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***Genetic Diagnostic Testing Method Patents: Their Widespread Monopolization and the
Need to Eliminate the Devastating Effects of Their Abuse***

Frank Fiorello

I. Introduction

There are currently thousands of known genetic disorders, many quite serious and deadly. In fact, the World Health Organization estimates that there are over 10,000 known “monogenic” human diseases alone, which only accounts for those diseases resulting from a mutation in a single gene out of tens of thousands of genes in human DNA.¹ In order to research and diagnose this ever-growing number of known genetic disorders, scientists and doctors have developed numerous methods of testing for the genetic peculiarities that cause them. Countless people have already benefited from the knowledge gained through genetic testing, and this number will doubtlessly increase as more is constantly learned.

The current, heated controversy surrounding genetic testing does not involve the testing itself, but rather the entitlement to and use of genetic testing method patents. A study conducted in 1995 determined that out of all genetics-related patents issued that year, diagnostic methods were the most popular.² As the number of genetic testing method patents is rapidly growing, so is the need for clear guidelines as to whether such

¹ See *Genes and Human Disease*, WORLD HEALTH ORGANIZATION, <http://www.who.int/genomics/public/geneticdiseases/en/index2.html> (last visited November 4, 2011).

² See Jon F. Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine*, CLINICAL CHEMISTRY, March 1999, at 324, 324 (describing the Thomas et al. study on the number of “patents claiming gene sequences issued between 1981 and 1994,” diagnostics was the fifth most common, but in the follow-up 1995 study, it had become the most common).

patent claims are in fact valid and permissible. Based on several recent court decisions, some general guidelines have been established, but full clarity as to the validity of genetic testing method patents, and what makes certain claims valid and others invalid, has by no means yet been provided.

Outside the courtroom, the patent-eligibility of genetic testing methods is causing quite a stir in the moral and political realm. The Constitution, as well as public policy, dictates that the availability of patents over inventions will promote “the progress of science and the useful arts.”³ The question is, however, with respect to genetic testing method patents, “to what extent” and “at what expense”? Should doctors and scientists be able to rely on the fact that their new genetic testing method can be patented so that they will be encouraged to discover it in the first place? Or should certain limits and restrictions be put in place so that holders of such patents are unable to cease or discourage further testing using their discovered method?

This paper will delve further into the details of genetic diagnostic testing and its many flavors and varieties, as well as discuss the importance and need for such testing methods, in Part II below. Part III will take a further look into the current status of case law regarding genetic testing method patentability. As will be shown below in Part IV, there are several valid arguments both for and against the patentability of genetic diagnostic tests. Part V will demonstrate, however, that it is in the public’s best interests

³ See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1017 (1989) (“The patent laws confer exclusive rights in inventions and discoveries in furtherance of a constitutional purpose ‘To Promote the Progress of Science and useful Arts.’ Yet the idea that exclusive rights in new knowledge will promote scientific progress is counterintuitive to many observers of research science, who believe that science advances most rapidly when the community enjoys free access to new discoveries.”).

to further restrict monopolization via broad genetic testing patents and allow all diagnostic and experimental uses of those methods to occur without risk of infringement.

II. What is genetic diagnostic testing?

“Genetic diagnostics analyze the sequence of a specific piece of DNA” and allow scientists and doctors to look for known genetic disorders.⁴ Genetic testing involves “a laboratory procedure [for] detecting the presence or absence of, or change in, a particular gene or chromosome, including an indirect test for a gene product or other specific metabolite that is primarily indicative of a specific genetic change,” so it is needless to say a highly complex, nuanced field of study.⁵ Thorough knowledge and understanding of the detailed processes behind collecting genetic data is needed, especially by doctors, as even *interpreting* the results of a genetic test is no easy feat.⁶ By analyzing this data, doctors can inform patients of their susceptibility to developing certain genetic diseases and their chances of passing on those diseases to their offspring.⁷ Knowledge of this information can not only “guide their life choices”, such as the choice of whether to conceive a child knowing it will be at high risk of developing a disease or to seek out a

⁴ See Asher Hodes, *Diagnosing Patentable Subject Matter*, 26 BERKELEY TECH. L.J. 225, 243-244 (2011).

⁵ See Sirpa Soini et. al., *Patenting and licensing in genetic testing: ethical, legal and social issues*, EUROPEAN JOURNAL OF HUMAN GENETICS, May 2008, at S10, S13.

⁶ See S. Ayme et. al., *Patenting and licensing in genetic testing: Recommendations of the European Society of Human Genetics*, EUROPEAN JOURNAL OF HUMAN GENETICS, May 2008, at S3, S5 (describing how “the complexity in the interpretation of the results and in intellectual property (IP) protection will [most likely] increase.”).

⁷ See *id.* at S4-S5.

donor, but it can lead to the availability of treatment of a disease that would not otherwise be known.⁸

The fact that a given genetic test is only useful if it aims to detect “a known, described” genetic disorder, it is not uncommon for the discoverer of a new “disease gene” to not only patent the gene itself, but also obtain a patent over its associated genetic diagnostic testing methods.⁹ For example, Myriad, a case that will be discussed below, involved the genes BRCA1 and BRCA2, which they discovered were linked to breast and ovarian cancer.¹⁰ Myriad patented not only the BRCA genes, but also several genetic diagnostic testing methods essentially comprising simply “analyzing” genes to seek out the BRCA mutation and ways of studying potential cancer treatments using the disease gene as a guideline.¹¹ The patented *BRCAAnalysis* Test requires the test-taker to seek a healthcare provider to obtain from them a blood sample that must be sent to Myriad’s laboratories¹² as Myriad is the only entity currently able to perform the full test.¹³ Myriad charges approximately \$3,200 for the *BRCAAnalysis* test, which is the source of 80% of the company’s revenue, and does not accept all insurance plans.¹⁴ If one tests positive

⁸ See Asher Hodes, *supra* note 4, at 248.

