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BILSKI ON BIOTECH: THE POTENTIAL FOR LIMITING THE NEGATIVE IMPACT OF GENE PATENTS

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I. INTRODUCION

While patents may serve as powerful incentives for advancing scientific and technical progress, they may also act as harmful restrictions on society. One field in particular where patents recently seem to play this latter role is genetics. Here, researchers discovering new information about genetic diseases and doctors diagnosing these devastating disorders have become infringers, subject to harsh monetary penalties or restrictive injunctions.[1] In these cases, a patent system created to encourage innovation has instead stifled the progress of research and impaired public healthcare. These patents, which have only relatively recently begun to emerge in this field, are collectively referred to as gene patents: patents that claim genes themselves, structures that mimic the function of genes, or methods for diagnosing conditions based on observing certain genes.[2]

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1. *See* Jon Merz & Mildred Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 COMMUNITY GENETICS 203, 205 (2005) (highlighting examples of certain genetic testing procedures for which patent holders have demanded royalties or threatened to take legal action).

2. *Id.* at 204-06.

Many of these patents contain broad claims that have far-reaching implications, often restricting the activities of researchers and physicians. Consider, for example, a method for detecting Alzheimer's disease, such as the method claimed in U.S. Patent No. 5,508,167 (the '167 patent). Claim 1 of this patent recites:

> A method of detecting if a subject is at increased risk of developing late onset Alzheimer's disease (AD) comprising directly or indirectly:
> detecting the presence or absence of an apolipoprotein E type 4 isoform (ApoE4) in the subject; and
> observing whether or not the subject is at increased risk of developing late onset AD by observing if the presence of ApoE4 is or is not detected, wherein the presence of ApoE4 indicates said subject is at increased risk of developing late onset AD.[3]

The "invention" in this case essentially consists of two steps: (1) searching for the presence of a particular gene (ApoE4); and (2) determining that a subject is at an increased risk for a particular condition (Alzheimer's disease) based on the presence of this gene. Thus, any person looking for the presence of the ApoE4 gene and making a determination of whether a subject is at risk for late-onset Alzheimer's based on the presence of the gene would infringe this patent, regardless of the tools or specific methodology used. The holder of such patents could therefore demand royalties from anyone who performed these steps or, worse still, ban the performing of the steps altogether. Hospitals could not test for this condition, and scientists could not conduct certain research, without falling under the scope of these broad claims. As will be shown, these patents place serious, harmful restrictions on society while giving little new, useful, and nonobvious information in return. As such, gene patents work against the purpose of granting exclusive rights as stated by the Constitution.[4] They are a burden on, not a benefit to, society. And some limitation on gene patents (or at least those that are most harmful) is necessary.

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3. U.S. Patent No. 5,508,167, at claim 1 (filed Apr. 13, 1994). The patent lists Duke University as the assignee. *Id.* at [73].

4. *See infra* Part II.A. (detailing that the constitutional power to grant patents arises from a desire to encourage innovation).

Accordingly, the aim of this article is threefold: to remind readers of the purpose of patent law as set forth in the Constitution, to highlight a particular class of patents that works against that purpose, and to propose a potential limitation, rooted in recent case law, on the harmful effects of these patents. In doing so, this article first briefly considers the constitutional clause that provides Congress with the power to grant patents, while also suggesting the importance of a governmental power to grant exclusive rights and the need for limitations on this power. Next, this article defines what is meant by "gene patent," provides examples of three main types of gene patents, and briefly reviews gene patents' origins in late-twentieth century case law. Having defined gene patents, this article then presents evidence of their harmful impact on society as "hold-ups" and "toll booths" to research and health care.[5] Next, this article reviews some previously suggested solutions to the gene patent problem before offering a novel solution in light of the recent *In re Bilski*[6] case, which may serve as a strong limitation on one particularly troubling type of gene patent. By reminding the reader why patents exist, highlighting a category of patents that harms society, and offering a solution to that harm, this article attempts to ensure that patents more effectively achieve their intended goal of encouraging innovation.

5. *See infra* Part IV.A.-C. (discussing gene patents' negative impact on research and public health).

6. *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (*en banc*), *petition for cert. granted*, 129 S. Ct. 2735 (2009). Note that, as of this writing, the United States Supreme Court has granted certiorari in this case, with oral argument heard on November 9, 2009. The decision is pending. Although it is unclear at this point what action the Supreme Court will take in this case, recent appeals to the Supreme Court from the Federal Circuit have each resulted in reversals. *See, e.g.*, LG Elecs., Inc. v. Bizcom Elecs., Inc., 453 F.3d 1364 (Fed. Cir. 2006), *rev'd sub nom*; Quanta Computer Inc. v. LG Elecs., Inc., 128 S. Ct. 2109 (2008); KSR Int'l v. Teleflex, Inc., 119 Fed. App'x. 282 (Fed. Cir. 2005), *rev'd*, 550 U.S. 398 (2007). Thus, the actual effect of *Bilski* may change depending on the Supreme Court's decision. This article describes a solution to the gene patent problem under the current state of the law, however.

II. BACKGROUND OF THE CONSTITUTIONAL PATENT POWER

The United States patent system exists to stimulate the progress of the "useful arts."[7] Accordingly, before describing gene patents and their impact on society, it is first necessary to briefly review the constitutional provision providing Congress the authority to issue patents. An examination of the language and history of this provision reveals the Framers' intention that patents serve to encourage innovation.[8] The following section then goes on to describe the importance of exclusive rights and the need for limitations on granting them.

A. The Purpose of the United States Patent System: To Promote the Progress of Useful Arts

As the eighteenth century drew to a close, the concept that the government could advance scientific and cultural progress by creating incentives for would-be inventors became widespread.[9] In early America—amidst the spreading influence of the Enlightenment—Benjamin Franklin played a key role in endorsing this concept.[10] The preambles of many state intellectual property statutes at the time echoed this sentiment, containing language that recognized the social utility and public benefit of encouraging innovation.[11] In addition, the Framers were all too familiar with the harms of overly-broad monopolies and were hesitant to give the new central government an unchecked authority to grant exclusive rights.[12]

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7. U.S. CONST. art. I, § 8, cl. 8.

8. *See id.* ("Congress shall have power . . . to promote the progress of . . . useful arts").

9. Frank Prager, *Historic Background and Foundation of American Patent Law*, 5 AM. J. LEGAL HIST. 309, 316 (1961).

10. JOHN BURY, THE IDEA OF PROGRESS 176 (Dover ed., 1955).

11. Prager, *supra* note 9, at 317.

12. George Ramsey, *The Historical Background of Patents*, 18 J. PAT. OFF. SOC'Y 6, 7- 8 (1936). In fact, Thomas Jefferson (often mistakenly labeled as the father of American patent law) vehemently opposed monopolies of any kind, including those for patents. *See* Letter from Thomas Jefferson to James Madison (July 1788) *in* 5 WRITINGS OF THOMAS JEFFERSON 45, 47(Washington ed. 1814) (detailing Jefferson's feelings that even the benefits of limited monopolies for the purpose of inciting ingenuity are "too doubtful" to warrant their existence).

The Framers likely had these ideas in mind when drafting the Constitution in 1787. These influences are apparent in the Patent Clause, found in Article I, Section 8, Clause 8 of the U.S. Constitution. The Patent Clause is unique among the eighteen enumerated powers of Congress in that it is the only power to have a conditional grant.[13] Accordingly, Congress may "secure" exclusive rights to inventors for limited times, but only in order "to promote the progress of . . . useful arts."[14] Thus, there is a limitation on the power of the federal government to grant exclusive rights; and it carries with it an important practical effect: a check on abuse of the patent right. Congress does not have the authority to issue patents to reward a particular industry or to bestow favor upon political supporters; it may only grant patents for the purpose of encouraging innovation.

In an effort to guarantee the patent system serves this function, Congress has placed various restrictions on patentability that tend to ensure that patents promote the country's technological progress. For example, § 102 of the Patent Statute ensures that patents issue only for "new" inventions,[15] as the offering of exclusive rights for an already known product or process does not promote progress. Similarly, § 103 bars the patenting of inventions that are mere obvious combinations of known subject matter,[16] as the reward of patent rights for the mere combination of articles already in the public domain also fails to further the progress of innovation.

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13. EDWARD WALTERSCHEID, TO PROMOTE THE PROGRESS OF USEFUL ARTS 34 (Fred B. Rothman & Co. eds., 1998).

14. U.S. CONST. art. I, § 8, cl. 8. Although other means of encouraging innovation were almost surely known to the drafters of the Constitution (most relating to monetary awards of some kind), the decision to promote the progress of creativity and invention through exclusive grants most likely arose out of the financial plight of the newly created federal government. Plagued by debts after the Revolutionary War, the infant federal government likely could not afford to promote innovation through monetary or land grants. DANIEL FARBER & SUZANNA SHERRY, A HISTORY OF THE AMERICAN CONSTITUTION 28-29 (West 2005) (1990).

15. *See* 35 U.S.C. § 102 (2006) (reciting, *inter alia*, various statutory bars to patentability based on prior disclosures).

16. *Id.* § 103.

