ In the same vein, the government of the Netherlands has requested the Court of Justice of the European Communities (ECJ) to annul the European Directive on several grounds, including offense to human dignity.²²

The argument raised by the Netherlands was defeated twice. First, the Advocate General Jacobs said that, under the Directive, only genes that are isolated from their natural state and purified can be patented and that because genes in their natural state (i.e., as found in the human body) are not patentable, the Directive does not infringe human dignity.²³ The ECJ adopted a similar view, finding that “the protection envisaged by the Directive covers only the result of inventive, scientific or technical work, and extends to biological data existing in their natural state in human beings only where necessary for the achievement and exploitation of a particular industrial application.”²⁴ The Court added that article 6 of the Directive offers additional security, because processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes “are contrary to *order public* and morality and thus are not patentable.”²⁵ Moreover, the 38th recital of the Directive’s preamble clarifies that “this list is not exhaustive and that all the processes the use of which offend against human dignity are also excluded from patentability.”²⁶

Another problem with the argument that gene patents are contrary to morality is that morality depends on cultural and religious beliefs, which are not the same in all countries and regions. Therefore, the notion of morality does not help explain whether gene patents should be patentable subject matter in those regions or countries where gene patents are seen

21. European Parliament Resolution, *supra* note 12.

22. The problem with that argument is that patents on genes relate directly to technical concepts, and only indirectly to the human body. Products and processes derived from those genes are used on the human body as a matter of course, but so are pharmaceutical products and medical devices. Patents on genes ultimately pose fewer moral concerns than property rights in human hair and blood, which are the subject of regular trade. Unlike the latter, patent rights on genes do not fall upon tangible materials but only on intangible, technical concepts.

23. Case C-377/98, Kingdom of the Netherlands v. European Parliament and Council of the European Union, 2001 E.C.R.I-07079, §§ 70–75, 77–79 (2001), available at <http://curia.eu.int/en/content/juris/index.htm> (last visited Feb. 3, 2004).

24. *Id.* § 75. The applicant was supported by the Italian Republic and by the Kingdom of Norway.

25. *Id.* § 76.

26. *Id.* The Netherlands raised a second argument concerning human dignity, which involved the risk of granting patents for material obtained or derived from material obtained without prior informed consent by the donors and recipients. The ECJ replied that the Directive concerns only the grant of patents and its scope “does not therefore extend to activities before and after that grant, whether they involve research or the use of patented products.” *Id.* § 7q.

more realistically (and, perhaps, more accurately) as mere rights in technical ideas.

International standards of patent protection pose a third problem, which is raised by article 27.2 of the TRIPs Agreement.²⁷ If a WTO Member excludes parts of the human body, even in circumstances where those parts are isolated from their natural environment, from patentability, under article 27.3(b) of the TRIPs Agreement, that member is not obliged to justify the exclusion or to observe certain conditions. Article 27.3(b) permits some inventions in the field of biotechnology to be excluded from patentability.²⁸ Article 27.3(b) is, indeed, an exception to the principle of non-discrimination as to the field of technology, which is set by article 27.1.²⁹

A WTO Member may also consider genes unpatentable subject matter because genes are not inventions. Under an *a contrario* reading of article 27.1, these members are then free to exclude them from patentability. As explained above, Brazil and the Andean Community have adopted this solution.³⁰

If a WTO Member considers genes, as a part of the human body, not patentable on *order public* or morality grounds, article 27.2 establishes that such inventions may be excluded from patentability only to the extent that such an exclusion is necessary to prevent their commercial exploitation within the member's state territory.³¹ Furthermore, "necessity" is not a subjective concept, but an objective one, the definition of which results from the operation of a two-step test.³² In other words, not all inventions protected from commercial exploitation may be excluded

27. See *supra* note 18.

28. TRIPs, *supra* note 8, art. 27.3(b).

29. *Id.*

30. See *supra* notes 19–20. Nothing prohibits WTO Members from granting patents for discoveries. They may not refuse patent protection for inventions (barring the exceptions explicitly mentioned in TRIPs arts. 27 & 73). Nothing prevents WTO Members from extending patent protection to other technical ideas, such as discoveries, provided such extended protection is consistent with the provisions of the TRIPs Agreement. Article 1.1 of the agreement serves as the controlling provision in this particular context. The article provides:

Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

TRIPs, *supra* note 8, art. 1.1.

31. TRIPs, *supra* note 8, art. 27.3.

32. For an explanation of the two-step necessity test, see CARVALHO, *supra* note 6, at 171–73.

from patentability. Such an exclusion is necessary to prevent the prohibited exploitation.

While some opponents of gene patentability invoke reasons of human dignity, opponents are also concerned about limiting scientific research and development of new products and therapies that are distributed commercially. Such a position represents a clear contradiction in terms from a WTO viewpoint: if the problem is one of morality, then there may be no commercial exploitation at all. Blocking development of commercial products is, therefore, not a matter of concern.

B. Establishing Exceptions to Rights Conferred by Gene Patents

Other opponents of broad patenting of human genes have not suggested that genes should be excluded from patentability. In contrast, they have proposed mitigating the standards of legal protection for the corresponding patents.

The Genomic Research and Diagnostic Accessibility Act of 2002³³ contains three limitations to rights conferred by gene patents: (a) a research exemption, under which “individuals who use patented genetic sequence information for non-commercial purposes” would be exempted from patent infringement;³⁴ (b) a liability exemption, under which “medical practitioners utilizing genetic diagnostic tests” would be exempted from patent infringement liability;³⁵ and (c) the requirement of “public disclosure of genomic sequence information contained within a patent application when federal funds were used in the development of the invention. The data would be released within 30 days of patent filing.”³⁶

33. H.R. 3967, *supra* note 10.

34. Statement of Hon. Rivers, *supra* note 10. Hon. Rivers justified this exemption on the ground that

[c]ontrary to the understanding of many scientists, patent law does not protect from patent infringement scientists doing basic, fundamental, non-commercial research when they use patented tools, techniques and materials. Surveys performed by researchers at Stanford University have shown that many universities and hospitals are avoiding promising genetic research areas because of patent infringement concerns. Another study published earlier this year in the Journal of the American Medical Association found that a majority of geneticists are being denied access to colleagues' data.

Id.

35. *Id.* Hon. Rivers informs that this section builds on a provision in patent law “which exempts health care providers from patent infringement suits when they use a patented medical or surgical procedure.” *Id.* She referred to 35 U.S.C. § 287(c)(1) (1996), which exempts medical practitioners and health care entities from liability for patent infringement covering therapeutic methods for which applications were filed on or after September 30, 1996.

36. *Id.*

A report on the impact of biotechnology on healthcare for the Canadian Province of Ontario suggests a similar approach.³⁷ The Report suggests that Canada should review its Patent Act with respect to gene patents and that the role of patents in supporting industry should be recognized, but “appropriate safeguards and protections for healthcare, medical practitioners and researchers” should be established.³⁸ In particular, healthcare professionals and institutions, when using genetic materials for research purposes and in providing care, should be shielded from legal action (or even the threat thereof) pertaining to patented genes or DNA sequences. This “would not allow one gene patent to, in effect, control future subsequent medical use of that gene sequence or portion thereof.”³⁹

A different solution has been proposed by Deborah Leonard, the president-elect of the U.S. Association of Molecular Pathologists. In an interview with *The Scientist* she suggested that, in addition to exempting researchers from liability, it is possible to require physicians be licensed to use gene patents.⁴⁰

The American College of Medical Genetics (ACMG) favors limiting patent rights on gene-related inventions. ACMG’s position on gene patents is that: (a) “genes and their mutations are naturally occurring substances that should not be patented;” (b) “patents on genes with clinical implications must be very broadly licensed;” and (c) “licensing agreements should not limit access through excessive royalties and other unreasonable terms.”⁴¹

The view that patents for genes should continue to be issued subject to limitations conceals an underlying assumption that patents are a necessary evil. In other words, patents are necessary because they promote technical creativity, but they are socially inconvenient because they establish commercial monopolies. As the argument goes, patents represent an exclusive right to sell the subject of the invention or the products embodying, directly or indirectly, this subject. Monopolies entail high

37. *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*, January 2002, Ontario (Canada), available at http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e____ (last visited Apr. 18, 2004).

38. *Id.* at 23.

39. *Id.*

40. Bunk, *supra* note 12. The idea of using compulsory licenses to diminish gene patent rights has received support among commentators. See Loon, *supra* note 6, at 413; Rimmer, *supra* note 11, at 31–33 (suggesting that the Australian Patent Law should be revised to ensure the experimental use exemption be available to medical researchers, as well as immunizing physicians performing surgical procedures and medical diagnostics against liability). Rimmer also proposes that compulsory licenses should be made available in the field of genetic diagnostics and tests. *Id.*

41. See *supra* note 14.

prices, a reduced number of offers, and social deadweight. Where patents (read “monopolies”) are associated with technology essential to the well being of humans—as gene patents certainly are—the argument that patents promote the social exclusion of those in need becomes even stronger. Moreover, patents bar access to protected technology, during their respective terms, for the scientific community and commercial competitors.

As will be shown in Part III, nothing could be further from the truth. But that line of thought is not a recent one. Thomas Jefferson, as quoted by Justice Clark in *Graham v. Deere*,⁴² acknowledged the difficulty in “drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.”⁴³ In Justice Clark’s view, Jefferson’s statement provided “the underlying policy of the patent system.”⁴⁴

Recently, some commentators have adopted similar views. They believe that patents on genes are an embarrassment, so governments must impose some limit on rights they confer in order to reduce inconvenience without discouraging invention and innovation in the biotechnology industry. John M. Golden, for example, condemns patent law when it reaches “subject matter traditionally reserved for the public domain of natural science, [because] patent law risks creating obstacles to future research and invention without adding proportionately to the actual motivations of those who do the inventing.”⁴⁵ However, Golden accepts that “biotechnology patent optimists” may have a case: “[t]he conclusion that patent law may impede innovation must be balanced by an understanding of how it can and does facilitate it.”⁴⁶

Another application of Jefferson’s argument can be found in Michael Heller and Rebecca Eisenberg’s paper on the anticommons tragedy of the fragmentation of biotechnology inventions through patenting.⁴⁷ According to Heller and Eisenberg, “[b]y conferring monopolies in discoveries, patents necessarily increase prices and restrict use—a cost society pays to motivate invention and disclosure.”⁴⁸

42. *Graham v. Deere Co.*, 383 U.S. 1 (1966).

43. *Id.* at 9.

44. *Id.* at 10.

45. Golden, *supra* note 6, at 110.

46. *Id.*

47. See generally Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (1998).

48. *Id.* at 699.

Heller and Eisenberg seem to ignore the fact that thousands of patents are issued every year for processes that aim only to reduce costs of production and, consequently, to reduce the price of products. Thousands of patents are also issued for products that are not entirely new but that contain new features that make them more useful than existing products, with which they will compete on the market at the same price. In other words, patents for inventions that compete with already existing technology sometimes reduce, rather than increase, prices. If, however, Heller and Eisenberg were focused on breakthrough inventions, they overlooked the fact that patents on new technology do not raise prices. For something to be raised, the *sine qua non* condition requires that the thing already exists. A new price can be higher only in comparison with a previously established price. But a new invention has no pre-existing price that the invention could raise. The same logic applies to restricting the use of an invention that was not previously available—such a restriction is materially impossible. Of course, Heller and Eisenberg might wish to compare the effects of raising prices and restricting the use of patented inventions with the prices and the free use of the same inventions if not patented. This comparison fails because it ignores the reality that, in many cases, private companies would not invest their money in developing inventions if they did not envision the possibility of filing for and obtaining a patent.

The different solutions that have been proposed for overcoming the inconveniences of gene patents pose their own set of problems. The first problem lies in the incorrect assumption that patents are an economic evil. Part III illustrates the fallacy of this assumption. On the contrary, patents are useful and efficient metering devices. If gene patents cause troubles, then there may be a problem with the application of the patent system rather than with the patent system itself.