⁹ See Soini, *supra* note 5, at S13 (explaining that genetic testing methods accompanying newly discovered genetic mutations are also often patented together with the mutations mainly because “[o]nce a link between a disease and a precise genetic defect has been established, the relevant diagnostic test can be relatively easily developed.”).

¹⁰ See generally *Ass’n for Molecular Pathology v. USPTO*, No. 2010-1406, 2011 U.S. App. LEXIS 15649 (Fed. Cir. July 29, 2011).

¹¹ See *id.* at *9-10.

¹² See *How Do I Get Tested?*, *BRACANALYSIS*, <http://www.bracnow.com/considering-testing/get-tested.php> (last visited December 6, 2011).

¹³ See Janice M. Mueller, *Facilitating Patient Access to Patent-Protected Genetic Testing*, 111-112 (University of Pittsburgh Legal Studies Research Paper Series, Working Paper No. 2010-32, 2010), available at <http://ssrn.com/abstract=1694760>.

¹⁴ See *id.* (“Myriad . . . , a for-profit corporation, derives 80% of its revenues from its proprietary *BRCAAnalysis*® testing, which it characterizes as ‘the standard of care in identification of individuals with hereditary breast and ovarian cancer.’”).

under the BRCA*Analysis* Test, it signifies the existence of a genetic mutation in a BRCA gene that is associated with a high risk for developing breast or ovarian cancer¹⁵ and also means that close blood relatives also have a 50% chance of having the same mutation.¹⁶ In recommending possible remedial measures, Myriad goes so far as to suggest breast and ovary removal surgery or chemoprevention,¹⁷ and this is all based on merely having a higher *probability* for developing the disease and without providing the patient any opportunity to obtain a second opinion.¹⁸

Genetic testing does not only occur on the gene level, but also on the chromosomal and protein levels, as different tests examine mutations on any size level.¹⁹ Genetic tests are conducted for several different purposes, including, but not limited to: diagnostic testing when a person shows signs of a certain genetic disorder or wants to know their chances for developing a given disorder that runs in their family (e.g. BRCA*Analysis*); preconception testing to determine whether individuals are carriers of a genetic disorder and thus more likely to pass it onto their offspring; prenatal testing on pregnant women test women at high-risk for producing children with genetic disorders; newborn screening, currently the most widely used type; and pharmacogenetic testing, which examines the effects a given drug has on certain genes, which is used in the rapidly

¹⁵ See *Positive: What Does My Result Mean?*, BRACANALYSIS, <http://www.bracnow.com/understanding-my-results/positive-results.php> (last visited December 6, 2011).

¹⁶ See *Positive: What Should I Do Now?*, BRACANALYSIS, <http://www.bracnow.com/understanding-my-results/positive-do-now.php> (last visited December 6, 2011).

¹⁷ See BRACANALYSIS, *supra* note 15.

¹⁸ See Mueller, *supra* note 13, at 111.

¹⁹ See *FAQ About genetic Testing*, GENOME.GOV, <http://www.genome.gov/19516567> (last visited December 6, 2011).

growing and promising field of pharmacogenetics.²⁰ Though the majority of genetic tests are performed for medical purposes, as seen above, and thus require consultation with a healthcare provider, there are also a number of direct-to-consumer genetic tests that do not.²¹ Direct-to-consumer tests are most commonly used not only to make test-takers aware of certain general health implications, but also for non-medical purposes such as uncovering ancestry and providing insight as to one's personality-related genetic information.²²

III. Are genetic diagnostic tests currently patent-eligible?

In recent years alone, the Court has gone back and forth several times, seemingly establishing workable legal tests to determine whether a genetic testing method claim is patentable or not, then proceeding to reject those principles in subsequent appeals. The single decision that had, perhaps, the greatest impact on the current state of genetic testing patentability did not concern a scientific-related method at all, but rather a method of hedging risk in commodities.²³ Though several other important cases have thereafter been decided regarding the field of diagnostic testing method claims, it is yet to be determined whether almost any of them are final as each maintains certain grounds for further appeal. Until the Supreme Court expresses a final, catch-all decision regarding the patentability of genetic testing method claims in these cases, the field remains somewhat open and the guidelines blurry.

²⁰ *See id.*

²¹ *See id.*

²² *See id.*

²³ *See* *Bilski v. Kappos*, 130 S. Ct. 3218, 3223 (2010) (explaining that *Bilski* obtained a patent on a method, or process, of hedging risk comprised purely of mental steps).

A. Before Bilski v. Kappos

Dating as far back as 1793, it was established that in order for any invention to be patentable, it had to be the result of the inventor's "mental labor", and not simply the discovery of a law of nature.²⁴ This key principle remains in place today, forming the basis for §101, the initial screening test applied to all claims to determine patentability based on whether or not, and the "abstract mental process" promoted in In re Bilski.²⁵ Between 1998 and the Court of Appeals' decision in 2008 in In re Bilski, the court made use of the UCT Test to determine method claim patentability, which looked only at whether the invention patented a "useful, concrete, and tangible result."²⁶ The Court in In re Bilski, in rejecting the UCT Test as "inadequate", found that the only inquiry required is asking whether claim seeks to "claim a fundamental principle (such as an abstract idea) or a mental process", prescribing the infamous Machine-or-Transformation Test ("MoT Test") as the appropriate test.²⁷ The MoT test, which was used as the exclusive

²⁴ See Timo Minssen & Robert M. Schwartz, *US Patent Eligibility in the Wake of Bilski v. Kappos: 'Business as Usual' in an Age of New Technologies?*, 29 BIOTECHNOLOGY L. REP. (forthcoming 2010) (manuscript at 12), available at <http://ssrn.com/abstract=1682574> ("Under section 3 of the 1793 registration system, patent holders claiming infringement were required to file a petition with the Secretary of State alleging under oath that their inventions were 'new and useful' and a product of the holder's 'mental labor or intellectual creation'.").

²⁵ See Eileen Kane, *Patenting Genes and Genetic Methods: What's at Stake?*, 6 J. BUS. & TECH. L. 1, 20 ("(*In re Bilski* . . . concluded that the UCT test was 'inadequate' [and] framed its inquiry as 'whether Applicants are seeking to claim a fundamental principle (such as an abstract idea) or a mental process.'").