B. The Importance of Exclusive Rights

An effective patent system provides several benefits to society. For example, each patent may be thought of as a social contract between the inventor and the general public. In return for the inventor's right to exclude, the public receives full disclosure of the invention, ensuring that any person having ordinary skill in the field can make or use the invention upon expiration of the patent term.[17] In this way, a patent acts as a blueprint for those in the field to which the patent relates, enabling anyone having ordinary skill in the field to make and use the invention. This allows the public to eventually enjoy the full benefit of the invention. After the period of exclusive rights ends, the invention falls into the public domain, and all are free to make and use it.[18] To ensure that the public receives this knowledge, the Patent Statute contains strict provisions mandating that the patent thoroughly describes what the invention is, how it is made, and how it may be used.[19]

Because much of the progress of research and development depends on a broad, publicly-available knowledge base, it is important to create incentives for researchers and inventors to contribute to this collective knowledge. Society typically benefits from disclosure rather than secrecy, so an additional goal for an ideal patent system should be to create an incentive for full disclosure of inventions. Perhaps in furtherance of this goal, all patents (and many patent applications) in the United States are made publicly available.[20] As all patents must sa-

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17. *See id.* § 112 (requiring that the patent contain a written description that would enable one of ordinary skill in the field to make and use the invention).

18. *See id.* § 271(a) (stating that whoever makes, uses, or sells a patented invention is liable for infringement "during the term of the patent").

19. *Id.* This requirement, codified in § 112 of the Patent Statute, is known as the "enabling disclosure" requirement. Some have even suggested that the disclosure requirement is so important that the provisions of § 112 alone are sufficient to satisfy the condition that all patents promote the progress of useful arts. Edward Walterscheid, *Within the Limits of the Constitutional Grant*, 9 J. INTELL. PROP. L. 291, 297-300 (2002).

20. In fact, patents and published applications have never been more easily accessible to the general public. The age of the internet has made it possible to read, search, and amass patents in ways never before possible. The governments of many countries make their patents available for free online, often with full-text search capabilities. *See, e.g.*, U.S. Patent and Trademark Office Homepage,

tisfy § 112's enabling disclosure requirement, the United States Patent Office has essentially created a massive catalog of previously discovered knowledge available to anyone willing to wade through the overwhelming amount of material. This free, readily-available knowledge can serve as a springboard for further research in a nearly limitless array of fields. Thus, § 112 confers an additional benefit on society: ensuring that inventors pool their findings in a central location, allowing others after them to improve and to build upon their previous work. [21]

C. The Importance of Limitations on Exclusive Rights

Although an efficient patent system offers numerous benefits for a society, the unchecked granting of exclusive rights for frivolous or already-known devices may likely lead to more harm than good. In order to prevent devious patent holders from removing knowledge already in the public domain or from extending the term of a patent indefinitely, some restrictions on patent grants are clearly necessary. The Framers surely realized this. In fact, shortly after the Constitution was adopted, the first Congress set to work on drafting the first patent act in 1790, which contained various requirements for patentability.[22] Among these requirements were the familiar concepts of novelty, utility, and the written description requirement.[23] Thomas Jefferson, one of the three original patent examiners, also unilaterally chose not to grant patents for devices that he felt to be frivolous or merely ob-

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http://www.uspto.gov (last visited Nov. 19, 2009) (providing publicly-available, full-text searches of issued patents and published patent applications). In addition, private corporations have even begun creating free, searchable patent databases on the world wide web, with Google, Inc. being among the most notable. Google Patents Homepage, http://www.google.com/patents (last visited Nov. 19, 2009).

21. One author also noted that multiple researchers or inventors simultaneously devoting time and efforts to the same invention is a waste of resources. Laurie Hill, *The Race to Patent the Genome*, 11 TEX. INTELL. PROP. L.J. 221, 238 (2003). Although the current patent system does not guarantee that such waste will not occur (patent applications are not made publicly available until eighteen months after filing), the ease by which a patent or published application may be obtained certainly helps to alert those in the field of what has already been discovered.

22. Kenneth Burchfeil, *Revising the Original Patent Clause*, 2 HARV. J.L. TECH. 155, 182 (1989).

23. *Id.*

vious improvements of old, known devices.[24] These limitations remain an important part of the Patent Statute and case law today. They serve as a check on the patent system, attempting to protect the public from frivolous patents that do not either advance technology or encourage inventors to design new products.[25] One must be careful to remember that patents are, in a sense, monopolies[26] that restrict the public's use of potentially beneficial products or methods. During the patent's term, no one may make, use, or sell what is claimed in the patent without the permission of the patent holder.[27] Thus, during this term each patent removes something from the public domain, albeit providing useful knowledge in return. As a matter of policy, the desire to promote the progress of useful arts must outweigh this burden on the public.

Furthermore, there is a notion that science will progress more rapidly in an environment where information and new discoveries are free-flowing and shared among the community.[28] Patents may inhibit this notion by restricting scientists' ability to use this information. For example, a patent on a revolutionary cancer drug would potentially prevent others from studying or conducting clinical trials on the drug without the permission of the owner of the patent rights, as the patent

24. DUMAS MALONE, JEFFERSON AND THE RIGHTS OF MAN 283 (1951).

25. Graham v. John Deere Co., 383 U.S. 1, 9 (1966) ("Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly. Jefferson did not believe in granting patents for small details, obvious improvements, or frivolous devices. His writings evidence his insistence upon a high level of patentability.").

26. A subtle point is worth noting here. Although patents resemble monopolies in some ways, the term is not a perfect description by any means. The word monopoly carries the connotation that patents convey some positive right on the inventor to use and practice the invention. This is not the case. Patents provide the right to exclude others from making, using, or selling the claimed invention. 35 U.S.C. § 271(a) (2008). They do not give the inventor an absolute right to use the invention if, for example, another patent or other law prevents her from doing so. Merz, *supra* note 1, at 204 ("A patent does not grant its owner the positive right to use an invention").

27. 35 U.S.C. § 271(a) (2008).

28. Rebecca Eisenberg, *Patents and the Progress of Science*, 56 U. CHI. L. REV. 1017, 1017 (1989).

prevents others from making or using the patented invention. In this way, certain patents may sometimes impede downstream research.[29]

With these concerns in mind, the Patent Statute provides that, in order to receive a patent, an invention must be directed to patentable subject matter[30] that is new,[31] useful,[32] and nonobvious.[33] Inventions that meet these requirements (at least in theory) contribute something of value to the public that makes the burden of exclusive rights worthwhile. In addition to these four "substantive" requirements, the patent application itself must contain a clear enabling disclosure and set forth the best mode for carrying out the invention.[34]

III. BACKGROUND ON GENE PATENTS

Having discussed the constitutional authority for the United States patent system, the importance of exclusive rights, and the need for limitations on exclusive rights, this article now turns to gene patents themselves: a group of patents whose benefit to society is often substantially outweighed by the burden their exclusive rights impose. After generally defining gene patents, this section describes three basic classifications. Examples of each of these classifications are given, and analyses of the harmful implications of each are provided. Finally, this section concludes with a discussion of the recent rush of gene patent applications, highlighting the severity of the gene patent problem.

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29. This concern is explored in greater detail in Part IV.C., *infra*. Although this seems inconsistent with the notion that patents encourage disclosure and therefore *aid* downstream research, this apparent discrepancy is easily resolved. While overly-broad patents may restrict some activities of downstream researchers during the patent term, the knowledge derived from the patents themselves may be used without restriction after the expiration of the term. Furthermore, even during the term, the restrictions placed on society by the patent may even encourage a clever inventor to design around the claimed invention to arrive at a new, better (and non-infringing) alternative.

30. 35 U.S.C. § 101 (2006).

31. *Id.* §§ 101-02.

32. *Id.* § 101.

33. *Id.* § 103.

34. *Id.* § 112.

A. Defining Gene Patents

Before discussing how gene patents often fail to promote the progress of useful arts, we must first describe what is meant by "gene patent." Generally, the term "gene patent" refers to a wide variety of patents relating to methods of testing for genetic conditions, various markers or probes using particular genes, or even the genes themselves.[35] Professor Jon Merz of the University of Pennsylvania School of Medicine suggests that gene patents consist of three broad categories: (1) diagnostic gene patents, (2) composition of matter gene patents, and (3) functional use gene patents.[36]

1. Diagnostic Gene Patents

The first of Professor Merz's classifications of gene patents—diagnostic gene patents—covers various genetic tests.[37] Because these patents typically claim methods that diagnose a particular genetic disease or condition, Professor Merz sometimes refers to these as "disease gene patents."[38] These methods essentially claim the process of observing a particular portion of a patient's genetic sequence in search of a sequence known to cause a particular disease.[39] Usually, the methods of these patents compare a patient's gene to a known gene, or a mutation of that gene, that indicates a particular condition. The patents in this class usually consist of process patent claims.[40]

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35. Merz, *supra* note 1, at 204.

