

Edible Equivalents: An Increase in Patent Protection for Genetically Modified Organisms

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GET OUT YOUR FORKS: THE ISSUE IS SERVED

At the close of the nineteenth century, the head of the Patent & Trademark Office exclaimed that everything conceivable had already been invented and that it was only logical for his agency to close.¹ As we enter the new millennium, though, members of the scientific and legal communities can reflect upon a century of incredible innovation in technology and the institutions related to its creation and control. Unfortunately, the law has been playing catch-up with industrial and academic advances.² As a consequence, there are instances where the inadequacies of the current legal framework impede technological development. One such area is the protection of intellectual property³ relating to genetically modified organisms (GMOs).

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1. ALAN L. DURHAM, PATENT LAW ESSENTIALS: A CONCISE GUIDE ix (1999). This oft quoted remark of Charles H. Duell was made in response to the explosion of innovation that occurred in the latter part of the nineteenth century. The administrator's exasperation is quite understandable in light of the flood of new patent applications related to transportation and communication which radically and quickly changed the lives of human beings. *Id.*

2. See, e.g., Ellis, *infra* note 12 and accompanying text.

3. "[I]ntellectual property law' is merely a convenient umbrella term to describe certain intangible products of creativity that society has deemed worthy of protection . . . [in the form of] trademarks, copyrights, patents, trade secrets, and the right of publicity." KENNETH L. PORT ET AL., LICENSING INTELLECTUAL PROPERTY 15 (1999). Many of the same rights that apply to real property also apply to some forms of intellectual property including the right to occupy, use, exclude, and transfer. GORDON V. SMITH & RUSSELL L. PARR, VALUATION OF INTELLECTUAL PROPERTY AND INTANGIBLE ASSETS 240 (2d ed. 1994). Chisum and Jacobs have generally described intellectual property law as "concerned with fostering human creativity without unduly restricting dissemination of its fruits." DONALD S. CHISUM & MICHAEL A. JACOBS, WORLD INTELLECTUAL PROPERTY GUIDEBOOK: UNITED STATES § 1A (1992). "Today more than ever before, the products of the mind—aesthetic, technological, and organizational—are humankind's most valuable assets." *Id.* § 1B.

Both the U.S. Supreme Court and Federal Circuit Court of Appeals⁴ have experienced a great deal of difficulty in applying the old doctrines of infringement litigation to the novel issues created by patenting biotechnology.⁵ While panels at the appellate level waffle, district court dockets are flooded with infringement disputes, and district court judges are left with few usable guidelines to resolve these disputes effectively.⁶ It is imperative, therefore, that the courts adopt a clear and readily applicable framework of analysis to handle the increase in litigation that is likely to result as scientists continue to build upon the patentable work of others.⁷ Uniformity in infringement judgments will be impossible without such a framework.⁸ This, in turn, will create a lack of predictability for those

4. While patent cases may be brought in any federal district court with jurisdiction, appeals are not heard in the eleven regional circuits. See 28 U.S.C. § 1338(a) (1999) (district courts have original and exclusive jurisdiction over "any civil action arising under any Act of Congress relating to patents"). Rather, all patent appeals are heard at the Federal Circuit Court of Appeals sitting in Washington, D.C. 28 U.S.C. § 1295(a) (1999). The "lack of uniform application of the patent law by various regional Circuit Courts of Appeals, and the need to improve the stability of patent law spawned the creation of this court." John B. Pegram, *Should There be a U.S. Trial Court with a Specialization in Patent Litigation?*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 766, 770 (2000). The Federal Circuit Court of Appeals also has appellate jurisdiction over "government claims, international trade, and taxes." *Id.* at 771.

5. The United States is not unique in its struggle with these emerging issues. "European patent law concerning genetically modified organisms is in a mess, and needs to be completely rethought to balance the commercial, ethical and scientific aspects of this difficult question." John R. Porter, *Patent Confusion in Law on New Plant Varieties*, 404 NATURE 13, 13 (2000). Porter and others have called for an "open consensus conference on patenting living things, organized by the EPO [European Patent Office], as the basis for an equitable European way out of the quagmire of patents for genetically modified organisms." *Id.*; see, e.g., Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biological Inventions, 1998 O.J. (L 213 13-21).

6. Approximately forty percent of trial court patent decisions are overruled at the appellate level, thus greatly diminishing the uniformity and finality values of the district court proceedings. See Laurence H. Pretty, *The Judicial Attack on Infringement*, in PATENT LITIGATION 245, 251-52 (1999). Moreover, the problem is compounded by district court judges' sporadic exposure to patent cases, which renders them unable to gain expertise in the application of the law in this practice area. Pegram, *supra* note 4, at 788-89.

7. "The very patentability of genetically engineered life forms is increasing patent activity, even amongst those opposed to the principle of patenting." Ruth McNally & Peter Wheale, *The Consequences of Modern Genetic Engineering: Patents, 'Nomads' and the 'Bio-Industrial Complex'*, in THE SOCIAL MANAGEMENT OF GENETIC ENGINEERING 317 (Peter Wheale et al. eds., 1998).

8. Patent law is "unique in that its primary, if not exclusive, objective is to motivate future behavior," but this goal cannot be met without "some degree of [confidence] of what the law will be across the nation." Rochelle C. Dreyfuss, *The Federal Circuit: A Case Study in*

seeking to develop and protect GMOs.⁹ Such a void will likely decrease investment in research and development, which in turn will cripple innovation and eradicate the benefits that society reaps from it.¹⁰

To address these issues, this Note proposes a new legal framework for the comparison of patented and accused devices¹¹ in GMO patent infringement litigation. Part I provides a primer on the development of genetically modified organisms and their place in science and society. Part II lays out a brief synopsis of patent law and focuses on infringement litigation and the current application of the doctrine of equivalents in the context of infringement litigation. Part III addresses the inadequacies of the current decision making calculus and summarizes a variety of solutions proposed to remedy this deficiency. Lastly, Part IV critiques those proposals and offers a new test of comparison to reform patent infringement litigation for GMOs.

I. GMOs AND THEIR HISTORICAL DEVELOPMENT

A. Definition and Development of GMOs

Professor John Ellis once stated that we are now in the "Third Industrial Revolution,"¹² in which humans can construct organisms to

Specialized Courts, 64 N.Y.U. L. REV. 1, 67-68 (1989).

9. See Pegram, *supra* note 4, at 790 (noting that with an increase in predictability comes a decrease in litigation, as people avoid acts of infringement and parties are more likely to enter into settlement negotiations).

10. This represents the bargain theory of patent protection, which asserts that "people will be encouraged to produce new inventions if there is some reward as an incentive." DURHAM, *supra* note 1, at 14; see also *infra* note 34 and accompanying text. But see Andrew Pollack, *U.S. Hopes to Stem Rush Toward Patenting of Genes*, N.Y. TIMES, June 28, 2000, at <http://www.nytimes.com/library/national/science/062800sci-genome-patents.html> (last visited Feb. 2, 2002) (noting that patenting may lead to a decrease in innovation as companies must conduct time-consuming searches through the "minefield" of existing claims). Cf. McNally & Wheale, *supra* note 7, at 317-18 (claiming that the innovation theory should not be applied to patent law where the creation of monopolies acts as a disincentive to research and development by decreasing the realm of available information to claim and build upon).

11. The alleged infringing entity is referred to as the "accused device." See, e.g., ARTHUR R. MILLER & MICHAEL H. DAVIS, *INTELLECTUAL PROPERTY: PATENTS, TRADEMARKS, AND COPYRIGHT IN A NUTSHELL* 128 (3d ed. 2000).

12. John Ellis, *Why Is Genetic Engineering Important and How Has It Come About?*, in *UNDERSTANDING GENETIC ENGINEERING* 9 (J.C. Murrell & L.M. Roberts eds., 1989). Ellis notes that the first industrial revolution "arose from the application of new sources of energy to

perform specific societal functions.¹³ These GMOs are created by introducing foreign genetic material into the cells of a naturally occurring life form. The insertion takes place at a sufficiently early stage in a cell's development, such that when the organism matures, all of its cells contain the introduced genetic material.¹⁴

Such genetic modifications are only the latest chapter in the age-old tale of human manipulation of plants and animals.¹⁵ Domestication, "the process whereby human management brings morphological changes in plants or animals," is likely to have begun by 12,000 B.C.¹⁶ In its most simple form, domestication involves "the propagation of those plants that yield the most, the largest, or the best in the breeder's judgment."¹⁷ The first and longest period of manipulation commenced as nomadic humans began to settle and

the mass production of goods," and the second from "the extension of information theory to industrial processes." *Id.* Just as the GMO controversy has and will continue to alter the way humans live, these first two revolutions "produced huge sociopolitical upheavals with concomitant changes in legal practice." *Id.*

13. *Id.*

14. U.S. Patent No. 4,405,829 (issued Apr. 12, 1988) (transgenic non-human mammals), reprinted in MILESTONES IN BIOTECHNOLOGY: CLASSIC PAPERS ON GENETIC ENGINEERING 556, 559 (Julian Davies & William S. Reznikoff eds., 1992) ("Transgenic animals carry a gene which has been introduced into the germline of the animal, or ancestor of the animal, at an early (usually one-cell) developmental stage."). For a more technical description of this process, see Lisa A. Karczewski, Comment, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 MCGEORGE L. REV. 1043, 1048-51 (2000); Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1236-39 (2000). This technique is distinct from gene therapy, in which foreign genetic material is inserted into the cells of an organism after development, namely to treat disease. The medical community and the public, however, have greatly scrutinized gene therapy. Interest has heightened since the death of a woman during a 1999 clinical gene therapy trial. See Gretchen Vogel, *FDA Moves Against Penn Scientist*, 290 SCIENCE 2049, 2049 (2000). Since that incident, the FDA has proposed several rules to increase the oversight of clinical trials. See *FDA Proposes More Open Gene Therapy Rules*, REUTERS NEWSWIRE, Jan. 17, 2001 (on file with author).