²⁶ See *id.* (explaining that while the UCT Test was the governing standard during those ten years, "patent applicants relied on [it] to advance many inventions that lacked obvious tangibility, but which, arguably, could achieve a useful result.").

²⁷ See *id.* ("The court announced that 'the machine-or-transformation (MOT) test outlined by the Supreme Court is the proper test to apply.'").

patentability test for about two years and led several decisions to be remanded and reversed (Prometheus v. Mayo), prescribed that “[a] claimed process is [] patent-eligible under §101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”²⁸ Due to the fact that the MoT Test was only used in In re Bilski on a business method claim, the ease with which this test was satisfied in the genetic testing method and other technological contexts would cause the test, as a whole, to be questioned for its generalized use among *all* method claims despite their nature.²⁹

B. *The Bilski v. Kappos Decision*

The Supreme Court’s decision in Bilski v. Kappos (“Bilski”) reverberates throughout the opinions of seemingly all post-June 2010 method patent claim cases. Bilski took a clear, definitive test and turned it into a mere factor of a wider analysis. According to the U.S. Court of Appeals in In Re Bilski, the MoT Test was “the sole test” governing method, or process, claim patentability, and as long as the court could find that either prong was satisfied, the invention would be deemed patentable subject matter.³⁰

The Supreme Court, however, overturned this ruling on appeal, holding that, because the

²⁸ See In re Bilski, 545 F.3d 943, 956 (CA Fed. 2008) (holding that the Machine-or-Transformation test was to be the sole governing patentability test for all method, or process, claims).

²⁹ See Kane, *supra* note 25, at 33 (“The legal standards from the business method patent cases arose to answer the central dilemma for that field – must an invention have a tangible form or be tied to physical processes? These were not the pressing questions from life science patenting. Instead, the central questions for biological patenting involved whether natural processes were being patented, and whether the preemption of basic scientific knowledge occurred.”).

³⁰ See Bilski v. Kappos, 130 S. Ct. at 3223 (explaining the effect of the holding in the court below in In re Bilski).

machine-or-transformation test would too easily be satisfied in many instances and that it “violate[d] [] statutory interpretation principles”, the machine-or-transformation test is only “a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under §101,” and therefore not exclusive or required.³¹ Each of the three most controversial and important ongoing litigations involving the patentability of diagnostic testing methods began prior to the Supreme Court’s words in Bilski and had their course drastically altered thereafter.

C. Prometheus Labs v. Mayo

The first of the three major cases decided after Bilski was Prometheus Labs., Inc. v. Mayo Collaborative Servs. & Mayo Clinic Rochester (“Prometheus”)³², a case the Supreme Court remanded the day after their decision in Bilski in June of 2010.³³ The disputed claims in Prometheus involved methods of determining proper dosage levels of certain drugs used for “inflammatory bowel diseases”.³⁴ Upon remand, the Federal Circuit U.S. Court of Appeals set out solely to determine the issue of whether the method claims passed the initial screening test of §101, that is, whether the patent claims sought to protect patentable subject matter.³⁵ In rendering a decision, the court focused on the Supreme Court’s explanation in Bilski “that while a law of nature, natural phenomenon,

³¹ See *id.* at 3226-3227.

³² Prometheus Labs., Inc. v. Mayo Collaborative Servs. & Mayo Clinic Rochester 628 F.3d 1347 (Fed. Cir. 2010).

³³ See generally Mayo Collaborative Servs. v. Prometheus Labs., Inc., 130 S. Ct. 3543 (U.S. 2010).

³⁴ See Prometheus Labs v. Mayo, 628 F.3d at 1350 (explaining that the administration of Thiopurine was found by Prometheus to treat certain gastrointestinal and autoimmune disorders).

³⁵ See *id.* at 1353.

or abstract idea cannot be patented, ‘an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection,’” though simply limiting an invention to a particular scientific field does not alone make an abstract scientific principle patentable.³⁶ Furthermore, the Court expressed that a given claim is “to be considered as a whole” when determining its patent-eligibility, not as individual parts.³⁷ For this reason, purely “mental steps”, though not patentable on their own by definition, *may* be included as part of a longer method claim that contains redeeming patentable clauses.³⁸ However, in these cases, the redeeming, patentable steps must be “central to the purpose of the claimed process.”³⁹

Essential to the outcome in Prometheus was that the disputed claims used the steps of “administering” and “determining”, two terms that will prove to be pivotal in the following two cases described below as well. After finding that the claims represented an “application” of a law of nature and were thus patentable, the court went on to explain why, together, the “administering” and “determining” steps satisfied the “transformation” prong of the machine-or-transformation test.⁴⁰ Though this case involved a method of treatment and not a genetic diagnostic test, the same rationale established in Prometheus has been used in both areas. Upon completing this two-part analysis and deciding that the method claims did not “wholly preempt all uses of the recited correlations”, the Court ruled that the method claims were patentable subject matter under §101.⁴¹

³⁶ See *id.* at 1354 (explaining a key principle established by the Bilski line of cases).

³⁷ See *id.* at 1354 (explaining a rule set forth by the Supreme Court in *Bilski v. Kappos*).

³⁸ See *id.* at 1358 (agreeing with one of the holdings of the District Court below).

³⁹ See *id.* at 1355 (applying a rule set forth in *In re Bilski*).

