MUCH ADO ABOUT GENE PATENTS: THE ROLE OF FORESEEABILITY

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INTRODUCTION

Since Gregor Mendel[1] discovered the gene, scientists have sought to unravel the intricacies of life's blueprint—the genetic code.[2] Today, insights into molecular biology and genetic engineering[3] fuel biotechnology, an industry promising to touch every aspect of human life.[4] Already, biotechnology has enabled major advances in medical therapeutics and diagnostics, and has spawned complex new fields such as genomics[5] and proteomics.[6]

Given the major role of gene-based technologies in biotechnology, gene patents are among a biotechnology company's most valuable assets.[7] Patents are government issued grants providing

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[1] *See infra* text accompanying notes 47-50 for a discussion of Mendel's work.

[2] *See infra* Part II for a discussion of the scientific discoveries that enabled the deciphering of the genetic code.

[3] Genetic engineering involves the use of processes (i.e., genetic manipulation, genetic modification, genetic technology, recombinant DNA technology) to move genes from one organism to another, often to solve medical or agricultural problems, with the goal of creating organisms with novel genetic make-ups. MICHAEL J. REISS & ROGER STRAUGHAN, IMPROVING NATURE? 1, 2 (1996).

[4] Examples of biotechnology's focus on genetics include the development of genetically engineered organisms that remove hazardous waste from the environment, the development of animals that make human products such as insulin, and the development of genetically engineered drugs for treating heart disease, cancer, AIDS, and strokes. *See* JEREMY RIFKIN, THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD 15-24 (1998).

[5] The goal of genomics is to study the functions and interactions of all genes in the genome. *See* Alan Guttmacher & Francis Collins, *Genomic Medicine: Genomic Medicine-A Primer*, 347 NEW ENG. J. MED. 1512, 1513 (2002).

[6] Proteomics involves the study of proteins, their biological functions, and the mechanisms by which they interact. HOWARD C. ANAWALT & ELIZABETH E. POWERS, IP STRATEGY: COMPLETE INTELLECTUAL PROPERTY PLANNING, ACCESS, AND PROTECTION § 4:21 (2002).

[7] RIFKIN, *supra* note 4, at 37 (referring to genes as the "green gold" of biotechnology).

their owner the right to exclude others from "making, using, offering for sale, or selling [their] invention"[8] for a period of twenty years from the date of filing.[9] In offering protection, patents also create incentives.[10] Barring exclusion, competitors could copy a patented invention and undersell the patent owner, who, unlike the competition, has incurred research and development costs.[11] The right of exclusion, however, prevents competitors from "making, using, offering for sale, or selling" the patented invention.[12] In so doing, the exclusionary right provides opportunity for economic recovery and gain, which in turn creates incentives to invest the time, effort, and money necessary for the creation of new and useful products.[13]

The importance of obtaining patent protection for commercially valuable genes has created a race to the United States Patent and Trademark Office ("USPTO").[14] Given the pressure to file first, biotechnology companies often choose to file broad patent applications in the early stages of research, before they understand the commercial applications of their inventions.[15] Biotechnologists defend these broad filings, arguing that limiting their patents to the "specific and narrow" lab results will make cost recovery an impossibility.[16] Legal commentators, clinicians, and researchers, however, argue that gene patents have the real potential of undermining biomedical research, health care, and the free exchange of information among researchers.[17] For instance, a gene patent holder may lawfully prevent the scientific community from conducting research or developing valuable therapeutic applications based on the patented gene's DNA sequence.[18] Even when the patent holder is willing to license the gene or DNA sequence, the cost of acquiring the license can be prohibitive.[19]

This Comment explores the key role American patent law plays,

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[8] 35 U.S.C. § 271(a) (2001).

[9] 35 U.S.C. § 154(a)(2) (1994).

[10] CHISUM ET AL., PRINCIPLES OF PATENT LAW 70-76 (2d ed. 2001).

[11] *Id.* at 69.

[12] 35 U.S.C. § 271(a) (2001).

[13] *See* CHISUM ET AL, *supra* note 10, at 70-76.

[14] *See* RIFKIN, *supra* note 4, at 59.

[15] ERIC S. GRACE, BIOTECHNOLOGY UNZIPPED: PROMISES AND REALITIES 204 (1997).

[16] *See id.*

[17] *See infra* Part IV for an in-depth examination of the policy issues surrounding the issuance of gene patents.

[18] *See* Part IV.A.

[19] *See id.*

and must continue to play, in preventing the ills associated with broad gene patents. Part I offers a basic explanation of genes and their functions. Part II provides an introduction to the biotechnology industry. This section examines the history of biotechnology with an emphasis on current technology and the scientific goals of the industry. Part III gives an overview of the American patent system. Part IV considers both the negative and positive implications of issuing gene-based patents. Also, this section briefly discusses various options for lessening the negative effects of gene patents. Part V suggests that the United States Court of Appeals for the Federal Circuit adopt a biotechnology-specific application of the foreseeability standard articulated in Judge Rader's concurrence in *Johnson & Johnston Associates, Inc. v. R.E. Service Co., Inc.*[20] Under this objective foreseeability-based limit on the doctrine of equivalents,[21] the patent applicant "has an obligation to draft claims capturing all reasonably foreseeable ways to practice the invention,"[22] and may not rely on the doctrine of equivalents to capture "subject matter that the patent drafter reasonably could have foreseen,"[23] but failed to claim. Judge Rader advocated the foreseeability standard as a general, rather than biotechnology-specific, patent law principle.[24] This section, however, argues for a biotechnology-specific application of the foreseeability standard.[25] It posits that applying a heightened, more restrictive version of the doctrine of equivalents in biotechnology cases will effectively limit gene patent scope, thereby promoting biotechnological progress.[26]

I. THE GENE

This Comment aspires to offer an in-depth examination of the challenges that gene patents pose, and the manner in which courts have and should continue to limit gene patent scope. However, in order to appreciate a gene's scientific value, gene patent case law,

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[20] 285 F.3d 1046, 1056-59 (Fed. Cir. 2002) (en banc) (per curiam) (Rader, J., concurring) (agreeing with the court's decision, but arguing that the court should have decided the issue under a foreseeability approach to the doctrine of equivalents).

[21] *See infra* text accompanying notes 131-42 for a discussion of the doctrine of equivalents.

[22] *Id.* at 1057 (Rader, J., concurring).

[23] *Id.* at 1056 (Rader, J., concurring).

[24] *See id.* at 1056-59 (Rader, J., concurring).

[25] *See infra* Part V.

[26] *See id.*

and the philosophical questions surrounding gene patents, it is helpful to comprehend the structure and function of the gene itself.

Deoxyribonucleic acid, also known as DNA, is the primary repository for genetic information in the human body.[27] DNA is located on chromosomes,[28] which are located in a cell's nucleus.[29] Although it may be difficult to understand the function of DNA, "[its] structure is really quite simple."[30]

DNA, in its double helix form, resembles a twisted rope ladder. The rope element (a strand) is composed of alternating molecules of sugar and phosphate.[31] Each step of the ladder is composed of a pair of bases (nucleotides) joined by chemical bonds.[32] There are four such bases: G (guanine), T (thymine), C (cytosine) and A (adenine).[33] The bases are complementary in that they always pair up the same way: A with T, and C with G.[34] Thus, each step of the ladder is either an A-T, T-A, C-G or G-C.[35] More importantly, the complementary nature of the bases means that the sequence of bases on one strand always complements the sequence along the other strand in the same way.[36]

DNA's incredible ability to store information lies in the bases, the arrangement of which makes up a gene.[37] A useful way to visualize a gene is as follows: imagine splitting the ladder in half down the middle, so as to separate each base pair. Now, imagine walking up one of the ropes, "reading off the bases as you go."[38] The sequence of bases might read ATGCTCCG. Another section might read an entirely different sequence of bases. Each section of bases is a particular gene, the lengths and sequences of which vary.[39]

Many people mistakenly believe that genes are the determinate

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[27] WAYNE BECKER ET AL., THE WORLD OF THE CELL 56 (3d ed. 1996).

[28] Chromosomes are thread-like strands containing nucleic acids that are located in a cell's nucleus. *Id.* at 83.

[29] The nucleus is the cell's control center, located near the middle of the cell. *Id.* at 89-99.

[30] REISS & STRAUGHAN, *supra* note 3, at 13.

[31] BECKER ET AL., *supra* note 27, at 60.

[32] *Id.* at 60-61.

[33] *Id.* at 61.

[34] *Id.* at 60-61.

[35] *Id.*

[36] Thus, if one strand of the DNA contains the bases TAATCG, its complement will read ATTAGC. *Id.* at 60-61.

[37] GRACE, *supra* note 15, at 17.

[38] *Id.*

[39] *Id.*

factor of our physical characteristics.[40] In actuality, genes do not directly determine our physical features.[41] Rather, they are the instructions for making proteins, the biological compounds directly responsible for making us what we are.[42] Proteins are "the very foundation of living systems,"[43] and are involved with nearly every product and process necessary for cell survival.[44]

II. OVERVIEW OF THE BIOTECHNOLOGY INDUSTRY

Although the word "biotechnology" conjures up thoughts of modern, cutting edge technology, its history dates back thousands of years.[45] The roots of traditional biotechnology trace back 12,000 years, when humans independently domesticated plants and animals in the Middle East, the Far East, and the Americas.[46] Such domestication involved farmers selecting various plants and animals, and breeding them to produce the largest and healthiest specimens.[47]

One of the most prolific and important figures in the era of traditional biotechnology was Gregor Mendel,[48] the founder of the study of genetics, which has enabled the success of modern biotechnology.[49] While observing the common pea plant in his monastery's garden, Mendel made numerous important discoveries known as Mendel's laws of inheritance. [50] Importantly, Mendel discovered that discrete "factors" (known today as genes) determine the traits of most organisms.[51]

The Twentieth Century scientific community witnessed numerous landmark discoveries that paved the way for the era of modern biotechnology.[52] Modern biotechnology is primarily

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[40] *Id.* at 18 (commenting that "[t]o the average person, a gene is something that gives you, say, blue eyes or brown eyes").

