

Medical Alert: Alarming Challenges Facing Medical Technology Innovation

I

A PUBLIC POLICY RATIONALE FOR THE ESTABLISHMENT of intellectual property rights, particularly patent grants, is the incentive to invent and the incentive to invest in innovation that exclusivity supports. The operation of this concept may be observed at several stages along the development cycle of new medical technologies.¹ For example, the basic research conducted at academic institutions may be funded in part by the transfer of this technology through the assignment or licensing of patent rights to the private sector.² In turn, the industry may obtain further investment based on the patent rights to support efforts to develop and commercialize innovative products and processes.³ The cycle is complete as the financial rewards of enhanced commercial competitiveness through patent exclusivity are realized and available for reinvestment in other basic research.⁴

This dynamic, however, is open to criticism focused on the third stage of the cycle described above, where the patent exclusivity may give rise to licensing practices and patent enforcement that hinder or block public access to innovations having cognizable benefits for public health, safety

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1. The development cycle includes (1) funding research and development, (2) investing in commercialization, and (3) reinvesting earnings into new research. *See infra* notes 2–4 and accompanying text.

2. *See, e.g.*, David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Survey*, 334 NEW ENG. J. MED. 368, 369 (1996) (estimating that industry funded \$1.5 billion for academic research in 1994).

3. *See id.* at 369–70, 372 fig. 3 (finding that approximately 62% of firms realized patents, 63% realized products marketed, and 61% realized a sales revenue based in part on the firm’s relationship with the university).

4. *See id.* at 372 (noting that because of the commercial gains realized, “industries in the life sciences would appear to have no reason to reduce spending on academic research sooner or more sharply than they would reduce research-related spending in nonacademic sites”).

and welfare.⁵ Indeed, the appreciation of intellectual property rights is perhaps further from universal acceptance today than ever before. Beyond continuing rallies against the notions of patent exclusivity as engines of innovation generally,⁶ the skepticism ignores the underlying premise that patent rights inherently foster innovation by demanding public disclosure of inventions in exchange for a temporary term of exclusivity. Perhaps unprecedented is the pervasive readiness to disavow this quid pro quo between the public and the inventor when the disclosed invention culminates in a product or process that achieves market demand.⁷

Particularly with medical technology, compromising patent exclusivity in the face of the public wants and needs for novel medical prevention, diagnosis and treatment seems a compelling case.⁸ But as with most

5. See generally OFFICE OF INDUSTRIES, U.S. INT'L TRADE COMM'N, Pub. No. 4039, PATENTING TRENDS AND INNOVATION IN INDUSTRIAL BIOTECHNOLOGY, 2, 4–5 (2008) (discussing the anticommons theory relating to biotechnology patents); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) (noting that “[a] proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development”).

6. See Tom W. Bell, *Prediction Markets for Promoting the Progress of Science and the Useful Arts*, 14 GEO. MASON L. REV. 37, 41 (2006) (asserting that researchers will likely “give up the search for fundamental discoveries and instead focus on patentable, and therefore more remunerative, inventions”); Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1258, 1283 (2009) (finding that startup executives report that patents are providing “relatively mixed to weak incentives to engage in innovation”); Andrew W. Torrance & Bill Tomlinson, *Patents and the Regress of Useful Arts*, 10 COLUM. SCI. & TECH. L. REV. 130, 134–35 (2009) (noting a study that suggests that the current patent system “may generate significantly lower rates of innovation”) (emphasis added).

7. See Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 107 (2009) (footnotes omitted) (“Patent theory presumes that a socially-beneficial product or technology accompanies each issued patent. This is the exchange society obtains — a new and non-obvious technology in return for the grant of a limited period of exclusivity.”); Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257, 292–93 (2007) (“Patent owners should not always be entitled to capture the full social benefit of their invention. Rather, particularly in circumstances where the defendant or third parties made significant contributions to the success of the product, social welfare requires that they be entitled to continue to make use of that product. Patent owners should be compensated for the use, to be sure, but in those cases compensation—and not a property right of complete control—is all they should receive.”).