15. "Humans have been manipulating the genetic make up of plants (and animals) for millennia." Crispin B. Taylor, *Factories of the Future? Metabolic Engineering in Plant Cells*, 10 THE PLANT CELL 641, 641 (1998). Only the pace of that manipulation has recently increased. *Id.*

16. DANIEL E. VASEY, AN ECOLOGICAL HISTORY OF AGRICULTURE: 10,000 B.C.—A.D. 10,000 26 (1992). Morphological changes in plants, an indication of domestication, may have been present as early as 8500 B.C. *Id.* Some scholars make the case for cultivation at 12,000 B.C. *Id.* Primary dependence on domesticated plants and animals dates between 8000 to 4000 B.C. *Id.*

17. *Id.* at 27.

domesticate plants by collecting seeds from the most robust and productive individual plants to sow in subsequent seasons.¹⁸ In the twentieth century, the second phase began when farmers started to deliberately select and sell seeds of improved quality for output and resistance to disease, pests, and drought.¹⁹ Farmers also followed similar practices to breeding animals during these first two periods.²⁰

Approximately thirty years ago, the third stage of management began with the advent of genetic engineering, a cumulative result of advances in biochemistry, molecular biology, and genetics.²¹ Laboratories moved beyond manipulating isolated DNA in test tubes, to cloning genetic material from cells, and finally to inserting foreign DNA into organisms to create GMOs.²² Today, these "transgenic" organisms include a variety of viruses, microbial organisms, plants, and animals.²³ Additionally, many of these organisms have extensive commercial applications in agriculture, medicine, and industrial material manufacturing.²⁴

18. Maarten Koornneef & Piet Stam, *Changing Paradigms in Plant Breeding*, 125 *PLANT PHYSIOLOGY* 156, 156 (2001).

19. *Id.*

20. Taylor, *supra* note 15, at 641. Thus, almost all foods in the human diet were "genetically modified" before the advent of GM technology. See J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 *FOOD & DRUG L.J.* 105, 106 (2000).

21. Robert B. Goldberg, *From Cot Curves to Genomics: How Gene Cloning Established New Concepts in Plant Biology*, 125 *PLANT PHYSIOLOGY* 4, 4-5 (2001). Goldberg also notes that basic genetic engineering was as controversial at its inception as genetically modified organisms are today. *Id.*

22. See generally Koornneef & Stam, *supra* note 18; Goldberg, *supra* note 21. See also Steven H. Yoshida, *The Safety of Genetically Modified Soybeans: Evidence and Regulation*, 55 *FOOD & DRUG L.J.* 193 (2000) ("Unlike selective breeding[,] . . . transgenic technology allows for the selection of individual genes from one species, their transfer to another species, and control over the expression . . . within the new host.").

23. Beales, *supra* note 20, at 107. Beales separates GMOs into three categories. First, there are those with input traits that add a valuable characteristic, such as disease resistance, to aid the producer. *Id.* Second, there is a group of organisms with quality traits that are materially altered in a way that affects the consumer or user. *Id.* For example, rice may be altered to have an increased level of Vitamin A to promote human health. Lastly, "biofactories" are organisms altered to generate a foreign product, such as a bacteria modified to produce synthetic enzymes used in cheese processing. *Id.*

24. For example, a jellyfish luminescence gene has been inserted into potatoes so that it will glow in times of water stress. See *New Super-Spud Glows to Ask for Water*, REUTERS NEWSWIRE, Dec. 18, 2000. The modified potato will act as a marker for unmodified potatoes growing in the same area. *Id.* When the plant experiences water stress, the fluorescence gene will cause its leaves to glow, thus signaling that the entire area is in need of irrigation. *Id.* Pigs

B. The GMO Problem

Scientific progress in genetic research has not enjoyed universal acceptance from either the research community or the public at large.²⁵ From an intellectual standpoint, genetic information resists control because it exists within every living being and will continue to do so regardless of the institutions created to deal with the legal repercussions of its manipulation.²⁶ On a less esoteric plane, there

are now engineered to produce human blood-clotting factors in their milk. Thomas Train Moga, *Transgenic Animals as Intellectual Property*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 511, 530 (1994). The Roslin Institute is developing a method to produce similar drugs in the eggs of chickens. *Dolly Creators to Make GM Chickens to Fight Cancer*, REUTERS NEWSWIRE, Dec. 6, 2000. Scientists expect that eggs will be less expensive and more expedient than milk. *Id.* They also cite the advantages of a "virtually unlimited production process through laying eggs." *Id.* Scientists are also strengthening plant fibers for industrial utilization to reduce the use of, and reliance on, those currently produced from petroleum products. See Chris R. Sommerville & Dario Bonetta, *Plants as Factories for Technical Materials*, 125 PLANT PHYSIOLOGY 168, 168-69 (2001). These products include modified starches, oils, fibers, and polymers. *Id.* at 169-70. Using plant materials as substitutes for synthetics produced from fossil fuels may result in "more sustainable and environmentally benign" industrial practices and preserve petroleum resources. *Id.* at 168. Cf. Taylor, *supra* note 15, at 641 (focusing on the manipulation of metabolic pathways to produce commercially useful products).

25. Perhaps the greatest outcry surrounding genetic engineering has been in response to the development of cloning and its possible extension to human applications. In particular, the focus is on cloning related to, but distinct from, genetic engineering and therapy. In cloning, rather than inserting foreign DNA into another organism, scientists use the original DNA to clone an exact replica of the original organism. While scientists have cloned viruses and microorganisms for decades, their use of the technique in plants and animals is a fairly recent phenomenon. See generally Mark Jagels, Note, *Dr. Moreau Has Left the Island: Dealing with Human-Animal Patents in the 21st Century*, 23 T. JEFFERSON L. REV. 115 (2000) (describing cloning and a recent patent application for human-animal chimeras); *Scientists Clone Endangered Guar But It Dies*, REUTERS NEWSWIRE, Jan. 12, 2001; *Texas Bull Cloned for Disease Resistance*, REUTERS NEWSWIRE, Dec. 18, 2000. For recent developments in cloning technology, see Elizabeth Pennisi, *After Dolly, a Pharming Frenzy*, 279 SCIENCE 646 (1998); A.W.S Chan et al., *Transgenic Monkeys Produced by Retroviral Gene Transfer into Mature Oocytes*, 291 SCIENCE 309 (2001). In contrast to the American situation, other nations have clamored over genetically modified food, but are seemingly more receptive to human cloning. See, e.g., *Britain Gives Green Light for Embryo Cloning*, REUTERS NEWSWIRE, Jan. 22, 2001; *Italian, U.S. Scientists Unveil Human Cloning Effort*, REUTERS NEWSWIRE, Jan. 26, 2001.

26. According to molecular biologist Jonathan King, "the notion that some company has a monopoly on my genes is like claiming ownership of the air." Pollack, *supra* note 10. Cf. Lee M. Silver, *The Meaning of Genes and "Genetic Rights,"* 40 JURIMETRICS J. 9 (1999). Furthermore, "[s]cientific inquiry thrives only in a society that fosters the free flow of ideas and information." Natasha V. Raikhel et al., *The Free Flow of Ideas, Information, and Materials*, 12 PLANT CELL 2297 (2000). The notion that information exists independently in nature contradicts the natural rights theory of patent protection which emphasizes that the "product of mental labor is by right the property of the person who created it." DURHAM, *supra* note 1, at

has been an explosion of public concern, both in the United States²⁷ and abroad,²⁸ regarding genetic modifications, most notably with respect to ethical²⁹ and environmental issues.³⁰ Despite such

15; see also *infra* note 34 and accompanying text.

27. As a result, the Food and Drug Administration (FDA) has proposed regulations to govern genetically modified food, which now occupies two-thirds of the U.S. processed food market. See Andrew Pollack, *F.D.A. Plans New Scrutiny in Areas of Biotechnology*, N.Y. TIMES, Jan. 18, 2001, at A12; see also Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (2001) (to be codified at 21 C.F.R. pts. 192, 592) (proposed Jan. 18, 2001). For an example of an American protest, see Bioengineering Action Network, *Militants Splice Animal Geneticists in Twin Cities*, 20 EARTHFIRST J. ¶ 11-14 (Oct. 14, 2000), available at <http://www.earthfirstjournal.org/feature.cfm?ID=56.html>, which describes a protest against a meeting of the International Society for Animal Genetics at which over eighty people were arrested in two days. The protest was based on the belief that GMOs are another example of animals having "no worth to scientists, corporations, or universities, beyond their economic use" due to the "extreme disregard for the role of non-human animals in the interdependent web of life." *Id.* ¶ 11-12.

28. For example, twenty-eight members of Greenpeace were acquitted on criminal charges in England for protesting the "genetic contamination of the environment." Press Release, Greenpeace, *Greenpeace Volunteers Acquitted in GM Trial* (Sept. 20, 2000) (on file with author). Specifically, the members attacked a genetically modified corn crop by cutting the stalks and sealing the corn in bags. *Id.* In contrast, Italy has placed severe restrictions on GMO research, and in response, has received harsh criticism from the scientific community. Lone Frank, *Italian Scientists Blast GMO Restrictions*, 290 SCIENCE 2046 (2000).

29. Those claiming moral outrage at the patenting of living things "argue that a gene is not an invention, but something that exists in nature, which should be the common heritage of mankind." Pollack, *supra* note 10. This claim begs the question: if genetic information is part of the common heritage, is it *res communis*, common property to be shared and protected by all, or *res nullis*, the property of no one to be exploited by all who have the ability to do so? As the inevitability of GMO development becomes more apparent, the debate is likely to shift to a reevaluation of the release of modified organisms into the wild and of the relationship in technology transfer between nations. See Baruch Brody, *On Patenting Transgenic Animals*, AG BIOETHICS FORUM 7 (Nov. 1995), reprinted in GENETIC ENGINEERING: A DOCUMENTARY HISTORY 56, 60 (Thomas A. Shannon ed., 1999). For a discussion of GMOs and the asymmetrical power structure that allows developed nations to exploit them, see KRISHNA R. DRONAMRAJU, *BIOLOGICAL AND SOCIAL ISSUES IN BIOTECHNOLOGY SHARING* (1999) (addressing international, social, and environmental issues related to biotech sharing); see also Julian Kinderlerer, *Genetically Modified Organisms: A European Scientist's View*, 8 N.Y.U. ENVTL. L.J. 556, 565 (2000) (noting that the acceptance of genetically modified foods in developed nations may be critical to their credibility in the developing world which desperately needs new ways to utilize limited agricultural resources).