[41] *Id.* at 20-25 (noting how genes code for proteins, which in turn are the foundation of living systems).

[42] *Id.* at 21.

[43] GRACE, *supra* note 15, at 21.

[44] Proteins' functions are vast and varied. *Id.* at 21. Some of their functions include carrying oxygen in the blood, carrying messages between cells, making up muscle, activating the immune system, and activating essential chemical reactions by acting as enzymes. *Id.*

[45] REISS & STRAUGHAN, *supra* note 3, at 3.

[46] *Id.*

[47] *Id.*

[48] *See* BECKER ET AL., *supra* note 27, at 509.

[49] *See* GRACE, *supra* note 15, at 6, 8.

[50] BECKER ET AL., *supra* note 27, at 509.

[51] *Id.*

[52] *See* GRACE, *supra* note 15, at 28-29 (discussing monumental discoveries such as

concerned with developing "commercially valuable therapeutic, biomedical, and pharmaceutical products and processes . . . that revolve around the manipulation of DNA molecules and their encoded proteins."[53] What separates "modern biotechnology" from "traditional biotechnology" is not the use of organisms to accomplish goals, but rather the processes employed in doing so.[54] Modern processes such as genetic engineering, specifically recombinant DNA technology, allow biotechnologists to "reach further into the genetic structure of organisms and to manipulate the building blocks of life directly."[55]

Recombinant DNA technology involves isolating and replicating the desired gene of one species and inserting it into the genome of another species.[56] Once transfected, the host cells become capable of producing ("expressing") the protein for which the foreign gene codes.[57] For example, recombinant DNA technology makes it possible for bacteria to mass produce lifesaving substances such as human insulin, growth hormones and blood clotting factors, previously available only in limited quantities.[58] Importantly, recombinant DNA technology made the Human Genome Project a reality.[59]

Launched in 1990 by the Department of Energy and the National Institute of Health, the Human Genome Project ("HGP") is a $250 million publicly funded international endeavor focused on sequencing the entire human genome.[60] In 2001, the HGP accomplished its first goal of mapping and sequencing all 100,000 genes of the human genome.[61] The information, in the form of three billion base pairs, is "enough to fill more than 200 telephone

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the recognition that DNA carries genetic information, DNA's helical structure, and the use of restriction enzymes to cut and splice genetic material).

[53] CHISUM ET AL., *supra* note 10, at 646.

[54] GRACE, *supra* note 15, at 2.

[55] *See* ANAWALT & POWERS, *supra* note 6.

[56] BECKER ET AL., *supra* note 27, at 520-27.

[57] *Id.*

[58] Aaron Xavier Fellmeth & Linda J. Demaine, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 308 (2002) (presenting the manner in which gene patents harm research and innovation, and suggesting a substantial transformation test that only allows patenting of truly novel gene-based inventions).

[59] *See* GRACE, *supra* note 15, at 69-70.

[60] Mary Breen Smith, Comment, *An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines*, 73 U. COLO. L. REV. 747, 754 (2002).

[61] *See id.* at 754-55.

books."[62]

The next wave of research in understanding human development and illness is proteomics.[63] Whereas the HGP focused on sequencing the entire human genome, proteomics seeks to understand all proteins, their biological functions and the mechanisms by which they interact.[64] Involved in the pursuit of this goal is the field of structural genomics, a subset of proteomics, which seeks to uncover the biological functions of proteins through study of their three-dimensional structure.[65]

Although modern biotechnology's applications are widespread, "its greatest impact so far has been in healthcare."[66] Equipped with the knowledge resulting from the Human Genome Project, biotechnology companies are currently developing innovative drugs and diagnostic tools.[67] Since many medical ailments are created by defective genes, knowledge of the location, structure and function of these genes will allow researchers to develop drugs and diagnostic kits that treat and diagnose disease at the genetic level, thus leading to safer and more effective treatments.[68]

Today, biotechnology companies, along with government and corporate laboratories, are mapping and sequencing the genomes of many species, from humans to bacteria, "with the goal of finding new ways of harnessing and exploiting genetic information for economic purposes."[69] Given the economic incentives, researchers will continue to seek broad patent protection for their genetic and biotechnological discoveries.[70] It is the role of the Federal Circuit and USPTO to maintain an appropriate level of patent protection that creates incentives while also preventing overly broad gene patent scope.[71]

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[62] *Id.* at 754.

[63] ANAWALT & POWERS, *supra* note 6.

[64] *Id.*

[65] *Id.*

[66] Sara Dastgheib-Vinarov, Comment, *A Higher Nonobvious Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 145 (2000) (arguing that given the detrimental effects of broad gene patents on biomedical research, they should be made more difficult to obtain by means of a heightened non-obvious standard) (quoting WILLIAM BAINS, BIOTECHNOLOGY FROM A TO Z V (1993).

[67] ANAWALT & POWERS, *supra* note 6.

[68] *Id.*

[69] RIFKIN, *supra* note 4, at 190.

[70] *See* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science,* 94 NW. U. L. REV. 77, 105-06 (1999).

[71] *See* Clarisa Long, *Side Bar. The Brouhaha Over Expressed Sequence Tags*, in CHISUM

III. PATENT LAW BACKGROUND

DNA-based inventions have provided special problems for patent law.[72] In order to understand these challenges, including the issue of broad gene patents, it is necessary to understand the American patent law system.

The constitutional basis for the American patent law system is found in Article I, Section 8 of the United States Constitution, which gives Congress the power "[t]o promote the Progress of Science and the useful Arts by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[73] Given colonial usage and syntax, the clause can be reworked as follows: (1) "To promote the Progress of Science . . . by securing for limited times to Authors . . . the exclusive Right to their . . . Writings; and (2) To promote the Progress of . . . useful Arts, by securing for limited times to . . . inventors the exclusive Right to their . . . Discoveries."[74] Although this interpretation highlights the framers' intent of encouraging the useful arts, "it does not however, define the exact nature of the patent grant, such as its appropriate balance or scope, and subject matter."[75] The founding fathers left that duty to Congress,[76] which enacted the first patent statute in 1790.[77] Since then, Congress has enacted several statutory revisions leading up to the 1952 Patent Act.[78]

Under the 1952 Patent Act, an invention may only receive a patent if it is "new and useful,"[79] "novel"[80] and "non-obvious" to a person of ordinary skill in the art.[81] Furthermore, the patent application's specification[82] must adequately disclose the invention to

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ET AL., *supra* note 10, at 725 (noting that one of the most critical issues surrounding the intersection of biotechnology and patent law is the appropriate scope of claims to genetic material).

[72] *See* CHISUM ET AL., *supra* note 10, at 273.

[73] U.S. CONST. art. I, § 8, cl. 8.

[74] Karl B. Lutz, *A Clarification of the Patent Clause of the U.S. Constitution,* 18 GEO. WASH. L. REV. 50 (1949).

[75] Michael S. Greenfield, Note, *Recombinant DNA Technology: A Science Struggling with the Patent Law,* 44 STAN. L. REV. 1051, 1056 (1992).

[76] *Id.* (citing Graham v. John Deere Co., 383 U.S. 1, 6 (1966)).

[77] CHISUM ET AL., *supra* note 10, at 18.

[78] See *id.* at 18-21 for a complete history of the patent statutes.

[79] 35 U.S.C. § 101 (2001).

[80] 35 U.S.C. § 102 (2001).

[81] 35 U.S.C. § 103 (2001).

[82] The specification consists of the written description and the claims. *See* CHISUM ET AL., *supra* note 10, at 92. The written description provides background, drawings, and a detailed description of the invention. *See id.* at 93-102. The claims

the public.[83]

Pursuant to 35 U.S.C. § 101, an invention must be "new and useful."[84] "For an invention to be useful within the meaning of the statute, a substantial and practical purpose must be discovered and disclosed."[85] The utility requirement is part of the patent system's quid pro quo.[86] In exchange for the right to exclude, the invention is required to work for its intended purpose.[87] Unlike mechanical and electrical inventions, which often show an end result, proving utility of biotechnology inventions is more difficult[88] because biotechnology inventions "possess an evolving utility,"[89] and "are more like building blocks rather than a completed building."[90] That is, many biotechnology inventions involve methods for producing intermediary products or products with unknown results.[91]

Under § 102, only novel inventions may be patented,[92] ensuring that the invention contributes something new to society.[93] To be considered novel, the invention must not have been "known or used" in the United States or "patented or described in a printed publication" either in the United States or abroad.[94] In patent terminology, an invention that is not new is anticipated by prior art.[95] That is, the prior art reference discloses every element of the invention's claims and enables one skilled in the art to make and use the invention.[96] In addition to the novelty requirement, § 102

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define the metes and bounds of the invention and as the "[f]ederal circuit has stated time and again, '[c]laims are infringed, not specifications.'" *Id.* at 103 (quoting SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed. Cir. 1985)). A patent application generally has numerous claims, which often vary in scope. *See id.* at 104. Since the claims define the outer bounds of an invention, when we refer to broad inventions, we are in fact referring to a patent with broad claims. *Id.* A broad claim is one that lacks limitations, which results in a wider scope. *Id.*

[83] 35 U.S.C. § 112 (2001).

[84] 35 U.S.C. § 101.

[85] Greenfield, *supra* note 75, at 1061 (citing Cross v. Iizuka, 753 F.2d 1040 (Fed. Cir. 1985)).