8. See, e.g., Weldon E. Havins, *Immunizing the Medical Practitioner “Process” Infringer: Greasing the Squeaky Wheel, Good Public Policy, or What?*, 77 U. DET. MERCY L. REV. 51, 70 (1999) (finding that most General Agreement on Tariffs and Trade (“GATT”) countries exclude medical procedures from patentability for public policy reasons); Karl Vick, *African AIDS Victims Losers of a Drug War; U.S. Policy Keeps Prices Prohibitive*, WASH. POST, Dec. 4, 1999, at A01 (explaining that anti-AIDS medical advances from the West were not reaching Africa because its countries and their citizens had to choose between buying drugs at their fair market price, which is

operations of law, the specific events that present the easiest justifications to succumb to current social pressures at the expense of principles create the true test of established legal doctrines.

This article addresses the recent federal court jurisprudence that has cast doubt on the continuing vitality of patent rights to medical technology, including genomic information-based innovations. In particular, the cases which have reopened the debate on the limitations of patentable subject matter will be discussed.⁹ This article concludes with a few insights and proffers regarding our sense of invention and discovery as applied to medical technology.¹⁰

II

As biotechnology has come to the forefront, the number of technological advances that have direct as well as indirect implications for human medical treatment has grown exponentially.¹¹ The completion of the initial mapping of the human genome has, for better or worse, enabled us to revisit the fundamental questions of who we are and how we exist.¹² In concert with the supercomputing power now available, bioinformatics has pushed researchers further away from the traditional scientific method.¹³ Modern research has largely eschewed the targeted observation-hypothesis-proof

way beyond the means of the vast majority of Africans, or risk trade sanctions by the U.S. for buying or developing generic drugs at lower prices).

9. See *infra* Parts IV., V.

10. See *infra* Part VI.

11. See Phil B. Fontanarosa & Catherine D. DeAngelis, *Medical Applications of Biotechnology*, 293 J. AM. MED. ASS'N 866, 866–67 (2005) (noting the recent advances in biotechnology, including new applications for fetal genetic analysis); Press Release, Nat'l Cancer Inst., New Method of Gene Therapy Alters Immune Cells for Treatment of Advanced Melanoma; Technique May Also Apply to Other Common Cancers (Aug. 31, 2006), available at <http://www.cancer.gov/newscenter/pressreleases/MelanomaGeneTherapy> (using genetically engineered white blood cells to successfully treat melanoma patients); see generally BIOTECHNOLOGY INST., *Historical Events in Biotechnology History*, available at http://www.biotechinstitute.org/what_is/timeline.html (providing a timeline of the major events in biotechnology).

12. See, e.g., David A. Hinds et al., *Whole-Genome Patterns of Common DNA Variation in Three Human Populations*, 307 SCI. 1072, 1079 (2005) (examining genetic variation among unrelated individuals of European, African, and Asian descent to “enable a wide variety of additional analyses to be carried out by scientists investigating the structure of human genetic variation as well as the genetic basis of human phenotypic differences”).

13. See, e.g., Leslie Roberts, *Controversial From the Start*, 291 SCI. 1182, 1182–88 (2001) (comparing National Institutes of Health’s deliberate, methodical approach to mapping the human genome with Venter’s technique, which used an automated sequencing machine to sequence the genome).

paradigm in favor of high throughput methods that involve whole sample disintegration and massive data analysis.¹⁴ In this latter approach, what is often stripped away is information about relevance. Moreover, research tools have become less the mere aids to the discovery process and more the actual discovery platform.¹⁵

Given the rapidity with which medical technology has evolved,¹⁶ the laws that regulate its use have had great difficulty keeping pace. Curiously, the governance of medical technology creation, namely through the patent law, has been remarkably static.¹⁷ The statutory framework enacted in 1952, well before the first computer and gene-based inventions, still applies much in its original form.¹⁸

Section 101 of Title 35 of the U.S. Code provides that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”¹⁹ In 1980, the U.S. Supreme Court interpreted this statute to endorse patentable subject matter “to include anything under the sun that is made by man.”²⁰ The Court held that Chakrabarty’s patent claims to a genetically

14. See Charles Vorndran & Robert L. Florence, *Bioinformatics: Patenting the Bridge Between Information Technology and the Life Sciences*, 42 IDEA 93, 105 (2002) (noting the need to use bioinformatics to “sift through and make sense of” the vast amounts of data acquired in the fields of genomics and proteomics); David S. Roos, *Computational Biology: Bioinformatics—Trying to Swim in a Sea of Data*, 291 SCI. 1260 (2001) (discussing the importance of database development and pattern recognition algorithms in computational biology).