30. For the most comprehensive analysis of studies related to the GMOs in the environment, see L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2008 (2000). Wolfenbarger and Phifer reviewed published studies of GMOs in the wild and concluded that "neither the risks nor benefits of [GMOs] are certain or universal," but they "may vary spatially and temporally on a case-by-case basis." *Id.* at 2092. Furthermore, the authors found prospective risk assessment highly unreliable due to an uncertain deficiency of environmental impact assessment data. *Id.* Many in the scientific community believe that GMO research should continue until there is conclusive

resistance, scientists around the world have manipulated genetic information for more than a generation, and will continue to do so.³¹ It is imperative, therefore, for the legal community to focus on fitting the products of this research into the normative structure of society,³²

proof that it is dangerous, but others find support in the study's findings for the need to cut back on GMO research until more definite conclusions have been reached. Carol K. Yoon, *Gene-Altered Crop Studies Are Called Inconclusive*, N.Y. TIMES, Dec. 14, 2000, at A22. See generally Les Levidow & Susan Carr, *Normalizing Novelty: Regulating Biotechnological Risk at the U.S. EPA*, 11 RISK: HEALTH, SAFETY & ENV'T 9 (2000) (describing EPA regulation of GMOs). For an international assessment of these issues, see Lyle Glowka, *Bioprospecting, Alien Invasion Species, and Hydrothermal Vents: Three Emerging Legal Issues in the Conservation and Sustainable Use of Biodiversity*, 13 TUL. ENVTL. L. REV. 329 (1999). Interestingly, another view notes that "concerns about transgenics are virtually absent in the area of medical applications." Koornneef & Stam, *supra* note 18, at 157. George B. Rathman, the first chief executive of Amgen, Inc., the nation's largest biotechnical company, believes that the difference in the need for agricultural applications is not as obvious to the public as "saving your mother's life, which is what biopharmaceuticals have done." Instead, the benefits of agricultural applications must "trickle-down" to the public from the farmer in the form of better products and lower prices. Andrew Pollack, *An Industry Patriarch at the Forefront as Genomics Science Comes of Age*, N.Y. TIMES, Dec. 18, 2000, at C3.

31. See generally Goldberg, *supra* note 21. In fact, nearly 2.5 billion people worldwide are already having intimate contact with GMOs, most notably in the food that they eat. Henrique Friere de Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 ANN. SURV. INT'L & COMP. L. 129, 140 (2000).

32. See Marco Ricolfi, *Bioethics Markets and Morals: The Case of Biotechnological Patents*, in A LEGAL FRAMEWORK FOR BIOETHICS 131, 132 (Cosimo Marco Mazzoni ed., 1998) (noting that there must be "a tradeoff between ultimate goals (values; moral perspectives) . . . and a different innovation . . . , which surely is of paramount importance for our societies but clearly is subordinate, in that allocative efficiency belongs to the realm of means and not of ends"). There is concern that widespread use of genetically modified foods will lead to further degradation of rural life, upon which much of American culture evolved. "[Genetically modified] crops and related technologies are likely to consolidate control over agriculture by large producers and agro-industry, to the detriment of smaller farmers." *Biotech Sees Riches in Weed's Genetic Secrets*, REUTERS NEWSWIRE, Dec. 13, 2000. Cf. Jon Lauck, *After Deregulation: Constructing Agricultural Policy in the Age of 'Freedom to Farm*, 5 DRAKE J. AGRIC. L. 3 (2000) (addressing a variety of problems associated with farming, legislation, and technology in the second half of the twentieth century including the extension of usurious loans to small farmers by conglomerates, which, at times, resulted in conditions amounting to "poultry peonage"); Paul S. Naik, *Biotechnology Through the Eyes of An Opponent: The Resistance of Activist Jeremy Rifkin*, 5 VA. J.L. & TECH. 5 (2000) (listing the dangers on increasing protection for GMO and the need to balance the promotion of innovation with the protection of society and the environment). But see Jeremy P. Oczek, Note, *In the Aftermath of the "Terminator Technology" Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Right to Save and Replant Seed*, 41 B.C. L. REV. 627 (2000) (arguing that farmers should not get the benefit of seed technology without having to provide the creator with just compensation). Oczek goes on to say that "terminator" genes allow companies to ensure that they will be paid yearly for the use of their technology. For a more general discussion of these issues, see ROSEMARY J. COOMBE, *THE CULTURAL LIFE OF INTELLECTUAL*

and to develop new principles to deal with their entry into the competitive economy.³³

II. PATENTS, INFRINGEMENT LITIGATION, AND THE DOCTRINE OF EQUIVALENTS

A. Patent Law Primer

1. Legal Basis

The U.S. Constitution grants Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."³⁴ Congress used this authority to create a system that encourages risk-based investment³⁵ within our

PROPERTIES: AUTHORSHIP, APPROPRIATION, AND THE LAW (1998).

33. In the first modern case concerning the patenting of a living organism, the Supreme Court noted that "[t]he grant or denial of patents on micro-organisms is not likely to put an end to genetic research or its attendant risks," but "whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives." *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980). Likewise, the same logic applies to the outcome of infringement litigation, as both concerns turn on the predictability of return at the time of investment. Thus, the central question, when applying for a patent, is whether the government will reward the applicant's investigation with a patent. In contrast, when the holder of a patent anticipates litigation, the question becomes whether the patent will protect the patentee from infringement by competitors.

34. U.S. CONST. art. I, § 8, cl. 8. The courts purposely construe this clause broadly. See FLOYD L. VAUGHAN, *ECONOMICS OF OUR PATENT SYSTEM* 180 (1925) (noting that the Patent Clause has been "bent to purposes and facilitated results never intended or expected by the framers of the constitution or the patent statutes") After all, the clause contemplates nothing more than innovation and advancement, and assumes that the government should act to further these goals. For a discussion of fitting recent scientific tools within the purview of the Constitution, see IRA H. CARMEN, *CLONING AND THE CONSTITUTION: AN INQUIRY INTO GOVERNMENTAL POLICYMAKING AND GENETIC EXPERIMENTATION* (1985). Interestingly, inventors did have property rights at common law, but those rights were ill-defined and could not provide the requisite stability needed for large scale innovation. FRANK E. ROBBINS, *THE DEFENSE OF PRIOR INVENTION: PATENT INFRINGEMENT LITIGATION* 207 (1977) (citing F. Gabrell, *The Constitution and the In Personam Defense of First Invention*, 39 J. PAT. OFF. SOC'Y 791, 802-08 (1957)).

35. Such investments spur innovation, which both requires and creates jobs, goods, and trade benefits. See ROBERT L. HARMON, *PATENTS AND THE FEDERAL CIRCUIT* 6 (1988) (citing *Locite Corp. v. Ultraseal Ltd.*, 781 F.2d 861 (Fed. Cir. 1985); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594 (Fed. Cir. 1985). Harmon argues that the patent system creates a "negative incentive to design around" a patented product because of the wide scope of the monopoly. This breadth ensures a "steady flow of innovations to the marketplace" as competitors try to improve on one

competitive economy.³⁶ In short, the patenting of an invention creates a monopoly³⁷ in the invention by giving the patentee the powerful right to exclude all others³⁸ from using the invention except in those instances where the patentee chooses to transfer her rights through a sale or to exploit those rights through a licensing agreement.³⁹

another's products and find their own product niche. *Id.* (citing *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226 (Fed. Cir. 1985) (holding that such innovation should not be hampered by giving patentees the right to punitive damages)). For a general discussion of the interplay between the Uniform Commercial Code (U.C.C.) and patent law, see PETER A. ALCES & HAROLD F. SEE, *THE COMMERCIAL LAW OF INTELLECTUAL PROPERTY* (1994).

36. See HARMON, *supra* note 35, at 6. Note that the express purpose of granting greater property rights to patentees than to other owners of intellectual property is to encourage invention, and to thereby benefit the development of science and technology. See Kenneth L. Port, *Foreword: Symposium on Intellectual Property Law*, 68 CHI-KENT L. REV. 585, 590-94 (1993), reprinted in KENNETH L. PORT ET AL., *LICENSING INTELLECTUAL PROPERTY* 16 (1999). Port describes the incentive theory of patents, which holds that patentees are encouraged to create innovative inventions as a monopoly guarantees them the sole claim to any profits derived from those inventions. *Id.* While this theory satisfies the economic analysis of patent rights, it does not counteract the concern discussed in the introduction of this Note which states that information resists control. Port's second justification for the patent monopoly stems from a natural rights argument grounded in this vein: "an inventor should own title to the creations of his/her mind." *Id.* While the creator can always claim ownership within the realm of ideas, she must have some way of enforcing those property rights against others. The statutory scheme and patent system fill this void. In a reflection on these concepts, Rines concluded, "[t]he American patent system needs no apologists." ROBERT H. RINES, *CREATE OR PERISH: THE CASE FOR INVENTIONS AND PATENTS* 1 (1925). Furthermore, "[c]reativity and any obstacles to it that exist or are put in its path are the concern of every person in the United States, and apply to every section of society and to every field of endeavor." *Id.* at 145.

37. See 35 U.S.C. § 154 (West 1984). The monopoly exists for twenty years from the date of application. In certain situations, this enforcement period can be extended for an additional five year period. 35 U.S.C. § 156(g)(6) (West 1984). A patent, however, cannot be renewed. Thus, when the patent expires, the invention enters the public domain, allowing anyone to use, make, or sell products covered by the patent claims.

38. See 35 U.S.C. § 261 (West 1984). There are a variety of strategic uses for patents. Most obviously, the patentee can exploit the patent to attract investments in the development of the invention for use in commerce. Likewise, an additional option for a patentee is licensing. See generally ALAN S. GUTTERMAN & JACOB N. ERLICH, *TECHNOLOGY DEVELOPMENT AND TRANSFER: THE TRANSACTIONAL AND LEGAL ENVIRONMENT* 28 (1997); see also *infra* note 39 and accompanying text.

39. For example, after an inventor develops a patented technology, she may realize that she does not have sufficient funds to produce and market it in commercial quantities. The inventor may then choose to enter into a contract in which she gives someone else permission to use the patented device for a certain length of time. In return, the inventor receives a set fee and royalties derived from the profits generated by the invention's use. For an extensive discussion of licensing, see PORT ET AL., *supra* note 3. Unpredictability regarding infringement litigation affects licensing in two ways. First, there is little reason to obtain a license if a non-patentee user does not believe that the use, or modified use, of the device will result in an accusation of infringement. Second, if a licensee accepts responsibility for defending against unlawful

2. Patent Requirements

In order for an invention to receive a patent from the U.S. Patent and Trademark Office (PTO), the patentee must meet several legal standards.⁴⁰ First, the utility requirement demands that the invention be useful at the time the patent is issued.⁴¹ Next, the invention must be novel with respect to the prior art⁴² and not obvious to others who are "skilled in the art."⁴³ Further, the specification⁴⁴ within the

infringement, the risk of loss to the licensee will increase with the possibility of litigation. GORDON V. SMITH & RUSSELL L. PARR, VALUATION OF INTELLECTUAL PROPERTY AND INTANGIBLE ASSETS 372 (2d ed. 1994). As such, this will decrease potential income, the primary indicator of value, generated by the patent. *Id.* at 298. This can have a variety of effects, all of which are negative for the patentee. The licensee may withdraw from the deal or demand that the patentee defend all infringements. Alternatively, the licensee may seek to offset this potential risk by paying a lower royalty to the patentee. Thus, the potential resolution of infringement issues is intrinsic to the valuation of patented intellectual property. *Id.* at 31.