[86] CHISUM ET AL., *supra* note 10, at 707.

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] *Id.*

[91] *Id.*

[92] 35 U.S.C. § 102(a).

[93] *See* CHISUM ET AL., *supra* note 10, at 323.

[94] 35 U.S.C. § 102(a).

[95] Prior art is a term used in patent law that refers to all known technical information. CHISUM ET AL., *supra* note 10, at 93. A patent's novelty and obviousness are judged in light of all known prior art. *See id.*

[96] *See id.* at 400.

contains a statutory bar forbidding patenting when, more than a year before filing a patent application, "the invention was patented or described in a printed publication" either in the United States or abroad, or the invention was "in public use or on sale" in the United States.[97]

The non-obvious requirement of § 103 is referred to as "the most significant obstacle that a patent applicant faces"[98] and the "final gatekeeper of the patent system."[99] The non-obvious requirement serves to prevent the patenting of inventions that while novel, are not that different from the prior art.[100] An invention is non-patentable if, based on all existing knowledge at the time of invention, those skilled in the art would have considered the invention obvious.[101] That is, a single prior art reference does not disclose each and every limitation in the claim (thus not novel), but a variety of references, when combined, do contain all of the limitations and show the invention was already in the public domain.[102] Further, in order for the references to be combinable, they must suggest to a person of ordinary skill in the art that he make the invention and that if made, the invention will have a reasonable likelihood of success.[103]

Finally, a patent specification must meet the disclosure requirements of § 112.[104] These requirements provide that the specification must (1) contain a "written description" that (2) provides sufficient information to "enable" any person skilled in the art to make or use the invention, and (3) sets forth the "best mode" contemplated by the inventor of making the invention.[105] The specification must also contain claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[106]

The first of the three requirements set forth in paragraph one of § 112 is that the specification contain a written description.[107] The written description provides the technical and background

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[97] 35 U.S.C. § 102(b).

[98] *See* CHISUM ET AL., *supra* note 10, at 514.

[99] *Id.* (quoting ROBERT PATRICK MERGES, PATENT LAW AND POLICY 479 (2d ed. 1997)).

[100] *See id.* at 515.

[101] *See* Greenfield, *supra* note 75, at 1061.

[102] CHISUM ET AL., *supra* note 10, at 514.

[103] *Id.* at 584.

[104] 35 U.S.C. § 112.

[105] *Id.*

[106] *Id.*

[107] *Id.*

explanation necessary for one to read and understand the patent application, including its claims.[108] To satisfy the written description requirement, the patentee need not describe the claimed subject matter exactly.[109] The description must, however, "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."[110]

Under the enablement requirement of § 112, the inventor must set forth in the patent specification enough information to enable one skilled in the art to make and use the invention without "undue experimentation."[111] Thus, in order for a patentee to receive the right to exclude, he must show others how to make and use the invention, presumably so competitors may improve upon the claimed invention.[112] Courts also use the enablement requirement as a claim narrowing device.[113] Broad claims must be supported by an equally broad enablement, and if they are not, the inventor has not taught how to "make or use" the invention, and the non-enabled claims will not be allowed.[114]

Lastly, the first paragraph of § 112 requires that the specification "set forth the best mode contemplated by the inventor of carrying out his invention."[115] The best mode requirement ensures that the inventor discloses the best way of carrying out his invention.[116] Its purpose is to prevent inventors from obtaining patent protection while keeping secret the best way to make their invention.[117]

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[108] *See* CHISUM ET AL., *supra* note 10, at 212.

[109] Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (citing In re Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989)).

[110] *Id.* at 1563 (quoting *In re Gosteli*, 872 F.2d at 1012).

[111] 35 U.S.C. § 112. The term "undue experimentation" does not appear in the statute, but it is well established that under the enablement requirement, the specification must teach those skilled in the art to make and use the invention without "undue experimentation." Nat'l Recovery Technologies v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) (stating "the scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation"); *see also* In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (discussing the factors involved for considering whether a disclosure requires undue experimentation).

[112] CHISUM ET AL., *supra* note 10, at 162.

[113] *Id.*

[114] *See id.*

[115] 35 U.S.C. § 112.

[116] *Id.*

[117] CHISUM ET AL., *supra* note 10, at 193.

A. Statutory Subject Matter

In addition to the patentability requirements, an invention must fall within one of four statutorily defined classes of subject matter as set forth in § 101: "processe[s], machine[s], manufacture[s] or composition[s] of matter."[118] In *Diamond v. Chakrabarty*,[119] the Supreme Court broadly interpreted these classes to "include anything under the sun that is made by man."[120]

The Supreme Court's decision in *Chakrabarty* is most noteworthy, however, for its ruling that genetically engineered multi-cellular organisms constitute patentable subject matter.[121] The Court explained that genetically engineered bacteria was patentable because the claim was not to a "hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity having a distinct name, character, [and] use."[122]

Under the reasoning in *Chakrabarty*, "products of nature" are patentable so long as the inventor has changed the product in some non-naturally occurring way to conform to the statutory requirements of the Patent Act.[123] Modern courts will allow patents for genes and DNA sequences "as long as the genetic materials are claimed in a non-naturally occurring form, that is, as an isolated or purified molecule."[124] Those seeking gene patents argue that their genes are isolated and purified because they "have been manipulated to eliminate the non-coding region[s]" found in the body's DNA, while still maintaining the same function.[125]

B. Infringement

Under 35 U.S.C. § 271(a), "whoever, without authority makes, uses, offers to sell, or sells any patented invention within the United States or imports into the United States any patented invention during term of the patent therefore, infringes the patent."[126] Because

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[118] 35 U.S.C. § 101.

[119] 447 U.S. 303 (1980).

[120] *Id.* at 309 (quoting S. REP. NO. 1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399).

[121] *Id.*

[122] *Id.* at 310.

[123] Greenfield, *supra* note 75, at 1067.

[124] *Id.*

[125] Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 71 (2002) (presenting the various arguments for why gene patents should not be issued as a matter of law and policy).

[126] 35 U.S.C. § 271(a).

inventions are defined by their claims,[127] courts compare the claims of the accused device to the claims of the patented invention when determining infringement issues.[128] The infringement analysis comprises two distinct inquiries.[129] First, courts determine whether the accused invention literally infringes.[130] That is, whether every "limitation recited in the claim is found in the accused device."[131] If the court does not find literal infringement, it next examines whether there is infringement under the doctrine of equivalents.[132]

The doctrine of equivalents allows a court to find infringement when the infringing device, although not literally infringing, "performs substantially the same function" as the patented invention "in substantially the same way, to obtain the same result."[133] The doctrine finds justification in the fact that "the language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty."[134] Given the imprecise nature of language, an interpretation of patent claims based on their literal terms would greatly diminish a patent's value.[135] For this reason the scope of a patent "is not limited to its literal terms but instead embraces all equivalents to the claims described."[136] Recently, in *Warner-Jenkinson Co.* v. *Hilton Davis Chemical Co.*,[137] the Supreme Court reaffirmed that "equivalents remain a firmly entrenched part of the settled rights protected by the patent."[138]

In extending the protection available to the inventor, the doctrine of equivalents also renders the true scope of a patent less clear.[139] This, in turn, diminishes the notice function of claims by

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[127] *See supra* note 82.

[128] CHISUM ET AL., *supra* note 10, at 830-83.

[129] Robert P. Merges & Richard. R. Nelson, *On the Complex Economics of Patent Scope,* 90 COLUM. L. REV. 839, 853 (1990).

[130] *Id.*

[131] Engel Indus., Inc. v. Lockformer Co., 96 F.3d 1398, 1405 (Fed. Cir. 1996).

[132] *See* Merges & Nelson, *supra* note 129, at 853.

[133] Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42 (1929) (quoting Union Paper-Bag Mach. Co. v. Murphy, 97 U.S. 120, 125 (1877)).

[134] Festo Corp. v. Shoketsu Kinzoku Kobyo Kabushiki Co., 535 U.S. 722, 731 (2002).

[135] *See id.* (explaining that a literal interpretation would destroy a patent's value by allowing would-be infringers to escape liability by making minor, insubstantial variations that do not literally infringe the patent).

[136] *Id.* at 732 (citing Winans v. Denmead, 56 U.S. (15 How.) 330, 347 (1854)).

[137] 520 U.S. 17 (1997).

[138] *Festo Corp.*, 535 U.S. at 733 (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997)).

[139] *See id.* at 727 (noting "that by extending protection beyond the literal terms in a patent, the doctrine of equivalents can create substantial uncertainty about where

making it hard for competitors to examine a patent's claims and predict what does and does not infringe.[140] To reduce the uncertainty created by the doctrine, rules exist that forbid resort to the doctrine, as a matter of law, under certain circumstances.[141] "One of the most important of these [rules] is prosecution history[142] estoppel," which estops the patentee from using the doctrine of equivalents to recapture subject matter surrendered during the patent's prosecution.[143]

Recently, in *Festo Corp.* v. *Shoketsu Kinzoku Kabushiki Co.*,[144] the Supreme Court announced two key findings regarding the scope of prosecution history estoppel.[145] First, the Court ruled that prosecution history estoppel arises for any amendment related to patentability, not just those to avoid the prior art.[146] Second, the Court ruled that when a patentee narrows his claim by amendment, he is presumed to have surrendered the subject matter lost through amendment.[147] As a result, the patentee may not invoke the doctrine of equivalents to capture amended subject matter unless he can show "that at the time of amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent."[148]

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the patent monopoly ends").

[140] *Id.*

[141] Michael P. Sandonato & Carl. B. Wischhusen, *What 'Festo' Portends*, THE NAT'L L. J., June 10, 2002, at A19.