15. See Press Release, Compugen, Ltd., Compugen Discovers Drug Target for Treatment of Multiple Myeloma (May 11, 2010), available at http://www.cgen.com/Content.aspx?Page=press_releases&NewsId=496 (discussing Compugen’s validation of a drug that treats multiple myeloma and noting that “[u]nlike traditional high throughput trial and error . . . Compugen’s discovery efforts are based on *in silico* (by computer) prediction and selection utilizing a growing number of field focused proprietary discovery platforms accurately modeling biological processes at the molecular level”).

16. See generally BIOTECHNOLOGY INST., *supra* note 11 (providing a timeline of the major events in biotechnology).

17. See Leah Nysten & Seth Stern, *S515—Patent Reform Act of 2009*, CQ BILL ANALYSIS, May 22, 2009 (“The last revision of patent law occurred in 1952 . . .”).

18. *Id.*

19. 35 U.S.C. § 101 (2006). U.S. patent rights are governed generally by Title 35 of the U.S. Code and Title 37 of the Code of Federal Regulations. The U.S. Constitution expressly sets forth the legislative authority for U.S. patent protection. See U.S. CONST. art. I, § 8, cl. 8 (“Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . .”).

20. *Diamond v. Chakrabarty*, 447 U.S. 303, 305, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952)).

engineered bacterium capable of breaking down multiple components of crude oil invention were eligible for patent protection.²¹ The Court based its conclusion, at least in part, on the fact that Chakrabarty's invention had significant value for the treatment of oil spills and possessed properties that no naturally occurring bacteria exhibited.²²

Furthermore, the Court embraced the sentiment that the scope of patent eligible subject matter be construed broadly.²³ But the Court also clearly acknowledged limitations to patent eligible subject matter, stating:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of. . . nature, free to all men and reserved exclusively to none."²⁴

However, the broad "anything under the sun that is made by man" prescription quickly became the enduring legacy of *Chakrabarty*, which opened the field of biotechnology patents.²⁵

For the next quarter of a century, the patenting of medical technology, including gene-based inventions, continued relatively unfettered despite vocal opposition over the potential ills of ownership of genomic information per se and genomic information as research tools for future discovery.²⁶ The discourse and patent law jurisprudence during this period

21. *Id.* at 310 ("His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.").

22. *Id.* ("[T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.").

23. *Id.* at 308 (noting that the Patent Act "embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement'" (quoting Letter from Thomas Jefferson to Oliver Evans (May 2, 1807), in 5 WRITINGS OF THOMAS JEFFERSON 75, 75–76 (Washington ed. 1871))).

24. *Id.* at 309 (internal citations omitted) (quoting *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)) (internal citations omitted).

25. *Id.* at 309–10 (holding man-made discovery patentable). *See infra* Part III.

26. *See Heller & Eisenberg, supra* note 5, at 700 (noting the potential of "holdout problems" that would stifle research); Douglas Robinson & Nina Medlock, *Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents*, 17 INTELL. PROP. & TECH. J. 12, 13 (2005) (noting that the number of biotechnology patents granted has increased from 2,160 in 1989 to 7,763 in 2002).

focused on the application of virtually every patent standard other than patentable subject matter.²⁷

III

In early 1997, the U.S. Patent and Trademark Office (USPTO) uncovered a hornet's nest when it announced the likelihood that patent claims would be granted to genomic fragments called expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).²⁸ In the heady times of The Human Genome Project, thousands of these ESTs and SNPs were being obtained with only a nominal understanding of their biological significance.²⁹

Undaunted, companies filed hundreds of patent applications, seeking intellectual property rights to these genomic fragments with bare indications of what they were and even fainter disclosures of what they did.³⁰ Moreover, these patent claims were of broad enough scope to capture as an infringer any user of a product derived from genomic material that included a patented sequence.³¹ Such fears rekindled the public outcry over gene

27. See, e.g., *In re Fisher*, 421 F.3d 1365, 1369 (Fed. Cir. 2005) (reviewing a patent application for satisfaction of the utility requirement); Joshua McGuire, *Nonobviousness: Limitations on Evidentiary Support*, 18 BERKELEY TECH. L.J. 175, 189 (2003) (arguing that the standard of obviousness should be based on "the general knowledge possessed by a person of ordinary skill in the relevant art"); C. Douglas Thomas, *Secret Prior Art—Get Your Priorities Straight!*, 9 HARV. J.L. & TECH. 147, 166–69 (1996) (stating that public policy concerns favor the adoption of a whole-contents novelty-only approach to the U.S. patent system). See *infra* Part III.