40. See generally DURHAM, *supra* note 1, at 61-114 (stating that 35 U.S.C. § 101 requires that the patented product or method be new, useful, and non-obvious).

41. See 35 U.S.C. § 101 (West 1984) (requiring that the patented device have some use that is not speculative). Applicants rarely have trouble meeting this requirement. See CHISUM & JACOBS, *supra* note 3, at 12-1; see also Anderson v. Natta, 480 F.2d 1392 (C.C.P.A. 1973) (holding that the statute requires no "quantum" of benefit). But see Brenner v. Manson, 383 U.S. 519 (1966) (illustrating a patent rejection on the grounds of utility). In Brenner, the Court refused to uphold a patent for a steroid producing process where there was no disclosed use for the steroid. Holding such a patent valid, the court reasoned, would stifle an entire area of scientific development with little benefit to the public. *Id.* at 534-35. Subsequent decisions have interpreted Brenner as requiring "substantial utility." See, e.g., *In re Kirk*, 376 F.2d 936 (1967). This standard may no longer be valid in light of the recent debate regarding the patentability of genetic sequences of unknown function discovered during the Human Genome Project. The PTO has issued guidance for the utility requirement that would only require the asserted use to be "credible." See 60 C.F.R. 36163 (July 14, 1995).

42. "Art" describes all of the patentable intellectual property that passes into the public domain after individual patent monopolies expire. See generally MILLER & DAVIS, *supra* note 11, at 82-87.

43. The non-obviousness requirement may be the most difficult aspect to overcome. 35 U.S.C. § 103 (1999). The relevant viewpoint is that of a person skilled in the art in question. The USPTO and the courts must decide whether someone working in the field could have looked at the prior art and come up with the same invention with little or no investment meaning that prior art contains all the elements of the invention and teaches a reasonable probability that the invention would succeed. See *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877 (Fed. Cir. 1998) (determining the scope of the prior art by the inventor's endeavor); *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861 (Fed. Cir. 1985) (obviousness must be determined as of the time of patenting and not with the benefit of hindsight); *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (stating that "the scope and content of the prior art are determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved). For an extensive analysis of the non-obviousness requirement, see NONOBVIOUSNESS—THE

inventor's application must enable the invention's use and disclose the patentee's best made⁴⁵ of practicing the invention. Lastly, the claims⁴⁶ within the patent must be definite and represent a full and clear disclosure of the invention.⁴⁷

3. GMO Patents

For generations, Congress purported to prohibit the patenting of biological organisms.⁴⁸ A major shift in this policy came in the 1930 Plant Patent Act, which extended patent-like protection to asexually reproducing plants that are discovered in cultivated settings.⁴⁹ The Act aimed to give those involved in agriculture the same opportunities as other inventions by providing "a sound basis for investing capital in plant breeding and consequently stimulate plant

ULTIMATE CONDITION OF PATENTABILITY: PAPERS COMPILED IN COMMEMORATION OF THE SILVER ANNIVERSARY OF 35 U.S.C. § 103 (John F. Witherspoon ed., 1980), containing many papers written by those who were present during the drafting and adoption of the requirement.

44. The "specification" is the invention's description within the patent application that allows someone skilled in the art to reproduce the invention, using the patent as a blueprint. See MILLER & DAVIS, *supra* note 11, at 10-11.

45. 35 U.S.C. § 112 ¶ 1 (1999). This requirement seeks to obtain full disclosure from the patentee. In other words, the patentee cannot know of two ways to make a product, one better than the other, and only choose to disclose the latter in the patent. One can think of this demand as a tradeoff for receiving a twenty year monopoly over that which you disclose. See *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923 (Fed. Cir. 1990) (discussing the best method from the perspective of someone skilled in the art by setting out a two-part test to determine the inventor's subjective knowledge of the best method along with an objective inquiry on the adequacy of the disclosure).

46. "Claims" are the patentable features of the patent or process that distinguish the invention from the prior art. See MILLER & DAVIS, *supra* note 11, at 10. Whereas the specification tells someone how to make and use the invention, the claims define the invention protected by the patent and what rights are due to the patentee. *Id.* at 110.

47. 35 U.S.C. § 112 (West 1984). This requires that the patent draw the boundaries around the sphere of ingenuity, which it wishes to claim. The test is "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." DURHAM, *supra* note 1, at 66 (quoting *Beachcombers v. Wildwood Creative Prods., Inc.*, 31 F.3d 1154, 1158 (Fed. Cir. 1994)); see also *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) (invalidating claims to recombinant plasmids and transgenic micro-organisms because the specifications did not adequately describe the claimed cDNA).

48. See, e.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); *In re Bergy*, 563 F.2d 1031 (C.C.P.A. 1977); *Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991). Even with these limitations, the PTO issued a patent on a living organism, yeast, to Louis Pasteur. Specifically, the patent claimed, "yeast, free from organic germs of disease, as an article of manufacture." See *Leder & Stewart*, *supra* note 14.

49. 35 U.S.C. § 161 (West 1984).

development through private funds."⁵⁰ The resulting protection of breeders' rights allowed for greater research and development, which in turn, provided the public with immediate benefits from improved plants.⁵¹

In *Diamond v. Chakrabarty*,⁵² the Supreme Court upheld the first explicit GMO utility patent issued in the United States. The Court found that a live human-made microbe constituted patentable subject matter as either a "manufacture" or "composition of matter" within the meaning of U.S. patent law.⁵³ It is now generally accepted that living, human-made, but non-human in form, organisms are patentable subject matter.⁵⁴ The scope of this entitlement may include the organism itself as well as the method or process used to produce the organism.⁵⁵ Subsequent patents have been issued for the first transgenic plants, created in the 1980s with the transfer of a bean gene into sunflower and tobacco plants.⁵⁶ Additionally, patents have been issued for mammals, including the first transgenic mouse.⁵⁷

50. S. REP. NO. 315 (1930), quoted in *In re LeGrice*, 301 F.2d 929, 934 (C.C.P.A. 1962).

51. In the 1970 Plant Variety Protection Act, congress extended *sui generis* protection to sexually reproducing plants. 7 U.S.C. § 2402(a) (1999).

52. 447 U.S. 303 (1980).

53. See Charles E. Lipsey & Amy L. Tsui Collins, *Patent Infringement in the Field of Biotechnology*, in UNDERSTANDING BIOTECHNOLOGY LAW: PROTECTION, LICENSING, AND INTELLECTUAL PROPERTY POLICIES 239 (Gale R. Peterson ed., 1993) (citing 35 U.S.C. § 101) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may contain a patent thereof, subject to the conditions and requirements of this title.")

54. The Court noted, however, that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter." Likewise, Einstein could not patent his celebrated law that $E=mc^2$ nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

55. The result is that the claim to an organism includes all of the avenues one may pursue to create that organism. "The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101." Naturally occurring organisms cannot be patented, but can provide a basis for alteration, the product of which will be patentable. See *In re Bergy*, 563 F.2d 1031, 1046 (C.C.P.A. 1977).

56. Shain-dow Kung, *Introduction: From Hybrid Plants to Transgenic Plants in TRANSGENIC PLANTS: VOLUME 1: ENGINEERING AND UTILIZATION* 8 (Shain-dow Kung & Ray Wu eds., 1993); see, e.g., *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. Int. 1985).

57. U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

B. Infringement: Don't Tread On Me . . . Or My Patent

Patent infringement involves the making, using, or selling of any patented invention during the term of the patent without the patentee's authorization.⁵⁸ The patentee may sue anyone whom she believes is infringing on the claims of her protected invention.⁵⁹ Initially, she will seek a temporary restraining order (TRO) and preliminary injunction to prevent the infringing party from practicing the invention.⁶⁰ If the matter proceeds to trial, the court will first examine the patent's claims to determine the scope of its protection.⁶¹ Much of this determination will depend upon the language used in

58. See 35 U.S.C. § 271(a) (West 1984). Note that there is no intent requirement in the statutory definition of infringement, therefore it is not a defense for the infringing party to claim that she was unaware that the patent existed. See also *Winans v. Denmead*, 56 U.S. 330, 343 (1853) (stating that "[t]he exclusive right to the thing patented is not secured, if the public are at liberty to make substantial copies of it, varying its form or proportions"). Patent infringement is not to be confused with patent interference. The latter involves a determination of the priority of invention between patentees claiming substantially the same invention. Thus, the parties to an interference dispute are both claiming that they are rightly entitled to the protections of the patent while a defendant in an infringement action argues that either the patent is invalid, unenforceable, or that she has not violated the monopoly it creates. See MAURICE H. KLITZMAN, *PATENT INTERFERENCE: LAW AND PRACTICE* xxiii (1984).

59. See 35 U.S.C. § 281 (West 1984). The patentee must prove infringement by a preponderance of the evidence. *E.g.*, *Amistar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1545 (Fed. Cir. 1987). The defendant will only bear the burden of proving an affirmative defense when the plaintiff meets the requirements of 35 U.S.C. § 295. *Genentech, Inc. v. Boehringer Mannheim*, 47 F. Supp. 2d 91, 108 (D. Mass. 1999). Note that the protection afforded by the patent only applies within the United States. To secure rights to the invention in other nations, the patentee must separately apply for patents in those countries. Brian G. Brunsvold & D. Patrick O'Reilly, *Intellectual Property Rights—What Are They and How Does A Company Secure Them?*, SF24 A.L.I.-A.B.A. 359, 362 (2000).

60. 35 U.S.C. § 283 (West 1984). TRO and preliminary injunctions are equitable decisions that the court may make in order to protect the rights of the parties until the substantive issues in the dispute can be determined at trial. Michael E. Melton, *"The Real Ordinance" (TRO) for Patent Enforcement*, 619 PLI/PAT. 371, 377 (2000). Before issuing the TRO, the court will balance: (1) the likelihood that the patentee will succeed on the merits of the dispute, (2) the prospect of irreparable harm if the accused infringing party to permitted to continue production or use, (3) whether justice in light of the hardships faced by each of the parties requires that the patentee be granted an injunction, and (4) the effect of the TRO on the public interest. *E.g.*, *Hybritech, Inc. v. Abbott Laboratories*, 849 F.2d 1446, 1451 (Fed. Cir. 1988).