[142] The "prosecution history" is the record of proceedings between the patent attorney and the examiner at the United States Patent and Trademark Office regarding the prosecution of the patent. CHISUM ET AL., *supra* note 10, at 109-16. Patent prosecution is the process of obtaining a patent. *Id.* In many ways, patent prosecution is a give and take between the patent attorney and the examiner, with the examiner objecting (through a process called an office action) to certain parts of the application (such as the claims as originally written) and the attorney acting to rectify the objections through amendment. *Id.* For instance, as is often the case, an examiner might reject a patent's original claims as being too broad. *Id.* In response to the office action, the patent attorney will amend and narrow the claims and resubmit the application for approval. *Id.*

[143] Sandonato & Wischhusen, *supra* note 141, at A19.

[144] 535 U.S. 722 (2002).

[145] *See Festo Corp.*, 535 U.S. at 740-41.

[146] *Id.* at 735-37.

[147] *Id.* at 738-40. In adopting this approach, the Supreme Court overruled the Federal Circuit's "complete bar," which permanently disallowed claims of equivalence for any material surrendered during the patent's prosecution. *See* Festo Corp. v. Shoketsu Kinzoku Kabushiki Co., 234 F.3d 558 (Fed. Cir. 1995).

[148] The Supreme Court offered three examples of how the patentee may overcome the presumption: by showing that the equivalent was unforeseeable at the time of amendment, by showing that the rationale for the amendment bears no more than a tangential relation to the equivalent, or when there is some other

IV. THE POTENTIALLY NEGATIVE EFFECTS OF GENE PATENTS ON INNOVATION, RESEARCH AND HEALTH CARE

Although gene patents have become a firmly entrenched part of the patent system,[149] "the wisdom of such action is now being questioned."[150] While biotechnologists argue that gene patents are necessary to promote cost recovery and investment in new research,[151] numerous researchers, clinicians, legal commentators and politicians feel otherwise.[152] Particularly, they point to the deleterious effects of gene patents on biomedical research, biotechnological innovation, patient care and the free exchange of information among researchers.[153]

Although the examples illustrating the deleterious effects of gene patents are numerous, they revolve around the same core principle: the right of exclusion is particularly harmful with gene patents because a gene patent gives its holder exclusive rights to the gene, its sequence, and all of the gene's derivatives.[154] Thus, the

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reason suggesting that the patentee could not reasonably be expected to have described the insubstantial variation in question. *Festo Corp.*, 535 U.S. at 740-41.

[149] Aaron Xavier Fellmeth & Linda J. Demaine, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 304 (2002) (noting that the USPTO now routinely grants, and the federal courts routinely uphold, patents on naturally occurring genes, DNA fragments, and other biochemicals).

[150] Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REVIEWS GENETICS 803 (2002) (discussing the mounting body of evidence suggesting that gene patents are harming biomedical research and patient care); *see also* Andrews, *supra* note 125 (presenting the various arguments for why gene patents should not be issued as a matter of law and policy); Rebecca S. Eisenberg & Michael A. Heller, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) (discussing how a proliferation of upstream patentees may deter innovation by blocking downstream patentees from developing innovative technologies); Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783 (2000) (discussing how patent law struggles to develop new tools for analyzing recent advances in DNA sequences); Fellmeth & Demaine, *supra* note 149 (presenting the manner in which gene patents harm research and innovation and suggesting a substantial transformation test that only allows patenting of truly novel gene-based inventions); Dastgheib-Vinarov, *supra* note 66 (arguing that given the detrimental effects of broad gene patents on biomedical research they should be made more difficult to obtain by means of a heightened non-obvious standard). *But see* John J. Doll, *The Patenting of DNA*, 280 SCIENCE 689 (1998) (positing that despite arguments to the contrary, genetically based patents are necessary to provide incentive to invest in and disclose DNA research).

[151] *See* GRACE, *supra* note 15, at 204.

[152] *See* Andrews, *supra* note 125, at 66 (presenting various arguments for why gene patents should not be issued as a matter of law and policy).

[153] *See supra* note 150.

[154] *See* Andrews, *supra* note 125, at 70-72; *see also* Fellmeth & Demaine, *supra* note

patent holder may prevent potential competitors from conducting any research or from developing any therapeutic applications based on the gene's DNA sequence.[155] Even when the patent holder is willing to license, the costs can be "exorbitant."[156]

This situation is unique to gene patents because unlike drugs and other devices, scientists often cannot design around gene patents.[157] Whereas a pharmaceutical company can design around a drug patent by creating an alternative drug that treats the same condition, the competitor of a gene patent holder has no such option.[158] In order to treat or diagnose a disease at the genetic level, a competitor needs access to the disease-causing gene.[159] However, the patent holder, arguably to the detriment of health care and biotechnological innovation, controls access to the gene.[160] Recognizing the consequences of gene patent ownership, the National Academy of Sciences has noted that broad gene patents "might seriously impede the research and development necessary to realize the promise of the human genome sequence in generating significant new treatments and cures for human disease."[161]

A. Gene Patent Proliferation as a Deterrent to Innovation

The right of exclusion is particularly harmful in biotechnology because biotechnological research and development involves the use of fundamental, but often patented biochemicals, [162] such as genes, ESTs,[163] SNPs,[164] and proteins. Today, given the proliferation of gene

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149, at 413-21.

[155] Andrews, *supra* note 125, at 70.

[156] Fellmeth & Demaine, *supra* note 149, at 415-19 (commenting that because fundamental biochemical products are needed for modern research and development, patents on such products "may cause costs to accumulate to the point where scientifically valuable research becomes infeasible for researchers or inaccessible to large portions of the public").

[157] Andrews, *supra* note 125, at 78-79.

[158] Andrews, *supra* note 150, at 805 (commenting that unlike technologies such as the picture tube, which can be designed around, there are no alternatives to the patented human genes needed for genetic diagnosis and gene therapy).

[159] *Id.*

[160] *See supra* note 150.

[161] Letter from Bruce Alberts, President National Academy of Sciences, to Commissioner of Patents and Trademarks (Mar. 22, 2000) (Comment 41 on the Revised Utility Examination Guidelines), *available at* http://www.uspto.gov/web/offices/com/sol/comments/utiliguide/nas/pdf.

[162] *See* Fellmeth & Demaine, *supra* note 149, at 420.

[163] The USPTO surprised many in 1997 by announcing that it would grant patents to small sections of genes lacking a known function, known as expressed sequence tags ("ESTs"), where novelty, non-obviousness and utility are proven. Andrews, *supra* note 125, at 83-84. EST's are short cDNA sequences that lack a known function that

related patents, a biotechnology company must first identify and overcome, through licensing negotiations, every blocking patent its research will infringe.[165] As a result, any one patent holder could derail the entire process by refusing to negotiate.[166] Even when the patent holder will negotiate, the costs of licensing are often prohibitively high.[167]

In effect, each blocking patent acts as "[a]nother tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation."[168] Although the cost of overcoming one "tollbooth" may not present a problem, "the impact of multiple tollbooths on downstream research . . . and costs can be profound."[169] Illustrating the reality of this situation, the Chief Executive Officer of Human Genome Sciences noted that "[a]ny company that wants to be in the business of using genes, proteins, or antibodies as drugs has a very high probability of running afoul of our patents.[170] From a commercial point of view, they are severely constrained-and far more than they realize."[171]

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scientists collect from expressed DNA. *See* Lawrence Kass & Michael Nitabach, *A Roadmap for Biotechnology Patents? Federal Circuit Precedent and the PTO's New Examination Guidelines,* 30 AIPLA Q. J. 233, 245 (2002). If an EST is ever found to be part of a valuable gene or code for a valuable protein, the patent holder may prohibit others from conducting research, producing proteins, or developing drugs that involve use of the EST's sequence. Greenfield, *supra* note 75, at 1090-91.

[164] Single Nucleotide Polymorphisms (SNPs) are areas in the human genome differing from another by only one base pair. Rai, *supra* note 70, at 105-06. They are of particular interest to scientists because of their potential utility in identifying genes responsible for disorders such as "diabetes, hypertension, asthma, common cancers, and major neuropsychiatric diseases." *Id.* Currently, much of SNP research is in its initial stages and the majority of newly discovered SNPs have not been linked to identifiable diseases. *Id.* Consequently, many of the patent applications filed on SNP research have been based on SNP's of unknown function, for which the commercial applications are not yet clear. *Id.*

[165] Fellmeth & Demaine, *supra* note 149, at 414-21.

[166] Andrews, *supra* note 125, at 85.

[167] Fellmeth & Demaine, *supra* note 149, at 415-19 (commenting that because fundamental biochemical products are needed for modern research and development, patents on such products "may cause costs to accumulate to the point where scientifically valuable research becomes infeasible for researchers or inaccessible to large portions of the public").

[168] *Id.* at 414 (quoting Rebecca Eisenberg & Michael A. Heller, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1998)).

[169] *Id.* at 418.

[170] Lawrence M. Fisher, *The Race to Cash In on the Genetic Code*, N.Y. TIMES, Aug. 29, 1999, § 3, at 1.