The second problem is a legal one. Patents generate property rights, and tampering with these property rights through exceptions or compulsory licenses diminishes their value as private assets. Accordingly, the TRIPs Agreement establishes a prohibition against discrimination in the acquisition and enjoyment of patent rights in the field of technology.⁴⁹

Therefore, H.R. 3967's proposed exceptions to rights conferred violates TRIPs obligations of the United States.⁵⁰ The research exemption might not conflict with the TRIPs Agreement *per se* because article 30 has

49. TRIPs, *supra* note 8, art. 27.1.

50. H.R. 3967, *supra* note 10.

language that seems to allow for it.⁵¹ Indeed, a vast number of WTO Members accept the research exemption and a WTO Panel Report, without judging the merit of such an exemption, has mentioned such a general practice as an example of an article 30-type exception.⁵² H.R. 3967 indicates that such an exemption is to be granted in the field of genomic research only, which clearly discriminates against that field.⁵³ On the other hand, it is true that the United States is free to exclude plants and animals (including the human body and parts thereof) from patentability.⁵⁴ However, the U.S. Patent Act⁵⁵ does not do so and, therefore, its protection of genomic inventions, which is more extensive than required by the TRIPS Agreement, must “not contravene the provisions of [the] Agreement,” as provided by article 1.1.⁵⁶ Therefore, protection that goes beyond the minimum standards of the TRIPs Agreement may not discriminate against the technology field.⁵⁷ Interestingly, Hon. Rivers, when justifying her submission of H.R. 3967, mentioned that doctors are exempt from liability for patent infringement for therapeutic and surgical methods.⁵⁸ The 1996 provision she referenced was introduced under protest from the General Counsel of the United States Trade Representative Office because it was discriminatory and possibly infringed TRIPs obligations.⁵⁹

The requirement of disclosure of government-funded genomic inventions might raise fewer problems of discrimination because of the narrower scope of the measure. Nonetheless, it clearly discriminates against government-funded genomic inventions, as compared with government-funded inventions in other fields of technology. Moreover, the period of secrecy of patent applications has a practical purpose: it permits inventors to prospect the market and select foreign countries where they will claim the same invention. Earlier disclosure of the

51. TRIPs, *supra* note 8, art. 30. “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interest of third parties.” *Id.*

52. See CARVALHO, *supra* note 6, at 220–29.

53. H.R. 3967, *supra* note 10.

54. TRIPs, *supra* note 8, art. 27.3(b).

55. 35 U.S.C. 101 (2002).

56. TRIPs, *supra* note 8, art. 1.1.

57. Regarding implementation of the TRIPs Agreement, the principle “*quid facit id quod plus est, facit id quod minus est*” does not apply. CARVALHO, *supra* note 6, at 57.

58. 35 U.S.C. § 287(c) (2002).

59. *Id.* at 176. See statement of Hon. Rivers, *supra* note 10.

invention, or of part of it, may reduce the “headstart” economic advantage of pioneer inventions.

The idea of blanket compulsory licenses of gene patents is at odds with articles 27.1 and 31 of the TRIPs Agreement. Under article 31(a), the grant of compulsory licenses “shall be considered on its individual merits.”⁶⁰ Similarly, under article 31(b), the prospective licensee must seek a voluntary license from the patent owner, on “reasonable commercial terms,” before any application for a compulsory license may be examined.⁶¹ The only exceptions are for cases of “national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” or if the license-seeker has not been successful “within a reasonable period of time.”⁶²

Likewise, ACMG’s suggestion that gene patent owners should be obliged to license their patents is in conflict with articles 27.1⁶³ and 28.2 of the TRIPs Agreement.⁶⁴ ACMG’s idea is parallel to the notion of the anticommons in genomic patenting because gene-related technology is prone to fragmenting. Fragmenting occurs either with regard to the nature of the claims (where the same gene may be fragmented into partial stretches of DNA—the ESTs) or with regard to the nature of the rights (several patents may cover different areas of technology necessary to produce a single product or process). It is a natural consequence of gene patenting that different patent owners will generate several layers of licensing agreements, each with a narrow scope, which increases transaction costs to unbearably high levels. Heller & Eisenberg illustrate this point persuasively when they suggest that “[p]olicy-makers should

60. TRIPs, *supra* note 8, art. 31(a)

61. *Id.* at art. 31(b).

62. Ng-Loy Loon notes that the use of compulsory licenses and dependency licenses “contravenes the current provisions of the TRIPs Agreement . . . however attractive and sensible this compromise [the use of compulsory licenses and dependency licenses] may be,” the compromise “contravenes the current provision [of] the TRIPs agreement.” Loon, *supra* note 6, at 413–14. Moreover, it is difficult to understand how a system of compulsory licenses that is blindfolded and does not look at the particular circumstances of each case is attractive and sensible. Indeed, such a blanket regime benefits not only downstream academic researchers, but also commercial competitors in pursuit of private gains. Furthermore, it would not encourage investment in genetic research.

63. Patent owners in other fields of technology do not have the same constraints on licensing rights. TRIPs, *supra* note 8, art. 27.1.

64. Art. 28.2 of the TRIPs Agreement reads: “Patent owners shall have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.” *Id.* art. 28.2. The language of article 28.2 contrasts with the language of article 21 regarding the licensing and assignment of trademarks. Article 21 states “[m]embers may determine conditions on the licensing and assignment of trademarks” Because article 28.2 does not contain similar language, it appears that members may not impose conditions on patent licensing other than those permitted by articles 8.2 and 40 (prohibition of patent misuse and anticompetitive licensing clauses).

seek to ensure coherent boundaries of upstream patents and to minimize restrictive licensing practices that interfere with downstream product development.”⁶⁵

C. Adopting Special Criteria for Assessing the Conditions of Gene Patentability

Commentators have also suggested that gene patent applications should be subject to greater scrutiny with regard to the conditions of patentability, particularly utility.⁶⁶ This suggestion raises two issues: (i) whether the conditions of patentability can be used to differentiate DNA sequences (and other elements of genomic technology) from products of nature; and (ii) how to establish that gene claims do not represent abstract, scientific concepts but are indeed useful to produce goods and services.

DNA sequences (or fragments thereof) are discoveries to the extent they represent nucleotide pairs in the same order and configuration as they exist in their natural environment, the human cell. Discoveries (naturally occurring materials or scientific theories) are not patentable as a matter of law. This concept is absolute in many countries,⁶⁷ but differs in the legal language and practices in the European Union and in the United States.

65. Heller & Eisenberg, *supra* note 47, at 701.

66. See, e.g., Loon, *supra* note 6; Golden, *supra* note 6; John M. Conley & Robert Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents* (Part III), 85 J. PAT. & TRADEMARK OFF. SOC'Y 371, 398 (2003); Nuffield Council on Bioethics, *The Ethics of Patenting DNA—A Discussion Paper 71* (2002), available at <http://www.nuffieldbioethics.org/filelibrary/pdf/theethicsofpatentingdna.pdf> (last visited Jan. 29, 2004). “We consider . . . that, in general, the granting of patents which assert rights over DNA sequences as research tools should be discouraged We take the view that the best way to discourage the award of such patents is by a stringent application of the criteria for patenting, particularly that of utility.” *Id.*

67. Section 1(3) of the International United Bureaus for the Protection of Intellectual Property [BIRPI]’s Model Law for Developing Countries on Inventions establishes that “Principles and discoveries of a scientific nature shall not be considered to be inventions.” BIRPI Publication No. 801(E), 1968. BIRPI administered the Paris and Berne Conventions until 1970 and preceded WIPO. Because many developing countries have followed that Model, the language quoted above is still found in several national statutes. The Model Law is no longer used by WIPO in its legislative assistance. The language on the patentability of discoveries for developing countries that the WIPO Secretariat currently suggests to its developing country Member States is the following:

1.(1) For the purposes of this Act, “patent of invention” means the title granted to protect an invention.

(2)(a) For the purposes of this Act, “invention” means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology.

...

(3) The following, even if they are inventions within the meaning of subsection (2), shall be excluded from patent protection:

discoveries, scientific theories and mathematical methods; . . .

Under the European Directive on Biotechnological Inventions, “[b]iological material which is isolated from its natural environment or produced by means of a technical process may be [the] subject of an invention even if it previously occurred in nature.”⁶⁸ The simple discovery of one element of the human body, such as the sequence or partial sequence of a gene, is not a patentable invention.⁶⁹ But “[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element,”⁷⁰ provided “[t]he industrial application of a sequence or a partial sequence of a gene [is] disclosed in the patent application.”⁷¹

Therefore, the European Directive provides that genes must comply with two conditions in order to be patentable: (a) they must be isolated from the human body or otherwise produced by means of a technical process (for example, they must be purified or synthesized);⁷² and (b) their industrial application must be known to the inventor (and described in the application).⁷³ Isolated, purified or synthesized genes may be patentable even if they are identical to those that exist in the human body.⁷⁴

These two conditions must exist for genes to be considered inventions rather than discoveries.⁷⁵ The Community’s legal framework on biotechnological inventions is limited to laying down certain principles, such as those “intended in particular to determine the difference between inventions and discoveries with regard to the patentability of certain elements of human origin”⁷⁶ Thus,

an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human

The text of the draft provisions on industrial property that WIPO uses in its activities of cooperation with developing countries are available at <http://www.wipo.int>.

68. Council Directive 98/44, art. 3.2, 1998 O.J. (L213) 18 (European Directive on the Legal Protection of Biotechnological Inventions) [hereinafter “European Directive”].

69. *Id.* art. 5.1.

70. *Id.* art. 5.2.

71. *Id.* art. 5.3.

72. *Id.* art. 3.2.

73. *Id.* art. 5.3.

74. *Id.* art. 5.2.

75. *Id.* at pmb1.

76. *Id.* at Rec. 13.

beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.⁷⁷

Without addressing the intricate distinction between an isolated or purified gene and a gene in its natural environment, the artificiality of the former separates, in board terms, an invention from a discovery. To simply state that inventions are novel, creative, and practical solutions for technical problems does not distinguish products of nature from inventions because nature often creates such novel solutions.⁷⁸ What actually distinguishes an invention from a discovery or product of nature is authorship. Inventions are human-made, while discoveries are nature-made, as the Supreme Court noted in *Diamond v. Chakrabarty*⁷⁹ where it stated that, “Congress thus realized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent’s microorganism is the result of human ingenuity and research.”⁸⁰

The European Directive attributes human authorship to genes that are isolated from their natural environment. It does not attribute patentability to the methods of isolating or purifying genes, but to the genes themselves.⁸¹ Therefore, in light of the Directive, genes borrow patentability from the artificial methods of their isolation and purification.⁸² Novelty and inventiveness of isolated genes are extrinsic to the genes because they are intrinsic to the methods of their isolation and purification.⁸³ More specifically, patentability of isolated materials arises from *indirect* human intervention. The element of artificiality is found in the processes and methods of isolation, not in the isolated or purified genes themselves, because the genetic composition remains the same as in their natural environment. Although the reasoning is uncommon, the Directive clearly takes a position in favor of gene patents, regardless of the fact that patent rights will be enforced in regard to the genes themselves and not the respective processes of obtaining them.

77. *Id.* at Rec. 21. See Derek Wood, *European Patents for Biotechnological Inventions—Past, Present and Future*, 23 World Pat. Inf. 339 (2001) (describing generally the European Directive).

78. See ERIC LAITHWAITE, AN INVENTOR IN THE GARDEN OF EDEN (1994) (elaborating on nature’s ingenuity in finding solutions for technical problems).

79. *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980).

80. *Id.*

81. European Directive, *supra* note 68.

82. *Id.* art. 5.2.

83. The same observation has been made regarding patentability of known substances for which a new pharmaceutical use is found. In that case, the argument is that the known substances borrow their novelty from the new uses and thus become patentable subject matter. See CARVALHO, *supra* note 6, at 149–50.

In spite of the different language used in the analogous United States statute, the legal solution adopted by the United States Patent and Trademark Office (USPTO) is identical. Actually, the United States Patent code establishes that *inventions* or *discoveries* are patentable subject matter.⁸⁴ It defines the term “invention” as “invention or discovery.”⁸⁵ Because discoveries are findings or disclosures of what is concealed in nature,⁸⁶ they are considered non-statutory subject matter. Therefore, one must distinguish between those discoveries that are non-statutory subject matter, and hence, non-patentable, and those discoveries to which the patent code refers.