61. See DONALD S. CHISUM & MAXIM H. WALDBAUM, *ACQUIRING AND PROTECTING INTELLECTUAL PROPERTY RIGHTS* § 14.02 (2000). The court will hold a pretrial, in reality, exact timing may vary, "Markman hearing" to allow both the patentee and defending party to present their interpretations of the claim. After this hearing, the court may either adopt one of the proposed constructions or develop one of its own. *Id.*

the patent itself⁶² and can only be supplemented with expert testimony when the language is ambiguous.⁶³ The trier of fact will then compare the claims patent to the accused device.⁶⁴

When there is an identical match between the patented claims and the accused device, the accused party's device has literally infringed on the patent.⁶⁵ In the absence of an identical match, the patentee is still protected under the principles of non-literal infringement that are embodied within the doctrine of equivalents,⁶⁶ which allows the reviewing body to go beyond the literal language of the patent.⁶⁷ The

62. It is important to keep in mind that "[p]atent claims are composed solely of words, and as such may imperfectly reflect the intent of their draftsman." Kurt L. Glitzenstein, *A Normative and Positive Analysis of the Scope of the Doctrine of Equivalents*, 7 HARV. J.L. & TECH. 281, 281 (1994) (citing Zechariah Chafee Jr., *The Disorderly Conduct of Words, in FREEDOM'S PROPHET* 35 (Edward D. Re ed., 1981)). Similar to applying contract principles, the reviewing body must "temper the strict literal meaning of words by exempting the parties from the rigid structure imposed by the traditional doctrine of integration and the parol evidence rule" in its interpretation of the claims. *Id.* at 290. Judge Learned Hand noted that in this respect, greater liberties are taken in the interpretation of patents than in other areas of law. See LEARNED HAND ON PATENT LAW (Paul H. Blaustein ed., 1983) [hereinafter Blaustein]. Thus, the patentee can serve as her own lexicographer, but must provide definitions that differ from the ordinary meaning given to terms somewhere in the patent application or within her correspondences with the PTO; when she fails to do so, the court will understand the terms to mean what they would to someone skilled in the art of the invention. See *Genentech, Inc. v. Boehringer Mannheim*, 989 F. Supp. 359, 363 (D. Mass. 1997).

63. See *Vitronics Corp. v. Conceptonic, Inc.*, 90 F.3d 1576, 1585 (Fed. Cir. 1996) (predicting that these "instances will rarely, if ever, occur"). Thus, the court is generally limited to the claims, specification, and file history established during the application process. See *Monsanto Co. v. Mycogen Plant Science, Inc.*, 61 F. Supp. 2d 133, 150 (D. Del. 1999).

64. Glitzenstein, *supra* note 62, at 281. *But see* Pegram, *supra* note 4, at 769 (claiming that the use of juries in patent trials is not on the rise, contrary to the popular belief of the legal community, and actually accounts for only three percent of all patent cases).

65. See DONALD CHISUM, PATENTS § 18.04 (2000); see also Glitzenstein, *supra* note 62, at 282.

66. The Supreme Court first established the doctrine of equivalents in *Winans v. Denmead*, 56 U.S. 330 (1853). In that case, the Court stated that no patent can be granted for a mere change in the form of an existing device. "To copy the principle or mode of operation described, is an infringement, although such copy should be totally unlike the original in form or proportion." *Id.* at 342. Absent a patentee's express intent to restrict her claims, the presumption is that she sought to cover as many claims as the prior art would allow. *Id.* at 341. An inventor, having the right, would cover and protect the whole invention. *Id.*

67. Judge Hand stated that "after all aids to interpretation have been exhausted, and the scope of the claims has been enlarged as far as the words can be stretched, on proper occasions courts make them cover more than their meaning will bear." *Royal Typewriter Co. v. Remington Rand, Inc.*, 168 F.2d 691, 692 (2d Cir. 1948); see also *Graver Tank Co. & Manufacturing v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950). "[T]o permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of

doctrine states that infringement exists when all elements of the invention are substantially equivalent to the elements of the accused device such that one skilled in the art would know of their interchangeability.⁶⁸ The doctrine does not expand the claims of the patent, but rather "expands the right to exclude the 'equivalents' of what is claimed" to account for minor changes and substitutions.⁶⁹ Findings of infringement under the doctrine of equivalents, however, are exceptions rather than the rule. Thus, the public can rely on the language of the claims rather than a prediction of what the courts may determine is the equivalent of that language.⁷⁰

The doctrine has several limitations to further this goal. For example, it cannot broaden the patent monopoly to include prior art. The rationale for this restraint is that the prior art is in the public

the patent grant into a hollow and useless thing." *Id.* Without the doctrine of equivalents, "the inventor [is] at the mercy of verbalism and would be subordinating substance to form." *Id.* The doctrine is not to be confused with the determination of equivalence under 35 U.S.C. § 112(6) in the context of means-plus-functions claims. This is in fact a subset of the literal infringement inquiry and asks if the accused performs the function claimed, and if so, whether performed by a structure that is identical or equivalent to that disclosed in the patent. DURHAM, *supra* note 1, at 146 (citing *Pennwalt Corp. v. Durland-Wayland Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987); *King Instruments Corp. v. Perego*, 65 F.3d 941, 945-46 (Fed. Cir. 1995); *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388-89 (Fed. Cir. 1992)).

68. See Mary S. Consalvi, *Objective Indicia of Equivalence and Nonequivalence*, 532 PLU/PAT. 265, 272 (1998); see also *Autogiro Co. of America v. United States*, 384 F.2d 391, 400 (Ct. Cl. 1967) (explaining that the doctrine forms a "penumbra [of protection] which also must be avoided if there is to be no infringement"); *Envtl. Instruments, Inc. v. Sutron Corp.*, 877 F.2d 1561, 1565 (Fed. Cir. 1989) (ruling that the "essence of the doctrine of equivalents is that it permits recovery for infringement where the accused device does not fall within the literal scope of the claims and is, therefore, outside their literal scope"); *Jurgens v. McKasy*, 927 F.2d 1552, 1560 (Fed. Cir. 1991) (noting that "[e]ven where there is no literal infringement, infringement may still be found under the doctrine of equivalents if the limitation or limitations not literally present are by there equivalents").

69. *Wilson Sporting Goods Co. v. David Goeffrey & Assocs.*, 904 F.2d 677, 684 (Fed. Cir. 1990), *cert. denied*, 111 U.S. 537 (1990). Non-literal infringement serves as a judicially created equitable doctrine that prevents the subtle pirating of a patentee's invention. See Lipsey & Collins, *supra* note 53, at 268.

70. See *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991) (noting that without such a limitation, "claims will cease to serve their intended purpose [and] [c]ompetitors will never know whether their actions infringe a granted patent"); see also *Sage Products, Inc. v. Devon Indus.*, 126 F.3d 1420, 1425 (holding that "as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection"). *But see Pretty, supra* note 6, at 260 (concluding that the foreseeability that these cases demand is often impossible to obtain, and it is exactly this deficiency that the doctrine of equivalents should be used to correct).

domain and belongs to everyone.⁷¹ This standard requires the reviewing body to draw a hypothetical claim that includes both the patent and accused device. If prior art lies within the hypothetical umbrella of coverage, then there is no infringement under the doctrine of equivalents.⁷² Generally, where a patent is a major departure, the range of equivalents is quite large, but when limited to avoid prior art, the scope of the doctrine's protection is limited.⁷³ The second limitation is referred to as prosecution history estoppel, and precludes patentees from including claims that were given up in order to obtain the patent.⁷⁴ Thus, the scope of the patent may not include anything that will circumvent the limitations that the PTO placed on the patent when accepting the patentee's application.⁷⁵

When the court finds that infringement has occurred, either literally or under the doctrine of equivalents,⁷⁶ it will usually issue a

71. See Lipsey & Collins, *supra* note 53, at 271. The patentee cannot use the doctrine to give herself something that she could not have gotten when she filed her patent application with the PTO. See *Wilson Sporting Goods*, 904 F.2d at 684.

72. See *id.* at 684.

73. The default in this analysis is that the patent's actual language leads to a small range of equivalents because no one can be sure of what the patentee and the USPTO officer said during prosecution. See, e.g., *Intervet Am., Inc. v. Kee-Vet Labs., Inc.* 887 F.2d 1050, 1054 (Fed. Cir. 1989).

74. This concept is also known as file wrapper estoppel because the file wrapper is the entire history of the patent prosecution including the initial application, suggestions made by the patent examiner, and replies of the patentee in response to those suggestions. See, e.g., *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 870 (Fed. Cir. 1985).

75. This determination is highly dependant on the "nature and purpose" of the amendment, as well as any arguments made during the patent's prosecution. *Id.* at 871. They "may have a limiting effect within a spectrum ranging from great to small to zero." *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1363 (Fed. Cir. 1983). Naturally, when the patentee makes the amendment for some reason other than avoiding prior art, it is unlikely that she will be estopped from using the doctrine of equivalents. Furthermore, if the patentee makes an amendment to one element to avoid copying the prior art, but the amendment does not affect a second element, the patentee will be able to assert equivalence with respect to the latter. See Lipsey & Collins, *supra* note 53, at 272; see also *Festo Corp. v. Shoketsu Kinzokv Kogyo Kabushiki, Co., Ltd.*, 234 F.3d 558 (Fed. Cir. 2000).

76. Even when infringement has occurred, the infringing party may assert an affirmative defense. See 35 U.S.C. § 282(1)-(4) (West 1984). These include claims that: (1) the patent issued by the PTO was invalid, (2) the patentee is guilty of misuse for trying to extend the patent beyond the monopoly granted by the PTO, or (3) the patent is unenforceable because of inequitable conduct on the part of the patentee during prosecution. The defendant has the burden of proving these claims by a preponderance of the evidence. See generally *THE ANTITRUST COUNTERATTACK IN PATENT INFRINGEMENT LITIGATION* 21-38 (Richard G. Schneider ed., 1994) [hereinafter *THE ANTITRUST COUNTERATTACK*]; see also *Enzo Biochem*,

permanent injunction to prevent further damage to the patentee's rights.⁷⁷ Additionally, the infringing party may be liable to the patentee for extensive damages related to any lost profits caused by the infringement.⁷⁸ The collective goal of these remedies is to put the patentee in the position she would have been in had the infringement never taken place.⁷⁹

C. Modern Applications of the Doctrine of Equivalents

The Supreme Court set forth the modern statement of the doctrine of equivalents in *Graver Tank & Manufacturing Co., Inc. v. Linde Air Products Co.*,⁸⁰ in which it stated that the doctrine applied where the accused device "performs the substantially same function in substantially the same way to obtain the same result" as the claimed invention.⁸¹ The "function/way/result" test, however, offered no

Inc. v. Calgene, Inc., 188 F.3d 1362, 1370 (Fed. Cir. 1999) (finding that a patent is not valid when its specifications do not enable the use of "anti-sense" technology, which is, required for the use of the invention).