36. *Id.*

37. *Id.*

38. Jon Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine*, 45 CLINICAL CHEMISTRY 324, 324 (1999).

39. *Id.*

40. Also referred to as "method" claims, process claims (one of the four "classes" of statutory subject matter under § 101) describe an invention comprising a series of steps rather than a specific product or physical item. *See* Merz, *supra* note 1, at 204. However, structural language can be included in process claims as well (in order to describe an apparatus for accomplishing a certain task, for example). *Id.* Examples of process claims include methods for making various products, methods for using products in novel, nonobvious ways, or various surgical techniques. *Id.*

U.S. Patent No. 5,753,441 (the '441 patent), directed to "170-linked breast and ovarian cancer susceptibility gene," serves as an example.[41] This patent claims, *inter alia*:

> [A] method for screening . . . a human subject for an alteration of a BRCA1 gene which comprises comparing a BRCA1 gene . . . with germline sequences of wild-type BRCA1 gene . . . wherein a difference in the sequence of the BRCA1 gene . . . of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject.[42]

This patent, having broad claims typical of many diagnostic gene patents, claims all methods of comparing a copy of the BRCA1 gene[43] in a human subject with a BRCA1 gene from a control group.[44] A difference between the control group gene (the "wild-type" gene) from the corresponding gene in the human subject indicates a mutation in the BRCA1 gene.[45] Although the patent does not claim the BRCA1 gene itself, its claims do cover all methods of comparing a wild type gene with a patient's gene to determine a difference.[46] The claim does not specify any specific steps to compare the genes, nor does it recite any structural limitations or otherwise link the method to any particular instrumentation or equipment.[47] Under this sweeping language, *all* methods of comparing the genes would infringe the '441 patent, regardless of the specific examples described in the patent's specification.

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41. U.S. Patent No. 5,753,441 (filed on Jan. 5, 1996). The patent is assigned to Myriad Genetics, Inc., the University of Utah Research Foundation, and the United States, as represented by the Department of Health and Human Services. *Id.* at [73].

42. *Id.* at claim 1.

43. The BRCA1 gene is thought to be a cause for certain forms of breast cancer. Lori Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REVS.: GENETICS 803, 804 (2002).

44. '441 Patent at claim 1.

45. *Id.*

46. *Id.*

47. *Id.*

2. *Composition-of-Matter Gene Patents*

Composition-of-matter gene patents, unlike diagnostic gene patents, cover physical compositions, such as genes themselves.[48] Professor Merz defines this category as encompassing various chemicals and materials, "including the isolated and purified gene (cDNA) and all derivative products (e.g., recombinant proteins or drugs, viral vectors and gene transfer 'therapies', transfected cells, cell lines and higher order animal models in which the patented gene has been inserted or knocked out)."[49] Professor Merz also notes that the various proteins or other therapeutic products formed through specific, claimed processes fall into this category.[50] Such claims are known as "product-by-process" claims.[51] This class generally consists of "product" claims—claims directed towards a physical thing rather than a method.[52]

An example of a composition-of-matter gene patent is U.S. Patent No. 4,703,008 (the '008 patent), directed to "DNA sequences encoding erythropoietin."[53] This patent claims, *inter alia*, a "purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human [or monkey] erythropoietin."[54] This claim covers all

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48. Merz, *supra* note 1, at 205.

49. *Id.*

50. *Id.*

51. A product-by-process claim is "a product claim that defines the claimed product in terms of the process by which it is made." U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2173.05(p) (8th ed., 7th rev. (2008)) [hereinafter MPEP].

52. A second broad classification for patentable subject matter is referred to as "product" claims. *Id.* § 2106(IV)(A). Product claims include the remaining three categories of patentable subject matter recited in § 101 (machine, manufacture, and composition of matter). *Id.*

53. U.S. Patent No. 4,703,008 (filed Nov. 30, 1984). The patent is assigned to Kiren-Amgen, Inc. *Id.* at [73].

54. *Id.* at claims 2, 3. The "isolated and purified" language seems to be typical in many composition-of-matter gene patents. *E.g.*, U.S. Patent No. 6,284,522 at claim 1 (filed Oct. 23, 1995). Presumably, claim drafters include these types of limitations in an effort to ensure that the subject matter of the claim is patentable. While products of nature (such as the human genome, which is comprised of the entire genetic code) are unpatentable, an isolated or purified piece of a product of nature (which does not occur naturally) is patentable. Judge Rader of the Federal Circuit provides an example of this concept: While out hiking in the woods, a hiker discov-

genes that code for erythropoietin (EPO), including mutated versions.[55] Thus, the patent holder had the right to exclude anyone else from making EPO (by any means, whether known to the inventor at the time or not) or using the isolated EPO gene. Also, the patent claims host cells "transformed or transfected" with the sequences of claims 2 and 3.[56]

This patent, typical of composition-of-matter gene patents, claims the gene itself. Such claims have far-reaching implications. Not only do these patents prevent others from using genes that fall under the scope of the claims, but they also bar others from extracting or isolating these genes from the genome by any means. Thus, researchers that wish to use an isolated gene that falls under the claims of a composition-of-matter gene patent would be unable to do so without permission from the patent holder. In addition, the very process of isolating this gene by any means would infringe such a patent. For these reasons, composition-of-matter gene patents are particularly troubling.

3. Functional-Use Gene Patents

An "emerging class of gene patents," according to Professor Merz, "is that which claims the functional use of a gene. These patents are based on discovery of the role genes play in disease or other bodily and cellular functions or pathways, and claim methods and compositions of matter . . . used to up- or down-regulate the gene."[57] Essentially, these patents claim products or methods that achieve a particular result or serve a particular function, such as the manipula-

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ers a previously undiscovered type of grass that, when rubbed on the feet, cures athlete's foot; although the hiker cannot patent the grass itself (as she merely discovered, and did not invent, the grass), she can patent the isolated active ingredient that causes the cure. Judge Randall Rader, Circuit Judge, United States Court of Appeals for the Federal Circuit, Lecture in the Patent Law Course at the George Washington University Law School (Fall 2007). Erythropoietin (EPO) is a "protein consisting of 165 amino acids which stimulates the production of red blood cells." Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1203 (Fed. Cir. 1991). EPO is useful in the treatment of blood disorders in which the body fails to produce an adequate number of red blood cells. *Id.*

55. '008 Patent at claims 2, 3.

56. *Id.* at claim 23.

57. Merz, *supra* note 1, at 206.

tion of the function of a target gene.[58] Accordingly, this class would include product, process, and, presumably, product-by-process claims.

U.S. Patent No. 6,410,516 (the '516 patent),[59] directed to "nuclear factors associated with transcriptional regulation," provides a good example of a functional-use gene patent.[60] Claim 1 of the '516 patent recites "[a] method for inhibiting expression . . . of a gene whose transcription is regulated by NF-KB, the method comprising reducing NF-KB activity in the cell such that expression of said gene is inhibited."[61]

Like the '516 patent, functional-use patents claim processes and products that mimic the function of certain genes.[62] Often, these patents do not cover the genes themselves but do claim all drugs or other chemicals that fulfill the same bodily or cellular function as a particular gene.[63] As in diagnostic and composition-of-matter gene patents, functional-use gene patents often cover a broad range of subject matter. Claims in these types of patents can encompass all products or processes that replicate the known function of a particular gene, including drugs, therapies, and other treatments not contemplated by the inventor at the time the application was filed.[64]

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58. *Id.*

59. This patent, owned by Ariad Pharmacueticals, was recently the subject of an infringement suit in the United States District Court for the District of Massachusetts. Ariad Pharms., Inc. v. Eli Lilly & Co., 529 F. Supp. 2d 106 (D. Mass. 2007). After a fourteen-day trial, the '516 patent survived Eli's invalidity contentions that the claims were in violation of the novelty, enablement, and written description requirements. *Id.* at 112. On appeal, however, the Federal Circuit reversed in part, holding that four of the claims in dispute (claims 80, 95, 144, and 145) violated the written description requirement of § 112. Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1380 (Fed. Cir. 2009). The court determined that the claims were too broad and "far beyond" the scope of the patent's specification. *Id.* at 1377.

60. U.S. Patent No. 6,410,516 (filed June 5, 1995). This patent alone contains over 200 claims. *Id.*

61. *Id.* at claim 1.

62. Merz, *supra* note 1, at 206.

63. *Id.*

64. It is worth noting here that the concept of extending claims to cover subject matter not considered or expressly described by the inventor does not always have a negative impact. In fact, the doctrine of equivalents is rooted, at least in part, on this principle. *See* Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605 (1950) (creating a doctrine allowing patent holders to enforce patent rights on subject matter not explicitly recited in the claims or even the specification). Under

B. The Gene Patent Rush

Having described various types of gene patents and discussed some possible implications of their claims, this article now discusses the origins of gene patents and how they have expanded since inception. Much like the explosive number of filings of patent applications for business methods spawned by the Federal Circuit's 1998 *State Street Bank* decision,[65] the so-called gene patent rush also has its roots in case law.