This view was articulated by the United States Supreme Court in *Parker v. Flook*.⁸⁷ The Court held that a method for updating alarm limits was not patentable subject matter under § 101 of the Patent Act because its only novel feature was a mathematical formula.⁸⁸ The Court stated:

The rule that the discovery of a law of nature cannot be patented rests . . . on the more fundamental understanding that they are not the kind of “discoveries” that the statute was enacted to protect. The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious.⁸⁹

As the Court stated in *Parker*, the notions of novelty and obviousness are not useful for distinguishing between patentable and non-patentable discoveries.⁹⁰ Yet, this distinction must be made before assessing these other conditions of patentability. Interestingly, the Supreme Court did not mention the third condition of patentability: usefulness or utility. This

84. 35 U.S.C. § 101 (1952) provides: “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

85. 35 U.S.C. § 100 (1952).

86. “This is not to suggest that 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.” *Diamond v. Chrakabarty*, 447 U.S. 303, 309 (1980) (citations omitted).

87. *Parker v. Flook*, 437 U.S. 584 (1978).

88. *Id.*

89. *Id.* at 593 (footnotes omitted).

90. *Id.* at 588. The United States Supreme Court attempted to distinguish between discoveries and inventions by differentiating their technical nature: “A new process is usually the result of discovery; a machine, of invention.” *Corning v. Burden*, 56 U.S. 252, 267 (1854). “The patent of Burden alleges no discovery of a new process, but only that he has invented a machine, and, therefore, correctly states the nature of his invention.” *Id.* at 269. The issue at bar was the alleged infringement of a patent, hence the need for interpreting the scope of the claims and assessing whether they covered a machine only or whether they extended to the process of using that machine. The court concluded that the patent only covered the machine, not the process of using it. *Id.*

omission might lead to the conclusion that utility, in contrast with novelty and non-obviousness, may distinguish a statutory discovery from a non-statutory one. This reasoning, in fact, was the main argument the USPTO used when responding to specific comments on the revised Interim Utility Examination Guidelines:

[A]n inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.

If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.⁹¹

The position of the USPTO (as well as of the European Directive) strongly emphasizes the manner in which patent applications are drafted. This emphasis may "have extinguished the [product of nature] doctrine as a plausible objection to almost any kind of biotechnology claim."⁹² Words like "isolated" and "purified," if associated with a particular utility, become the relevant factors of patentability, as both the European Directive⁹³ and the USPTO Guidelines⁹⁴ seem to acknowledge.⁹⁵ It is worth noting that such an emphasis on claim drafting has already been disallowed by the United States Supreme Court in unequivocal terms. In *Parker v. Flook*⁹⁶ the Court rejected such an argument, stating:

if a process application implements a principle in some specific fashion, it automatically falls within the patentable subject matter of § 101 and the substantive patentability of the particular process can then be determined by the conditions of §§ 102 and 103. This

91. United States Patent and Trademark Office, Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (2001).

92. Conley & Maskowski, *supra* note 66, at 379.

93. European Directive, *supra* note 68.

94. *Supra* note 91.

95. Very suggestively, Conley & Makowski say that these words have received "talismanic status" and have, thus, become a sort of "incantation." Conley & Makowski, *supra* note 66, at 392.

96. *Parker v. Flook*, 437 U.S. 584, 593 (1978).

assumption . . . would make the determination of patentable subject matter depend simply on the draftsman's art and would ill serve the principles underlying the prohibition against patents for "ideas" or phenomena of nature.⁹⁷

The idea of using the utility element as the sole test of invention (or of statutory discovery) was rejected by the U.S. Supreme Court in *McClain v. Ortmyer*, which was a case of patent infringement.⁹⁸ In this case, the defendant contested one of the allegedly infringed patents based on lack of invention.⁹⁹ The plaintiff argued that the particular patent's strong commercial success fulfilled the prevailing test of invention.¹⁰⁰ The Court rejected that argument because commercial success is frequently the product of extensive and judicious advertising, not of the intrinsic merits of the articles themselves.¹⁰¹ Thus, commercial success is not necessarily synonymous with utility for the purposes of the Patent Act. More importantly, the Court added language that clarifies its reasoning regarding mandatory patentability requirements. The Court stated:

Counsel for the plaintiff in the case under consideration has argued most earnestly that the only practical test of invention is the effect of the device upon the useful arts, in other words, that utility is the sole test of invention. . . . He cited in this connection certain English cases, which go far to support his contention. These cases, however, must not be construed in such a way as to control the language of our statute, which limits the benefits of patent laws to things which are new as well as useful.

. . . We do not care to inquire how far [the second patent] was anticipated by the various devices put in evidence, showing the use of a similar spring for analogous purposes, since we are satisfied that a mere severance of the double spring does not involve invention, at least in the absence of conclusive evidence that the single spring performs *some new and important function not performed by it in the prior patent*.¹⁰²

Utility alone is not sufficient to determine patentability. A device is patentable when, as compared to prior art, it performs a *new and important*

97. *Id.* at 593.

98. *McClain v. Ortmyer*, 141 U.S. 419 (1891).

99. *Id.* at 425, 426.

100. *Id.* at 427.

101. *Id.* at 428.

102. *Id.* at 427, 429 (emphasis added).

function not performed by devices that constitute prior art. Only when utility is thus qualified does the invention overcome the product of nature barrier to patentability. It is necessary that the practical function which the claimed invention performs be distinct from the function performed by the emulated natural product.

By the same token, the Supreme Court in *Diamond v. Chkarabarty*¹⁰³ deemed a modified bacterium patentable. The Court noted that “the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”¹⁰⁴ A bacterium, therefore, is statutory patentable subject matter when, cumulatively: (a) it has “markedly different characteristics from any found in nature”); (b) it is useful (effectively or potentially); and (c) the inventive activity can be directly attributed to the inventor and not to the nature.¹⁰⁵

Under *Diamond*, isolated, purified and synthesized genes are not statutory patentable subject matter because, when isolated from the human body, they maintain identical¹⁰⁶ or very similar characteristics to those found in nature. It follows that purified and synthesized genes are also not patentable because they realize exactly the same function that genes inserted in their natural environment perform.

However, as noted above, this article does not intend to revisit the product of nature doctrine.¹⁰⁷ The utility requirement in the field of biotechnology has been scrutinized with greater care as a consequence of gene patenting. This increased scrutiny assumes a stronger utility requirement will allow commercial development without hindering scientific research.¹⁰⁸

103. *Diamond v. Chakrabaty*, 447 U.S. 303, 310 (1980).

104. *Id.* at 310.

105. *Id.*

106. See also European Directive, *supra* note 77, art. 5.2 and accompanying text; Wood, *supra* note 77.

107. Conley & Makowski argue that, if revisited, the product of nature doctrine, as established by the Supreme Court, might greatly narrow the granting of gene patents if it were revisited. See Conley & Makowski, *supra* note 66, at 391–93.

108. See, e.g., Loon, *supra* note 6. Similarly, Golden proposes that “to ensure that the biotechnology industry’s success continues, existing patent law doctrines, and in particular the utility requirement for patentability, must be carefully construed and enforced.” He adds that the USPTO and courts should use the utility requirement “to impose real, albeit non insurmountable, obstacles to the patenting of genetic sequences.” Golden, *supra* note 6, at 112. See also M. Scott McBride, *Patentability of Human Genes: Our Patent System Can Address the Issues Without Modification*, 85 MARQ. L. REV. 511, 528 (2001).

Actually, resorting to the conditions of patentability in order to address eventual problems arising from patenting genes, unlike proposals to tamper with the rights granted by gene patents may be consistent with the TRIPs Agreement. Imposing the conditions of patentability of genes differently from conditions for other fields of technology may constitute prohibited discrimination.¹⁰⁹ On the other hand, patent law is clearly industry-specific to the extent that claimed inventions are submitted to patent offices in different forms that are compatible with the specific nature of the technology to which they belong.¹¹⁰ For example, United States Patent Code¹¹¹ does not require that plants be described in the same full, clear, concise and exact terms as required for inventions in general: where the description of plants “is as complete as is reasonably possible,” the respective patents shall not be declared invalid for lack of enabling disclosure.¹¹² The European Directive states that where an invention concerns biological material that is not available to the public and that cannot be fully described in a patent application,¹¹³ the patent may be granted nonetheless if the biological material has been deposited under the Budapest Treaty.¹¹⁴

Disparate treatment of patent applications helps patent offices assess whether patent applications in certain fields meet the conditions of patentability, and does not affect the protection of patent rights. The differences comply with the TRIPs Agreement,¹¹⁵ because they represent the legal systems and practices of WTO Members in implementing TRIPs obligations.¹¹⁶

109. TRIPs, *supra* note 8, art. 27.1.

110. See generally Dan L. Burk and Mark A. Lemley, *Biotechnology's Uncertainty Principle*, U.C. BERKELEY PUB. L. Res. Paper No. 125, U. MINN. PUB. L. Res. Paper Series, Research Paper No. 03-5 (Mar. 2002), available at <http://ssrn.com/abstract=303619> (last visited Mar. 11, 2004).

111. 35 U.S.C. § 172 (2000).

112. 35 U.S.C. § 112 (2000).

113. European Directive, *supra* note 68, art. 13.

114. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1241, 1861 U.N.T.S. 361 (as amended Sept. 26, 1980) [hereinafter Budapest Treaty]. The Budapest Treaty is administered by the International Bureau of WIPO. It does not define microorganisms, therefore some of its Parties have extended it to other biological materials, such as cells and cell lines. See generally Nuno Piers de Carvalho, *The Budapest Treaty and its Applicability to Human Stem Lines; the WIPO Approach on Ethical Issues*, in THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES TO THE EUROPEAN COMMISSION, OPINION ON THE ETHICAL ASPECTS OF PATENTING INVENTIONS INVOLVING HUMAN STEM CELLS, Opinion No. 16, 99 (Nov. 20, 2001), available at http://europa.eu.int/comm/european_group_ethics/docs/avis16_en_complet.pdf (last visited Mar. 12, 2004).

115. TRIPs, *supra* note 8, art. 1.1.

116. See TRIPs, *supra* note 8, art. 29.1.

Members shall require that an applicant for a patent shall disclose the invention in a manner

The same can be said about conditions of patentability. The TRIPS Agreement does not define the three conditions of patentability. Thus, WTO Members are presumptively free to follow their own practices in that regard.¹¹⁷ The only condition is that national practices must not discriminate as to the availability of patent protection and the rights enjoyed therefrom. Utility, therefore, should be considered an assessment of patentability and not an obstacle to patentability. As a matter of course, a patent application in a technical field with inherent utility is not necessarily required to reference that condition. Indeed, such a reference could be redundant. Nevertheless, it is reasonable for patent offices to request that applicants state the practical purpose of their alleged invention in the field of biotechnology, and particularly in the field of genes, because so many patent applications have been filed for DNA sequences that have no known purpose.¹¹⁸

II. THE CONDITION OF ALTERNATIVENESS OF INVENTIONS AND THE RATIONALE OF THE PRODUCT OF NATURE DOCTRINE

The product of nature doctrine, namely that products of nature and scientific principles and rules are not patentable subject matter, is well established and deeply embedded in patent law.¹¹⁹ However, its boundaries may not be well defined. From a purely legal perspective, the scope of patentability depends ultimately, and exclusively, on the will of Congress. More fundamental questions then arise: why are products of nature not

sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

Id.

117. TRIPS, *supra* note 8, art. 27.1. See CARVALHO, *supra* note 6, at 58.

118. The WIPO Secretariat has acknowledged that the condition of utility may apply to the biotechnological field in a specific manner:

For example, with respect to an invention concerning a gene sequence that produces a protein, not only which protein is produced, but also the function or utility of the protein should be disclosed in order to meet the requirement of industrial applicability. In this case, a decisive question raised is not whether a gene sequence concerned can be isolated (i.e., “an invention can be made or used” in the field of biotechnology), but whether that gene sequence has a practical or useful application. It may also be noted, however, that this approach does not appear to be applied to the same extent to all categories of inventions.

See Standing Committee on the Law of Patents, World Intellectual Property Organization, “*Industrial Applicability*” and “*Utility*” Requirements: *Commonalities and Differences*, 9 (Mar. 17, 2003) at http://www.wipo.int/scplen/documents/session_9/pdf/scp9_5.pdf (last visited Mar. 12, 2004).