77. See THE ANTITRUST COUNTERATTACK, *supra* note 76, at 40.

78. See 35 USC § 284 (West 1984). The Patent Act creates a cause of action for infringement. *Rite-Hite Corp. v. Kelly Co.*, 56 F.3d 1538, 1551 (Fed. Cir. 1995), *cert. denied*, 116 U.S. 184 (1995) (citing *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1578 (Fed. Cir. 1991)). The first step in this process is to actually enjoin the infringing party from using the protected property. See 35 USC § 283 (West 1984). See generally ERIC M. DOBRUSIN, INTELLECTUAL PROPERTY LITIGATION: PRETRIAL PRACTICE GUIDE 51-52, 87-123 (1996). Injunctions are readily granted upon a clear showing that the accused device is infringing in fact. GUTTERMAN & ERLICH, *supra* note 38, at 30. The patentee is also entitled to damages and a permanent injunction for the remaining life of the patent. *Id.* (citing *Roche Prods. Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984)). The upper bounds of the possible damages will be the profits lost from the infringement. These may be calculated according to sales made by the infringer, price reductions made in response to an infringer's competition, and a loss in sales growth resulting from the patentee being forced to raise prices. *Id.* (citing *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065-68 (Fed. Cir. 1983)). At a minimum, the patentee will receive reasonable royalties calculated over the period of infringement as adjusted for interest and costs. *Id.* Treble damages may be available in the case of willful infringement. *Id.*

79. GUTTERMAN & ERLICH, *supra* note 38, at 30.

80. 339 U.S. 605 (1950).

81. *Id.* at 608 (citing *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929)). Note that the proofs of these elements cannot be subsumed in the proofs for literal infringement, though the latter may have a bearing on equivalence. See generally *Nestier Corp. v. Menasha Corp.-Lewisystems Division*, 739 F.2d 1576 (Fed. Cir. 1984), *cert. denied*, 470 U.S. 1053 (1985). Thus, the trier of fact is left with little more than the advice to read the specifications liberally, in accordance with the design of the Constitution and U.S. patent laws. These seek to

guidance on how that comparison should be conducted because it does not further define the meaning of the test's linguistic elements.⁸²

In an attempt to solve this problem, the Court extensively revised the test in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*⁸³ The Court now advocates a standard of comparison that asks whether a person of ordinary skill in the relevant art would have known of the interchangeability of the features of the patent claim and the accused device.⁸⁴

When comparing two elements under this standard, the reviewing body must examine the circumstances surrounding the purpose and function of the claimed element.⁸⁵ Thus, what constitutes equivalency must be

determined against the context of the patent, prior art, and the particular circumstances of the case . . . Consideration must be given to the purpose for which an ingredient is used in the patent, the qualities it has when combined with other ingredients, and the function which it is intended to perform.⁸⁶

Additionally, the trier of fact should give considerable weight to the status of the invention. This will allow for a larger realm of equivalents where the invention represents a wide variation from the prior art.⁸⁷ All of these determinations are made at the time of the

promote the progress of the useful arts by allowing inventors to retain the use of their own creation. *Winans v. Denmead*, 56 U.S. 330, 341 (1853).

82. See *Consalvi*, *supra* note 68, at 268; see also *Glitzenstein*, *supra* note 62, at 283 (arguing that this test does not provide a "yard stick" to conduct that comparison).

83. 520 U.S. 17 (1996).

84. *Id.*

85. *Genetech, Inc. v. Wellcome Foundation Ltd.*, 14 U.S.P.Q.2d 1363, 1371 (D. Del. 1990) (explaining part of the doctrine of equivalents analysis in a pre-*Warner-Jenkinson* setting).

86. *Id.*

87. A pioneering invention is almost completely unrestrained by prior art. See *Glitzenstein*, *supra* note 62, at 287. A secondary invention is an advancement on some other invention that operates as an outside limit on how far one can extend the range of equivalents ascribed to the secondary invention. *Id.*; see also *Autogiro Co. of America v. United States*, 384 F.2d 391, 401 (Ct. Cl. 1967):

A pioneer parent which occupies symbolically a six-inch circle will have three inches of equivalence if its range is fifty percent. An improvement patent occupying a two-inch circle has only one inch of equivalence with the same range. Thus with relatively

alleged infringement.⁸⁸

Warner-Jenkinson also elevates the importance of the all-elements test,⁸⁹ as it requires a court to find equivalence for every limitation of the patented device.⁹⁰ Though the rule requires a finding of equivalence somewhere in the accused device, it need not be in a corresponding location.⁹¹ Furthermore, claimed elements can be combined in the accused entity in order to meet the test.⁹² The all-elements test is more difficult for the patentee to satisfy than the "function/way/results test because the patent will not be able to focus on the invention as a whole to draw attention away from specific claim limitations that may be absent. This increase in stringency represents the Court's decision to promote predictability and certainty in patent law rather than allowing a patentee to correct her patent's deficiencies during litigation."⁹³

III. APPLICATION OF THE DOCTRINE TO BIOTECHNOLOGY: PREDICAMENT AND PROPOSALS

The Court's decision to demand an all-elements analysis is indicative of the courts' and public's frustration with the doctrine of equivalents. Inventors do not have perfect foresight, but still desire protection against an infringing party who may make minor unforeseeable changes to avoid literal infringement. There is also a need, however, to provide sufficient public notice regarding the specific intellectual property that is claimed in each patent.⁹⁴

identical ranges, the scope of the patent provides the pioneer patent with absolutely a larger range of equivalence.

Even a pioneer invention, however, can not be accorded a range of equivalents broader than its mode of operation. *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 684 (Fed. Cir.), *cert. denied*, 498 U.S. 992 (1990).

88. *Warner-Jenkinson*, 520 U.S. at 37.

89. *Id.* at 29.

90. *See Pennwalt Corp. v. Durland-Wayland Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987).

91. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1259 (Fed. Cir. 1989).

92. *Sun Studs, Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 989 (Fed. Cir. 1989).

93. *See Consalvi*, *supra* note 68, at 293.

94. "The claim was not intended to be verbally definitive, but to cover the 'invention' which should, to some extent anyway, be gathered from the disclosure at large." *Claude Neon Lights, Inc. v. E. Machlett & Son*, 36 F.2d 574, 575 (2d Cir. 1929) (citing *Winans v. Denmead*,

The uncertainty surrounding the application of the doctrine of equivalents does not further either of these purposes. It frustrates a competitor's ability to design around the patent, impedes the discovery of ways to gain the advantages of the invention without infringing upon it, and forecloses accurate predictions of litigation results.⁹⁵ Thus, individual inventors are less likely to utilize the teachings of the patent, and, therefore, the public does not benefit⁹⁶ from competitive research and development.⁹⁷ In order to address these issues, the courts must find an application of the test that provides sufficient guidance to remedy the current state of affairs in which "each case is inevitably a matter of degree"⁹⁸ and is "bound to have an arbitrary color."⁹⁹

15 Haw. 343, 14 L.Ed. 77 (1853)). But Judge Hand, however, goes on to say that, "it is plain that such latitude violates in theory the underlying principle that the disclosure is open to the public save as the claim forbids, and that it is the claim and that alone which measures the monopoly." *Id.* (citing *Keystone Bridge Co. v. Phoenix Iron Co.*, 95 U.S. 274, 278 (1887)).

95. See Matthew C. Phillips, *Taking A Step Beyond Maxwell to Tame the Doctrine of Equivalents*, 11 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 155, 164, 165 (2000). This debate dates back to the origin of the doctrine where the majority focused on applying the broadest construction possible, and therefore instructed courts to look at the substance of the invention rather than the form that is claimed. *Winans v. Denmead*, 56 U.S. 330, 343 (1853). Conversely, Justice Campbell's dissent held that the doctrine contradicts the requirement that a patent applicant "particularly specify and point out what he claims as his invention." *Id.* at 347 (Campbell, J. dissenting):

Fullness, clearness, exactness, preciseness, and particularity, in the description of the invention, its principle, and of the matter claimed to be invented, will alone fulfill the demands of Congress or the wants of the country. Nothing will be more mischievous, more productive of oppressive and costly litigation, of exorbitant and unjust pretensions and vexatious demands, more injurious to labor, than a relaxation of these wise and salutary requisitions of the act of Congress.

See also *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 615-16 (1950) (Black, J., dissenting) (arguing that, in appreciation of the complexity of the subject matter and the difficulties inherent in determining proper patent claim scope, Congress has given the PTO the power to make these decisions).

96. See *supra* note 24 and accompanying text for examples of these benefits.

97. See *supra* note 36.

98. Blaustein, *supra* note 62, at 110.

99. *Id.*

A. The Courts Cannot Figure It Out

The Supreme Court is well aware of the problems associated with the doctrine of equivalents, but has chosen not to address them all.¹⁰⁰ In failing to do so, the Court has left jurors, often untrained in science, with little guidance to undertake the daunting task of comparing highly complex and technical inventions.¹⁰¹ The Court has not given the framework any substance that has a meaningful use in completing comparison process.¹⁰² For example, after retaining the all-elements test in *Warner-Jenkinson*, the Supreme Court declined to define the parameters of an element.¹⁰³

The Federal Circuit has had a particularly difficult time creating a definition for biotechnology patents.¹⁰⁴ One solution proposes to change the all-elements test to the all-limitation test so the accused device does not infringe on the patent if it excludes any one of the claim limitations.¹⁰⁵ Other members of the Federal Circuit have noted that limitations may partially comprise elements or modify them.¹⁰⁶ Under this approach, an element may refer to a single limitation. It

100. See *Warner-Jenkinson*, 520 U.S. at 27-28 ("Congress can legislate the doctrine of equivalents out of existence any time it chooses. The various arguments [for and against this proposal are] best addressed to Congress, not this court."). *Id.* at 28. Such a stance is rather unusual because the doctrine was judicially created by the Court in equity, not by statute. See generally Janice M. Mueller, *Crafting Patents for the Twenty-First Century: Maximize Patent Strength and Avoid Prosecution History Estoppel In A Post-Markman/Hilton Davis World*, 79 J. PAT & TRADEMARK OFF. SOC'Y 499, 506 (1997) (predicting that, because of the lack of clarity in the Court's decisions, liability under the doctrine will be the "main battle ground in twenty-first century patent trials").