Since the Supreme Court's decision in *Diamond v. Chakrabarty*, "everything under the sun that is made by man" may be patented, including living organisms and genetic material.[66] By 1991, the Federal Circuit regularly seemed to accept the notion that purified DNA sequences constitute patentable subject matter.[67] This opened the floodgates for gene patents, and beginning in the 1990s, the first patent ap-

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the doctrine of equivalents, a party that does not literally meet each and every element of a claim can still infringe a patent if elements of the accused device or method are the equivalent of the claimed elements. *Id.* at 609. For example, if a hypothetical patent claims an electric guitar having "steel strings," and an accused product contains all the elements of the claim but uses a steel alloy for its strings, the accused product can still infringe the patent. This doctrine prevents would-be infringers from avoiding liability simply through making simple design-arounds that are not expressly disclosed in the patent. This doctrine releases the patent applicant from the burden of describing every conceivable variant of her invention. However, the doctrine of equivalents, like much patent case law, developed out of cases involving the mechanical arts. Some scholars argue that these doctrines, many of which developed before the boom of the biotech industry, are both unworkable and unsuitable for the chemical or biological arts. *See* Rebecca Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 783 ("Is a patent system developed to establish rights in mechanical inventions of an earlier era up to the task of resolving competing claims to the genome on behalf of the many sequential innovators who elucidate its sequence and function, with due regard to the interests of the scientific community and the broader public?"); *see also In re* Bilski, 545 F.3d 943, 1011 (Fed. Cir. 2008) (Rader, J., dissenting) (stating that the majority opinion "links patent eligibility to the age of iron and steel at a time of subatomic particles and terabytes").

65. Josh Lerner, *Where Does State Street Lead? A First Look at Finance Patents, 1971 – 2000*, 57 J. OF FIN. 901, 901 (2002).

66. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

67. *See* Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) (holding that "[a] gene is a chemical compound, albeit a complex one").

plications for human genetic material were filed.[68] Shortly thereafter, and not unlike the Gold Rush of the 1800s, there began a race to patent as much of the isolated portions of the human genome as possible.[69] Much of this "gene patent rush" likely stemmed from the rapidly evolving capabilities for sequencing and cloning genes.[70]

As a result, the United States Patent and Trademark Office (PTO) was flooded with applications relating to genes and genetic testing methods. According to one source, as of 2003, an astounding three million genome-related patent applications had been filed with the PTO.[71] During this period, the PTO received heavy criticism for granting patents too liberally.[72] In response, the PTO issued new guidelines for determining utility, inviting the public to comment on the issue of gene patents.[73] Ultimately concluding that it was bound by policy and case law such as *Chakrabarty*, the PTO rejected arguments that genes were products of nature and thus unpatentable.[74] The final version of these guidelines left the door open for gene patents, concluding that a patent would issue "[a]s long as one specific, substantial and credible use is disclosed and the statutory requirements are met."[75]

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68. Debra Greenfield, *Greenberg v. Miami Children's Hospital: Unjust Enrichment and the Patenting of Human Genetic Material*, 15 ANN. HEALTH L. 213, 229 (2006).

69. Jonathan Kahn, *What's the Use? Law and Authority in Patenting Human Genetic Material*, 14 STAN. L. & POL'Y REV. 417, 420-21 (2003).

70. Merz, *supra* note 1, at 204.

71. Kahn, *supra* note 69, at 420-21 (citing U.S. Dep't of Energy, Human Genome Project Information: Genetics and Patenting (2001), http://www.ornl.gov/hgmis/elsi/patents.html (last visited Nov. 19, 2009)).

72. *Id.* at 421.

73. *Id.*

74. *Id.* at 439.

75. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001). These guidelines gave the green light for gene patents, despite recognizing that "[s]everal comments state that patents should not issue for genes because patents on genes are delaying medical research and thus there is no societal benefit associated with gene patents" and that "[o]thers state that granting patents on genes at any stage of research deprives others of incentives and the ability to continue exploratory research and development." *Id.* The PTO's response to these criticisms was simply that "incentives to make discoveries and inventions is generally spurred, not inhibited, by patents." *Id.*

During this rush, lots of "land-grabbing" occurred without actually knowing what was being claimed.[76] Applicants raced to the patent office in an effort to be the first to stake a claim to newly discovered genes, having only the slightest notion of their usefulness or potential. This, of course, stands contrary to the principle that "a patent is not a hunting license."[77] Patentability requires that an applicant have *some* idea of an invention's utility before filing a patent application.[78] This land-grabbing trend continues today, and as of 2005 "[n]early 30,000 human genes have been patented" in the United States.[79] The substantial number of filings of gene patents throughout this rush compounds the problems highlighted above.

IV. GENE PATENTS' POTENTIAL TO IMPEDE THE PROGRESS OF USEFUL ARTS

As noted above, gene patents are both far-reaching and highly prevalent. This section explores the various ways that gene patents negatively affect the progress of the useful arts, including their potential to impede innovation. In addition, this section discusses gene patents' likely detrimental effect on public health.

A. Gene Patents as "Toll Booths" on Scientific Research and Health Care

We first explore gene patents' potential to hinder research efforts, a concern not wholly unheard of. In fact in 2000, Francis Collins, then-director of the Human Genome Project, expressed concern that gene patents may act as "toll booths on basic science."[80] As much of the advancement of scientific research depends on the free-flowing sharing and use of information, any restrictions on the use of upstream research would impede this progress. Instead of sharing their findings and building off each other's discoveries, patent holders constrain one another while negotiating licenses or attempting to collect royalties for

76. Greenfield, *supra* note 68, at 234.
77. Brenner v. Mason, 383 U.S. 519, 536 (1966).
78. *Id.*
79. Merz, *supra* note 1, at 203.
80. Hill, *supra* note 21, at 241.

the use of their inventions.[81] As a result, scientific advancement as a whole may suffer.

Due to the large volume of patented material in genetics, substantial licensing (and likely a fair amount of cross-licensing) would be necessary in order to conduct any meaningful research.[82] This means that researchers and physicians will need to negotiate and to pay royalties[83] in order to continue their research efforts and diagnostic testing. The need for attorneys to negotiate licenses, as well as the licensing fees themselves, translates to a substantial expense for researchers and physicians. These heavy tolls may discourage a significant number of researchers, unable to afford the additional cost, from conducting work in a particular area. Although physicians would likely pass on the added expense to patients and insurance companies, these costs ultimately result in more expensive, and thus more exclusive, health care.

This concern applies to all three of Professor Merz's classes of gene patents. In the case of clinical care, however, this concern is especially applicable to diagnostic gene patents, where restrictions on testing due to diagnostic gene patents may limit the availability of adequate care to patients and the resources available to physicians.[84]

B. Gene Patents as Detriments to Public Health

In addition to the financial harms discussed above, gene patents impose additional detriments to the public health. The rush to patent the findings from research in the genetic arts prevents others in the field from verifying the results of these findings.[85] Due to this rush, the accuracy of newly patented genetic tests, for example, cannot be confirmed.[86]

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81. *Id.*

82. Greenfield, *supra* note 68, at 234.

83. Professor Merz provides some examples of licensing fees imposed for genetic testing methods, ranging from $2 to over $20 per test. Merz, *supra* note 1, at 205.

84. Greenfield, *supra* note 68, at 233. As the potential for gene therapy and similar treatments increases, functional use gene patents may be of particular concern to physicians as well. *Id.*

85. *Id.*

86. *Id.*

In extreme cases, a patent holder may even decide not to practice the invention while simultaneously refusing to allow others to do so, although there seem to be few reported cases of this.[87] This is not surprising, as the typical rationale for seeking a patent is to obtain money through licensing fees. Nevertheless, these so-called patent trolls could have a seriously negative impact on the public health.[88]

Although one rarely hears of a gene patent holder's refusing to allow any party to practice the invention, highly restrictive licensing is much more prevalent. In the case of genetic testing for example, some companies such as Myriad Genetics and Athena Diagnostics have aggressively exercised their rights to exclude, requiring that physicians and researchers send tissue samples only to approved licensees in order to use the patented testing methods.[89] Additionally, the owner of a patent for the test for Canavan disease, Miami Children's Hospital, has licensed this test only to select laboratories.[90] By requiring physicians to send all samples to a limited number of facilities for testing, the potential for significant delay is a particular concern. Such delays in obtaining results for genetic tests prevent physicians from diagnosing diseases in their early stages. As timing is often a critical factor for certain diseases, many conditions that could have been treated earlier may be too advanced by the time test results are received. These concerns are most relevant to gene patents that cover genetic testing, falling into Professor Merz's diagnostic gene patent category.

C. Gene Patents as "Hold-Ups" to Research

There is potential for further delay, or even outright halting, of research due to licensing negotiations between patent holders. While owners of the patent rights haggle back and forth with one another,

87. Merz, *supra* note 1, at 205.

88. "Patent troll" is the less-than-flattering name often given to patent holders who attempt to extort money from various businesses using extensive patent portfolios. JAMES BESSEN & MICHAEL MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 17 (Princeton University Press 2008). Rather than produce any product themselves, these entities acquire large numbers of patents and generate capital by seeking out infringers and requesting royalties or filing infringement suits. *Id.* at 17, 159. Such patent holders typically refer to themselves as "non-practicing entities."

89. Merz, *supra* note 1, at 205.

90. *Id.*

dust grows thick in laboratories as scientists wait for a license to conduct their research.[91] Because isolated genes, genetic testing processes, and purified protein production methods often carry a special interdependence with other genes and gene products, any tie-ups due to failed licensing negotiations are of particular concern for genetics researchers.[92]

In addition, the potential profitability of gene patents can cause researchers to be more hesitant about sharing data and other information with others in the scientific community.[93] In an effort to avoid rejections under § 102 of the Patent Act—which can bar patentability even if the inventor himself publicly discloses the invention more than a year before filing for a patent[94]—researchers may also delay publication of their findings until filing a patent application. Such secrecy means less information contributed to the pool of collective knowledge from which researchers often base their work. Thus, by delaying the sharing of new information in the hopes of obtaining a patent, less knowledge is contributed to the collective, and the overall progress of research is further hindered.