⁴⁰ See *id.*

⁴¹ See *id.*

D. Myriad

The next major diagnostic method patent holding after Bilski took place in the Federal Circuit U.S. Court of Appeals in Ass'n for Molecular Pathology v. USPTO (“Myriad”).⁴² Myriad involved three challenged method claims, each method somehow incorporating the newly patented *BRCA* gene sequences, which Myriad discovered were “associated with a predisposition to breast and ovarian cancers.”⁴³ The first and second disputed method claims, which were analyzed together by the court, utilized the key terms “analyzing” and “comparing”, respectively.⁴⁴ The “analyzing” claim described a method of analyzing DNA to determine whether the *BRCA1* gene is altered in a certain way.⁴⁵ The “comparing” claim attempted to patent a method of essentially comparing a healthy *BRCA1* gene to a tumorous *BRCA1* gene.⁴⁶ The court’s two-part test entailed, first, applying the machine-or-transformation test to the individual steps in the claim, then making a determination as to whether, as a whole, “the claim is not so ‘manifestly abstract’ as to claim only a scientific principle” and thus not be patentable.⁴⁷ By applying this two-part test, the court seemingly conformed to the Supreme Court’s ruling in Bilski, not basing its determination solely on the machine-or-transformation test. The actual

⁴² Ass'n for Molecular Pathology v. USPTO, No. 2010-1406, 2011 U.S. App. LEXIS 15649 (Fed. Cir. July 29, 2011).

⁴³ *See id.* at *10 (describing how Myriad patented the *BRCA1* and *BRCA2* genes themselves as well as several methods of looking for genetic mutations in those genes).

⁴⁴ *See id.* at *9-11.

⁴⁵ *See id.* at *9-10.

⁴⁶ *See id.* at *10-11.

⁴⁷ *See id.* at *74 (borrowing the second test prong from the U.S. Court of Appeals decision in Research Corp. Techs. v. Microsoft Corp., 627 F.3d 859 (Fed. Cir. 2010) (“Research Corp”).).

significance of this second step, however, still remained to be seen, as it admittedly had no effect in this instance.

The court reasoned that because the “comparing” claim did “nothing more than [recite] the abstract mental steps necessary to compare two different nucleotide sequences”, it fell short of being a “transformation”.⁴⁸ With regard to the “analyzing” claim, the court found that even though it was targeted toward analyzing a highly particular nucleotide sequence, pursuant to Bilski, this fact alone does not render an abstract idea patentable.⁴⁹ In summation, the court proclaimed that both of these claims were absolutely unpatentable based on the above analyses as well as the fact that all the claims did, in reality, was “compar[e] two DNA sequences” and nothing more.⁵⁰ The court disagreed with Myriad’s suggestion that “additional, transformative steps” should be “read into” the method claims presented.⁵¹ In so holding, the court set a new standard for method claim review, namely that in order to satisfy the machine-or-transformation test, the court should hesitate to look beyond the words contained in the claims themselves for a “transformative step”.

The third Myriad method claim involved the three steps of “growing’ transformed cells”, “determining’ the cells’ growth rates”, and “comparing’ the growth rates”.⁵² The court reasoned that as both the “growing” and “determining” steps required, to some extent, “physical manipulation of the cells”, both of these steps satisfied the

⁴⁸ See *id.* at *68.

⁴⁹ See *id.* at *69.

⁵⁰ See *id.* at *69 (holding that the first two method claims failed to satisfy the Machine-or-Transformation Test for this reason).

⁵¹ See *id.* at *69. (reasoning that because “extracting” and “sequencing” were not actually anywhere in the claims themselves, these words could not simply be “read into” the claims to make them satisfy the transformation prong of the MoT Test).

⁵² See *id.* at *73-74.

machine-or-transformation test.⁵³ Though the “comparing” step would not be patentable on its own, based on Prometheus, a single step’s unpatentability is not defeating as to the claim taken in its entirety when the other, redeeming steps are the real key to the claimed method’s purpose, which they indeed were.⁵⁴ As for part two of its analysis of the last method claim, the court indeed held that the claim was limited enough and “not so ‘manifestly abstract’ as to claim only a scientific principle”, thus satisfying the standard first announced in Bilski and later used in Prometheus.⁵⁵ For the foregoing reasons, the court held that of the three challenged Myriad method claims, only the claim containing three steps, two of them patentable on their own, was patent-eligible subject matter under §101.⁵⁶

E. *Classen v. Biogen*

The most recent diagnostic testing method claim patentability issue was decided in Classen Immunotherapies, Inc. v. Biogen Idec (“Classen”),⁵⁷ which is widely anticipated to reach the Supreme Court on appeal sometime in the near future. Like Myriad, Classen involved three method claims. The first two claims covered were so similar, according to the court, that they chose only to use one for their analysis, “Claim 1

⁵³ See *id.* at *73-74.

⁵⁴ See *id.* at *74.

⁵⁵ See *id.* at *74 (explaining that this was the case because the “claim [did] not cover all cells, all compounds, or all methods of determining the therapeutic effect of a compound,” but was rather “tied to specific host cells.”).

⁵⁶ Even if only one of the three steps were patentable on its own, the claim likely still would have been deemed patentable since there was a transformation. See *id.* at 75.

⁵⁷ Classen Immunotherapies, Inc. v. Biogen Idec, No. 2006-1634, 2006-1649, 2011 U.S. App. LEXIS 18126 (Fed. Cir. August 31, 2011).

of the ‘739 *patent*’, and not examine the “‘139 *patent*”.⁵⁸ These claims generally described a method of analyzing “immunization schedules” and administering immunization treatment based on the analysis, reciting the steps of “screening”, which includes “identifying” and “comparing”, and “immunizing”.⁵⁹ According to Classen, all a potential infringer had to do to infringe upon these claims was “read[] the relevant literature and select[] and use[] an immunization schedule that is of lower risk for development of a chronic immune-mediated disorder”.⁶⁰ The third disputed method claim, found in the “’283 *patent*”, was directed toward the “screening” portion of the first two claims.⁶¹ This claim covered the method of reviewing of “published information on the effects of immunization schedule” among different mammals “with respect to the occurrence of immune-mediated disorders,” and did not include any type of active step, such as administering an immunization, as the first two claims did.⁶² Classen argued, quite literally, that this patent could be infringed whenever *any* person reviews this type of information.⁶³ The court would recognize this, however, and find this lacking claim patent ineligible.

The district court below found that all three Classen method claims failed to satisfy §101’s requirements because they all “include[d] the mental step of reviewing the

⁵⁸ See *id.* at *6.

⁵⁹ See *id.* at *6-7.