101. See Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After Warner Jenkins Co. v. Hilton Davis Chemical Co.*, 6 J.L. & POL'Y 741, 786-89 (1998).

102. See *supra* note 82. While the Court has purported to reject linguistic tests that offer meaning, it has done little more than change the words from "function/way/result" to "all elements" and "insubstantial change." *Id.*

103. See generally *Warner-Jenkinson*, 520 U.S. at 17.

104. See, e.g., *Genentech v. Boehringer Mannheim GmbH*, 989 F. Supp. 359 (D. Mass. 1997) (applying the doctrine of equivalents to gene fragments); *Genentech v. Boehringer Mannheim GmbH*, 47 F. Supp. 2d 91 (D. Mass. 1999) (analyzing patents for compounds to dissolve blood clots); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362 (Fed. Cir. 1999) (analyzing accused infringement of anti-sense technology).

105. *Pennwalt Corp. v. Durland-Wayland Inc.*, 833 F.2d 931, 950 (noting that "where a part of the claimed invention, that is, a limitation of the claim, is lacking in the accused device exactly or equivalently, there is no infringement").

106. *Id.*

has also been used, however, to refer to a series of limitations which, taken together, make up a component of the claimed invention. Finally, Judge Louries has proposed that, with respect to genetically engineered elements, the comparison should focus on their structure rather than what they do or how they work.¹⁰⁷

B. Neither Can the Scholars

A brief review of the literature quickly discloses that the problems discussed here have received extensive attention within the legal community. Scholars, practicing attorneys, and law students have tried to aid the courts by devising their own solutions. A consensus has yet to emerge, however, as the proposals range from those that suggest an approach outside of the patent system to proposals creating specific tests for subsets of biotechnology.

A proposal at one extreme suggests to eliminate patent protection for all GMOs.¹⁰⁸ Paul Blunt argues that this would do away with any confusion resulting from the doctrine of equivalents because there would be no monopoly to infringe upon. Furthermore, such a scheme would limit some of the ethical and environmental concerns associated with GMOs¹⁰⁹ because fewer organisms would be protected.¹¹⁰ Rather, plants and animals selectively bred for certain traits, without genetic modifications, would be given patent protection.¹¹¹ Thus, the manipulation that pre-dated genetic engineering would once again become competitive.¹¹²

Another proposal,¹¹³ advocated by Laura E. Ewens, aims at lowering the incentive to infringe on patented material by decreasing the duration that the patents are in force.¹¹⁴ If the monopoly is only

107. See *Genetech, Inc. v. Wellcome Foundation Ltd.*, 29 F.3d 1555, 1570 (Fed. Cir. 1994) (Lourie, J., concurring).

108. See Paul Blunt, Note, *Selective Breeding and the Patenting of Living Organisms*, 48 SYRACUSE L. REV. 1365, 1374 (1998).

109. *Id.* at 1374, 1377; see also *supra* notes 25-33 and accompanying text.

110. Blunt, *supra* note 108, at 1383-85; see also *supra* note 39 and accompanying text.

111. Blunt, *supra* note 108, at 1387-89.

112. *Id.* at 1389; see also *supra* notes 15-20 and accompanying text.

113. Lara E. Ewens, Note, *Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds*, 23 B.C. INT'L & COMP. L. REV. 285 (2000).

114. *Id.* at 308.

enforceable for ten years, the patentee still has the ability to recoup her research and development expenditures. At the same time, however, the public would have greater access to the genetic information, and therefore, would be less likely to pirate the information.¹¹⁵ Such a system is likely to facilitate technology transfers with developing nations, as well as others in desperate need of farming innovations.¹¹⁶

Instead of altering the patenting system, Qing Lin encourages an extension of the non-obviousness test from patentability to biotechnology infringement.¹¹⁷ The first step in this analysis is similar to the initial non-obviousness determination for a patent and asks whether, in light of prior art, the accused device would have been issued a patent by the PTO.¹¹⁸ The second step asks whether the accused device is obvious to a person skilled in the field.¹¹⁹ Difficulties do not arise from the all-element requirement under this test because the patented device is never compared to the accused device.

A number of proposals¹²⁰ call for the complete eradication of the doctrine of equivalents in biotechnology patent jurisprudence because of the broad patent constructions that the courts have drawn in the first step of the infringement analysis.¹²¹ Consequently, a test that goes beyond protecting against literal infringement not only encourages predatory litigation but increases the potential for infringement because of the uncertainty of that litigation.¹²² The dissatisfaction with retaining some form of the test stems from the requirements of the all-elements rule and its seeming inapplicability

115. *Id.*

116. *Id.*

117. Qing Lin, *A Proposed Test for Applying the Doctrine of Equivalents to Biotechnology Inventions: The Non-obviousness Test*, 74 WASH. L. REV. 885 (1999).

118. *Id.*

119. *Id.*

120. See Graham, *supra* note 101, at 770; see also Cliff Weston, *Chilling of the Corn: Agricultural Biotechnology in the Face of U.S. Patent Law and the Cartagena Protocol*, 4 J. SMALL & EMERGING BUS. L. 337 (2000).

121. Graham, *supra* note 101, at 772.

122. *Id.* at 793; see *supra* note 61 and accompanying text for a description of this process.

to biotechnology inventions,¹²³ even though the comparison might be more straight forward in other areas.¹²⁴

IV. THE RESOLUTION? A SPECIFIC SOLUTION

A. Inadequacy of Current Proposals

Neither Congress nor the courts have adopted any of these proposals. Each proposal exhibits major flaws that will consequentially prevent the progress of technology.¹²⁵ For example, the all-limitations proposal¹²⁶ would make the application of the test manageable yet useless because the comparison of limitations is essentially the same inquiry as that used to determine literal infringement.¹²⁷ Furthermore, those that alter the patentability of GMOs will either decrease or eliminate the incentive for investing the large sums of money necessary to develop transgenic organisms. Without the patent monopoly, there may be a lack of infringement, but there will also be a societal void from the absence of useful GMO products.¹²⁸ Furthermore, the proposal for patenting selectively bred organisms is unworkable because those plants and animals could be generated through natural processes such as cross-pollination.¹²⁹

Similarly, decreasing the term of a patent will decrease the incentive for investment because it would limit the time that

123. Weston, *supra* note 120, at 383.

124. For example, one may take apart two motors to compare their parts and run both to study their function and the means by which they achieve it. The situation is much more complex in biotechnology. Consider the transgenic pig whose milk has been engineered to contain human blood clotting factor. Depending on the nature of the claims, an element or limitation in this invention, may be the foreign DNA, the modified pig gene containing the DNA, the pig itself, or the processes by which the pig was created. If the focus is on the gene, the infringing party is likely to avoid defeat because she can argue that a number of different sequences within the gene could have been modified to achieve the same result. See Weston, *supra* note 120, at 383. Similarly, she may also prove that any number of other genes could have received the insertion.

125. See *supra* note 34-39 and accompanying text.

126. See *supra* note 105 and accompanying text.

127. ROBERT P. MERGES, PATENT LAW AND POLICY: CASES AND MATERIALS 676 (1992).

128. See *supra* note 24 and accompanying text.

129. There is no such problem in the case of a GMO, especially in those instances where the foreign DNA is contrasted synthetically or comes from an organism or, at times, from another kingdom or phyla.

patentees could recoup their research and development costs. At any rate, ten years is still a considerable amount of time for a non-patentee to create infringing devices or processes. The courts would still be left with the existing unworkable test for equivalents during this period. While the desire to share technology may be compelling, mere changes to patent terms will not increase transfers.¹³⁰ Any change would have to be accompanied by a program to work with those in need of technology, to help them produce inventions, and use them in their specific situations.¹³¹

Likewise, the application of patentability principles does not solve the present doctrinal dilemma. The Lin approach asks whether the accused device would have been patentable with respect to the non-obviousness requirement. This contradicts the requirement of analyzing the accused device as of the time of infringement and recognizes that its patentability is irrelevant.¹³² It also completely disregards the patentee's expectation that her claims will be protected from identical or equivalent matches.

Finally, even in light of the courts' frustration with the doctrine of equivalents, it is highly unlikely that the test will be abandoned altogether. Even the doctrine's staunch critics concede that it is an integral component of patent law because of the impossibility of foreseeing all possible equivalents to a given invention's elements or limitations. Additionally, it appears that the doctrine's elimination could only come about with congressional action.¹³³ Congress is unlikely to do away with the doctrine of equivalents because of the ability it would give puntative infringers to avoid liability by making insubstantial changes to the claimed invention. In the absence of protection, the resulting uncertainty from non-literal infringement will lead to a decrease in investment, as limiting a patent to its exact wording will open the door for infringers to make insubstantial but permissible changes.¹³⁴

130. See generally DRONAMRAJU, *supra* note 29; Kinderlerer, *supra* note 29.

131. For example, the knowledge needed to grow a vitamin A enriched strain of rice will not help to feed the people of a developing nation that lack the resources to exploit the technology on a widespread basis.