119. See *e.g.*, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 64 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); *O’Reilly v. Morse*, 56 U.S. 62 (1854); *Le Roy v. Tatham*, 55 U.S. 156 (1852).

patentable subject matter? What is the rationale of the product of nature doctrine?

In reality, the trend is to assume that products of nature are not patentable without further inquiry into the underlying rationale. For example, a commentator has mentioned that the patent law in the area of biotechnology has extended “to subject matter *traditionally* reserved for the public domain of natural science.”¹²⁰ Another commentator has noted that the non-patentability of scientific discoveries expresses a “bias against basic research.”¹²¹ The Commissioner of Patents said in 1889 that granting patents on “the trees of the forest and the plants of the earth . . . would be unreasonable and impossible.”¹²²

Certainly none of these views explain the reasons for barring products of nature from patentability. This bar may simply represent a tradition in patent law. But what is the logic behind such a tradition? It may be intuitive that scientific discoveries are not patentable, but where does that intuition stem from? Indeed, patent law may be biased against scientific research—but, absent a frivolous bias, what is the reason behind the discrimination? It may sound unreasonable to grant patents on the trees of the forest and on the plants of the earth, but why exactly is that unreasonable?

The U.S. Supreme Court has defined the product of nature doctrine as follows: “[t]he qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.”¹²³ But why are manifestations of laws of nature free to all men? The reason is that effective operation of the patent system depends on the limited grant of patents. Patents should be granted only for those new, non-obvious and useful inventions or discoveries that provide alternatives to existing technology that can be alter-invented.¹²⁴

120. Golden, *supra* note 6, at 110 (emphasis added).

121. Donald F. Turner, *The Patent System and Competitive Policy*, 44 N.Y.U. L. REV. 450, 457 (1969).

122. *Ex parte Latimer*, 1889 Dec. Comm’r. Pat. 123, 126 (1889).

123. *Funk Brothers Seed Co.*, 333 U.S. at 130.

124. The term “alter-invention” can be contrasted with “reinvention,” which means to invent again the same technical solution that had already been invented. To alter-invent is to invent a different, non-overlapping and non-equivalent solution for the same technical problem. Alter-inventions may be entirely different, or they may be careful variations of the original invention designed to avoid infringement (“inventing around”). Alter-inventions compete with the original inventions. This term will be used, for the purposes of this article, to describe the “condition of alternativeness of inventions.”

The condition of alternativeness of inventions was first articulated by the U.S. Supreme Court in *Le Roy v. Tatham*¹²⁵ and was invoked subsequently in *O'Reilly v. Morse*¹²⁶ and *Corning v. Burden*.¹²⁷ Additionally, although not mentioned explicitly, the condition of alternativeness undergirds the Court's opinions in *Funk Brothers Seed. Co. v. Kalo Inoculant Co.*¹²⁸ and *Diamond v. Chakrabarty*.¹²⁹

In *Le Roy*, the Supreme Court examined allegations of patent infringement for a machine that improved upon an earlier patented machine. In the allegedly improved machine, lead pipes were "wrought under heat, by pressure and constriction, from set metal," while the original invention had them cast formed in a mold.¹³⁰ The circuit court had instructed the jury that the machine itself was not novel, but the practical application of a principle, "by which a useful article of manufacture is produced, and wrought pipe made as distinguished from cast pipe."¹³¹ The Court held that the instruction was erroneous because the patent did not claim the practical application of the principle, only the machine's features. The novelty of those features was a question of material fact for the jury to decide.¹³² The Court stated the condition of alternativeness of inventions for the first time when discussing how patent law addresses the issues of patentability of principles of nature:

It is admitted that a principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known. Through the agency of machinery a new steam power may be said to have been generated. But no one can appropriate this power exclusively to himself, under the patent laws. The same may be said of electricity, and any [the] of other powers in nature, which is alike open to all, and may be applied to useful purposes by the use of machinery.

125. *Le Roy v. Tatham*, 55 U.S. 156 (1852).

126. *O'Reilly v. Morse*, 56 U.S. 62 (1853).

127. *Corning v. Burden*, 56 U.S. 252 (1854).

128. *Funk Brothers Seed Co. v. Kalo Inoculant*, 333 U.S. 127 (1948).

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

130. *Le Roy v. Tatham*, 55 U.S. 172 (1852).

131. *Id.* at 174.

132. *Id.* at 177.

In all such cases, the processes used to extract, modify, and concentrate natural agencies, constitute the invention. The elements of the power exist; the invention is not in discovering them, but in applying them to useful objects. Whether the machinery used be novel, or consist of a new combination of parts known, the right of the inventor is secured against all who use the same mechanical power, or one that shall be substantially the same.

A patent is not good for an effect, or the result of a certain process, *as that would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws.*¹³³

Under the condition of alternativeness, as articulated by the Supreme Court, patents cannot be granted on ideas or on knowledge that other persons cannot otherwise use. A patent grants exclusive rights in a certain invention; but that exclusivity may not impede other persons from using the same natural principle or material by different means from those claimed in the patent. If the patent is granted on the principle or material itself rather than on the use of the natural principle or material, other people will necessarily be barred from using that same principle or material, regardless of their level of ingenuity in developing different means. Patents on a principle or material, therefore, become monopolies that discourage “the progress of science and useful arts,” a condition that stands in sharp conflict with the constitutional function of the patent system.¹³⁴

In *O’Reilly*, the Court scrutinized and denied the validity of one of Morse’s patent claims on the telegraph.¹³⁵ In that claim, Morse went beyond “the specific machinery, or parts of machinery, . . . the essence of [his] invention being the use of the motive power of the electric or galvanic current, which [he] call[ed] electromagnetism, however developed, for making or printing intelligible characters, letters or signs, at any distance[.]”¹³⁶ The Court noted that Morse actually claimed “the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing [of]

133. *Id.* at 174–75 (emphasis added).

134. U.S. CONST., art. I § 8, cl.8.

135. *O’Reilly v. Morse*, 56 U.S. 62, 78 (1853).

136. *Id.* at 78.

intelligible characters, signs, or letters at a distance.”¹³⁷ The Court acknowledged that Morse’s claim at bar was not acceptable because:

If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff’s specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

Nor is this all, *while he shuts the door against inventions of other persons*

[I]t makes no difference, in . . . respect [of using the means the applicant specifies to produce the result or effect he describes, and nothing more], whether the effect is produced by chemical agency or combination; or by the application of discoveries or principles in natural philosophy known or unknown before his invention; or by machinery acting altogether upon mechanical principles. In either case he must describe the manner and process . . . and the end it accomplishes. *And any one may lawfully accomplish the same end without infringing the patent, if he uses means substantially different from those described.*¹³⁸

Because the telegraph as described and claimed by Morse could be alter-invented at any time in the future, it was undoubtedly patentable. However, the properties of electromagnetism were not patentable, because electromagnetism, as a principle of nature, is unique and can not be alter-invented. If Morse’s claim had been allowed, he could have blocked any future use of electromagnetism.

In *Corning*, the Court scrutinized the claims of a certain patent to identify whether its subject was a process or a machine.¹³⁹ In concluding that the patent covered a machine,¹⁴⁰ the Court said:

137. *Id.* at 112.

138. *Id.* at 113, 119 (emphasis added). The second reason the Court identified for rejecting Morse’s claim was that it included future applications of electromagnetism that he had not yet invented. *Id.*

139. *Corning v. Burden*, 56 U.S. 252, 267 (1854).

140. *Id.* at 269.

His patent having a title which claims a machine, and his specification describing a machine, to construe his claim as for the function, effect, or result of the machine, would certainly endanger, if not destroy, its validity. His claim cannot change or nullify his previous specification with safety to his patent. He cannot describe a machine which will perform a certain function, *and then claim* the function itself, and *all other machines that may be invented to perform the same function.*"¹⁴¹

Thus, in *Corning*, the Court again took into account that the patent on the machine's features allowed for it to be alter-invented by other persons, in contrast with a claim on the machine's function.¹⁴²

Similarly, genetic material, because it lacks the condition of alternativeness, should not be considered patentable subject matter. No one can deny that the human body is full of wonderful technical solutions for problems posed by its environment. The human cell is an extremely complex machine, and genes are merely one of its components. Genes are indeed technical solutions that mutation and evolution have improved. Genes, however, are nature-made; they are unique in the sense that they cannot be alter-invented by scientists to produce identical results. Any given protein is coded for by a single gene which is formed by a unique sequence of As, Cs, Gs, and Ts.¹⁴³ No scientist can construe a gene containing a different sequence of nucleotides to produce the same protein. A scientist simply cannot produce an artificial gene that does not copy a gene created by nature.

On the other hand, an isolated, purified and synthesized gene contains exactly the same DNA sequence as the gene in the human body, otherwise, it would not work. The scientist who isolates, purifies and synthesizes a gene may be praised for the method employed, but he has not actually invented the gene.

To give a simple example, if a prospector develops new equipment to extract water from a well, what he extracts is still water (H₂O), although "isolated" from its original environment. If a laboratory purifies that water, eliminating some substances from it and making it more adequate for human consumption, the final result will still be H₂O. If that laboratory adds some substances to the water to make it more pleasant to the human taste, the combination of the water with those substances can even be the

141. *Id.* (emphasis added).

142. *Id.*

143. *See supra* note 3.

result of human direct intervention. But any patent issued should not claim water (H₂O) in isolation. The issue of human genomics is curing genetic diseases caused by mutations in certain genes. The cure for those diseases is in the genes that exist now in the human body. Genes themselves cannot be alter-invented, and thus should not be patentable.

As stated in *Funk Brothers* and *Diamond*, only those inventions that are the direct result of human intervention are statutorily patentable.

In *Funk Brothers*, the Court held that packaging six different types of bacteria to produce a combination capable of inoculating the seeds of plants belonging to several cross-inoculation groups was not patentable.¹⁴⁴ Inoculated bacteria enable the plants to fix nitrogen. Prior to that bacteria combination, a farmer with different crops would need to use separate inoculants, one for each crop.¹⁴⁵ The Court stated:

Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. *It is no more than the discovery of some of the handiwork of nature and hence is not patentable.* The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria and no enlargement of their range of utility. Each species has the effect it always had. . . . Their use in combination does not improve in any way their natural functioning. *They serve the ends nature originally provided and act quite independently of any effort of the patentee.*¹⁴⁶

Under *Funk*, DNA sequences are not patentable subject matter regardless of their utility identified and described in the patent application, because the ability of isolated and purified genes to code for certain proteins has always been their natural function.¹⁴⁷ Isolated genes “serve the ends nature

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

145. *Id.* at 131–32.

146. *Id.* at 131 (emphasis added).

147. *Id.* at 130.

originally provided” and “act quite independently of any effort of the patentee.”¹⁴⁸ Moreover, genes cannot borrow patentability from the inventiveness of the methods used for isolating and purifying them. Under *Funk*’s rationale, “however ingenious the discovery of that natural principle [that a certain combination of genes codify for a certain protein] may have been,” the isolated gene in itself is not statutorily patentable subject matter.

The Court’s opinion in *Diamond* also relies on the distinction between nature-made and man-made inventions.¹⁴⁹ In affirming that § 101¹⁵⁰ covers modified bacteria, in spite of bacteria being living things, the Court quoted the House and Senate Committee Reports accompanying the 1952 Patent Act, stating that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”¹⁵¹ Later, the Court noted that “respondent’s micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomena, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’”¹⁵² Putting crucial emphasis on the artificial character of the bacterium as modified by the patent applicant, the Court remarked that “[h]is discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”¹⁵³

The handiwork of man was not in identifying the bacterium and isolating it from the environment, because such a bacterium would have the same composition as in nature and would perform exactly the same function.¹⁵⁴ Instead, it was in the bacterium itself, which was new because its composition had been modified by the patent applicant as a result of incorporating four plasmids capable of degrading oil to perform a function that it could not accomplish in its natural state.¹⁵⁵ The invention was in the bacterium itself, not in the methods used to modify and isolate bacterium.

148. *Id.* at 131.

149. *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

150. 35 U.S.C. § 101 (1952).

151. *Diamond*, 447 U.S. at 309 (quoting S. Rep. No. 82-1979 at 5 (1952); H.R. Rep. No. 82-1923 at 6 (1952)); 35 U.S.C. § 101 (1952).