28. See Ed Susman, *U.S. PTO to Allow Patents on Gene Fragments Called ESTs*, BIOTECHNOLOGY NEWSWATCH, Mar. 3, 1997, at 1 ("A Clinton Administration official dropped a Valentine's Day bombshell on genetic scientists, announcing that the government Patent and Trademark Office has begun allowing patents on controversial expressed sequence tags (ESTs).").

29. Andrew Pollack, *Is Everything for Sale? Patenting a Human Gene As if It Were an Invention*, N.Y. TIMES, June 28, 2000, at C1 (stating that "companies have filed for patents in large numbers without knowing the functions of many genes" and referencing a Human Genome Science patent for a gene as an immune system reporter only to find out later by other researchers that the gene was useful in AIDS treatment).

30. See David S. Corwin & Paul A. Lesko, *Make, Use, Cell: Debunking the Uncertainty Surrounding Genomic-Related Patents*, INTELL. PROP. WORLDWIDE, Sept. 1, 2000 (discussing the perceived limited utility of ESTs and fragments of genes); Tom Reynolds, *Pricing Human Genes: The Patent Rush Pushes On*, 92 J. NAT'L CANCER INST. 96–97 (2000); Pollack, *supra* note 29; Vorndran & Florence, *supra* note 14, at 105 (discussing the literature criticizing genomic fragment patents for lacking utility).

31. See generally Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECH. 1091, 1091–92 (2006) (discussing the problems with designing around the broad patents); Simon Mazzola, *Compulsory Licensing of Genome Biotech Patents*, 4 INTELL. PROP. L. BULL. 1, 2 (1999) (discussing EST patents and

patenting generally and its potential chilling effect on biotechnology and pharmaceutical research and development.³² But the Patent Gold Rush was on.

Still, like most gold rushes, the dreams of riches from the ownership of genomic data alone began to fade almost as quickly as they arose.³³ The USPTO established *instanta de facto* moratorium on the examination of EST and SNP claims.³⁴ To qualify for patent protection, an invention must be useful, new and nonobvious to one skilled in the pertinent technical field.³⁵ Also, the invention must be described in a manner compliant with the standards of written description, enablement, best mode, and definiteness.³⁶ These requirements help ensure that the public receives a valuable benefit from the disclosure of an innovative technology in return for a grant of temporary exclusivity to the patentee.³⁷

In particular, a patent applicant must be able to teach the public about the invention by providing a reasonably clear answer to two fundamental questions: “What is it?” and “What does it do?”³⁸ With regard to ESTs and SNPs, the response to “What is it?” was problematic enough, and the

patent infringement lawsuits); Michael Crichton, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A23 (discussing the gene patent holder’s practice of blocking competitors).

32. See generally Heller & Eisenberg, *supra* note 5, at 698–99 (discussing the tragedy of the anticommons related to biomedical patents); David B. Resnik, *DNA Patents and Human Dignity*, 29 J.L. MED. & ETHICS 152, 152 (2001) (discussing criticism of DNA patenting); Crichton, *supra* note 31 (describing how gene patents “can be used to block innovation, and hurt patient care”); Carl T. Hall, *Biotech Industry Battles Move to Ban Patents*, S.F. CHRON., May 16, 1995, at D1 (discussing a religious movement’s public outcry against genetic patents).

33. See John T. Bentivoglio & Martha L. Cochran, *Policy Issues Could Have Major Impact on Industry*, NAT’L L.J., June 25, 2001, at C9 (explaining how intellectual property laws may dramatically impact the value of biotechnology companies). See also *infra* notes 34–37 and accompanying text.

34. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (“If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable.”). See generally Timothy A. Worrall, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKLEY TECH. L.J. 123 (2001) (discussing the impact of the new USPTO examination guidelines on gene patent applications); *But see* Corwin & Lesko, *supra* note 30 (discussing the public’s misinterpretation that there was a moratorium).

35. 35 U.S.C. §§ 101 & 103 (2006).

36. 35 U.S.C. § 112 (2006).

37. See *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (“The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”).