⁶⁰ See *id.* at *7 (explaining Classen’s argument that simply the *use* of the immunization would constitute a transformation in satisfaction of the MoT Test).

⁶¹ See *id.* at *8.

⁶² See *id.* at *8.

⁶³ Classen’s argument alone showed that this claim was not limited to any particular use or application. See *id.* at *9.

relevant literature to determine the lower-risk immunization schedule.”⁶⁴ As it is no longer the case that a single mental step can invalidate an entire claim, the Court of Appeals altered their decision. For this reason, as well as because two of the three claims included a “specific, tangible application” step, §101 was satisfied by those claims.⁶⁵ As expected, the ‘283 *patent* claim still did *not* satisfy §101, a ruling in line with the court in Myriad that explained “without *applying* the data in a step of the overall method,” a method that, as a whole, “simply collect[s] and compare[s] data” will rarely be declared patentable subject matter.⁶⁶ So, in Classen, unlike in Myriad, the case essentially turned on the *broader* §101 filter that uses overall abstractness as its criteria rather than on the machine-or-transformation test.

The court proceeded to run the challenged method claims through the machine-or-transformation test for good measure, though this analysis would expressly have no effect on the outcome.⁶⁷ As to the two patentable claims, the court decided that under the principles set forth in Prometheus, and for the same reasons, both included the requisite “transformative steps” in satisfaction of the machine-or-transformation test.⁶⁸ This was so because these two method claims included an immunization step, which was logically equivalent, in the court’s opinion, to the “administering drugs” step in Prometheus, which

⁶⁴ This case was decided by the lower court before *Bilski v. Kappos* and *Prometheus*, which established that a single unpatentable step in a method claim was not necessarily defeating as to the whole claim. *See id.* at *19.

⁶⁵ *See id.* at *24 (analyzing these two claims using the test set forth in *Research Corp*).

⁶⁶ *See id.* at *25.

⁶⁷ It was just common practice to do a two-step inquiry using the abstractness test and the MoT test in light of *Prometheus* and *Myriad*, though this was essentially the first of these three decisions to place more emphasis on the abstractness portion. *See id.* at *29.

⁶⁸ *See id.* at *29.

was also held patentable.⁶⁹ As for the third, unpatentable claim, which solely involved making a determination based on reading literature, the court found no such “transformative step”, so the machine-or-transformation test was failed.⁷⁰ The dissenting opinion, written by Judge Moore, took a wholly different approach, declaring that *all* the challenged method patents failed to attain §101 subject matter patentability as they attempted to patent “basic and abstract” “fundamental scientific principle[s].”⁷¹

IV. The Debate Over Genetic Diagnostic Testing Method Patentability

As the above cases have illustrated, this is an important question that will likely soon be decided once and for all upon Supreme Court review. Between 1980 and today, the U.S. Patent and Trademark Office granted over 20,000 gene patents claiming isolated DNA segments,⁷² quite an alarming number if one considers that there are only an estimated 20,000 – 25,000 genes in the human genome.⁷³ As these types of patents, which claim only the genes themselves, are continually being granted and challenged unsuccessfully in numerous cases, disputing the validity of such claims has become rather futile practice. On the other hand, due to the uncertainty surrounding the §101

⁶⁹ See *id.* at *29 (explaining that the immunization, when administered, could be described as being metabolized by the patient’s body and in effect transforming the make-up of their blood, similar to the reasoning behind the transformation in *Prometheus*).

⁷⁰ See *id.* at *29-30.

⁷¹ The majority specifically addressed and rejected each of the dissent’s arguments. See *id.* at 51.

⁷² See Mueller, *supra* note 13, at 102.

⁷³ See *The Science Behind the Human Genome Project: Basic Genetics, Genome Draft Sequence, and Post-Genome Science*, HUMAN GENOME PROJECT SCIENCE, http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml (last visited December 6, 2011).

patentability of genetic testing method claims and the constant teetering on the courts' behalf in regard to establishing a workable legal doctrine for such claims has left these types of claims open to dispute. Furthermore, due to the many public policy concerns associated with granting patents for genetic diagnostic testing methods, especially the limiting effect on availability of the best medical care for the public, many have felt a need to challenge these claims.⁷⁴ However, there remains a question as to whether the biotechnological advances that have been made and that continue to be made would still be pursued if there were no expectation of patent protection over such findings.

A. Arguments For the Patentability of Genetic Diagnostic

Because the market in the biotech industry is currently so competitive, much of the focus understandably becomes gaining an advantage, mainly a financial one, so that further and more research can be conducted. And by what better means, in this industry, is there gaining an advantage than by discovering a gene linked to a disease and patenting it along with any diagnostic application of it, thus preventing anyone else from using or profiting off of it? For this reason, the majority of the arguments *for* allowing genetic diagnostic method patentability center around creating incentive to discover and innovate. As the patent statutes were intent on accomplishing, offering exclusivity of use, for a limited time, on one's invention theoretically promotes progress of the sciences using the old-fashioned, proven reward system, money.

The U.S. is a breeding ground for biotechnology, and compared to the rest of the

⁷⁴ See Kane, *supra* note 25, at 26 ("Numerous amicus briefs filed in [*Prometheus*] noted the chilling effect of the method claims on the use of basic scientific facts.").

world, our industry is booming. No one would argue that it has done wonders for our economy and played a major role in getting this country to where it stands today. For this reason, it would be difficult to suggest such a drastic change such as taking away patent protection for diagnostic method patents, and possibly disrupt this thriving industry. Questions arise as to the effect this type of policy-making would have, such as whether it might discourage future growth in the industry or lead companies to venture elsewhere to conduct their research and obtain patents outside the U.S., as Judge Rader pointed out in his separate opinion to Classen.⁷⁵ In the biotechnology and pharmaceutical industry, “patents are seen as necessary to enhance an inventor’s ability to recoup the substantial investments of many years and hundreds of millions of dollars necessary to bring a new drug or device to market.”⁷⁶ Some also believe that if there were no patent protection in this area, “research would not be done to make the discoveries on which genetic tests are based, and the test would not be developed after the discovery was made.”⁷⁷ This is clearly not the type of scenario the courts would want to create or the public would want to face.