152. *Id.* (quoting *Hartront v. Wiegmann*, 121 U.S. 609 (1887)).

153. *Id.* at 310.

154. *See Funk Bros. Seed Co. v. Kalo Inoculant*, 333 U.S. 127 (1948).

155. The Court noted: “In the work represented by the patent application at issue here, Chakrabarty discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single *Pseudomonas* bacterium, which itself has no capacity for degrading oil.” *Id.* at 305 n.1.

The relationship between the condition of alternativeness of inventions, as identified in *Le Roy*,¹⁵⁶ and the principle that only directly human-made inventions are patentable, as established in *Funk Bros.*, is that only the latter can be alter-invented.¹⁵⁷ Contrast this with natural inventions, which are unique and unsusceptible to being alter-invented.¹⁵⁸ A patent on a natural product leaves competitors without any alternative, because the natural product cannot be alter-invented.¹⁵⁹ Human intervention can combine that natural product with another to produce a different result. Such a combination is within the patent statute because another person can at any time combine that same product with a different material (alter-invent) or prepare the same combination but under a different dosage (invent around).

In summary, only human-made inventions meet the standards imposed by the condition of alternativeness of inventions; thus only these human-made inventions can, or should be, statutorily patentable subject matter. It is very important to emphasize that only directly human-made inventions are (or should be) patentable. Where the discoverer isolates or purifies a natural substance without modifying it, the condition of alternativeness is not met because the composition of the purified substance remains the same. An isolated and purified gene remains the same as in nature and performs only its natural function. Therefore, patentable inventions must meet not only the three substantive¹⁶⁰ conditions of patentability, but also a fourth—alternativeness.

156. *LeRoy v. Tatham*, 55 U.S. 156 (1852).

157. *Funk Bros. Seed Co.*, 333 U.S. 127.

158. However, some human inventions cannot be alter-invented as a matter of law. Such cases are exceptional and are subject to blanket compulsory licenses. See *infra* notes 196–97 and accompanying text. But when man-made inventions are an alternative to natural creations, the inventions are patentable subject matter provided they are not slavish imitations or reproductions of natural ingredients or features. Actually, many man-made inventions are often inspired by nature and its own creative solutions; such a fact does not make them less patentable. Alternativeness is the key to the distinction between man-made copies of nature that are patentable and those that are not patentable.

159. Any use of that natural product depends on its availability from the patent holder. It is impossible to obtain artificial products that have the same or similar properties and functionality.

160. Substantive conditions of patentability are those requirements that concern the nature of the invention itself. Failure to meet those conditions is sanctioned with either rejecting the patent application or, if detected *a posteriori*, with invalidation of the patent. This is why these are more than simple requirements but instead constitute conditions of patentability. Substantive conditions are the requirements of novelty, non-obviousness and utility. This Article submits that alternativeness is a fourth condition of patentability. Another substantive requirement, which is not a substantive condition, is the unity of invention. In general, the failure to meet this requirement causes the patent application to be divided, not rejected, if detected during the examination of the patent application. If the unity of invention is detected after the patent is granted, the patent is preserved. In contrast, formal requirements concern the form in which the invention is submitted to prosecution. The main formal requirement, which is mandatory, is disclosure of the invention, which must be enabling. Failure to

To a certain extent, the term “condition of alternativeness of inventions” is redundant because the notions of inventions and alternativeness overlap, except for inventions that are transformed *ex post facto* into technical standards.¹⁶¹ Only inventions (i.e., human-made technical solutions) can meet the condition of alternativeness; creations of nature cannot. However, the same can be said about non-obviousness, as the WIPO Secretariat has stated:

To some extent, it could be argued that [the] criteria [of novelty, non-obviousness and utility] are overlapping with the inherent notion of “invention.” However, it is possible for an invention, so defined, to fail to meet the criteria, for instance for want of novelty or utility. The reverse engineering of a technique that the emulator ignored had been previously disclosed is an invention, in spite of not being new. The only criterion that is actually overlapping with the notion of ‘invention’ is non—obviousness. There are no obvious inventions. But there are inventions that are more inventive than others. In other words, in contrast with the two other criteria, non—obviousness is a relative one. Patentability depends on the amount of level of inventiveness. If correctly worded, a statutory provision on patentability should actually read: “patents shall be available for any invention provided that it is new, *involves a sufficient inventive step* and is useful.”¹⁶²

The Supreme Court, in *Le Roy*, stated that the alternativeness of patentable inventions was instrumental to “the avowed policy of patent laws.”¹⁶³ The following section will describe such an avowed policy and discuss how the condition of alternativeness is instrumental to it.

comply with this requirement will cause the patent application to be denied. *See generally* TRIPS, *supra* note 8, art. 29.1.

161. For this reason, it is not strictly necessary to provide for the condition of alternativeness in patent statutes. The word “invention” should already contain or imply that condition in its meaning.

162. *See* INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE (FIFTH SESSION); COMPOSITE STUDY ON THE PROTECTION OF TRADITIONAL KNOWLEDGE 18 n.48 (Apr. 28, 2003), *available at* http://www.wipo.int/documents/en/meetings/2003/igc/pdf/grthf_ic_5-8.pdf (last visited Feb. 1, 2004).

163. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852).

III. THE CONDITION OF ALTERNATIVENESS OF INVENTIONS, AN INSTRUMENT OF THE METERING FUNCTION OF PATENTS

A. *The Primary Function of Patents: Accurately Metering Inventions*¹⁶⁴

The function of the patent system has thus far been explained in two different ways. The most common and accepted view is that patents are rewards granted to individuals who make contributions toward economic and technological progress by inventing and disclosing their inventions.¹⁶⁵ This notion is the reward doctrine in a nutshell. A second theory, the prospect theory, was proposed by Edmund Kitch.¹⁶⁶ It challenges the reward doctrine on the ground that when patents are granted, inventors may not yet be aware of the usefulness of their inventions. Patents, therefore, operate as titles of legal security that permit the inventors to prospect the market for commercial opportunities, very much like concessions granted to gold prospectors.¹⁶⁷

Three elements of patent law show that the primary function of patents is not a rewarding function. First, patents represent a technical evaluation that an invention is new, non-obvious, capable of industrial application, and represents a conceptual unity. Patents do not contain any judgment as to the economic relevance of inventions. Actually, most patented inventions are economically irrelevant, because most remain unexploited and never reach the market. Second, patents are subject to identical standards, regardless of the field of technology and the technical merits of their subject matter.¹⁶⁸ Third, the laws of some countries expressly establish that patents advance social goals, rather than rewarding individuals.¹⁶⁹ Moreover, the U.S. Supreme Court has several times made

164. A more lengthy discussion on the metering function of patents can be found in CARVALHO, *supra* note 6, at 1–22.

165. *See, e.g.*, ARTHUR R. MILLER & MICHAEL H. DAVIS, *INTELLECTUAL PROPERTY: PATENTS, TRADEMARKS, AND COPYRIGHT IN A NUTSHELL* 14–15 (1990); J. SCHMIDT-SZALEWSKI & J.L. PIERRE, *DROIT DE LA PROPRIETE INDUSTRIELLE* [The Law of Industrial Property] 1–7 (1996).

166. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 *J.L. & ECON.* 265, 266 (1977).

167. *Id.*

168. However, an exception to the non-discrimination principle might be identified in the laws of several WTO Members, which extend patent terms in some fields of technology, such as pharmaceuticals and agricultural-chemical products. *See, e.g.*, Council Regulation 1768/92, 1992 O.J. (L182) 2 (European Union regulation concerning the creation of a supplementary protection certificate for medicinal products). *See also* 35 U.S.C. § 155 (2000) (providing for extension of patents whose subject matter is subject to Food & Drug Administration review). However, such an extension does not relate to the merits of the technology, but the fact that those products are delayed in reaching the market by the necessity of obtaining administrative approval.

169. *See, e.g.*, Patent Law, Law No. 121 of 1959, art. 1 (as amended by Law No. 220 of 1999)

the same point.¹⁷⁰ Consequently, courts may not allow patentees to extract as large a market reward as they would like.

Kitch's proposal that patents are not rewards and that they act to guarantee that inventions will not be pillaged by free riders, enabling patentees to seek the highest market value for their inventions, relies on three features of the patent system. The first is the scope of patent claims, "a scope that reaches well beyond what the reward function would require."¹⁷¹ Second, some rules, such as priority and time-bar, compel the inventor to apply early "whether or not something of value (and hence a reward) has been found."¹⁷² Third, many technologically important patents were issued before the possibility of commercial exploitation existed.¹⁷³ Kitch concluded, therefore, that patents are not rewards.¹⁷⁴ Kitch added that it is common practice that, when a patent is issued, there is no reward to gain because the patentee does not yet know the practical value of the invention.¹⁷⁵

The prospect theory poses the same problems as does the reward doctrine: both are only partially correct and neither constitutes a primary concern of the patent system. Inventions are always patented before being market-tested due to the fact that legal requirements, such as novelty and statutory bars, urge inventors to rush to patent offices.¹⁷⁶

(Japan), available at <http://www.jpo.go.jp/shoukaie/patent.htm> (last visited Mar. 30, 2004). "The purpose of this Law shall be to encourage inventions by promoting their protection and utilization so as to contribute to the development of industry."

170. See, e.g., *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330–31 (1945) ("The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences.") (internal citation omitted); *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942) ("[T]he promotion of the progress of science and the useful arts is the 'main object'; reward of inventors is secondary and merely a means to that end.") (quoting *Pennock v. Dialogue*, 27 U.S. 1 (1829)); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) ("[T]his court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents, but is 'to promote the progress of science and useful arts'" (internal citations omitted); *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 492 (1942) ("The grant to the inventor of the special privilege of a patent monopoly carries out a public policy adopted by the Constitution and laws of the United States, 'to promote the Progress of Science and useful Arts.'" (internal citations omitted).

171. Kitch, *supra* note 166, at 267.

172. *Id.*

173. *Id.* at 267. A practical application of the prospect theory (an optimal patent life economic model) can be found in Lawrence M. DeBrock, *Market Structure, Innovation, and Optimal Patent Life*, 28 J.L. & ECON. 223 (1985).

174. Kitch, *supra* note 166, at 268.

175. *Id.* Kitch cited fifty examples of inventions whose inventors were obliged to apply for a patent early, but whose commercial success took too long to become a reality. *Id.* at 272.

176. See 35 U.S.C. § 102 (2004) (the statutory bar rule). In several countries that follow the first-to-file system, the so-called one-year "grace period" exempts inventions disclosed by the inventor itself (or by a third party who obtained the information from the inventor) from being included in prior

Nevertheless, a considerable amount of patented inventions correspond to the actual needs of the market. Roger Beck asserts that “40 percent to 50 percent of patents apparently are not used,” thus we may infer that only 50 percent to 60 percent of patented inventions are practiced.¹⁷⁷ Regardless of the exact percentage of unused patented inventions, there exist many patents that have been developed as an answer to immediate market needs, yet technical and economic failure, rather than anticipation, makes these patents worthless.¹⁷⁸ Moreover, individual inventors commonly author inventions without any concern for market demands; they may have no commitment other than the mere pleasure of inventing. Such individuals represent a small percentage of patent applicants,¹⁷⁹ but firms generally are more conservative.¹⁸⁰

Patents function primarily as metering devices for society to measure an invention’s value, thus allowing patentees to stipulate competitive prices for inventions and, consequently, for the products and services that embody them. Patents, therefore, are primarily neutral social mechanisms

art, if the disclosure takes place within a certain period prior to filing of the patent application. The “grace period” does not supersede the duty to rush to the patent office; it is merely a mechanism to permit the inventor to seek his or her peers’ cooperation without fear of losing the right to apply for a patent. The “grace period” has been adopted in many national and regional laws, but to date it has not been contemplated in any multilateral treaty. Some examples of national laws with a “grace period” include those of Brazil, Bulgaria, Germany, France, New Zealand, Norway, Panama. Examples of regional laws include OAPI (the Organisation Africaine de la Propriété Intellectuelle), and the Andean Community of Nations (Bolivia, Colombia, Ecuador, Peru and Venezuela). The EPO (European Patent Organization) also follows this practice. These laws and treaties are available at <http://clea.wipo.int> (last visited May 14, 2004).