38. See 35 U.S.C. § 102–04 (2006) (setting forth the requirements of the patent specification).

response to “What does it do?” was simply unknown.³⁹ The USPTO struggled with attempts to reconcile the applicability of traditional, generic principles of patent law to this emerging technology.⁴⁰ The USPTO initially issued the 1999 Revised Interim Utility Examination Guidelines, only to withdraw them in the face of critical public comment.⁴¹ The reissuing of the USPTO prescriptions in this regard ultimately came in the form of the 2001 Utility Examination Guidelines.⁴² The operative framework for meeting the requirements of 35 U.S.C. § 101 now includes the mandate for a patent applicant to articulate a specific, substantial and credible utility.⁴³

One inherent problem with making sense of the patent law is the temporal distortion that occurs between the time patent claims are filed and the time the USPTO and/or federal courts pass on the patentability or invalidity of those claims. In some cases, a decade or more can separate these two events.⁴⁴

Of course, much, if not everything, can change in that time. What seemed impossible back then can be child’s play today. When ESTs and SNPs were discovered, their elucidation through the automated isolation and purification of vast numbers of genomic fragments to facilitate chemical formula descriptions (high throughput polynucleotide sequencing) occurred without learning anything about their origin, fit, or function.⁴⁵ Such an abstract process of invention hardly came with a complete answer to what the invention was, much less yielded any insight as to what the invention did.⁴⁶

39. See Vorndran & Florence, *supra* note 14, at 105 (stating that the sequences themselves do not reveal what the genes do).

40. The USPTO issued several sets of revised examination guidelines in a short period. See *infra* notes 41–43 and accompanying text.

41. See Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, ¶1, “Written Description” Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001) (stating “[t]hese Guidelines supersede the ‘Revised Interim Guidelines [from December 1999]’” and responding to comments received in response to the December 1999 interim guidelines).

42. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

43. See U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE 2100-20 (8th ed., rev. July 8, 2010).

44. See, e.g., Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352 (Fed. Cir. 2000) (assessing the state of biotechnology art twenty years earlier); Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371 (Fed. Cir. 1999) (assessing the state of biotechnology art sixteen years earlier); Kridl v. McCormick, 105 F.3d 1446, 1448 (Fed. Cir. 1997) (assessing the state of biotechnology art thirteen years earlier).

45. See generally Robin Marantz Henig, *The Rush to Claim a Little Slice of Life*, WASH. POST, Jan. 9, 2000, at B05 (describing patent applications as place holders until companies determine the value of the genetic material).

46. See Vorndran & Florence, *supra* note 14, at 105.

The U.S. Court of Appeals for the Federal Circuit, which has exclusive jurisdiction of patent appeals from trial forums nationwide,⁴⁷ addressed the patentability of these genomic inventions in *In re Fisher*⁴⁸ under 35 U.S.C. § 101, but not for the lack of patent eligible subject matter, and instead for the lack of utility.⁴⁹ The Federal Circuit held that a claimed invention must have a specific and substantial utility to satisfy 35 U.S.C. § 101, that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research, and that an asserted use must show that that claimed invention has a significant and presently available benefit to the public.⁵⁰ The Federal Circuit specified that an asserted use must also show that a claimed invention can be used to provide a well-defined and particular benefit to the public.⁵¹

The Federal Circuit noted that as of the filing date of its patent application, Fisher admitted that the underlying genes had no known functions and that the claimed ESTs acted as no more than research intermediates that may help scientists to isolate the particular underlying

47. 28 U.S.C. § 1295(a) (2006).

48. 421 F.3d 1365 (Fed. Cir. 2005) (reviewing *Ex parte Fisher*, 72 U.S.P.Q.2d 1020 (B.P.A.I. 2004) (concerning U.S. patent application Serial No. 09/619, 643)).