B. Arguments Against the Patentability of Genetic Diagnostic Methods

⁷⁵ Judge Rader’s views were neither addressed nor taken into consideration by the majority, nor were they intended to be. In issuing this opinion, Judge Rader wished simply to bring these concerns to the attention of future courts hearing cases involving diagnostic method claim patentability, which he knew were not far off. *See Classen v. Biogen*, 2011 U.S. App. LEXIS 18126 at *45.

⁷⁶ *See* Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, JOURNAL OF MOLECULAR DIAGNOSTICS, Feb. 2003, at 3 (noting also, though, that “it has been proposed that patents are not necessarily an effective incentive for the development of clinical genetic diagnostic tests.”).

⁷⁷ *See id.* at 3-4.

There are a number of reasons why so many argue against allowing patents over genetic diagnostic methods, mostly coming from a public policy standpoint.

Substantiating the issue is the fact that once a laboratory discovers “a link between a disease and a precise genetic defect . . . the respective diagnostic test can be relatively easily developed.”⁷⁸ This essentially means that there is a potential for the number of genetic diagnostic testing method patents to increase exponentially as more and more genes are linked to disease, as multiple method patents may revolve around a single discovery.⁷⁹ The biggest concern with allowing such patents, which indeed directly affects perhaps the largest number of people, is the consequential reduction of patient access to genetic diagnostic testing.⁸⁰

As noted earlier, genetic diagnostic testing provides doctors with the ability to diagnose and warn patients of the existence or likelihood of genetic disorders for them and their offspring alike, valuable, occasionally life-saving information. However, no matter what the negative impact genetic diagnostic method patents may have, it all stems from the ongoing monopolization of genetic testing. In line with the fear of restricting patient access to genetic testing is the concept of “monopoly rents, or excess profits attributable to the patent, [that] will be extracted from those able to pay, to the detriment

⁷⁸ See Soini, *supra* note 5, at S13.

⁷⁹ See Kane, *supra* note 25, at 30 (“Potentially, any knowledge of the data point/primary fact — whether deliberately procured or assayed or incidentally obtained—will set up the possibility of infringement if the data is interpreted to arrive at a correlative conclusion/secondary fact.”).

⁸⁰ See Mueller, *supra* note 13, at 102 (stressing the “critical importance to society of facilitating patient access to genetic testing” and patient access concerns studied by the Department of Health and Human Services Advisory Committee originating from the “restrictive licensing of some gene patents.”).

of those patients effectively priced out of testing by the monopolist.”⁸¹ Patent-holders of genetic testing methods are given the freedom “to dictate what kind of test may be done” or not be done and limit “the conditions for which testing may be done,”⁸² powers that do not belong in the hands of those profiting off of restricting access to care. For example, through Myriad is the only way a person may have a BRAC*Analysis* Test performed, and Myriad charges approximately \$3,200 per test and does not accept all insurance plans.⁸³

Not only does this monopolization restrict patient access to genetic testing, but it also restricts further research by the scientific community using known, patented methods, which clearly will have a wider-spread negative impact on society in the long run.⁸⁴ According to a research study conducted in 2001, in which the researchers directly surveyed “clinical laboratory directors that perform DNA-based genetic tests”, the effects of patents on these technologies are quite real.⁸⁵ The survey determined that “[t]wenty-five percent of respondents reported that they had *stopped* performing a clinical genetic test because of a patent or license,” and “[f]ifty-three percent of [all] respondents reported deciding not to *develop* a *new* clinical genetic test because of a patent or license.”⁸⁶ Staggering numbers indeed if indicative of the entire population of genetic researchers, seeing as these were the results over ten years ago, one must assume that they have only increased since then in correlation to the increasing number of such method patents. Additionally finding that “[a]lmost two-thirds of the lab[] directors in [their] sample had been contacted [at some point] by a patent- or license-holder about the laboratory’s

⁸¹ See Merz, *supra* note 2, at 326.

⁸² See *id.* at 327.

⁸³ See Mueller, *supra* note 13, at 111.

⁸⁴ See Merz, *supra* note 2, at 326-327.

⁸⁵ See Cho, *supra* note 76, at 3.

⁸⁶ See *id.*

potential infringement [via] performance of a genetic test,” the results of this study should shed some light on just how common and pervasive genetic testing method patents are.⁸⁷

V. Restricting Patentability by Abolishing the Machine-or-Transformation Test for Genetic Testing Claims and Permitting the Use of Patented Genetic Testing Methods for All Diagnostic and Research-Related Use

In order to provide somewhat of an idea of the reality of patent abuse, which clearly is most detrimental when it directly affects people’s health, a closer look into the background of Myriad may shed some light on just how far inventors will go to secure a patent they can use to block all other use and benefit financially off of infringers. Mark Skolnick, a researcher who was employed by the University of Utah, was taking part in the efforts of “an international consortium” to uncover the genetic marker for breast and ovarian cancer.⁸⁸ The consortium had every intention of placing the gene into the public domain once they discovered it, most likely to fuel additional research using their discovery and in effect benefit society.⁸⁹ Instead, once the consortium got very close to pinpointing the disease gene and began sequencing the gene, Skolnick broke away and formed Myriad Genetics, taking the newly discovered BRCA genes with him and obtaining patents on the genes themselves as well as on the simple tests that could be

⁸⁷ See *id.* at 5.

⁸⁸ See Joshua D. Sarnoff, *Patent Eligible Medical and Biotechnology Inventions After Bilski, Prometheus, and Myriad*, 19 TEX. INTELL. PROP. L.J. 393, 408 (2011).