132. See *supra* note 79.

133. See *supra* note 100.

134. See *supra* note 94.

B. The Essential Components of A Successful Framework For Comparison

Each of these proposals fail to meet the general goal of increasing patent protection to secure reliable incentives for GMO research and development.¹³⁵ To reach this end, the application of the doctrine of equivalents must contain a number of elements. First, and most importantly, the test must account for characteristics unique to GMOs in order to facilitate comparisons between inventions within subgroups of biotechnology.¹³⁶ Second, district court judges must be able to apply the test, as most lack science backgrounds, and are even less likely to have experience in the specific subject matter of a given patent.¹³⁷ Third, the test should attempt to avoid litigation by allowing for predictability in the patent writing process.¹³⁸ To this end, it must put the public on notice and define the scope of the intellectual property monopoly created by the patent.¹³⁹ Fourth, the test should encourage more negotiated settlements, as "patent litigations are probably some of the most consuming and expensive litigations that

135. See Mueller, *supra* note 100, at 515. "Foremost consideration must be given to the ultimate goal of maximizing patent strength," to give the patentee "an optimal competitive advantage while withstanding legal challenge for years to come." *Id.*

136. For example, it is incredibly difficult to break GMOs into comparable elements because they often involve genetic modifications, the means of incorporating foreign DNA into the organism to be modified, and the modified organism itself. See Mueller, *supra* note 100, at 508. The Federal Circuit's use of technology-specific rules for determining enablement in the context of patentability may indicate an openness for technology specific tests in other areas, such as infringement. *Id.*

137. The courts have concluded that juries should be treated no differently in patent cases than in other trials. See Harmon, *supra* note 35, at 183 (citing Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506 (Fed. Cir. 1984); Connell v. Sears, Roebuck & Co., 722 F.2d 1542 (Fed. Cir. 1983)). There is, however, a marked lack of scientific expertise at the district court level as judges are not trained in the field. Pegram, *supra* note 4, at 788. This problem is compounded by the fact that the attorney making the argument often has little experience in the hard sciences, as well as the judicial clerks whom often lack backgrounds in science or engineering. *Id.*

138. See generally Mueller, *supra* note 100.

139. This can only be accomplished by providing the fact-finder with a clear system of comparison that is simplistic enough to follow and review in an objective manner.

exist."¹⁴⁰ Finally, uniformity in the test's application by the district courts and in the Federal Circuit is essential.¹⁴¹

C. The Pyramid Test

The framework proposed here for a new application of the doctrine of equivalents, the pyramid test,¹⁴² attempts to address each of these concerns. Rather than forcing the court to complete the nearly impossible task of defining elements within the context of a GMO, the test guides the trier of fact to search for equivalents to the claims in the accused device at successively increasing levels of complexity. Consider an example where the patent claims an organism with characteristic x and an accused infringer creates an organism that may have the equivalent to characteristic x. First, the processes by which the DNA fragment or gene is created or isolated are evaluated. This is followed by an assessment of the genetic code itself and the mode by which it is inserted into the foreign organism. The trier of fact will then compare the mechanism by which the transcription is induced and the protein encoded for by the DNA. Finally, the protein's effect on the overall function of the organism or

140. CHISUM & WALDBAUM, *supra* note 61, at § 14.02. There is a risk in accusing a party of infringement because it gives them a right to seek declaratory judgment against the patent holder. *Id.* Thus, the patentee should investigate the alleged infringing activities, record her findings, and take action based on them. *Id.* (citing *Lucasey Mfg. Corp. v. Anchor Pad Int'l Inc.*, 698 F. Supp. 190 (N. D. Cal. 1988)). This should also shield the patentee from damages awarded for making bad faith infringement claims. *Id.* (citing *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891 (Fed. Cir. 1998)). It is interesting to note that in light of the great technological strides made in the United States, the U.S. legal system may not be that far ahead of where it was a century ago. As early as 1908, at least ten percent of the federal court system's time was devoted to patent litigation. VAUGHAN, *supra* note 34, at 180 (citing Prindle, *The American Patent System*, in 1 AM. INDUSTRIES 20 (1908)). In fact, about one million dollars was spent to protect Thomas A. Edison's incandescent lamp. *Id.* at 181 (citing W. Kaempffert, *Our Defective Patent System*, in THE OUTLOOK (July 6, 1912)). Vaughan critiques the pre-*Graver Tank* doctrine of equivalents test for encouraging litigation just as many scholars and practitioners do today with the *Warner Jenkins* test. Furthermore, Vaughan not only points out the lack of predictability with respect to infringement, but argues that the expanding doctrine gives a patentee an incentive to try to stretch the umbrella of her claims over the use of others and engage in predatory litigation. *Id.* at 188-89.

141. One of the primary purposes of the circuit is to create uniformity in the district courts. See generally *Patlex Corp. v. Mossinghoff*, 758 F.2d 594 (Fed. Cir. 1985).

142. See Figure 1.

the products generated by the GMO will be compared. The presumption is that as one progresses from the simplest component of the patent toward the products derived from the GMO, the range of equivalents will decrease; there are many DNA fragments that may code for the same protein, but few proteins that will produce the desired effect in the GMO.¹⁴³ If each level of the accused organism matches the patented invention, either literally or as an equivalent, then the accused party is guilty of infringement.¹⁴⁴

D. The Pyramid Test Meets the Requirements of a Successful Framework

The pyramid test thus accounts for the difficulties in defining elements in genetically modified organisms by allowing for a comparison of each level necessary for creation, in connection with the organism as a whole. By focusing on each level of complexity, this approach does not allow the patentee to draw attention away from the absence of similarities that are crucial to the patent. The test does not, however, analyze each element in a vacuum apart from its effect on the invention as a whole.¹⁴⁵ The test is readily applicable by both lay judges and jurors, because it directs the comparison along the logical process that must be followed during the creation of a GMO rather than focusing on abstract elements.¹⁴⁶ This analysis also provides a methodical level of predictability that patentees can use in the application process. The inventor can list each of the steps in the GMO production and sufficiently describe those steps to protect her rights rather than having to anticipate what the trier of fact will actually compare.¹⁴⁷ This decreases the problems associated with a lack of foreseeability because the patentee can anticipate other ways that each step can be achieved, and thus, can directly state them in the

143. See *supra* note 24.

144. See Figure 1.

145. See *Pretty*, *supra* note 6, at 285-86.

146. The jury should also hear expert testimony to provide background for the evaluation. "Without such testimony, a jury 'is more or less put to sea without guiding charts when called upon to determine infringement under the doctrine.'" *Glitzenstein*, *supra* note 62, at 300-01 (quoting *Lear Sigler, Inc. v. Sealy Mattress Co.*, 873 F.2d 1422, 1426 (Fed. Cir. 1989)).

147. See *supra* notes 68-69.

application. Accused GMOs falling within those claims will literally infringe upon the patent and further decrease the need for the court to resort to the doctrine of equivalents.¹⁴⁸ These effects, during both the litigation and application stages, will put the public on notice regarding the exact scope of protection afforded by the patent, and will thereby allow competitors to design around the invention without infringing upon the patent.¹⁴⁹ When infringement does occur, however, the parties will be more likely to settle before entering into litigation because they will be able to readily predict the outcome of that litigation.¹⁵⁰

The pyramid test's benefits are only obtainable if it is uniformly applied in patent litigation. To guarantee its use, the test should be adopted by Congress where a substantial legislative inquiry can be conducted to generate extensive guidance documents for the courts.¹⁵¹ Should Congress choose not to act, either the Supreme Court or Federal Circuits should adopt the test and provide a clear explanation of its general applicability as well as any possible dicta for other categories of GMOs not before the court.

V. CONCLUSION: ANYONE FOR DESSERT?

The application of doctrine of equivalents must be reformed so that it may be used efficiently and equitably in GMO infringement litigation. By connecting the comparison of invention subparts to the organism as a whole, the pyramid approach provides the courts with suitable guidance to apply the doctrine of equivalents and to provide predictability for patentees and the public regarding the results of that application. This combination will encourage the level of investment in research that is essential to the development of genetically modified organisms, which will benefit humanity by improving health and protecting the environment. While some of these effects

148. See *supra* note 65.

149. See *supra* note 94 and accompanying text.

150. See *supra* note 141.

151. This would require Congress to do more than merely focusing on issues related to the appropriateness of GMOs within the context of modern society. See *supra* notes 25-33 and accompanying text.

may be disputed, the entry of GMOs into our competitive economy is not doubted, thus it is time for patent infringement jurisprudence to address these innovations.

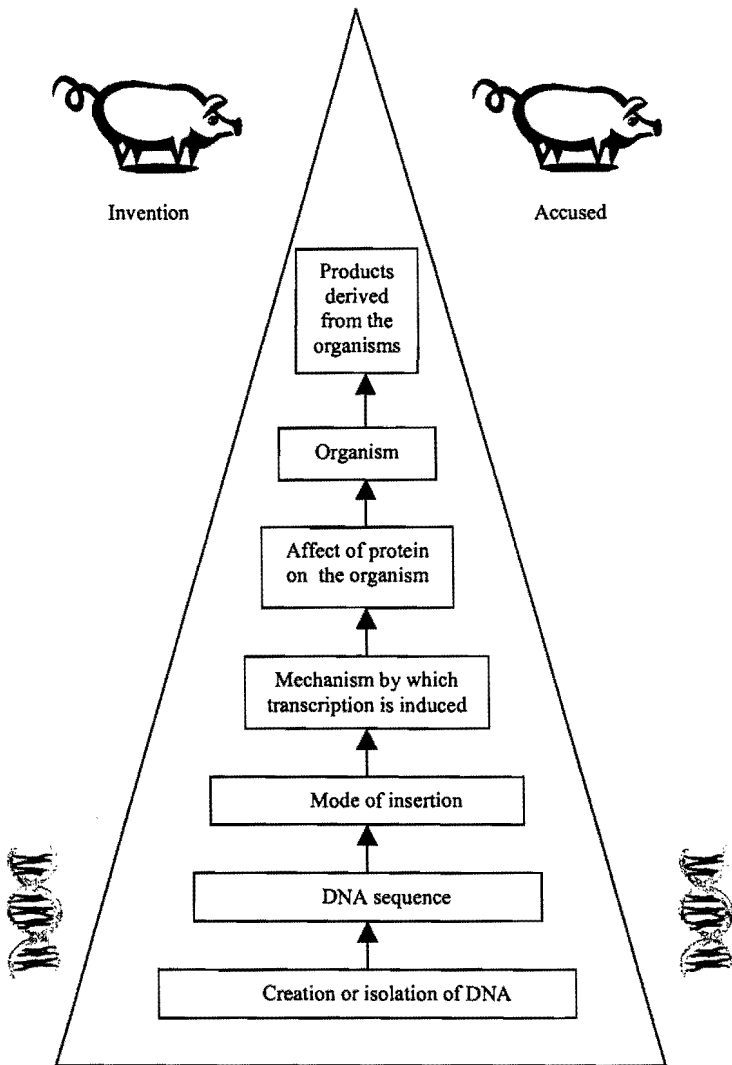


Figure 1. The Pyramid Approach: The doctrine of equivalents will be applied by searching for insubstantial changes at each level of creation required to develop a GMO. In this example, two pigs are compared. Assume that they both produce a human blood factor in their milk. Rather than asking the court to define what constitutes an element in a claimed genetically modified pig, the trier of fact will begin by comparing the relevant DNA inserted into the parent organism and work its way up to the organism as a whole. At each level, there are less possible ways to achieve the desired result. Consequently, the range of equivalents will depend on how much latitude exists to allow competitors to design around the patent.