177. Roger L. Beck, *Competition for Patent Monopolies*, in 3 RESEARCH IN LAW AND ECONOMICS 91, 98 (Richard O. Zerbe, Jr. ed., 1981). In contrast, Ernest Gellhorn states that up to ninety percent of all patents are unused “because they have no commercial value.” ERNEST GELLHORN, *ANTITRUST LAW AND ECONOMICS IN A NUTSHELL* 387 (3d ed. 1986).

178. An example of this kind of invention can be found in *United States v. E. I. Du Pont de Nemours & Co.*, 118 F. Supp. 41 (D. Del. 1953), *aff’d*, 351 U.S. 377 (1956). Du Pont owned 368 patents relating to the manufacture of cellophane, sixty-eight of which were to be used by Du Pont’s customers. *Id.* at 140. Du Pont used only ninety-three (31%) of the 300 remaining patents. *Id.* at 141. The remaining 207 patented inventions were not practiced because of several technical problems, such as non-availability of critical materials, high costs and obsolescence. *Id.* at 140–41. One may conclude that those 207 patents had no prospective function even though, when Du Pont developed them, the expectation was that they would be exploited immediately.

179. Alfred E. Kahn, *Deficiencies of American Patent Law*, 30 AM. ECON. REV. 475, 481 (1940).

180.

Despite the encouraging tendency of modern industrial laboratories to become scientific centers as well as improvement workshops, it cannot be doubted that “insiders” do tend to be more conservative and to the lose broader view. . . . When private enterprise provides the means and compensation for research, those who pursue it will fix their attention on what business looks upon as practical tasks and practical results.

Id. at 482.

that allow inventors to adequately allocate private resources to promote new technology.

Allowing inventors to obtain rents from the results of their activities promotes invention and innovation. This result can be achieved in two different ways. The first method is to require users of the inventions to pay for them directly. For this result to happen, it is necessary to establish a legal mechanism that allows inventors to put a price on their inventions. Patents and trade secrets perform precisely this role. The second method to obtain rents is to provide inventors with public funds or other privileges. In this case, governments allocate rents to inventors and, thus, users of the inventions will pay for them indirectly through taxes.

Social welfare and economic growth depend, in part, on technological innovation, which facilitates a more efficient utilization of available scarce resources and also provides access to new resources. Society certainly requires that a continued flow of inventions be developed and made generally available. To many, patents are also necessary to induce this essential flow of inventions. However, this proposition is untrue: patents are not strictly necessary to promote inventive activities. History shows that societies around the world have lived and evolved technologically without a patent system (i.e., without a system of private property rights whereby owners have the right to exclude others from using their technical creations). For thousands of years, governments relied on public awards to promote and encourage invention. In technological fields, where awards did not reach inventors or were not granted, economic interests in inventions have been protected through trade secrets.

Obviously, patents do not necessarily lead to an optimal exploitation of inventions, but by providing disclosure, patents reduce the enormous transaction costs involved in trade secrets.¹⁸¹ Transaction costs, as Eggertsson explains, are closely related to the cost of acquiring information.¹⁸² Thus,

181. Transaction costs include the costs of measuring and enforcing rights. *See generally* R. H. COASE, *THE FIRM, THE MARKET AND THE LAW* 178 (1990). Chapters one (*The Firm, The Market, and The Law*) and two (*The Nature of the Firm*) explain the role of transaction costs in the market. In the absence of transaction costs, the law would be irrelevant because individuals would always negotiate without cost in hopes of increasing the value of production. In a world of zero transaction costs, property rights would not be necessary. The cornerstone of Coase's thesis and known as (the "Coase theorem") was thus formulated by Stigler: "under perfect competition private and social costs will be equal." *Id.* at 14. The axiom that arises from the Coase theorem is that a clear definition of property rights reduces transaction costs and thus leads to a higher aggregate value of conflicting interests' output.

182. THRÁINN EGGERTSSON, *ECONOMIC BEHAVIOR AND INSTITUTIONS* 15 (1991).

[w]hen information is costly, various activities related to the exchange of property rights between individuals give rise to transaction costs. These activities include: 1. The search for information about the distribution of price and quality of commodities and labour inputs . . .; 3. The making of contracts; 4. The monitoring of contractual partners to see whether they abide by the terms of the contract; 5. The enforcement of a contract and the collection of damages when partners fail to observe their contractual obligations; 6. The protection of property rights against third-party encroachment—for example, protection against pirates or even against the government in the case of illegitimate trade.¹⁸³

The problem with trade secret protection is that it fails to provide accurate and reliable information on the quality and quantity of technology. A trade secret licensee cannot fully monitor the complete disclosure of the secret by the licensor.

When it comes to enforcement, trade secrets lack a predetermined term of protection. As a result, there is no established rule on how long court injunctions should last. When transaction costs are positive, Coase states:

the law plays a crucial role in determining how resources are used. But it does more than this. With zero transaction costs, the same result is reached because contractual arrangements will be made to modify the rights and duties of the parties so as to make it in their interest to undertake those actions which maximize the value of production. With positive transaction costs, some or all of these contractual arrangements become too costly to carry out. The incentives to take some of the actions which would have maximized the value of production disappear.¹⁸⁴

Trade secrets increase transactions costs by inducing trading partners to engage in actions that maximize the value of production. Patents serve to reduce these transaction costs by lifting the veil of secrecy and increasing the amount of information available. They help the market *quantify* technology through specifications and claims, and also by *qualifying* the rights granted.

Technology is quantified by describing the invention “in a manner sufficiently clear and complete for the invention to be carried out by a

183. *Id.*

184. COASE, *supra* note 181, at 178.

person skilled in the art.”¹⁸⁵ This requirement may be supplemented by indicating “the best mode for carrying out the invention known to the inventor at the filing date.”¹⁸⁶ Claims, which point out the specific aspects that the inventor regards as his or her invention, contribute to the precise identification of subject matter. To some extent, patents describe inventions in the same manner as deeds describe the geographical limits of real estate.

A problem with quantifying technology, however, is that identifying an invention is far from a matter of mathematical precision. In particular, describing prior art and giving accurate notice of the technical background of the invention may be extremely difficult. For this reason, legal enforcement of patent rights frequently becomes a problem of interpreting patent specifications. Even so, patents are valuable as accurate meters and as an alternative to trade secrets, although their accuracy is not absolute.

Qualification of rights is provided by two factors. First, rights created *erga omnes* are property rights, which generate a negative duty to refrain from trespassing.¹⁸⁷ Second, patent terms predetermine the extent of any injunction that courts may issue against infringers; this stands in sharp contrast to the indefinite duration of secrecy available for trade secrets.

Trade secrets are protected for as long as their holders are willing or able to keep them secret. However, the law does not protect knowledge *per se* with respect to trade secrets, but efforts undertaken to conceal that knowledge. In other words, secrecy is protected only to the extent that competitors may not illegitimately invade the secret holder’s privacy.

One should not forget that patents are essentially a market mechanism and that the reduced cost of obtaining information is only relevant in a free market. Actual or potential competitors, pressed by market needs and expectations, are the only significant users of the patent system, insofar as the system permits them to better evaluate inventions. It follows then, that in the absence of competitive forces, as in a monopolistic market or a centrally-planned economy, the value of the patent system is limited to

185. TRIPS, *supra* note 8, art. 29.1.

186. *Id.* The “best mode” requirement is optional in most WTO Member states, but mandatory in the United States. See 35 U.S.C. § 112 (2004).

187. Patents are property rights in intangible goods, possession of which does not prevent others from simultaneously possessing them. In contrast, domain over tangible goods excludes others *per se*. For example, no one can construct a house on land where another house stands. Therefore, property rights in tangible goods are defined as rights *to use and exploit*. The right to exclude others from use is a natural, if not physical, consequence of possession. This situation is reversed for intangible goods, knowledge and ideas. Rather than a right to use intangible goods, property owners must have the right to *exclude* others from using and exploiting ideas.

peripheral and secondary functions, serving as a source of technical information and of commercial prestige.

The fact that patents and public funding are alternate mechanisms does not mean that the concepts that lie behind these mechanisms are necessarily incompatible; they are simply different. Governments still rely upon those earlier tools to promote specific technical innovations. The patent system assumes that the inventor will seek to recoup the costs of research and development (“R&D”) from the market.¹⁸⁸ Governments may also subsidize inventive activities in areas where the private sector is unwilling or incapable of undertaking the necessary research. In the health sector, for example, mechanisms for private appropriation of inventions frequently co-exist with government subsidies.¹⁸⁹

Accordingly, patents are alternatives to public funding only insofar as they do not pose the problems of efficiency that politically-biased decisions tend to generate. Patents reduce transaction costs that arise from managing technology through trade secrets and government funding to the extent that they improve the evaluation and pricing of protected technology. They do so both by improving the quantification of the subject matter and by improving the qualification of rights granted. Rewards and public funding certainly continue to play a role where governments want inventors to undertake research in specific fields of technology. These government funds should be used to cover the costs of R&D, but, governments must determine in advance that the inventions they want developed are socially worthy in order to make those funds available. It is exactly the issue of government predetermination that evokes the problem of social costs because political choices naturally take precedence over concerns with economic efficiency.

188. This explains the bizarre format given to the patent system in the former Soviet Union, where, besides patents, a mechanism of “inventors’ certificates” was established, through which patents split into two different sorts of rights. The right to a public reward was granted to the inventor, and property rights were granted to the State. Regulation on Discoveries, Inventions and Rationalization Proposals, SP SSSR 584 § 23 (1973). Because a patent system cannot effectively operate in a centrally-planned economy, it is not surprising that Soviet inventors almost invariably opted to apply for an “inventors’ certificate.” See Y.E. Maksarev, *L’essor de l’activité inventive en Union Soviétique [The Development of Inventive Activity in the Soviet Union]*, LA PROPRIÉTÉ INDUSTRIELLE [INDUSTRIAL PROPERTY] 154, 156 (1978). In the first three years of the Regulation, Soviet inventors did not apply for patents, but only for certificates. *Id.* Soviet patents became mere springboards for the Soviet Government to obtain private property rights in market-oriented economies. *Id.* at 159. After three years of Regulation operation, the Soviet Government had filed more than thirty-five thousand patent applications in foreign countries. *Id.*

189. The U.S. Patent Act includes an entire chapter dealing with patent rights for inventions made with federal assistance and funding. 35 U.S.C. §§ 200–212 (2000).

To operate efficiently, patents need a free-market environment. In the absence of the interplay of market forces, patents are merely pieces of paper with some technical content.¹⁹⁰ For that reason, the TRIPs Agreement assumes in its preamble that intellectual property rights, including patents, “are private rights.”¹⁹¹ The TRIPs agreement extends transitional preferential treatment to any “[m]ember which is in the process of transformation from a centrally-planned into a market, free-enterprise economy.”¹⁹² Likewise, in very poor countries, patents play an extremely limited role. In those countries, market forces are nearly irrelevant; consequently, the competitive framework, without which patents cannot operate as metering devices, is absent.

Of course, patents may also have an important role to play as a mechanism to transfer publicly funded inventions to private companies. Patents not only permit public institutions to collect private revenues, which may be needed to fund new research, but also reduce the costs and increase the efficiency of licensing of technology patents.

In conclusion, the patent system exists as the only known legal institution that allows inventors to put a price on technology while, at the same time, allowing society to measure the adequacy of such a price with relative efficiency through the competitive interplay of market forces. The cornerstone justification of the patent system is that it reduces transaction costs, compared with government subsidies and trade secrets.