⁸⁹ See *id.* at 408-409.

performed using the genes.⁹⁰ Using his new gene and method patents to target any and all infringers in order to obtain royalties or sue for infringement, Myriad established a complete monopoly over the genes and prevented any research or diagnostic tests that utilized the BRCA genes from being performed.⁹¹ Clearly, this type of behavior must not be reinforced, and any incentive-creating, beneficial effect of granting patents in such instances is outshone by the potential for abuse and inhibition of the “progress of science” as a whole. In order to counteract these concerns, the courts must strike down more genetic testing methods as unpatentable for abstractness and overextending preemption and congress must put into place statutory exemptions to allow diagnostic uses and beneficial research to freely occur without risk of infringement.

A. Addressing Judicial Guidelines to Place Greater Limits on the Patentability of Genetic Diagnostic Testing Methods

As long as the MoT Test remains in place, it will be incorrectly applied by courts and afforded far too much weight in all types of method claim cases, especially genetic testing method claims.⁹² As discussed above, the MoT Test was made relevant again by the In re Bilski court when they held, in what is widely understood as the judge’s

⁹⁰ *See id.*

⁹¹ *See id.* at 409 (“After the Myriad patents were granted, they were subjected to substantial public criticism in the United States (principally on utilitarian grounds) for interfering with research, for raising the costs of breast-cancer diagnostic treatment, and for preventing the use of a better (more comprehensive) diagnostic test that had been developed by others and was being used in Europe.”).

⁹² *See Kane, supra* note 25, at 32 (“The legal tests that originated with business method patent cases – the UCT and the MOT tests – are capable of dictating outcomes that may be directly opposite to the public domain protecting analysis of the preemption inquiry. . . [t]hus, the tests may not be congruent; the relative weight accorded to the transformation analysis or the preemption analysis may be outcome-determinative.”).

misinterpretation of an earlier Supreme Court holding, that this was to be the exclusive test for determining method patent eligibility.⁹³ Judging from the subject matter in that case alone, it is difficult to justify how the court believed a test they felt should be applied to methods of hedging risk should also be applied to biotechnological method claims.⁹⁴ Because a transformative step is apparently accomplished quite easily according to the Court of Appeals with genetic testing method claims, this will result in many otherwise unpatentable abstract mental processes being declared patentable under the MoT Test.⁹⁵

Examples of this were seen in Prometheus and Myriad, where a strong argument existed that each of the method claims later deemed patentable by the court claimed “natural phenomena” and were overly broad in failing to claim the use of a “particular test method or device,” factors that should defeat any claim under §101.⁹⁶ However, both courts seemed to overlook this glaring, fatal insufficiency to focus more on the outcome of the MoT Test, which was easily satisfied in both cases and overwhelmingly outcome-determinative. Placing their analysis under the guise of having evaluated the claim “as a whole”, the Prometheus court mistakenly examined it “as a whole” to see if it could be deemed a transformation, not to determine whether the claim was sufficiently inventive

⁹³ See Minssen, *supra* note 24, at 5 (“In *In re Bilski* a majority of the Federal Circuit judges misinterpreted Supreme Court precedent holding the so-called ‘machine or transformation’ test (MOT) to be the sole applicable test for deciding upon patent-eligibility for all process claims.”).

⁹⁴ See *id.* (“Although the facts of the case did not involve biotech or pharmaceutical subject matter but rather, a process for hedging risk in commodity markets, the decision implicitly included claims for biotechnological processes. The Court basically changed the patent eligibility examination from whether a claimed biotechnology process covered a ‘fundamental principle’ to whether or not it encompassed enough involvement of a machine or transformation.”).

⁹⁵ See Kane, *supra* note 92, at 30-31.

⁹⁶ See *id.* at 30.

in its entirety as it should have, which would have likely led to a far different result.⁹⁷ In a similar holding, the Myriad court essentially held that as long as a genetic testing method claim exhibits at least one step that involves *doing* something, and not just steps that involve *looking* at something, and the patentee can show that the active step is important, the claim, as a whole, is patentable.⁹⁸

The changes brought about by the Supreme Court in Bilski v. Kappos did little in reality to combat the clearly erroneous decision in In re Bilski, and further change is required. Immediately following the decision therein, the USPTO on June 28, 2010 circulated a Memorandum among all patent examiners informing them of the Bilski v. Kappos decision and instructing them not only to continue applying the MoT Test to method patent applications, but informing them that basically all methods satisfying that test are patent-eligible: “*unless* there is a clear indication that the method is directed to an abstract idea.”⁹⁹ About a month later, the USPTO handed down an *Interim Guidance*, which unambiguously explained to patent examiners that method patents satisfying either prong of the MoT Test are almost never going to be patent-ineligible under §101 for abstractness.¹⁰⁰ Even in their interpretation of the court’s decision, the USPTO conclusively afforded vastly greater importance to the MoT Test over any other test or

⁹⁷ See Sarnoff, *supra* note 88, at 404 (“The Federal Circuit thus improperly allowed the newly discovered but ineligible correlation to contribute to the “invention” assessed for eligibility.”).

⁹⁸ See *id.* at 414-415 (explaining that if the court would have treated the location of the BRCA genes correctly as biological facts, “it would be apparent that no creativity went into isolating the genetic DNA or identifying their sequences, particularly given the advanced state of genetic technologies at the time, or into using them for comparison once the sequences were known and the molecules were isolated.”).

⁹⁹ This memo also instructed examiners to reject claims that failed to satisfy the MoT Test on that basis alone. See Minssen, *supra* note 24, at 62.

¹⁰⁰ The *Interim Guidance* also clearly said that it would very rarely, if ever, be the case that a method claim failing to satisfy the MoT Test would nonetheless be patentable. See *id.* at 63.

principle. So essentially, the current rule is that even though the MoT Test is no longer the *exclusive* test for determining genetic diagnostic testing method claim patentability, it is very nearly always the outcome-determinative test. For the above reasons, the Machine-or-Transformation has no place in the biotechnology context, and must be fully abandoned in cases involving genetic testing methods in favor of a new, much more difficultly satisfied legal examination, so that it can no longer be so disastrously misconstrued.