[171] *Id.*

B. The Potential to Harm Health Care

Gene patents threaten to undermine the overall quality of health care by preventing biomedical research[172] and by decreasing the quality and availability of diagnostic testing.[173] Gene patents endanger biomedical research in numerous ways. First, the opportunity to patent discoveries has led to a decrease in the free exchange of information once common among scientists.[174] Now, researchers may delay publishing valuable information until their patent rights are secured, which may take several years.[175] As noted by Lori Andrews, Professor of Law at Chicago-Kent College of Law, "scientists directly involved with commercializing their research [are] three times more likely to delay publication and twice as likely to refuse sharing research than scientists conducting basic work."[176] In another example offered by Andrews, progress in autism research has been delayed because researchers have refused to share tissue samples in an effort to be the first to find and patent the autism-causing gene.[177]

Another way in which gene patents harm biomedical research is by preventing it altogether.[178] For instance, although numerous mutations in the same gene are often responsible for certain diseases, companies such as Athena Neuroscience Inc., which holds a patent for the gene associated with Alzheimer's Disease, forbid laboratories other than their own from screening for mutations in the gene.[179] As a result, the chances of finding additional mutations are severely diminished—a quite unfortunate result considering that knowledge of such mutations could prove useful in diagnosing those who would not otherwise be diagnosed.[180]

A further example of this phenomenon offered by Professor Andrews is the European patent for BRCA1, a gene implicated in breast cancer.[181] In 2001, the United States biotech company Myriad

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[172] *See generally* Dastgheib-Vinarov, *supra* note 66.

[173] Andrews, *supra* note 125; *see also* Fellmeth & Demaine, *supra* note 149, at 413-22.

[174] GRACE, *supra* note 15, at 205.

[175] Andrews, *supra* note 125, at 79-81.

[176] *Id.* at 80.

[177] Andrews, *supra* note 150, at 804.

[178] *See* Andrews, *supra* note 125, at 79; *see also* Fellmeth & Demaine, *supra* note 149, at 415-21.

[179] Andrews, *supra* note 150, at 804.

[180] *See* Andrews, *supra* note 125, at 89.

[181] Andrews, *supra* note 150, at 804.

Genetics received the European patent on BRCA1.[182] The broad patent covers "all methods for diagnosing breast cancer by comparing a patient's BRCA1 gene with the BRCA1 gene Myriad describes in its patent."[183] After acquiring the patent, Myriad refused to allow French doctors to test for the BRCA1 gene.[184] Instead, Myriad insisted on conducting all testing in its laboratory.[185] French physicians allege that Myriad's test screens for only ten to twenty percent of potential BRCA1 mutations.[186] However, additional tests aimed at identifying the remaining mutations cannot be developed without infringing Myriad's broad patent.[187] This same patent prevented a Yale researcher from continuing his breast cancer research due to fear of infringing the license limitations on the patented gene.[188]

Gene patents also impede the progress of pharmacogenomics.[189] Although many drugs only work on a percentage of users with a particular genetic disposition, pharmaceutical companies may use their gene patents to prevent customers from determining if the drug is efficacious for them.[190] For example, even though genetic tests could reveal for whom certain drugs will work, pharmaceutical companies have prevented the development of such tests by patenting the tests and refusing to develop or let anyone else develop them.[191] As a result, customers can only speculate whether their costly drugs are compatible with their genetic make-ups.[192]

The downstream costs of gene patents also threaten to decrease access to gene-based diagnostics and therapeutics.[193] On the road to product development, biotechnology companies must overcome the

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[182] *Id.*

[183] *Id.* (citing Declan Butler & Sally Goodman, *French researchers take a stand against breast cancer gene patent*, 413 NATURE 95 (2001)).

[184] *Id.*

[185] *Id.*

[186] *See id.* (citing Gad et al., *Identification of a large rearrangement of the BRCA1 gene using color bar code on combed DNA in an American breast/ovarian cancer family previously studied by direct sequencing*, 38 J. MED. GENET. 388 (2001)).

[187] Andrews, *supra* note 150, at 804.

[188] Fellmeth & Demaine, *supra* note 149, at 417.

[189] Andrews, *supra* note 150, at 804. Pharmacogenomics is "the application of genomics to pharmaceutical research, using genome studies to identify genes that account for differences in different individuals." Am. Med. Assoc., Pharmacogenomics, *at* http://www.ama-assn.org/ama/pub/category/2306.html (last visited Nov. 28, 2003).

[190] Andrews, *supra* note 150, at 804.

[191] *Id.*

[192] *Id.*

[193] *See* Fellmeth & Demaine, *supra* note 150, at 416-17.

prohibitively high costs of numerous blocking patents.[194] Such costs are likely passed on to consumers.[195] As a result, consumers face decreased accessibility to valuable products, such as genetic testing.[196] As noted by Professor Andrews, this concern has recently become reality in Canada.[197] The province of British Columbia has stopped paying for genetic breast cancer testing because the health care system could not afford to pay what Myriad, the owner of the patent, was charging.[198]

C. The Positive Attributes of Gene Patents

Recognizing the arguments against gene patents, John Doll, the USPTO's Director of Biotechnology Examination, argues that isolated and purified DNA sequences must be patentable.[199] He believes that "[w]ithout the incentive of patents, there would be less investment in research, and scientists might not disclose their new technologies to the public."[200] He notes that such investment is necessary for the survival of small biotech companies.[201] In addition, Doll compares the current controversy of gene patents to the controversy surrounding polymer chemistry patents thirty years ago.[202] He reminds us that although commentators, fearing the destruction of an industry, argued against broad claims to the building blocks of basic polymers, no such destruction occurred.[203]

Further, commentators posit that without gene patents, biotechnology companies would turn to trade secret protection.[204] As a result, companies would refuse to disclose any information, which would prove extremely harmful to biotechnology, an industry dependent on the free exchange of information.[205] This in turn would lead to duplicate work, as companies would be unwilling to

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[194] *See supra* pp. 726-727.

[195] *See* Fellmeth & Demaine, *supra* note 149, at 416.

[196] *Id.*

[197] *See* Andrews, *supra* note 125, at 91.

[198] *Id.*

[199] Doll, *supra* note 150, at 689.

[200] *Id.* at 690.

[201] *Id.*

[202] *Id.* at 689.

[203] *Id.*

[204] *See* Sheila R. Arriola, *Biotechnology Patents After Festo: Rethinking the Heightened Enablement and Written Description Requirements*, 11 FED. CIR. B.J. 919, 947 (2002) (arguing for relaxed standards of enablement and written description in light of the Federal Circuit's complete bar rule).

[205] *Id.*

license their technologies for fear of reverse engineering.[206] In the end, the absence of disclosure could harm innovation by depriving researchers of the building blocks necessary to further the current state of the art.[207]

D. Appropriate Solutions to the Gene Patenting Dilemma

The compelling arguments both for and against the issuance of gene patents highlight the challenges facing courts, legislators and policy makers alike.[208] Although the ill effects of gene patents on research and health care are real,[209] without such patents venture capitalists may be less willing to invest in new technologies.[210] Such lack of investment could make it difficult for small biotech companies to succeed.[211] At the same time, the proliferation of gene-based patents has created multiple "tollbooth[s] on the road to product development."[212] Even if small companies receive investment, the prohibitively high cost of navigating through today's intellectual property minefield may very well prove disabling.[213] Further, gene patents arguably have reduced the exchange of information among researchers by delaying publication times.[214] If such patents were not in existence, however, companies might resort to trade secret protection, thus precluding all disclosure.[215]

In light of the complexities gene patents create, remedies are needed that maintain a level of economic incentive without causing significant harm to health care and biotechnological innovation.[216] Suggested alternatives include government encouragement of patent pools,[217] compulsory licensing schemes for researchers,[218] and a "fair

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[206] *Id.* Reverse engineering involves "starting with the known product and working backward to divine the process which aided in its development or manufacture." Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 476 (1974).

[207] Arriola, *supra* note 204, at 947.

[208] According to Professor Andrews, commentators have proposed various solutions to the gene patent dilemma, such as banning them altogether, patent pools, and mandatory licensing. Andrews, *supra* note 125, at 67, 101-06.

[209] *See generally supra* note 150.

[210] *See* Doll, *supra* note 150, at 689; *see also* GRACE, *supra* note 15, at 204.

[211] *Doll*, *supra* note 150, at 690.

[212] Eisenberg & Heller, *supra* note 150, at 699.

[213] Fellmeth & Demaine, *supra* note 149, at 413-23.

[214] Andrews, *supra* note 125, at 79-81; *see also* GRACE, *supra* note 15, at 205 (noting that broad gene patents "create[] possessiveness about basic information") .

[215] *See* Arriola, *supra* note 204, at 947.

[216] *See generally* Andrews, *supra* note 125.

[217] *Id.* at 101-03.

[218] *Id.* at 103.

use" exception for research involving genetic sequence information.[219] Others, recognizing the problem of broad patents in biotechnology,[220] have suggested patent law specific means of regulating gene patents, such as a higher non-obvious standard,[221] and a substantial transformation test that would only allow patenting of gene-based inventions "transformed in such a way as to create a new product that is substantially different in function from the naturally occurring phenomenon."[222] Recently, Judge Gajarsa of the Federal Circuit noted the possible need for higher standards of patentability in biotechnology cases.[223] Consistent with those who advocate the creation of higher standards for biotechnology patents, this Comment proposes a foreseeability-based restriction on the doctrine of equivalents in biotechnology patent cases.[224]

V. LIMITING GENE PATENT CLAIM SCOPE THROUGH A BIOTECHNOLOGY-SPECIFIC, FORESEEABILITY-BASED LIMITATION ON THE DOCTRINE OF EQUIVALENTS

Recognizing the detrimental effects that broad gene patents may have on biotechnological progress, Professors Robert Merges and Richard Nelson offer a solution.[225] They argue that "scope limitations based on close adherence to the inventor's disclosure and judicious

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[219] *See* The Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002). In March of 2002, Rep. Lynn Rivers introduced the "Genomic Research and Diagnostic Accessibility Act of 2002," aimed at addressing the "troublesome" effects of gene patenting on biomedical research and patient care. 29 CONG. REC. E353 (daily ed. Mar. 14, 2002) (statement of Rep. Rivers). Among the bill's provisions is a subsection exempting from infringement liability the "use [of] patented genetic sequence information for non-commercial research purposes." *Id.* at E354. Rep. Rivers likened this exemption to the "fair use" defense in copyright law. *Id.*

[220] *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology Specific?*, 17 BERKELEY TECH. L.J. 1155, 1204 (2002) (discussing the emergence of technology-specific patent law doctrines).