49. *Id.* at 1369. The *Fisher* case arrived for the Federal Circuit's review from a decision by the USPTO Board of Patent Appeals and Interferences that affirmed in-part and reversed in-part the patent examiner's rejection of the patent claims in a Monsanto Co. patent application to ESTs derived from a maize leaf tissue cDNA library. *Fisher*, 72 U.S.P.Q.2d at 1020–30. The Board agreed with the patent examiner that the claimed invention failed to satisfy the utility and enablement requirements, but disagreed with the written description rejection. *Id.* Monsanto had asserted that the claimed ESTs were useful for producing a plant containing reduced levels of a protein; determining an association between a polymorphism and a plant trait; isolating a genetic region or nucleic acid; determining a level or pattern in a plant cell of a protein in a plant; determining a mutation in a plant whose presence is predictive of a mutation affecting a level or pattern of a protein; acting as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function; and identifying tissues. *Id.* However, the Board reasoned that virtually any nucleic acid could manifest these generic uses. *Id.* Among other things, Monsanto argued to the board that ESTs have real-world value as seen from the growth of a multimillion-dollar industry in the United States premised on the usefulness of ESTs. *Id.* The Board noted that the claims were drawn to ESTs alone, rather than EST databases, clone sets or micro arrays, or other practical applications of ESTs. *Id.* In any event, the patent examiner and the Board found that absent a teaching about particular plant proteins or traits, these asserted uses were not specific or substantial enough to satisfy the utility requirement of 35 U.S.C. § 101. *Id.* Based on the same scarcity of information of a specific or substantial utility, the patent examiner and the Board concluded that the patent applicant did not satisfy the enablement requirement of 35 U.S.C. § 112, which demands an adequate instruction to one skilled in the art about how to make and use the claimed invention without undue experimentation. *Id.*

50. *Fisher*, 421 F.3d at 1371.

51. *Id.*

protein-encoding genes and conduct further experimentation on those genes.⁵² Fisher compared “the claimed ESTs to certain other patentable research tools, such as a microscope.”⁵³ The Federal Circuit explained that while a microscope can offer an immediate, real world benefit in a variety of applications, the same could not be said for the claimed ESTs.⁵⁴ The Federal Circuit found that the claimed ESTs were “unable to provide any information about the overall structure let alone the function of the underlying gene.”⁵⁵ The Federal Circuit thus held that Fisher’s asserted uses, therefore, did not meet the standard for a “substantial” utility under 35 U.S.C. § 101.⁵⁶

According to the Federal Circuit, “Fisher’s asserted uses represent[ed] merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, *could* possibly achieve, but none for which they have been used in the real world.”⁵⁷ The Federal Circuit further explained that Fisher’s asserted uses were not sufficiently “specific” — that is, nothing about Fisher’s “alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the . . . [patent] application or indeed from any EST derived from any organism.”⁵⁸

In addressing the patentability of the EST claims in *Fisher*, the Federal Circuit reinforced the quid pro quo of a suitable primer on the claimed invention in exchange for the patent grant.⁵⁹ In the words of the U.S. Supreme Court about the utility requirement, “. . . a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”⁶⁰

After the *Fisher* decision, the concerns over the implications for gene patents largely returned to a focus on patents claiming DNA sequences that

52. *Id.* at 1373.

53. *Id.* The Federal Circuit explained, however, that although both a microscope and one of the claimed ESTs can be used to generate scientific data about a sample having unknown properties, Fisher’s analogy was flawed because a microscope has the specific benefit of optically magnifying an object to immediately reveal its structure. *Id.* One of the claimed ESTs, by contrast, could only be used to detect the presence of genetic material having the same structure as the EST itself. *Id.*

54. *Id.*

55. *Id.*

56. *Id.* at 1374.

57. *Id.* at 1373.

58. *Id.* at 1374.

59. *Id.* at 1371.

60. *Brenner v. Manson*, 383 U.S. 519, 536 (1966).

encode a complete protein or a portion thereof.⁶¹ The standards for patenting inventions generally became stricter in light of the evolving jurisprudence in the doctrines of inherent anticipation and obviousness.

To receive patent protection, the invention must be novel, i.e., not anticipated by the prior art.⁶² An invention is anticipated if a single prior art reference expressly or inherently discloses each and every limitation of the claimed invention.⁶³ Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency.⁶⁴ Inherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.⁶⁵ The new realization alone does not render that necessary prior art patentable.⁶⁶ This evolution of the doctrine of inherent anticipation arguably has made it more difficult for applicants to obtain gene patents, particularly those claiming only certain fragments of a gene, which is otherwise disclosed in the prior art.⁶⁷

61. See Christopher M. Holman, *Learning from Litigation: What Can Lawsuits Teach Us about the Role of Human Gene Patents in Research and Innovation?*, 18 KAN. J. L. & PUB. POL'Y 215, 222–23 (2009) (“As a class, litigations involving therapeutic proteins are pursued much more vigorously than other human gene patent litigations.”).