B. Creating Statutory Exemptions for Diagnostic and Research-Related Uses of Genetic Diagnostic Testing Patents

For those genetic diagnostic method patents that do survive stricter judicial analysis and USPTO review, such patent holders must still not be able to detrimentally cease all research and diagnostic activity using their patented methods. In order to legislatively reinforce the policy of inhibiting the overly restrictive, crippling use of genetic testing method patents by their patent holders in such important fields as genetic diagnostics and research, Congress must create an overarching statutory exemption for such uses. Rather than completely banning the patenting of medically related diagnostic methods altogether, as most countries indeed do without suffering heavy consequences,¹⁰¹ and risking disturbing the current U.S. patent system to a fault as discussed earlier, such statutory exemptions would serve only to limit the liability of two

¹⁰¹ See Sarnoff, *supra* note 88, at 407 (“Unlike in the United States . . . most countries entirely prohibit patents on medical methods of diagnosis and treatment.”); See Mueller, *supra* note 13, at 112 (“Germany, Japan, and the U.K. have long included a research use exemption in their domestic patent laws. These patent systems have not fallen apart because of the exemption, nor has innovation in these countries stopped.”).

types of literal infringers, leaving patents enforceable in all other instances.¹⁰² For the same reasons, the use exemptions put in place must not be applied retroactively, and all pre-existing patents should be entitled to the same protections they were afforded at the time they were granted, leaving them vulnerable only to stricter judicial review.¹⁰³

Similar to the Fair Use Doctrine of Copyright Law, which affords non-liability for copyright infringement in only certain non-commercial or non-exploitative circumstances, the broad liability exemption for certain uses of genetic testing method patents should be targeted solely toward benefiting the furtherance of research, public health, and greater access to healthcare, not the commercial use and profiting off of those patented inventions.¹⁰⁴ As suggested by the Secretary's Advisory Committee on Genetics, Health, and Society, the diagnostic use of genetic testing method patents for at least "patient care" reasons should not only constitute non-infringement, but also "no remuneration [should be] due to the patentee" and the exemption should apply to *all* laboratories wishing to use those diagnostic methods, not just non-commercial ones.¹⁰⁵

¹⁰² See Mueller, *supra* note 13, at 115 ("Specifically, the proposed exemptions would allow unlicensed use of gene patents for research and diagnostic, but not therapeutic, purposes.").

¹⁰³ See *id.* at 113 ("So as not to unduly disrupt those reliance interests, legislators should consider implementing any liability exemption (or compulsory licensing scheme) in a prospective-only manner" even though "a prospective implementation would not necessarily address the immediate problem of access to the patented *BRCA1/2* genes.").

¹⁰⁴ See *id.* at 112 ("Many scholars have advocated a statutory exemption in U.S. patent law from infringement liability when researchers use patented materials for non-commercial purposes such as research and experimentation—a sort of 'fair use' doctrine for patent law.").

¹⁰⁵ The SACGHS report proposed a "liability exemption, which would apply when patented genetic tests are offered for 'patient-care' (i.e., diagnostic) purposes" and supported the position that "no act of infringement and no remuneration [should be] due to the patentee, analogous to the operation of fair use in copyright law." It further held that the exemption "would apply to both non-commercial and commercial laboratories." See *id.* at 115.

At the very least, a diagnostic use exemption should allow patent-holders to charge users only *reasonable* royalties for their patented invention and not the inflated royalties they are likely to charge due to their test monopolization, which is the preferred method by many advocates and chosen as the best method by a recent survey.¹⁰⁶ Along those same lines would be the enforcement of required compulsory licensing for “physicians providing medical services” in exchange for reasonable royalties, thus “preserving the patent system’s incentives” function.¹⁰⁷ Compulsory licensing describes a system in which “an official instance or a court forces the patent holder to grant a license to a third party.”¹⁰⁸ On its face, this would seem to greatly alleviate the high costs and lower availability associated with genetic testing monopolization while still giving patent holders the ability to financially profit off such uses. However, any remuneration at all seems unnecessary, as patentees would still be able to freely obtain licensing fees or sue for infringement anyone who uses their patented methods for other uses.¹⁰⁹ This is why full genetic diagnostic and research use exemptions remain the preferred method, though not the only viable method, of striking a balance between public health concerns and maintaining incentives to invent, tipping perhaps only slightly in favor of the public as it should.

¹⁰⁶ See Soini, *supra* note 5, at S30 (“Clinical use exemption was held as the best remedy regarding patents in a Swiss survey.”).

¹⁰⁷ See Merz, *supra* note 2, at 329.

¹⁰⁸ See Soini, *supra* note 5, at S27 (defining “compulsory licenses”).

¹⁰⁹ See Mueller, *supra* note 13, at 115-116 (“The [SACGHS] committee does not consider remuneration for patient-care purposes to be necessary, because the continued enforceability of gene patents against therapeutic uses would be sufficient to preserve incentives for the development of gene based therapeutics.”).

VI. Conclusion

The U.S. Patent system that was put in place around the same time this country was founded has more than proven that it works. The U.S. has been the source of countless inventions, many of which dominate the world market in a given field. However, our patent system is no longer identical to what it was when it was first set into motion, as the need for change was continually recognized and the patent system adjusted accordingly to further enhance the progress of science. In this highly technological age in which new findings are being made nearly every day in highly complex fields that are perhaps worthy of patent protection, inventors from all over the world have relied upon the very inventor-friendly patent system that is in place in the U.S. Though it can easily be argued that our patent system has “worked” thus far and should continue on unchanged for that reason, sometimes alterations must be made to make such a practice more efficient, more up to date, and more universally beneficial. The widespread abuse and exceedingly detrimental use of patents in the ever-expanding biotechnology industry today should alert us of this need for reformation in the form of judicial and legislative involvement. The continued practice of permitting the use of overly broad genetic testing method patents to prevent research and diagnostic testing performed for the benefit of either ill or at-risk members of society is not only affecting the present community at large, but also placing unnecessary roadblocks in the path to future discoveries. The best way to cease and deter this type of activity is through the enactment of diagnostic and research use exemptions and the abandonment of outdated, inapplicable legal patentability tests in favor of more restrictive ones.