The concerns about patent trolls are applicable here as well. While complete bans for licensing patents to researchers are still rare,[95] highly restrictive licensing practices seem to be more common in research than in health care. Because these restrictions will likely never mean the difference between life or death, the concern that gene patents hold up research progress are not as serious as the health care concerns addressed above. Yet, by restricting the free-flowing use of information, hold-ups to genetic research certainly do not promote the progress of useful arts.

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91. This topic is discussed at length in Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 78-79 (1994).

92. Hill, *supra* note 21, at 234 ("Since no gene operates in isolation, a single patentee effectively controls any and all upstream and downstream commercialization efforts.").

93. Greenfield, *supra* note 68, at 233.

94. 35 U.S.C. § 102(b) (2006).

95. However, at least one study suggests that gene patents are regularly licensed to researchers on exclusive terms. Michelle Henry, et al., *A Pilot Survey on the Licensing of DNA Inventions*, 31 J. L.& MED. ETHICS 442, 444-45 (2003).

Additionally, any restriction on research has a substantial effect on progress downstream. By preventing scientists from arriving at (or sharing) important findings in their field, less information is contributed to the general pool of knowledge. Lacking certain findings on which to base their research, other scientists may be unable to reach meaningful conclusions and contribute to the collective. This additional lack of contribution further compounds the problem, and the pool slowly runs dry. Certainly such effects are inconsistent with the Framers' intention that patents promote the progress of useful arts.[96] These concerns likely apply to all three of Professor Merz's classes of gene patents.

D. Litigious Nature of Gene Patent Holders

Fearful of facing a lawsuit from a litigious patent holder, researchers and (perhaps more importantly) sponsors may not wish to invest time, funds, or other efforts into a project that may potentially result in legal action. Because at least some gene patent holders seem quite willing to assert their patent rights,[97] researchers and physicians alike may be justified in their fear of potential litigation. Their concerns are furthered by the often high costs of litigation in patent cases.[98] This is particularly true in highly complex fields, such as biotechnology, which often necessitates the hiring of expensive experts to explain difficult technical concepts to a judge or jury. Parties that cannot afford such astronomical legal fees (and those that can but are still scared by the uncertainty often associated with patent litigation) may often be forced into unfair, one-sided settlement agreements, rendering them unable to conduct research on certain subject matter or to diagnose certain conditions.

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96. U.S. CONST. art. I, § 8, cl. 8.

97. *See, e.g.*, Amgen Inc. v. Chugai Pharm. Co. (*Amgen II*), 13 U.S.P.Q.2d 1737, 1738 (D. Mass. 1990) (case in which patent holder sued a biotechnology company and its exclusive licensee the same day its patent issued). In this case, the patent claimed "[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin." Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1204 (Fed. Cir. 1991). Despite this broad language, on appeal the court found that the claim was valid and enforceable. *Id.* at 1219.

98. BESSEN, *supra* note 88, at 18. In some industries, these litigation costs even exceed the profits earned from such patents. *Id.* at 15, 18.

As described above, a significant amount of evidence points to gene patents' ability to deter the progress of useful arts and to have an adverse effect on public health.[99] By discouraging researchers from contributing to the collective pool of knowledge and limiting their ability to conduct their work, gene patents act as roadblocks to downstream research. Through these and other research hurdles, many gene patents violate the constitutional authority of Congress to grant exclusive rights solely to encourage innovation.[100]

V. SOLUTIONS TO THE GENE PATENT PROBLEM

The constitutional provision that forms the basis for the United States patent system states a purpose for granting exclusive rights.[101] Gene patents, for the reasons outlined above, often work against that purpose.[102] Accordingly, a solution is necessary. This article now explores the possibilities available to resolve this issue. As it is both unlikely and impractical that gene patents will be struck down on a case by case basis for directly violating the Patent Clause,[103] another solution must be found. While numerous sources have proposed a variety of legislative and judicial solutions to this issue, none would adequately resolve this problem, as shown below.[104] Recent case law, however,

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99. *See supra* Part IV.A-C.

100. *See* U.S. CONST. art. I, § 8, cl. 8 (stating that Congress may grant inventors exclusive rights in order to "promote the Progress of . . . useful Arts"). Of course, not all gene patents are categorically a burden to society. Simply claiming a means for diagnosing a genetic disorder should not be a *per se* ban on patentability. A new, novel, and nonobvious instrument for testing for a specific gene, for example, would not necessarily violate the Patent Clause. *See infra* Parts V.A.3., V.B.4. for further discussion on this point.

101. *See* U.S. CONST. art. I, § 8, cl. 8.

102. *See supra* Part IV.

103. One notable author in the history of patent law doubts whether there exists any sufficiently definite constitutional standard set forth by the Patent Clause that would serve as a basis for invaliding patents. Walterscheid, *supra* note 19, at 359. Walterscheid notes that, although the word "discoveries" is used in the Patent Clause, this term should be interpreted to include only those discoveries falling under the category of "useful Arts." *Id.* at 360. However, as the Supreme Court has never defined "useful Arts" as the phrase appears in the Patent Clause, *id.*, it is unlikely that courts will invalidate individual patents for failing to fall under this category.

104. *See infra* Part V.A.

offers a new possibility. After reviewing several previously proposed solutions, this section discusses the potential of a recent *en banc* Federal Circuit case to limit gene patents' harm to the progress of useful arts.

A. Previously Proposed Solutions

A number of solutions have previously been offered as possible limitations to the harmful impact of gene patents. Several of these are discussed briefly below.

1. Legislative Solutions

One legislative solution may be to expand the "march-in" rights of the federal government, originally enacted as part of the Bayh-Dole Act of 1980.[105] A little-known and as-of-yet unused provision of the United States Code allows the federal government to step in and grant licenses to a party so long as the terms are "reasonable under the circumstances" and provided certain conditions are met.[106] In order to exercise these march-in rights, the federal government must have funded (at least partially) the research that gave rise to the patented invention.[107] A similar provision (or an amendment to the current provision for march-in rights) may allow the government to grant licenses to researchers or health care providers for gene patents, even if the patent holder itself refused to provide such licenses. In addition, it has also been suggested that a provision to the Patent Statute could be added to require that holders of gene patents (specifically diagnostic gene patents) provide licenses to physicians providing medical services.[108] However, because the government's march-in rights under the Bayh-Dole Act have rarely been used for this purpose, it seems unlikely that a broad expansion of this authority will occur in the near future.

105. 35 U.S.C. §§ 202-12 (2006).
106. *Id.* § 203.
107. *Id.* § 201.
108. Merz, *supra* note 38, at 324.

2. *Judicial Solutions*

As many of the most sweeping changes in patent law have occurred through the courts rather than the legislature,[109] perhaps a solution lies with the courts. Indeed, revised interpretations of the various statutory requirements for patentability (new, useful, nonobvious, patentable subject matter with an enabling written description) may act as a check on gene patents and their detriment on the progress of useful arts. Recall that the Patent Clause itself does not place any *specific* restrictions on Congress's ability to grant exclusive rights to inventors so long as the granting of exclusive rights promotes the progress of useful arts.[110] However, Congress has chosen to limit the granting of exclusive rights through various restrictions on patentability.[111] The present Patent Statute, enacted in 1952, requires an invention to be new,[112] useful,[113] and nonobvious[114] eligible subject matter[115] in order to be patentable. In addition, the patent itself must comprise a written description that has an enabling disclosure.[116] Some suggest that the key to encouraging innovation, notwithstanding gene patents, lies in revised case law on one or more of these statutory requirements.[117] Yet many of these suggestions fail to adequately address the problem,

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109. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 303 (1980) (allowing for the patenting of living organisms); Graver Tank & Mfg. v. Linde Air Prods., 339 U.S. 605 (1950) (creating the doctrine of equivalents and expanding what constitutes infringement); United States v. Univis Lens Co., 316 U.S. 241 (1942) (creating the doctrine of patent exhaustion, whereby a patent holder's exclusive rights are exhausted upon the first sale of a patented article); State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998) (allowing for the patenting of so-called business method patents).

110. U.S. CONST. art. I, § 8, cl. 8.

111. *See, e.g.*, 35 U.S.C. §§ 101-03 (2006) (limiting the granting of a patent to inventions that are useful, new, and nonobvious).

112. *Id.*

113. *Id.* § 101 (providing that a person is entitled to a patent for inventing "any new and *useful* process, machine, manufacture, or composition of matter") (emphasis added).

114. *Id.* § 103.

115. *Id.* § 101.

116. *Id.* § 112.