B. The Metering Function of Patents and the Condition of Alternativeness of Inventions

Accurately metering inventions requires a competitive approach: society must compete for the claimed invention. The interaction of competitive forces allows society to evaluate patents; however, this interaction only takes place when the patent owner is under pressure from other existing or potential technologies. When an inventor obtains a patent and the claimed invention is commercially useful, competitors may adopt one or more of the following options: they may obtain a license from the patent owner; they may continue using available technology; they may obtain a license to use a competing technology owned by another

190. Under the former Soviet regime, patents clearly did not give additional rights to inventors. See *supra* note 188.

191. TRIPs, *supra* note 8, at pmb1.

192. TRIPs, *supra* note 8, arts. 65.2, 65.3. Those WTO Members were entitled to the same five-year transitional period as developing country Members. *Id.*

competitor; or they may make their own invention, either by alter-inventing or by inventing around the invention in question.¹⁹³

Alter-invention provides a means of competition with patented inventions, as well as an accurate metering of competition. Without alter-invention, the patent system loses its efficiency and its purpose. One notable exception is gene patents, which are not susceptible to alter-invention, and therefore run counter to the very rationale of the patent system.¹⁹⁴

One could argue that gene patents are important for encouraging scientists to identify genes and their role in the human body as a tool for the development of the biotechnology industry. This assertion is mistaken because, notwithstanding all the incentives that the biotechnology industry

193. Obtaining a license from the patent owner is generally not a competitors' first choice. It is not evident that the patent owner will agree to transfer his knowledge and accept increased competition without imposing conditions that limits the licensee's ability to reduce his or her market share. Contractual licensing may indeed be the last resort. Licensing agreements imply the payment of fees, which necessarily gives the patent owner a competitive advantage over licensees, assuming other manufacturing and distribution cost factors are equal.

194. One commentator has followed exactly the opposite reasoning to reach the same conclusion (that pure product patents for DNA sequences should not be patentable subject matter). See Denis Schertenleib, *The Patentability and Protection of DNA-based Inventions in the EPO and the European Union*, 25 EUR. INTELL. PROP. REV. 125 (2003). This commentator bases his view on the notion that "patents are fundamentally anti-competitive and great care is needed for an acceptable balance to be found between the promotion of competition and the protection of intellectual property rights." *Id.* Because "widespread patenting of sequences will lead to uncertainties in the scope of claims and to litigation, with the inevitable unfairness of the first patentees gaining a stranglehold on this area of technology," and having in mind that "[p]atent law evolved to ensure progress and competition. If, within the current legislative framework, it cannot promote these functions, then there should be no impediments to change" (change referring to the change in practice of the European Directive on Biotechnological Inventions)." *Id.* at 138. The commentator states that, because the same sequence can appear in different genes, granting a patent on a certain sequence gives the patentee control over other (non-claimed) genes. *Id.* at 137. As a matter of course, if one agrees that patents are inherently anti-competitive, the obvious and necessary conclusion is that if more inventions are refused patents, the system will be more competitive. The problem with this reasoning is one of economics: patents do promote competition for the reasons explained in this Article. See *supra* Part III.A. The microeconomic environment of rivalry and business opportunities is not harmed by granting patents. This environment of rivalry and business opportunities is a crucial component of productivity, which is the single most important element for assessing microeconomic competitiveness. See Michael Porter, *Building the Microeconomic Foundations of Prosperity: Findings from the Business Competitiveness Index*, GLOBAL COMPETITIVENESS REPORT 2003–2004 at 38, available at http://www.weforum.org/pdf/gcr/GCR_2003_2004/BCI_Chapter.pdf (last visited Mar. 24, 2004). Otherwise, countries that grant fewer patents, such as Honduras, would be more competitive than those that grant more patents, such as the United States. See <http://www.wipo.int/ipstats/en/publications/a/pdf/patents.pdf> (last visited Apr. 19, 2004) (includes statistical data on patents granted per country); Microeconomic Competitiveness Index 2002–2003, http://www.weforum.org/pdf/gcr/GCR_2002_2003/GRC_Rankings_2002_2003.pdf (last visited Sept. 25, 2003). The problem of gene patents is not in the scope of the claims or in the risk of litigation arising from patents on partial sequences; rather it is in the nature of the sequence itself, which does not meet the conditions of patentability, regardless of the scope of the respective claims.

needs, the patent system is not the appropriate mechanism to promote upstream scientific research. The patent system was devised for evaluating inventions, not for promoting scientific discoveries. The government can promote these discoveries through tax and credit incentives. If society values the work of identifying genes and the proteins they code for, it may allow the government to divert tax money to benefit biotechnology research. Promoting scientific research is not, as the U.S. Supreme Court stated in *Le Roy*, “the avowed policy of patent laws.”¹⁹⁵

One exception stands, however, to the condition of alternativeness of inventions: in some exceptional cases, a patented invention may become a technical standard imposed by the government for the sake of public policy, in areas such as health or environmental protection. For example, under the Clean Air Act,¹⁹⁶ when patentees’ competitors are legally required to adopt the technical solution invented by the patent owner, they may be entitled to obtain a compulsory license from a district court.¹⁹⁷

The Clean Air Act does not provide for a blanket, compulsory licensing scheme but instead requires a case-by-case test under which possibly existing alternatives must be scrutinized. It is true that the options for alternative inventions are greatly reduced in the case of standardized technology. However, this option is not totally absent, because a competitor can alter-invent or reinvent the standard technology. In this case, the competitor convinces the appropriate government agency that the alternative invention is at least as safe, or even safer, than the adopted technical standard. In that case, the agency may decide to adopt a different standard technique or device that would compete with or modify the original standard.

Second, standardizing techniques that reduce the alternativeness of inventions are the exception rather than the norm. Because they hinder the efficiency of a free competitive environment, techniques are standardized only in exceptional cases where human health and safety are at risk. Normally, the market should be open to different techniques so that

195. *LeRoy v. Tatham*, 55 U.S. 156 (1852).

196. 42 U.S.C. §§ 7401–7671q (2000).

197. 42 U.S.C. § 7608 (2000). Compulsory licenses are ordered when: (i) the patented technology is “not otherwise reasonably available” (for example, the patent owner fails to agree on a voluntary license when offered in reasonable commercial conditions); (ii) the patented technology “is necessary to enable any person required to comply with the technical standard in question;” and (iii) “there are no reasonable alternative methods to accomplish such purpose.” *Id.* The mandatory licensing shall be granted when “the unavailability of such right may result in a substantial lessening of competition or tendency to create a monopoly in any line of commerce in any section of the country. The technical standards to which § 7608 refers concern standards of performance of air pollutant emission, and relates to both stationary and moving sources.

consumers may select the products, methods and devices of their own choice. To achieve this free choice, patented inventions must be subject to alternativeness.

Finally, in the case of mandatory technical standards, alternativeness is reduced *ex post facto*, that is only after the competent government authorities have assessed the technical relevance of a given invention and decided to transform it into a standard. In contrast, products of nature cannot be alter-invented *ex ante facto*.

C. The Impossibility of Applying the Essential Facility Doctrine in the Field of Patents as a Consequence of the Condition of Alternativeness of Inventions

Compulsory licenses of mandatory technical standards may be scrutinized under the essential facility doctrine, which states that “the owner of a properly defined ‘essential facility’ has the duty to share it with others, and that a refusal to do so violates § 2 of the Sherman Act.”¹⁹⁸ Essential facilities have been classified according to three types of categories: (1) natural monopolies or joint venture arrangements subject to significant economies of scale; (2) structures, plants, or other valuable productive assets that were created as part of a regulatory regime, whether or not they are properly natural monopolies; or (3) structures that are owned by the government and whose creation or maintenance is subsidized.”¹⁹⁹

The essential facility doctrine was comprehensively articulated by the Seventh Circuit Court of Appeals in *MCI Communications*.²⁰⁰ The court identified four elements of the doctrine:

- (1) control of the essential facility by a monopolist; (2) a competitor’s inability practically or reasonably to duplicate the essential facility; (3) the denial of the use of the facility to a competitor; and (4) the feasibility of providing the facility.²⁰¹

198. HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE, 273 (1994). Section 2 of the Sherman Act states: “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony. . . .” 15 U.S.C. § 2 (2003).

199. HOVENKAMP, *supra* note 198, at 274.

200. *MCI Communications Corp. v. AT&T Co.*, 708 F.2d 1081 (7th Cir. 1983).

201. *Id.* at 1132–33.

Thus, in an “essential facility” situation, the owner is a monopolist who wishes to keep his monopoly or to deny it to a downstream use. However, a facility is only essential when it cannot be practically or reasonably duplicated. This situation occurs in the case of inventions concerning mandatory technical standards. Government regulations require equipment manufacturers to use this technology, therefore competitors cannot adopt different technical solutions. In cases where those standards are covered by exclusive patent rights, competitors do not have access to those standards without the patent owner’s authorization. This gives rise to an essential facility situation.²⁰²

Absent regulatory standardization, the essential facility doctrine does not apply to patents because patentable inventions are essentially susceptible to being alter-invented. Thus, the doctrine’s second element, as defined in *MCI*, cannot be logically met.²⁰³ This was the reasoning of the District Court in *Data General Corp. v. Grumman Systems Support Corp.*,²⁰⁴ the case providing the most extensive discussion of the essential facility doctrine in the context of intellectual property law.²⁰⁵

The facts of the case were as follows: Data General (DG) sold computer systems and provided services for their maintenance and repair. Grumman provided services to maintain and repair several computer systems, including those manufactured by DG.²⁰⁶ DG brought an action for damages and injunctive relief against Grumman’s use of a diagnostic program (MV/ADEX) developed by DG.²⁰⁷ The program is used both to design DG’s computer systems and to repair systems in use.²⁰⁸ Grumman counterclaimed against DG, alleging, among other claims, a violation of section two of the Sherman Antitrust Act.²⁰⁹

Grumman’s reliance on the essential facility doctrine was grounded on the fact that DG licensed the diagnostic tool only to those purchasers of DG computer systems in its Cooperative Maintenance Organization (CMO program).²¹⁰ Third Party Maintainers (TPM), such as Grumman, were

202. Government regulations that establish this essential facility typically provide access to this as well. *See, e.g., supra* note 196 and accompanying text.

203. *See MCI Communications Corp.*, 708 F.2d 1081.

204. *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 761 F. Supp. 185 (D. Mass. 1991), *aff’d*, 36 F.3d 1147 (1st Cir. 1994).

205. *See Gregory V.S. McCurdy, Intellectual Property and Competition: Does the Essential Facilities Doctrine Shed Any New Light*, 25 EUR. INTEL. PROP. REV. 472, 475–76 (2003).

206. *Data General*, 761 F. Supp. at 187.

207. *Id.*

208. *Id.*

209. *Id.*

210. *Id.* at 189.

denied access to the CMO program, except as required to maintain their own DG computers.²¹¹ In other words, DG refused to authorize Grumman to use its diagnostic program to provide maintenance services to third parties. Grumman invoked two U.S. Supreme Court opinions dealing with the essential facility doctrine, *Aspen Skiing Co.*²¹² and *Otter Tail Power Co.*²¹³

The District Court concluded that the issue at bar differed from the two Supreme Court cases. In its analysis of *Aspen*, the District Court noted that:

Grumman and other TPMs have the opportunity to develop competing diagnostics and tools for maintenance. Two diagnostics have, in fact, been developed by TPMs. . . . Grumman protests that it is unable to produce a diagnostic because it cannot get the necessary schematics and DG could easily drive any competing diagnostic into obsolescence by simple modifications in design. . . . Grumman, however, makes no allegations that DG has in fact attempted to subvert competitors' efforts to develop and implement competing diagnostics. TPMs have demonstrated the ability to develop diagnostics, even if they are not as efficient as MV/ADEX.²¹⁴

The District Court also examined Grumman's allegation that MV/ADEX was an essential facility "which DG must share with its competitors."²¹⁵ "The [c]rux of Grumman's essential facility argument," the District Court noted, "is that only the manufacturer of computer systems is capable of developing a diagnostic tool which is an essential device in the repair of those computers."²¹⁶ After confirming the four-part test for the essential facility doctrine established in *MCI*, the District Court invoked the condition of alternativeness to affirm that intellectual property assets can by definition be duplicated and, thus, cannot be considered "essential facilities."²¹⁷ The District judge said:

DG does not have monopoly power in the sale of computer systems and thus is not using a bottleneck to create another monopoly. The

211. *Id.*

212. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985).

213. *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973).

214. *Data General*, 761 F. Supp. at 191.

215. *Id.*

216. *Id.*

217. *Id.* at 192.