[221] *See generally* Dastgheib-Vinarov, *supra* note 66.

[222] *See* Fellmeth & Demaine, *supra* note 149, at 392.

[223] Arthur J. Gajarsa, *Hon. Helen Wilson Nies Memorial Lecture: The Fifth Annual Honorable Helen Wilson Nies Memorial Lecture in Intellectual Property Law*, 6 MARQ. INTELL. PROP. L. REV. 1, 6-7 (2002).

[224] See *infra* Part V for an examination of how a foreseeability-based limit on the doctrine of equivalents can spur biotechnological innovation.

[225] In their work on the economics of patent scope, Robert P. Merges and Richard R. Nelson argue that the proper scope of patents is a dynamic, industry-based issue. *See* Merges & Nelson, *supra* note 129, at 880. With regard to science-based industries, such as biotechnology, Merges and Nelson warn of the dangers that result from "awarding overly broad patents early in the history of an industry founded on recent scientific advances." *Id.* at 915.

use of the doctrine of equivalents provide the surest way around [the] danger" of broad gene patents.[226] The Federal Circuit has already acted to limit gene patents through "close adherence to the inventor's disclosure,"[227] by elevating the standards of written description and enablement for biotechnology cases in *Amgen v. Chugai Pharmaceuticals Co.*,[228] *Fiers v. Revel*,[229] and *Regents of the Univ. of Calif. v. Eli Lilly & Co.*[230] This Comment proposes that the Federal Circuit heed Merges and Nelson's second piece of advice, "[j]udicious use of the doctrine of equivalents,"[231] and adopt a biotechnology-specific version of the foreseeability standard articulated in Judge Rader's concurring opinion in *Johnson & Johnston Assocs., Inc.*[232]

In *Johnson & Johnston Assocs., Inc.*, the patentee claimed an assembly of a printed circuit board "that prevent[ed] most damage during manual handling."[233] The invention involved adhering fragile copper foil used in the circuit board to a stiffer substrate sheet of aluminum.[234] This construction allowed workers to handle the aluminum, rather than the copper foil, during the production process, thus preventing the damage to the copper circuits associated with handling the copper foil directly.[235] The specification identified aluminum as the preferred material for the substrate, but also

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[226] *See id.*

[227] Merges & Nelson, *supra* note 129, at 915. *See* Alison E. Cantor, *Using the Written Description and Enablement Requirement to Limit Biotechnology Patents*, 14 HARV. J.L. & TECH. 267 (2000) (discussing how the Federal Circuit has raised the bar with regard to written description and enablement in an effort to limit the scope of gene based patents); *see also* Emanuel Vacchiano, Comment, *It's a Wonderful Genome: The Written Description Requirement Protects the Human Genome from Overly-Broad Patents*, 32 J. MARSHALL L. REV. 805 (1999) (discussing how the Federal Circuit has applied the written description requirement to narrow gene patent scope); 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 (2000) (discussing the current trend of the Federal Circuit to heighten both the enablement and written description requirements for biotechnological inventions under 35 U.S.C. § 112).

[228] *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991).

[229] *See* Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).

[230] *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

[231] Merges and Nelson's second piece of advice for limiting gene patent scope is "[j]udicious use of the doctrine of equivalents." Merges & Nelson, *supra* note 129, at 915.

[232] *See Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1056-59 (Rader, J., concurring).

[233] *Id.* at 1049.

[234] *Id.*

[235] *Id.*

identified that "other metals, such as stainless steel or nickel alloy, may be used."[236] Despite disclosing steel and nickel alloy, the patentee only claimed aluminum as a substrate.[237] The accused device used steel.[238]

Sitting en banc, the Federal Circuit held that the accused patent did not infringe.[239] Notably, the court's opinion settled an issue over which Federal Circuit judges have long disagreed: whether subject matter that is disclosed, but not claimed, is within the purview of the doctrine of equivalents.[240] The court ruled that such subject matter may not be captured through the doctrine of equivalents and is dedicated to the public.[241] While concurring with the majority opinion, Judge Rader, joined by Chief Judge Mayer, argued that the court should have instead adopted a broader foreseeability bar to the doctrine of equivalents.[242]

Judge Rader articulated his foreseeability standard in a desire to achieve a "better balance between the notice function of claims and the protective function of non-textual infringement."[243] Under the foreseeability approach, the patentee "has an obligation to draft claims that capture all reasonably foreseeable ways to practice the invention."[244] If the claims do not "capture subject matter that the patent drafter reasonably could have foreseen,"[245] the patentee may not rely on the doctrine of equivalents in extending the scope of his claims beyond their literal meaning.[246] Thus, with the exception of objectively unforeseeable subject matter, such as after arising technology,[247] or subject matter "cloaked by the subtlety of language,"[248] the patent applicant may not broaden his claims to

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[236] *Id.* at 1050.

[237] *Id.*

[238] *See Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1050.

[239] *Id.* at 1055.

[240] Joseph M O'Malley Jr. & Bruce M. Wexler, *Battle Lines Form on Matter Disclosed But Not Claimed*, 227 N.Y. L.J. S4 (2002).

[241] *See Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1054-55.

[242] *Id.* at 1056-59 (Rader, J., concurring).

[243] *Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1059 (Rader, J., concurring).

[244] *Id.* at 1057 (Rader, J., concurring).

[245] *Id.* at 1056 (Rader, J., concurring).

[246] *Id.* at 1056-59 (Rader, J., concurring).

[247] *Id.* at 1058 (Rader, J., concurring) (citing Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1425 (Fed. Cir. 1997) (noting that the doctrine of equivalents applies to after-arising technology)). "After arising" technology refers to technology that is developed after the claims are drafted. Lawrence M. Sung, *On Treating Past as Prologue*, 2001 U. ILL. J.L. TECH. & POL'Y 75, 81 n.29 (2001).

[248] *Id.* (quoting *Sage Prods., Inc.*, 126 F.3d at 1425).

reach objectively foreseeable, yet unclaimed subject matter.[249]

Compared to the Supreme Court's *Festo*[250] pronouncement regarding prosecution history esoppel, the foreseeability standard is an even greater restraint on a patentee's ability to broaden his claims through the doctrine of equivalents. It is so highly limiting because it applies to the claims as originally drafted, regardless of whether they are amended,[251] and thus before prosecution history estoppel arises.[252] Consequently, under a foreseeability approach, the patentee is precluded from using the doctrine of equivalents to capture any foreseeable, yet unclaimed subject matter,[253] notwithstanding a lack of prosecution history estoppel.

Although Judge Rader spoke generally about the desirability of limiting the doctrine of equivalents via a foreseeability standard, he did not speak in terms of biotechnology or gene patents.[254] This comment, however, argues for a biotechnology–specific application of the foreseeability standard. It examines the legal authority for applying a heightened, more restrictive version of the doctrine of equivalents in biotechnology patent cases. It seeks to highlight both how and why a biotechnology specific, foreseeability-based limitation on the doctrine of equivalents would prevent broad reaching gene patents, thereby contributing to biotechnological innovation.

A. The Foreseeability-Based Limitation is Consistent with Recent Patent Law Precedent Limiting the Availability of the Doctrine of Equivalents

The foreseeability approach, which restricts a patentee's access to the doctrine of equivalents, is in accord with recent Federal Circuit and Supreme Court decisions generally limiting the doctrine's

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[249] *See Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1056-59 (Rader, J., concurring).

[250] *Festo Corp.*, 535 U.S. 722; see *supra* text accompanying notes 144-48 for a discussion of *Festo*.

[251] See *supra* note 142 for the difference between original and amended claims.

[252] Jessica L. Bagner & Steven J. Rizzi, *Litigating Infringement Under the Doctrine of Equivalents After Festo*, 721 PLI/PAT 345, 365 (2002) (examining *Festo* and the implications of a foreseeability standard in guiding the application of prosecution history estoppel). Prosecution history estoppel precludes the patentee from capturing subject matter lost through amendment. See *supra* text accompanying notes 142-48. In contrast, the foreseeability approach applies to the original claims before they are amended, and thus before prosecution history estoppel becomes applicable. *See Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1056-59 (Rader, J., concurring). See *supra* note 142 for a discussion of patent prosecution.

[253] *See Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1056-59 (Rader, J., concurring).

[254] *Id.*

applicability.[255] The holdings in *Pennwault Corp. v. Durand-Wayland, Inc.*[256] and *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*[257] made it more difficult to prove non-textual infringement by requiring a patentee to show equivalence for every element in the claim, not just the claim as a whole. In *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*,[258] the Federal Circuit again limited the doctrine in holding that it cannot be used to embrace prior art.[259] Further, the court-created doctrine of prosecution history estoppel,[260] a major limitation on the doctrine of equivalents, prevents the patentee from claiming equivalence for any amendment related to patentability made during the patent's prosecution.[261] Finally, in *Johnson & Johnston Assocs., Inc.*, the Federal Circuit held that subject matter disclosed but not claimed, "perhaps the ultimate example of subject matter that is foreseeable,"[262] may not be reached by the doctrine of equivalents.[263]

Also, the Federal Circuit has, on occasion, used a foreseeability approach to limit the application of the doctrine of equivalents.[264] For instance, in *Sage Products, Inc. v. Devon Indus., Inc.*,[265] the Federal Circuit held that the doctrine of equivalents may not be used to capture foreseeable modifications to a claimed invention.[266] According to the court, "a skilled patent drafter would foresee the limiting potential of the 'over said slot' limitation."[267] The court stressed that the patentee could have sought claims with fewer structural limitations if it wanted broad patent protection but instead "left the PTO with manifestly limited claims that it now seeks to expand through the doctrine of equivalents."[268] Thus, the court declared, "as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it

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[255] *Id.* at 1056-57 (Rader, J., concurring).