117. *See, e.g.*, Hill, *supra* note 21, at 232 (suggesting that a revision of current case law interpreting § 101's utility requirement could limit the harmful effects of gene patents).

as case law seems to indicate a reluctance among the courts to steer the law towards an interpretation necessary to restrict gene patents.[118] A sampling of some of these suggestions and a description of their inability to effectively resolve the gene patent problem follows.

i. The Utility Requirement (35 U.S.C. § 101)

One area having potential to limit gene patents' tendency to discourage the progress of useful arts is § 101's utility requirement. Historically, the utility requirement's primary function was to prohibit the patenting of inventions considered, at the time, to be immoral or against public policy.[119] Today, however, the utility requirement has become in most cases a nominal bar to patentability, requiring only that the claimed invention has the ability to function for its intended purpose.[120] As a result, the utility requirement is typically only at issue in the chemical and biotechnological arts, where the use of a particular invention may not be readily apparent.

Brenner v. Mason outlines much of the utility standard for the chemical and biotechnological arts.[121] There, the Court held that the claimed chemical compound, which was a homologue for another compound shown to have tumor-inhibiting effects in mice, had no stated use or utility apparent to one of skill in the art (other than as a stepping stone for research endeavors) and was thus unpatentable.[122] However, the Federal Circuit has since seemed to recognize the value of research and has steered away from this proposition, finding that the utility requirement of § 101 is satisfied so long as "a properly claimed invention meets at least one stated objective."[123]

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118. *See, e.g.*, Roche Prods. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (classifying the experimental use doctrine, one potential avenue for limiting gene patents' harmful impacts, as "truly narrow"). *But see* Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366 (Fed. Cir. 2009) (striking down several claims of a gene patent for failing to comply with § 112).

119. Lowell v. Lewis, 15 F. Cas. 1018 (D. Mass. 1817) (No. 8,568).

120. Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999). However, inventions that inherently violate the laws of nature, such as perpetual motion devices, or that cannot function at all are still unpatentable under this standard. Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989).

121. Brenner v. Manson, 383 U.S. 519 (1966).

122. *Id.* at 534.

123. Raytheon Co. v. Roper Corp., 724 F.2d 951, 958 (Fed. Cir. 1983).

Still, some have proposed that a clear assertion by the Federal Circuit (or the Supreme Court) of the unpatentability of a chemical compound having no use other than as a stepping stone for research would alleviate many of the concerns associated with gene patents.[124] However, this solution does not adequately address the full problem. Even if a court were to issue such a ruling, clever claim drafters may still be able to circumvent such a holding by disclosing that the invention's utility lies in areas other than research, such as for diagnostic testing purposes. In addition, this limitation would not serve as a check at all on diagnostic gene patents, such as genetic test kits or cDNA used in gene therapy, as these patents clearly have utility other than use as a stepping stone to research.

ii. The Enablement Requirement (35 U.S.C. § 112)

Another potential avenue for limiting gene patents may lie in § 112's enablement requirement.[125] In the *Amgen* case, the Federal Circuit used this provision to invalidate a patent that claimed a DNA sequence consisting of amino acid sequences duplicative of EPO.[126] The court held that the generic claim directed to an isolated DNA sequence was not enabled when the claim read on about 4,000 nucleotides but only disclosed how to make a few examples.[127] Because "the scope of enablement [must be] as broad as the scope of the claim," the overly broad claim at issue in *Amgen* violated the enablement requirement.[128] The enablement requirement ensures that claims will be construed only as broadly as the examples and descriptions in the patent's written specification. Thus the enablement requirement may limit the scope of claims in gene patents.

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124. Hill, *supra* note 21, at 232.

125. Recall that this section of the Patent Act requires all applications to describe the claimed invention in a way that allows one of ordinary skill in the field to make and use it. 35 U.S.C. § 112, ¶ 1 (2006).

126. Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1214 (Fed. Cir. 1991)

127. *Id.* (stating that claims to genetic sequences will be valid if "they are of a scope appropriate to the invention disclosed by the applicant").

128. *Id.* at 1212; *see also In re* Fisher, 427 F.2d 833, 836, 839 (C.C.P.A. 1970) (holding that 35 U.S.C. § 112 "requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art").

A limitation of scope, however, is not as effective as a total bar to patentability. Under *Amgen*, as long as the patent's description of the genes or methods it intends to cover reasonably correlates to the scope of the claims, the enablement requirement will be satisfied.[129] An applicant for a patent could easily list this subject matter, turning gene patents into voluminous copies of reference manuals and known databases. Thus, while the enablement requirement could potentially limit the scope of gene patents, it would only minimally diminish the harm caused by them.

Furthermore, this course of action would leave most diagnostic gene patents relatively untouched, as the claimed methods would likely be described in detail in the patent's specification. Even relatively broad method claims, such as those of the '167 patent,[130] would likely not be construed as unduly broad in light of the numerous examples a patentee would likely describe in the specification. Accordingly, this proposal is also inadequate.

iii. The Experimental Use Doctrine

In addition to the attacks on patentability, some authors have proposed limiting the scope of issued patents.[131] One such limitation may lie in an exception to infringement known as the experimental use doctrine. The experimental use doctrine—a distant, albeit watered-down, cousin of the fair use doctrine in copyright law—allows for the use of patented inventions "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[132] The experimental use doctrine, however, is extremely limited.[133] Arguably, an expansion of this doc-

129. *Amgen*, 927 F.2d at 1214.

130. U.S. Patent No. 5,508,167, at claim 1 (filed Apr. 13, 1994).

131. Merz, *supra* note 1, at 206.

132. Embrex, Inc. v. Service Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000).

133. *See* Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) ("[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. [T]he profit or non-profit status of the user is not determinative.").

trine to publicly and privately funded research would prevent the negative downstream impact of patenting genetic material.[134]

However, because of this doctrine's extremely limited application, even use for research or diagnostic purposes is likely to fall outside of this narrow exception. Thus, a broad expansion of the experimental use doctrine would be required. In fact, in 2002, a bill that would have exempted use of genetic sequences for purposes of research was submitted to a House subcommittee.[135] However, no further action has been taken since its submission. In addition, courts have been quite apprehensive to apply this doctrine.[136] Due to the longstanding nature of this narrow common law exception,[137] it is unlikely that the broad expansion necessary to curb the harm of gene patents will occur.

iv. The Nonobviousness Requirement (35 U.S.C. § 103)

Another statutory requirement for patentability is the nonobvious requirement of § 103.[138] This provision states that an applicant is not entitled to a patent "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art."[139] This requirement attempts to bar patentability for inventions that, although not explicitly disclosed in any one source, amount to only minor modifications or combinations of already known subject matter.[140]

Due to advances in the understanding of genetics, it is now fairly routine and easy to determine the function of particular genes.[141] In

134. *See* Merz, *supra* note 1, at 207 ("[R]esearch on the invention should be exempt while research using the invention [should be deemed] infringement.").

135. *See* The Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002).

136. *See Madey*, 307 F.3d at 1360 ("Our precedent . . . continues to recognize the judicially created experimental use defense, however, in a very limited form.").

137. The experimental use exception has its origins in early-1800s case law. Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (D. Mass. 1813) (No. 17,600).

138. 35 U.S.C. § 103(a) (2006).

139. *Id.*

140. *Id.*

141. Andrews, *supra* note 43, at 803 ("[T]he function of human genes can now be predicted on the basis of their homology to other genes.").

addition, the processes for isolating human genes and for determining which genes encode for specific proteins are relatively well-known and documented.[142] For these reasons, some feel that the nonobviousness requirement can limit gene patents.[143] In particular, this solution seems very likely to limit composition-of-matter (and certain functional-use) gene patents in the future.

Nevertheless, this avenue is unlikely to have an impact on diagnostic gene patents. In a series of cases in the early- to mid-nineties, the Federal Circuit addressed the obviousness requirement as applied to methods in the biotechnological arts.[144] In these cases, the court definitively stated that a general method for DNA isolation will not, on its own, render a DNA sequence obvious.[145] This reluctance of the court to find diagnostic gene patents obvious despite their roots in known, non-novel methods makes the nonobviousness requirement an unlikely solution to limiting diagnostic gene patents.

3. Separating the Good from the Bad

An additional fault with each of the solutions presented above is that none adequately separates the chaff from the wheat. An ideal patent system should grant patents for inventions that make meaningful (*i.e.* new, useful, and nonobvious) contributions to society in order to encourage the progress of useful arts. Simultaneously, an ideal system should preclude from patent eligibility those inventions that do not contribute meaningfully and thus fail to promote progress. Because there may be some patents related to the field of genetics that do not violate the Patent Clause, it is important to distinguish those that do from those that do not.

These concerns are particularly present for diagnostic gene patents. Here, more than in Professor Merz's other categories, there exists potential for meaningful contribution. In the case of composition-of-matter gene patents, for example, claims directed to genes them-

142. Jeffrey Dillen, Comment, *DNA Patentability—Anything But Obvious*, 1997 WIS. L. REV. 1023, 1030 (1997).

143. *Id.* at 1029-30.

144. *In re* Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995); *In re* Bell, 991 F.2d 781, 782 (Fed. Cir. 1993); and Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1214 (Fed. Cir. 1991).

145. *In re Deuel*, 51 F.3d at 1559; Dillen, *supra* note 142, at 1036.

selves add little or no beneficial knowledge to society, as these patents merely claim specific portions of the genome rather than a new, useful, and nonobvious innovation.[146] And because these patents have the potential to be so damaging, there is little need for concern with separating so-called good composition-of-matter gene patents from so-called bad composition-of-matter gene patents.