“bottleneck” of its superior knowledge in the design of DG computers is insufficient to invoke the essential facilities doctrine; *a better mousetrap is not necessarily an essential facility*. The Sherman Act has not been interpreted to require manufacturers to abandon their advantage in creating accessories to their systems. If manufacturers of complex and innovative systems were required to share with competitors the development of accessories, because they had a possibly absolute advantage through producing the system, the incentives of copyright and patent laws would be severely undermined. Not only would the manufacturer, who is in the best position to create these accessories, have less incentive to do so, *but also the impetus for competitors to reverse engineer and produce competing solutions would be reduced*.²¹⁸

The District Court assumed that one of the patent system’s goals is to lead competitors to produce competing solutions. That assumption, however, is only possible when one understands that competing solutions are always obtainable. A better mousetrap is not necessarily an essential facility because there is always a worse mousetrap to compete with it. Consumers may prefer to acquire the latter if the price or other commercial conditions are more appealing than the technical advance of the former. Therefore, it is impossible, as a matter of law, to apply the essential facilities doctrine to patent law, because a certain technical solution may never be deemed incapable of being duplicated invented around or re-invented.

D. Problems of a Poorly Functioning Patent System

There is a practical need to make known the inconvenience of gene patents. Gene patents run counter to the procompetitive rationale of the patent system; as a result, they do not conform with the basic function of patents. Poorly functioning patents are not merely a question of legal logic, but are indeed a source of serious economic problems.

The biotechnology industry in the medical field is still at its early stages, so it is perhaps too soon to determine how gene patents negatively impact society by means more precise than anecdotal evidence.²¹⁹ However, some events in the history of the patent system clearly illustrate

218. *Id.* at 192 (emphasis added).

219. *See supra* note 10–12 and accompanying text (referencing patents on breast cancer genes and the gene for Canavan disease).

how a poorly functioning patent system can undermine competition and thus contribute to unbalanced distribution of income and market power concentration.

Historian Earl Hayter eloquently identifies how the malfunctioning of the patent system in the last decades of the nineteenth century caused agrarian discontent and ultimately contributed to the populist revolt of the 1890s.²²⁰ Farmers, at the time, felt suffocated by a patent system that deprived them of the fruit of their work.²²¹ Patent owners proliferated numerous frivolous lawsuits against “innocent” farmers who resisted payment.²²² This state of affairs led the farmers to organize and voice their anger and criticism against the Patent Office,²²³ Congress,²²⁴ and the judiciary.²²⁵ Several bills were unsuccessfully introduced in Congress to modify the patent system.²²⁶ As a result, farmers found themselves

220. Earl W. Hayter, *The Patent System and Agrarian Discontent, 1875–1888*, 34 *MISS. VALLEY HIST. REV.* 59 (1947). Hayter details how thousands of small American farmers were charged royalties for patents on agricultural devices, most of which had been inappropriately granted. Farmers were often irritated because patents on various essential articles were controlled

most generally by a group of manufacturers called a patent “ring”. . . . [Old claims that] had become inoperative and unremunerative to the inventor were often bought up at a small fee by a patent “ring” and through “manipulation of the Patent Office, or by inadvertance of the officials,” were reissued not on the original claim, but on a broadened or revised patent to cover subsequent improvements. Extension of a patent for a seven-year period was also possible under the law through congressional action if the owner could show that he had not secured adequate compensation for the benefits derived. . . . This practice not only kept a patent in effect for a longer period of time, but it also made it possible for a “ring” to use original and enlarged claims to develop a monopoly of the article.

Id. at 62 (internal citation omitted). Moreover, many patents were issued to different persons on the same article. *Id.* at 63. Trifling improvements were eligible for patent protection and thus every article would be covered by patents. A Michigan farmer had the following comment: The patent system is

in our boots, it is in our clothes, it is in the tool we work with, in the buggy we ride in, in the harness on the horse, in the whip we strike him with. It is to be found in our fences, in our gates, in our pumps, in our kitchen, in our food, and finally in our coffin.

Id. at 63–64 (internal citation omitted).

221. In several cases, “persons were sued for articles that they had developed themselves or which they had borrowed from neighbors before any patents had been granted.” *Id.* at 66 (internal citations omitted).

222. By 1878, “as many as five hundred cases [had been] filed in the St. Paul district court alone.” *Id.* at 67 (internal citations omitted). In Des Moines, “two hundred drive-well cases were filed in one single day.” *Id.* (internal citations omitted). Hayter notes that “the drivewell patent was one of the most bitterly contested patents in the history of the United States.” *Id.* at 76. The Supreme Court, “in a fourth hearing, more than two years after the patent expired, . . . reversed its earlier judgment and ruled “that that patent was void and ought never to have been issued.” *Id.* at 76–77 (internal citation omitted).

223. *Id.* at 64.

224. *Id.* at 79.

225. *Id.* at 79–80.

226. *Id.* at 81. In addition to the lack of political support in the conservative Senate, farmers were opposed by inventors, including Thomas Edison. *Id.*

“embroiled in constant conflict with the patent owners, and the nature of patent laws resulted in continual harassment by royalty collectors and patent agents.”²²⁷

Hayter describes a serious situation, one of general unrest, that arose from mishandling of the patent system a misapplication of its purpose of promoting invention. While it is true that invention must be promoted, the facts narrated by Hayter clearly show that the patent system was used to encourage greed rather than to promote further invention.²²⁸ Under a capitalist regime, an inventor is entitled to reap as many benefits as he or she can from his or her invention. The patent that allows the inventor to do so is a good patent when the idea covered is an invention (as opposed to a product of nature) and meets the conditions of novelty, non-obviousness and utility. However, in this case, patents granted for trifling improvements or to the wrong inventors were the origin of the problem. Furthermore, the poor performance of the patent system was aggravated by competitors’ collusion and misuse of patents.

Hayter’s article is a powerful illustration of the proposition that a poorly performing patent system can indeed cause serious economic and social problems. A more recent example of social discontent with the patent system occurred with regard to patents on therapeutic and surgical methods.²²⁹ In the latter case, Congress moved swiftly to eliminate the

227. *Id.* at 82. Hayter concludes:

It would appear that if there were any assessable contributions resulting from these struggles, they added to the irritations of the already discontented Grangers. For it was these additional economic grievances of the late [nineteen-] seventies and eighties, heaped upon those that had accumulated from the early and middle seventies, which finally culminated in, and laid the basis for, the Populist revolt of the nineties.

Id. at 82. Even if agrarian discontent did not lead to a thorough review of the patent system, most of the problems that caused it were solved by the enactment of the Sherman Antitrust Act, ch. 647, 26 Stat. 209 (1890) (current version 15 U.S.C. §§ 1–7 (2000)). Patent owners organizing under “rings” and lodging frivolous lawsuits could thereafter be scrutinized as antitrust violators and hence, were subject to criminal penalties. *Id.*

228. *Id.*

229. Doctors and surgeons are immune from patent infringement lawsuits arising from therapeutic and surgical methods. 35 U.S.C. § 287(c) (1996). This legislation was introduced after an infuriated public debate caused by a lawsuit lodged by Dr. Pallin, an ophthalmologist surgeon, who had obtained a patent for the shape and the location of the incision for cataract surgery. U.S. Pat. No. 5,080,111 (issued Jan. 14, 1992). Dr. Pallin attempted to enforce his patent against a colleague and his colleague’s clinic. The District Court of Vermont, in a consent order dated March 28, 1996, dismissed the action on grounds of invalidity of the claims. This case outraged the medical community as it revealed Dr. Pallin’s intention to recover damages from all surgeons who had used his technique. Because this technique was commonly used, virtually every ophthalmologist in the United States was threatened with a costly lawsuit. See <http://www.ascrs.org/advocacy/patpr2.html> (last visited May 14, 2004); *supra* notes 35 and 59 and accompanying text.

problem even if it did so with possible disregard for TRIPs provisions.²³⁰ At the same time, patents on therapeutic and surgical methods are not economically relevant because doctors have other mechanisms for appropriating inventions in that field.²³¹ Therefore, no one should fear a reduction or slowing in technical development of medical methods and techniques for want of patent incentives.

Genes are the building blocks of life. Therefore, any method or product for treating genetic disease depends on identifying and describing the genes involved. Property rights in genes structures are disruptive to the establishment of a sound, viable, and competitive industry, and do not promote competition or spur development of new biotechnological products and processes.

Certainly the biotechnology industry should be able to reap substantial profits from its research and product development. This author firmly believes that the patent system, when adequately framed, is the best tool society possesses for the accurate evaluation of inventions. The patent system is not the appropriate mechanism for obtaining gains from identifying, isolating, and purifying genes. Other social tools, such as tax credits and other government financial incentives, have demonstrated their worth for this purpose. A parallel can be made with statistical data, which, in spite of its importance, is not protected by intellectual property.²³² Genes and their functions are scientific facts, not inventions. The patent system was not devised to permit gains from revealing and understanding

230. In a letter dated September 27, 1996, addressed to Sen. Orrin Hatch, Chairman of the Senate Judiciary Committee, Ambassador Jennifer Hillman, then General Counsel of the USTR, noted that the proposed exception to patent rights raised questions about whether it was covered by Article 30 of the TRIPs Agreement. See CARVALHO, *supra* note 6, at 176.

231. Therapeutic methods are generally considered non-patentable subject matter. The justification for this treatment has traditionally been based on professional ethics—therapeutic methods have traditionally been scrutinized by peer review, not by patent offices, and the inventors' colleagues have been considered entitled to share the inventions. However, the true reason for the lack of patent protection in the field of therapeutic methods lies elsewhere. Therapeutic methods, as well as diagnostic and surgical methods, are, with few exceptions, individual procedures whose success depends much more on the individual skills of doctors or surgeons than on the methods themselves. In other words, therapeutic methods are not to be mass applied, even where they are repeatedly applied. This confines their economic relevance to the extremely narrow market of the few patients of a given doctor or surgeon. Therefore, it is not necessary to patent those methods in order to appropriate them. Indeed, creative doctors and surgeons will be compensated through increased professional prestige and higher fees. See CARVALHO, *supra* note 6, at 175.

232. Statistics are the basis for any sort of economic, financial, or political decisions made by individuals, firms and governments. Nonetheless, census data does not trigger copyright regulation. *Feist Publ'n Inc. v. Rural Tel. Serv. Co.* 499 U.S. 340, 347 (1991). "The same is true of all facts—scientific, historical, biographical, and news of the day." *Id.* at 348.

those facts. To do otherwise is to distort the patent system and diminish its value as a social and economic tool.

Due to patents' operation as "meters" that society uses to evaluate technology, and because gene patents cannot perform that function, when a patent office grants a patent on a DNA sequence it is in fact delivering a "broken meter." The problem of gene patents is not that they are patents; the problem is that they are *bad* patents.

CONCLUSION

This Article argues that gene patents are not, nor should they be, patentable subject matter. Alternativeness is the first of four substantive conditions of patentability²³³ and genes, as an invention of nature, rather than of man, fail to meet the condition of alternativeness, as identified by the U.S. Supreme Court.²³⁴

The condition of alternativeness is essential for the patent system to work as a social mechanism to accurately meter inventions. Creations, like genes, that cannot be alter-invented are not prone to evaluation through competing market forces. Those creations cannot be accurately metered, which therefore reduces the merit of patents as a tool to reduce transaction costs. Gene patents ultimately undermine the social value of the patent system.

The attention of law-makers and policy-makers must be drawn toward the risks of granting patents for human genes, both in their natural environment and after being identified, isolated, purified, and synthesized. The historical example of the agrarian discontent in the late nineteenth century and the social unrest that arose therefrom should serve as an alert for the risks of tolerating a malfunctioning patent system.²³⁵ In the European Union, such a mistake is a *fait accompli*: the European Directive allows DNA sequences to be patented when the respective genes are isolated and purified and their respective function is clearly stated.²³⁶ The present warning should, therefore, serve as a recommendation for future legislative action by the European Parliament and the European Council. In the United States, the Supreme Court may, at any time, resolve the

233. The other three conditions are novelty, non-obviousness and utility.

234. *LeRoy v. Tatham*, 55 U.S. 156 (1852). *See supra* section 2. This means that inventions are patentable when other persons are able to use or develop other methods, products or devices to employ the same natural principles for the same purposes.

235. *See supra* note 220 and accompanying text.

236. *See supra* note 78 and accompanying text.

issue. It should move to stop current USPTO practices granting patents on DNA sequences, which are based on a misunderstanding of the law.

This Article is not opposed to the patent system. On the contrary, the article's view against gene patents constitutes a defense of a properly functioning patent system. Society will be better off if the patent system works properly—a malfunctioning patent system diminishes competition, creates an imbalance in the distribution of wealth, and slows the pace of invention.