[256] Pennwault Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 935 (Fed. Cir. 1987).

[257] *Warner-Jenkinson Co.*, 520 U.S. at 40.

[258] 904 F.2d 677 (Fed. Cir. 1990).

[259] *Id.* at 683.

[260] See *supra* text accompanying notes 142-48 for an overview of prosecution history estoppel.

[261] *Festo Corp.*, 535 U.S. at 734-40.

[262] *See* Sandonato & Wischhusen, *supra* note 143, at A19.

[263] *Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1054-55.

[264] *See id.* at 1057-58 (Rader, J., concurring).

[265] The patent at issue in *Sage* involved a system for safely disposing of sharp medical instruments. *See Sage Prods.*, 126 F.3d at 1422.

[266] *Id.* at 1425 (noting that "[i]t is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure").

[267] *Id.*

[268] *Id.*

is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure."[269]

B. The Foreseeability Standard is Consistent with Federal Circuit Precedent Creating Heightened, Biotechnology-Specific Patent Law Principles for Preventing Broad Gene Patents

A biotechnology-specific application of the foreseeability standard would be consistent with recent Federal Circuit precedent employing biotechnology-specific means to limit gene patent scope.[270] In particular, the Federal Circuit has adopted elevated standards of enablement[271] and written description[272] for biotechnology patents, in an attempt to limit claims to gene-based inventions.[273] These heightened patentability standards for biotechnology patents are set forth in *Amgen,*[274] *Fiers*[275] and *Eli Lilly*.[276]

One of the Federal Circuit's most notable decisions involving the use of the enablement requirement to limit biotechnology patent claims is *Amgen*.[277] In *Amgen*, the plaintiff, Amgen, and defendant both held patents on technology relevant to the production of erythropoietin ("EPO"), a protein responsible for stimulating the production of red blood cells.[278] Amgen's patent was for a recombinant DNA version of EPO.[279] Amgen claimed all possible DNA sequences coding for functional equivalents or "analogs" of the human EPO protein.[280] EPO analogs were defined as those proteins having the biological properties of normal EPO, "but encoded for by a DNA sequence different than the normal EPO DNA sequence."[281]

In its decision, the Federal Circuit invalidated claim 7,[282] which

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[269] *Id.*

[270] *See supra* note 227.

[271] See *supra* text accompanying notes 111-14 for an overview of the enablement requirement.

[272] See *supra* text accompanying notes 107-10 for an overview of the written description requirement.

[273] *See supra* note 227.

[274] *See Amgen*, 927 F.2d at 1200.

[275] *See Fiers*, 984 F.3d at 1164.

[276] *See Eli Lilly*, 119 F.3d at 1559.

[277] *See* Cantor, *supra* note 227, at 291.

[278] *Amgen*, 927 F.2d at 1203-04.

[279] *Id.*

[280] *Id.* at 1204.

[281] Sampson, *supra* note 227, at 1241 (interpreting claim 7 in *Amgen*).

[282] Claim 7 was directed to:

> A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid

was directed to "[a] purified and isolated DNA sequence," for lack of enablement.[283] According to the court, Amgen had not disclosed enough information to enable one skilled in the art to predictably produce DNA sequences coding for EPO analogs with EPO-like activity.[284] Whereas one could read Amgen's patent to claim thousands, if not millions, of DNA sequences, Amgen had only generated fifty to eighty analogs.[285] Regarding the analogs, an Amgen scientist testified that he could not say whether they possessed the same biological properties as human EPO.[286] As a result, the court concluded that "mak[ing] the gene and disclos[ing] a handful of analogs whose activity has not been clearly ascertained," is not sufficient to claim "all of the gene sequences that have EPO-like activity."[287]

Significantly, the Federal Circuit's decision in *Amgen* limits an inventor's ability to obtain broad gene patents by claiming every biologically active variation of a gene's DNA sequence.[288] While an inventor "may be able to write down the possible variations of a gene's DNA sequence, unless the inventor can reliably predict the effect of the variations on the activity of the encoded protein, the inventor has no right to claim all biologically significant analogs of a gene."[289]

In addition to the enablement requirement of § 112, a patent specification must also contain a written description describing the invention in "sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention."[290] Whereas a generic statement describing the invention is usually sufficient with regard to chemical materials, such has not been the case with genetic material.[291] An adequate written description of a DNA sequence "requires more than a mere statement that it is part of

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> sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.

Amgen, 927 F.2d at 1204.

[283] *Id.* at 1213.

[284] *Id.* at 1213-14.

[285] *Id.* at 1213 (noting the district court's findings).

[286] *Id.*

[287] *Id.* at 1214.

[288] *See* Sampson, *supra* note 227, at 1242.

[289] *Id.*

[290] *See Eli Lilly*, 119 F.3d at 1566 (quoting Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)).

[291] *See id.* at 1568.

the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself."[292] Thus, whereas constructive reduction to practice is usually sufficient to satisfy this requirement, the Federal Circuit has heightened the written description requirement for biotechnology by requiring a description of the DNA itself.[293]

In *Fiers*, the Federal Circuit heard an appeal from a three-way interference action in the USPTO between Sugano, Revel and Fiers regarding conflicting claims to a gene coding for beta interferon.[294] Fiers's patent application disclosed a method for isolating the DNA sequence coding for beta-interferon, which experts testified was adequate to allow one skilled in the art to isolate beta-interferon without undue experimentation.[295] The court, however, relying on its reasoning in *Amgen*, ruled that Fiers was not the first to conceive this method because he had not defined the gene other than by its biological function or activity.[296] As for Revel, the court ruled his application invalid for lack of a satisfactory written description.[297] While Revel disclosed methods for isolating the DNA coding for beta-interferon, he did not disclose a complete DNA sequence coding for beta-interferon.[298] The court reasoned that a satisfactory written description for DNA must contain the same degree of specificity required to prove conception.[299] Thus, according to the court, a method for isolating beta-interferon without disclosure of the complete nucleotide sequence does not suffice.[300] The court awarded priority to Sugano, whose application disclosed a method for isolating the DNA sequence as well as the DNA's complete nucleotide sequence.[301]

In 1997, the Federal Circuit created an even higher written description standard for biotechnology inventions in *The Regents of California v. Eli Lilly*.[302] In *Eli Lilly*, the patent at issue related to recombinant plasmids and microorganisms that produce human

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[292] *Id.* at 1566-67.

[293] *See* Arriola, *supra* note 204, at 937.

[294] *Fiers*, 984 F.2d at 1166-68.

[295] *Id.* at 1167.

[296] *Id.* at 1169.

[297] *Id.* at 1170-71.

[298] *Id.*

[299] *Id.* at 1171.

[300] *Fiers*, 984 F.2d at 1170-71.

[301] *Id.* at 1167.

[302] *See* Arriola, *supra* note 204, at 936 (discussing *Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997)).

insulin.[303] The patent featured broad claims for cDNA[304] coding for human, vertebrate and mammalian insulin,[305] and disclosed the relevant cDNA sequence for rat insulin.[306] The patent application also disclosed a general method for obtaining human cDNA.[307] According to the court, while the specification supported a claim to cDNA coding for rat insulin, it did not support a broader claim for human insulin or the genus claim covering the cDNA of vertebrates or mammals.[308]

Building on *Fiers*, the Federal Circuit reasoned that an adequate written description of a DNA sequence requires more than a description of the protein for which it encodes or a method for preparing it.[309] The court opined that the specification did not adequately describe the claim to human insulin because, while the specification described a method for preparing human insulin cDNA, it failed to provide the actual nucleotide sequence of human cDNA.[310] As for the genus claims, the court found the description of rat insulin insufficient to describe the broad classes of vertebrate or mammalian insulin cDNA.[311]

C. A Biotechnology-Specific Foreseeability Limit on the Doctrine of Equivalents will Reinforce the Federal Circuit's Goal of Limiting Gene Patent Scope

A biotechnology-specific application of the objective foreseeability standard will complement and further buttress the Federal Circuit's purpose in raising the biotech patentability bar: the prevention of overly broad gene-based patents.[312] In *Amgen,* the Federal Circuit used a heightened enablement standard to prevent the patentee from claiming all DNA sequences coding for EPO analogs.[313] In *Eli Lilly* and *Fiers*, the Federal Circuit raised the bar for written description to prevent applicants from demonstrating

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[303] *Eli Lilly*, 119 F.3d at 1562.

[304] Complementary DNA (cDNA) is DNA that is synthesized using mRNA as a template. *See* BECKER ET AL., *supra* note 27, at 525-26. Through this process, known as reverse transcription, scientists can isolate the original gene minus its non-coding regions. *Id.*

[305] *See Eli Lilly & Co.*, 119 F.3d at 1567-69.

[306] *Id.* at 1566-69.

[307] *Id.* at 1567.

[308] *Id.* at 1566-69.

[309] *Id.* at 1567.

[310] *See id.*

[311] *Eli Lilly*, 119 F.3d at 1567.

[312] *See supra* note 227.

[313] *Amgen*, 927 F.2d at 1214.

possession of the claimed invention until they could describe the exact DNA sequence.[314] If adopted, a biotechnology-specific, foreseeability-based limitation on the doctrine of equivalents will further prevent inventors from broadening claims to DNA-based patents.