While the case for weeding out the bad in functional-use gene patents is stronger than for composition-of-matter gene patents, it is still not as great a concern as that for diagnostic gene patents. Because the benefits of many functional-use gene patents (essentially claiming structures that mimic the functionality of certain genes) is limited at this point, the separation of good from bad is not a significant concern.

Contrary to other types of gene patents, an incredible breakthrough in genetics testing (falling under the diagnostic gene patent category) is just the sort of invention that the patent system should seek to protect. Therefore, an adequate solution to the gene patent problem should be able to separate the good from the bad.

B. A New Potential for Limiting Diagnostic Gene Patents: In re Bilski *and Patent-Eligible Subject Matter*

While the nonobvious requirement may effectively keep composition-of-matter and functional-use patents in check, a new means to limit diagnostic gene patents is necessary. As described above, diagnostic gene patents work against the constitutional mandate by acting as hold-ups to scientific research, as detriments to public healthcare, and as tolls that increase the cost of research and healthcare. For these reasons, diagnostic gene patents are, at present, the most troubling of Professor Merz's three categories.

A recent *en banc* Federal Circuit decision, *In re Bilski*,[147] however, may hold a key to restricting the patentability of harmful diagnostic gene patents through the eligible subject matter requirement of § 101 of the Patent Statute. Although the primary impact of the *Bilski* decision will likely be felt in the areas of business method patents and other, software-based process claims, this notable decision may also pro-

146. *See, e.g.*, U.S. Patent No. 4,703,008, at claim 2 (filed Nov. 30, 1984) (claiming merely a "purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin").

147. *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008).

vide a potential avenue for keeping diagnostic gene patents in check. In *Bilski*, the Federal Circuit clarified the standard for assessing whether certain process claims constitute patent-eligible subject matter under § 101.[148] However, before turning to this decision (and its potential effect on gene patents), the reader may find helpful a brief review of the controlling law on patent-eligible subject matter as applied to the biotechnological arts.

1. Patent-Eligible Subject Matter (35 U.S.C. § 101)

Under § 101 of the Patent Statute, an applicant is entitled to a patent for any new and useful "process, machine, manufacture, or composition of matter."[149] These four groups represent the four categories of patent-eligible subject matter. In order to be eligible for a patent, the subject matter of the invention must fall within at least one of these categories.[150]

Originally, living things were considered to be outside the scope of patent-eligible subject matter, as they were viewed not as inventions but as products of nature.[151]However, under *Chakrabarty*, products of nature in a purified form constitute patent-eligible subject matter, as they are still compositions of matter.[152] Thus, biological material, including isolated or purified genes, constitutes patent-eligible subject matter.[153]

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148. *Bilski*, 545 F.3d at 949. Section 101 states that "any new and useful process, machine, manufacture, or composition of matter" may be patented, subject to the other provisions of the patent statute. 35 U.S.C. § 101 (2006). For this reason, the patent-eligible subject matter requirement is often considered a "threshold" requirement. *Bilski*, 545 F.3d at 950.

149. 35 U.S.C. § 101.

150. However, the invention need not fall squarely within just one of the categories, and it is not necessary to specify precisely which category an invention falls under in order to be eligible for patentability. *E.g.*, M.P.E.P., *supra* note 51, § 2173.05(p).

151. *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are basic tools of scientific and technological work."); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("Patents cannot issue for the discovery of the phenomena of nature . . . .They are manifestations of laws of nature, free to all men and reserved exclusively to none.").

152. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

153. *See id.*

2. *The* Bilski *Decision*

The recently decided *Bilski* decision marks a notable change in the court's interpretation of patent-eligible subject matter as applied to process patents and may even partially limit the broad eligibility interpretations rooted in *Chakrabarty*.[154] Claim 1 of Bilski's application recites:

> A method for managing the consumption of risk costs of a commodity[,] comprising the steps of:
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> (a) initiating a series of transactions between [a] commodity provider and consumers of said commodity . . .;
>
> (b) identifying market participants for said commodity . . .;
>
> (c) initiating a series of transactions between said commodity provider and said market participants . . . such that said series of market participant transactions balances the risk position of said series of consumer transactions.[155]

The *Bilski* court attempted to redefine the standard for determining whether a claimed method constituted a patent-eligible "process" under § 101 of the Patent Statute.[156] In so doing, the case made the "machine-or-transformation" test the new standard for making this determination.[157] Thus, under *Bilski*, a claim contains patent-eligible subject matter if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."[158] The machine-or-transformation test apparently arises from a desire to prevent the patenting (or "preemption") of "fundamental principles," such as abstract ideas, laws of nature, or other traditionally-ineligible subject matter.[159] In *Bilski*, the court (after first noting that the claimed

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154. The *Bilski* decision holds that a process claim will satisfy § 101 eligibility by showing that the claimed process either is tied to a machine or transforms an article, *In re* Bilski, 545 F.3d 943, 961 (Fed. Cir. 2008), while *Chakrabarty* holds that "everything under the sun made by man" is patentable, *Chakrabarty,* 447 U.S. at 309.

155. *Bilski*, 545 F.3d at 943.

156. *Id.*

157. *Id.* at 966.

158. *Id.* at 954.

159. *See id.* at 963 ("So long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is

process was not tied to any specific machine or apparatus) concluded that the process above did not transform any article to a different state or thing, thus failing the machine-or-transformation test.[160]

Although the court elected to "leave to future cases" elaboration on the machine prong of the test, it did provide an analysis of what does and does not satisfy the transformation prong.[161] Here, the court held that a process would satisfy this prong (and thus constitute eligible subject matter) if it transformed "an article into a different state or thing."[162] The court further held that "[t]his transformation must be central to the purpose of the claimed process."[163] The court then considered the question of what sorts of things constituted "articles," and concluded that mere abstract concepts or other traditionally-unpatentable subject matter did not constitute an article for these purposes.[164] In this way, the machine-or-transformation test could serve to prevent patentees from claiming all, or an overly-broad range of, uses of a fundamental principle.[165] The fundamental principle claimed in *Bilski* was the use of abstract ideas and mental processes to calculate the hedging of risks between commodities and market participants.[166] Quoting an earlier case, the court concluded that a claim that requires an "application of [only] human intelligence to the solution of practical problems" is merely a claim to a fundamental principle, and thus unpatentable.[167] Although the court focused on the claimed process's lack of transformation of a physical object or substance in rejecting the claims in *Bilski*,[168] the application of this principle seems clear: process claims that involve the use of fundamental principles (whether abstract concepts, physical phenomena, or other traditionally

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limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle.").

160. *Id.*

161. *Id.* at 962.

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.* at 956.

166. *Id.* at 949-50.

167. *Id.* at 965 (quoting *In re* Comiskey, 499 F.3d 1365, 1377-79 (Fed. Cir. 2007)).

168. *Id.* at 963-64.

ineligible subject matter) do not constitute a "process" under § 101 unless the claims are tied to some physical apparatus or are capable of a transformation that is central to the purpose of the process.[169]

3. *Limitations on Gene Patents Through* Bilski

In gene patents, the fundamental principle is not an abstract idea or a mental process as in *Bilski*, but rather naturally occurring compositions of matter: genes. The concern, however, remains the same in either case: namely, the use of otherwise unpatentable subject matter as the foundation for a patent.

For example, in the case of the '167 patent, any laboratory can easily test for the APOE gene (without using any patented device or product) simply by knowing the sequence of the APOE gene.[170] Claim 1 of the '167 patent, like the claims of many diagnostic gene patents, essentially recites two basic steps: (1) comparing a discovered gene to a sample of a subject's DNA, and (2) determining whether a particular condition exists based on the presence or absence of the gene in the sample.[171] Such a claim contains no transformative step and would

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169. For example, the *Bilski* court cites to a case in which the Federal Circuit's predecessor court held that a broad independent claim reciting the process of displaying variances of data from average values constituted ineligible subject matter. *Id.* at 962-63 (citing *In re* Abele, 684 F.2d 902, 909 (C.C.P.A. 1982)). However, the court held that a narrower, dependent claim was eligible when it recited "said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner." *Id.* at 962 (citing *Abele*, 684 F.2d at 908-09). The court found this "transformation of . . . raw data into a particular visual depiction of a physical object on a display unit" to be a patent-eligible process. *Id.* at 963. Although this language seems to suggest that a display of data would satisfy the transformation prong of the *Bilski* standard, this is not the case. The process in *Abele* translated data that represented information on the physical structures of bones, organs, and other tissue into a physical depiction of those organs on a display. *Abele*, 684 F.2d at 908. Thus, diagnostic gene patents will not pass the machine-or-transformation test simply by claiming the display of genes on a smear.