As things currently stand after *Festo*,[315] inventors seeking to patent gene-based inventions face two major hurdles: prosecution history estoppel[316] and the elevated standards of written description and enablement.[317] That is, patent applicants wish to protect their inventions by claiming all variants, i.e., analogs of the invention.[318] The heightened standards of enablement and written description, however, inevitably preclude broadly claiming all of the variants.[319] Further, once the enablement or written description rejection is made, prosecution history estoppel will prevent capturing those variants through the doctrine of equivalents.[320] Thus, the applicant will be left with the literal and narrower language of the original claims.[321]

To avoid this possibility, commentators suggest claiming an invention narrowly, in order to avoid prosecution history estoppel, and attempting to broaden the claims through the doctrine of equivalents.[322] A foreseeability limit, however, prevents the patentee from employing these means to broaden gene patent scope because it applies to the original claims as drafted, regardless of the existence of prosecution history estoppel.[323] Thus, once the patentee *foresees* a

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[314] *See* Sampson, *supra* note 273, at 1258-65 (offering an overview of how the Federal Circuit has applied a heightened standard of written description).

[315] *Festo Corp.*, 535 U.S. 722.

[316] See *supra* text accompanying notes 142-48 for an overview of prosecution history estoppel.

[317] *See supra* note 227.

[318] *See* Arriola, *supra* note 204, at 944.

[319] *Id.* at 944 (referring to the "all too common written description and enablement rejection").

[320] *Id.* This result occurs because any amendment related to patentability gives rise to prosecution history estoppel. *See Festo Corp.*, 535 U.S. 722, 735-77. Thus, once the patent applicant narrows his claims in response to an enablement or written description rejection (an amendment related to patentability under 35 U.S.C. § 112), prosecution history estoppel prevents broadening the claims to capture the subject matter lost in amendment. See *supra* text accompanying notes 142-48 for an overview of prosecution history estoppel.

[321] *See supra* note 320.

[322] *See* John M. Benassi & Kurt M. Kjelland, *Still Not the Same as it Ever Was . . . Proving Infringement After the Supreme Court's Festo Decision*, 721 PLI/PAT 253, 306 (2002); *see also* Arriola, *supra* note 204, at 945 (making this suggestion in the context of the complete bar announced by the Federal Circuit in *Festo I*).

[323] *See* Bagner & Rizzi, *supra* note 252, at 365.

particular DNA sequence, protein or analog, he must draft his claims to include such material.[324] If the applicant fails to claim this foreseeable subject matter, by narrowly claiming the invention with an eye to broadening through the doctrine of equivalents, he will fall prey to the foreseeability standard.[325] By deliberately claiming a subset of possibilities, the applicant recognized and chose not to claim foreseeable subject matter.[326] Thus, he knowingly drew the line and is precluded from resorting to the doctrine of equivalents to later capture such subject matter.[327]

Further, in requiring the patentee "to draft claims that capture all reasonably foreseeable ways to practice the invention,"[328] the foreseeable standard places quite a burden on the claims drafter.[329] With regard to claims to DNA sequences and their proteins, the patent applicant faces the formidable task of having to claim all objectively foreseeable variants of the sequence or protein.[330] Although Judge Rader did not provide explicit guidance as to what constitutes objective foreseeability, the Federal Circuit recently delineated such a standard in its latest *Festo* pronouncement, on remand from the Supreme Court.[331] According to the court, objective foreseeability is determined from the perspective of one skilled in the art.[332] The Federal Circuit further expounded that if an equivalent is known in the relevant prior art, "it certainly [should] be foreseeable."[333]

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[324] *See Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1057 (Rader, J., concurring) (noting that "when one of ordinary skill in the art would foresee coverage of an invention, a patent drafter has an obligation to claim those foreseeable limits").

[325] *See id.* at 1058 (Rader, J., concurring) (quoting *Sage Prods.*, 126 F.3d 1420 ("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 for this foreseeable alteration of its claimed structure.")).

[326] *See* James Pooley & Marc David Peter, *Proof of Equivalence After Festo: The Impact of Foresight*, 725 PLI/PAT 101, 107 (2002) (examining the role and application of foresight on the doctrine of equivalents after *Festo*).

[327] *See Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1056 (Rader, J., concurring) (noting "the doctrine of equivalents does not capture subject matter that the patent drafter reasonably could have foreseen during the application process and included in the claims").

[328] *Id.* at 1057 (Rader, J., concurring).

[329] *See id.* (noting the premium that the foreseeability standard places on claims drafting).

[330] *See id.* (noting the "objective standard" set by foreseeability).

[331] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 344 F.3d 1359, 1369 (Fed. Cir. 2003).

[332] *Id.*

[333] *Id.* (citing Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352, 1357 (Fed. Cir. 2003)).

In patent law, the person of ordinary skill in the art possesses knowledge of every relevant prior art reference.[334] Thus, gene patent applicants face an uphill battle when arguing that the subject matter they failed to claim was objectively unforeseeable. Under the Federal Circuit's most recent foreseeability analysis in *Festo*, subject matter is likely objectively foreseeable if it exists in the relevant prior art.[335] Thus, applicants who fail to claim a sequence, protein or variant either deliberately, by mistake or because it was unknown to them at the time of invention, each a real possibility given the breadth of biotechnology prior art,[336] may very well be precluded from arguing that the material was unforeseeable and thus reachable by the doctrine of equivalents.[337]

D. The "Premium"[338] that the Foreseeability Approach Places on Notice will Serve to Further Spur Biotechnological Innovation

The doctrine of equivalents, while allowing patentees to bring non-literal infringement claims, also creates a level of uncertainty among competitors.[339] Given that "claims, like the words with which they are written, are inherently imprecise,"[340] competitors can never be sure whether their activities are safe from infringement suits under the doctrine of equivalents.[341] This leads to increased risk and decreased incentives to invent technologies that may infringe the outer, undefined boundary of other patent claims.[342] Arguably, such uncertainty is further magnified in biotechnology, a field characterized by a proliferation of intellectual property rights

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[334] *See* Burk & Lemley, *supra* note 220, at 1188 (citing In re Winslow, 365 F.2d 1017 (C.C.P.A. 1966)).

[335] *Festo*, 344 F.3d at 1369 (citing *Pioneer Magnetics, Inc.*, 330 F.3d at 1357).

[336] *See* Arriola, *supra* note 273, at 942-43 (noting that "[m]any molecular manipulations involved in the quest for scientific discoveries, although scientifically complex, are something more akin to routine testing in the field," and that "it is no longer a novel concept for scientists to 'design' functional equivalents"); *see also* Fellmeth & Demaine, *supra* note 149, at 306 (commenting how technologies such as gene cloning, computer controlled sequencing machines, and polymerase chain reactions have significantly increased scientists' ability to rapidly locate and sequence commercially valuable genes).

[337] *See* Bagner & Rizzi, *supra* note 252, at 305.

[338] *Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1057 (Rader, J., concurring) (noting that the foreseeability standard places a "premium on notice").

[339] *See* Sandonato & Wischhusen, *supra* note 143, at A19.

[340] *Id.*

[341] *See* Mathew J. Conigliaro et al., *Foreseeability in Patent Law*, 16 BERKELEY TECH. L.J. 1045, 1058 (2001) (arguing for a foreseeable approach to prosecution history estoppel).

[342] *Id.*

regarding the fundamental biochemicals needed for research.[343]

Under a foreseeability limit on the doctrine of equivalents, which disallows equivalence for objectively foreseeable yet unclaimed subject matter, the claims become "the sole definition of invention scope in all foreseeable circumstances."[344] Thus, competitors in the biotechnology industry need only consult the claims for reliable guidance regarding what does and does not infringe the patent.[345] In providing clearer boundaries regarding infringement, the foreseeability standard eliminates some of the risks associated with new product development in this age of intellectual property right proliferation.[346] Hopefully, this decreased level of risk will translate to increased incentives to develop innovative technologies.

Further, although the foreseeability standard makes claims "the sole definition of invention scope," it does not harm the patentee by providing competitors with a "blueprint" for avoiding infringement.[347] As noted by various commentators, "[w]here foreseeability is found, the patentee is deemed to have intended to abandon that particular equivalent, and thus neither patent law nor equity is offended by the competitor's use of the equivalent subject matter . . . ."[348]

CONCLUSION

Advances in molecular biology, genomics, and proteomics will continue to spawn new drugs, therapeutics and other biotechnological innovations that change the way humans encounter life.[349] In order to maintain this era of biotechnological innovation, the USPTO and Federal Circuit must remain mindful of the harm that broad gene patents may have on biotechnology, health care and biomedical research.[350] Accordingly, the Federal Circuit and USPTO must continue to limit claims to gene-based inventions. Already, the Federal Circuit has raised the bar of patentability for biotechnology

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[343] See *supra* text accompanying notes 162-71 for a discussion of biotechnology patent proliferation and the manner in which such blocking patents threaten to impede scientific progress.

[344] *Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1056 (Rader, J., concurring).

[345] *See id.*

[346] Mathew J. Conigliaro et al., *supra* note 341, at 1071.

[347] *Id.* (addressing this concern with regard to a foreseeability approach to prosecution history estoppel).

[348] *Id.*

[349] *See supra* Part II for an overview of the biotechnology industry and its current scientific focus.

[350] *See supra* Part IV for an analysis of the detrimental effects of broad gene patents.

patents through heightened standards of enablement and written description.[351] The Federal Circuit should further act to prevent broad gene-based patents by adopting a biotech-specific, foreseeability-based limitation on the doctrine of equivalents.[352] Through superior notice and decreased opportunities to broaden claims beyond their literal meaning, the foreseeability limit could prove an effective patent law mechanism for preventing broad gene patents and promoting biotechnological progress.

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[351] *See supra* note 227 and Part V.B for an analysis of Federal Circuit case law elevating the enablement and written description requirements for biotechnology patent cases.

[352] *See Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1056 (Rader, J., concurring).