170. Andrews, *supra* note 43, at 804.

171. U.S. Patent No. 5,508,167, at claim 1 (filed Apr. 13, 1994). At least three Justices of the Supreme Court seemed to express that such processes are undeserving of patent protection, and, in a dissent to a dismissal of a writ of certiorari, Justice Breyer stated that a similar claim constituted unpatentable subject matter. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 135-36 (2006) (5-3 decision) (Breyer, J., dissenting). One of the claims at issue in *Lab. Corp.* recited a process comprising the steps of "[(1)] assaying a body fluid for an elevated level of

almost certainly fail the machine-or-transformation test, thus placing the method outside the scope of eligible subject matter. As in *Bilski*, diagnostic gene patents "seek to claim a non-transformative process that encompasses [a fundamental principle] without the aid of . . . any other device."[172] Such claims would preempt all uses of the "fundamental concept" of diagnosing a particular genetic condition, regardless of the specific methodology or equipment used. This preemption is precisely the type of claim that the machine-or-transformation test attempts to exclude from eligibility.[173]

The claims of the '167 patent, much like the claims in many diagnostic gene patents, are not tied to any specific machine or apparatus.[174] Thus, as in *Bilski*, the patentability of such claims rests solely on their ability to satisfy the transformation prong of the machine-or-transformation test.

The process recited by claim 1 of the '167 patent is not transformative either.[175] Typical of many diagnostic gene patents, this claim simply involves comparing a particular gene or group of genes with a sample of DNA to determine the presence or absence of the gene or genes.[176] The claim recites no physical or chemical alteration; nor does it refer to anything changing, reforming, or otherwise becoming another thing.[177]

One may argue that applicants could draft otherwise unpatentable process claims to include ties to machines or apparatuses in order to overcome the machine-or-transformation test. However, even if applicants began doing so, this practice itself would help to solve many of the problems of diagnostic gene patents. Because tying the process to a specific tool or group of tools requires that those exact tools be used

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total homocysteine; and [(2)] correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." *Id.* at 129; U.S. Patent No. 4,940,658 claim 13 (filed Nov. 20, 1986).

172. *Bilski*, 545 F.3d at 965.

173. *Id.* at 961. Such overbroad claims have historically been excluded from patent protection. *See* O'Reilly v. Morse, 56 U.S. 62, 113 (1853) (holding that a claim reading on all uses of electromagnetic waves for printing characters over a distance was ineligible).

174. '167 Patent at claim 1.

175. *Id.*

176. *Id.*

177. *Id.*

in order to infringe, the scope of the claim is drastically limited.[178] In addition, although *Bilski* leaves an elaboration of the machine prong of the test to future cases, it seems likely that a future court will require that the claimed machine or apparatus, like the transformation prong,[179] be *central* to the claimed process. In this way, the mere inclusion of "known tools in a way known to those of skill in the art" would not overcome the *Bilski* standard, as this inclusion is not central to the claimed process.[180] Thus, many of these harmful, overbroad processes would still be open to rejection under the machine-or-transformation test.

4. Separating the Chaff from the Wheat

Applying the machine-or-transformation test to diagnostic gene patents would have the additional benefit of blocking harmful diagnostic gene patents while simultaneously allowing claims directed to truly innovative methods. For example, an application containing claims that recite the use of a novel machine or apparatus would likely satisfy the as-of-yet undefined machine prong of the *Bilski* test. In a less clear-cut case, this test would still separate the bad from the good. Consider, for example, U.S. Patent No. 5,272,055 (the '055 patent), which claims methods for detection of Alzheimer's disease and other diseases using a photoaffinity.[181] Claim 1 of the '055 patent recites:

> A method for aiding in the diagnosis of Alzheimer's disease in a mammal comprising:

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178. In addition, the tying of a method to a specific component may render the claims vulnerable to rejection under the novel and nonobvious requirements of §§ 102 and 103 of the Patent Statute, as many of these tools are well-known to those of skill in the art. Those processes that *do* contain new tools or machinery would likely pass this standard, thus ensuring that truly novel innovations receive patent protection, as intended by the Framers. *Infra* Part II.A.

179. *See In re* Bilski, 545 F.3d 943, 962 (Fed. Cir. 2008) (holding that the "transformation must be central to the purpose of the claimed process").

180. By "central," it is meant the true inventive or novel aspect of the process. *Id.* This aspect of the machine-or-transformation test ensures that the nominal addition of known transformations (or components) in known ways does not allow claims to circumvent the test. *Id.*

181. U.S. Patent No. 5,272,055, at [54] (filed Dec. 24, 1991). Although not a gene patent, the methods of the '055 Patent provide a helpful illustration. *Id.*

> a) contacting a cerebrospinal fluid sample which contains a nucleotide binding protein having an apparent M_r of about 42,000 daltons, wherein said protein is glutamine synthetase, with an effective amount of a labeled ATP- or GTP-analog photoaffinity-labeling reagent which specifically binds said nucleotide binding protein at the nucleotide binding site to photoaffinity label said nucleotide protein;
>
> b) fractionating said cerebrospinal fluid sample to separate the photoaffinity-labeled nucleotide binding protein;
>
> c) detecting the presence of the separated photoaffinity-labeled nucleotide binding protein; and
>
> d) correlating the presence of the photoaffinity-labeled nucleotide binding protein to the presence of Alzheimer's disease.[182]

Here, unlike many diagnostic gene patents, the method does not attempt to preempt all uses of fundamental principle. The method recited by claim 1 of the '055 patent does not simply claim the process of comparing and determining (as in the '167 patent) but instead recites specific steps for setting up this comparison.[183]Accordingly, the '055 patent and similar patents do not carry the concerns raised by many diagnostic gene patents. For example, in order to infringe claim 1 of the '055 patent, a specific binding protein and photoaffinity-labeling reagent would need to be used.[184] A party seeking to avoid infringement need only find a substitute for either of these components. Thus, a researcher or physician attempting to test for Alzheimer's disease could circumvent this patent by using other methods that do not utilize glutamine synthetase. In reciting the use of a nucleotide binding protein and a photoaffinity-labeling reagent, the claim may satisfy the machine prong of the *Bilski* test.[185] However, even if this prong were not satisfied, it is likely that the claim would still pass under the transformation prong, as the "contacting" step (or even the

182. *Id.* at claim 1.

183. *Id.*

184. *See id.* (claiming "a cerebrospinal fluid sample which contains a nucleotide binding protein having an apparent M_r of about 42,000 daltons, wherein said protein is glutamine synthetase").

185. *Id.*

"fractioning" step) could be considered as changing the sample "into a different state or thing."[186]

In either case, because the holding of *Bilski* stems from a deeply rooted desire to bar patents that preempt *all* uses of a fundamental principle[187] and because the '055 patent and others like it merely claim *one* use of a fundamental principle, gene patents similar to the '055 patent and deserving of patent protection would likely pass the machine-or-transformation test. In this way, the machine-or-transformation test ensures that diagnostic gene patents that actually do foster the progress of useful arts remain patent-eligible subject matter, while those diagnostic gene patents that hinder this progress are excluded from patent protection.

VI. CONCLUSION

In drafting the Patent Clause of the Constitution, the Framers—both well aware and fearful of the potentially devastating effects of monopolies on society—were careful to include an important limitation to the power to grant exclusive rights: that such a grant encourage the progress of useful arts.[188] In acting in accordance with this constitutional mandate, the United States patent system should make every effort to ensure that patents issue for inventions that serve this goal. However, gene patents represent a group of patents that generally hinder innovation and therefore act contrary to the Patent Clause. In particular, diagnostic gene patents place an especially heavy burden on society, as they act as a substantial detriment to public healthcare while doing little to encourage the progress of useful arts. While many solutions have been proposed to deal with the gene patent problem, none adequately resolve the particular harmfulness of diagnostic gene patents.

However, the Federal Circuit's decision in *Bilski* has the potential to severely limit the harmful effects of diagnostic gene patents through

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186. *In re* Bilski, 545 F.3d 943, 962 (Fed. Cir. 2008). Note also that the "transformation" by combining the sample with the photoaffinity-labeling reagent appears to be a central part of the process. *See* '055 Patent at col.15 *ll.*3-11.

187. *See Bilski*, 545 F.3d at 957 ("pre-emption is merely an indication that a claim seeks to cover a fundamental principle itself rather than only a specific application of that principle").

188. U.S. CONST. art. I, § 8, cl. 8.

the court's restatement of the machine-or-transformation test.[189] Under *Bilski*, patent claims directed to processes that are not tied to some machine or that do not involve a transformation that is central to the claimed process fail this test.[190] Because such processes serve to claim a fundamental principle itself, rather than a use of a fundamental principle, these processes are not directed to patent-eligible subject matter. Many harmful diagnostic gene patents, which are typically not tied to any specific article or piece of equipment and which typically involve no meaningful transformation that is central to the purpose of the claimed process, would likely fail this test. As a result, the clear intentions of the Framers are preserved, and the patent system may more effectively serve its goal: to promote the progress of useful arts.

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189. As of this writing, at least one Federal Circuit case seems to support this proposition. *See* Classen Immunotherapies, Inc. v. Biogen IDEC, No. 2006-1634, slip op. at 2 (Fed. Cir. Dec. 19, 2008). Although non-precedential, the single-paragraph opinion in *Classen* invalidated, under *Bilski*'s machine-or-transformation test, a patent similar to a diagnostic gene patent. *Id.* Claim 1 of this patent reads:

> A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises:
> immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and
> comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

U.S. Patent No. 5,723,283, at claim 1 (filed May 31, 1995).

This method essentially discloses nothing more than (1) the inserting of one or more doses of immunogens into an animal, and (2) the comparing of the results to a control group. Thus, the framework of this method bears a strong similar to many diagnostic gene patents.

190. *Bilski*, 545 F.3d at 962.