62. 35 U.S.C. § 102 (2006).

63. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991) (overruled on other grounds) (“Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference.”).

64. See *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1373 (Fed. Cir. 2007) (finding inherent anticipation for a patent claim about a method for making pharmaceutical formulation); *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 471 F.3d 1363, 1365, 1368 (Fed. Cir. 2006) (holding that a patent application on degradation-preventing of water or other “Lewis acid inhibitors” with sevoflurane was anticipated by inherency by a prior art patent that disclosed sevoflurane saturated with water); *In re Crish*, 393 F.3d 1253, 1256–59 (Fed. Cir. 2004) (holding asserted claims covering a gene’s nucleotide sequence anticipated where the gene, though not its particular sequence, was already known to the art); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349–50 (Fed. Cir. 2002) (ruling that an inventor’s recognition of substances that render broccoli and cauliflower particularly healthy does not permit patent on identifying broccoli seeds or preparing broccoli as a food product); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 781–82 (Fed. Cir. 1985) (holding asserted claims on alloy anticipated by inherency).

65. See *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art).

66. See *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (explaining that newly discovered results of known processes are not patentable because those results are inherent in the known processes); *Verdegaal Bros., Inc. v. Union Oil & Co. of Cal.*, 814 F.2d 628, 633 (Fed. Cir. 1987) (holding that the recognition of a new aspect of a known process is not a patentable invention of a novel process).

67. See James DeGiulio, Comment, *The Genomic Research and Accessibility Act: More Science Fiction than Fact*, 8 NW. J. TECH. & INTELL. PROP. 292, 295 (2010) (asserting that the doctrine of inherent anticipation has made obtaining gene patents more difficult).

To receive patent protection, an invention must also be nonobvious at the time of the invention to one of ordinary skill in the relevant art.⁶⁸ In *KSR International Co. v. Teleflex Inc.*,⁶⁹ the U.S. Supreme Court rejected a rigid application of the Federal Circuit's approach known as the [t]eaching, suggestion, or motivation (TSM) test, under which a patent claim is only proved obvious if some motivation or suggestion to combine the prior art teachings can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art.⁷⁰

The Court opined that "inventions in most, if not all, instances rely upon building blocks long since uncovered and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known."⁷¹ According to the Court, the obviousness analysis "cannot be confined by an overemphasis on the importance of published articles and the explicit content of issued patents."⁷² The Court noted that "granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility."⁷³ The Court admonished that "when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."⁷⁴ The Court noted, "[i]f this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."⁷⁵ This relaxation of the obviousness standard arguably also has made it more difficult for applicants to obtain gene patents, particularly those claiming a novel combination or other use of known genes and/or gene fragments.⁷⁶

68. 35 U.S.C. § 103 (2006).

69. 550 U.S. 398 (2007).

70. *Id.* at 407, 415.

71. *Id.* at 418–19.

72. *Id.* at 419.

73. *Id.*

74. *Id.* at 421.

75. *Id.*

76. See, e.g., Michael Risch, *The Failure of Public Notice in Patent Prosecution*, 21 HARV. J.L. & TECH. 179, 229–30 (2007) (discussing the impact of the Supreme Court's relaxing of the obviousness standard); see also DeGiulio, *supra* note 67, at 295 (asserting that relaxation of the obviousness standard could possibly make obtaining gene patents more difficult).

IV

In 2008, the spotlight on patent law issues relating to medical technology turned to patent eligible subject matter along with the general attention to *In re Bilski*.⁷⁷ In that case, the Federal Circuit held that a process must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing (“machine-or-transformation” test), to be eligible for patenting under 35 U.S.C. § 101.⁷⁸ While much public attention had focused on the implications for financial services and computer software companies (the factual context from which the *Bilski* case arose),⁷⁹ there were broad implications for the patenting of all technologies, including medical technology.

On December 19, 2008, the Federal Circuit issued a nonprecedential decision in *Classen Immunotherapies Inc. v. Biogen IDEC*,⁸⁰ and on September 16, 2009, the Federal Circuit issued a precedential decision in *Prometheus Labs. v. Mayo Collaborative Services*.⁸¹ The *Classen* and *Prometheus* cases were the first appeals at the Federal Circuit that applied the *Bilski* machine-or-transformation test to a medical technology invention.⁸²

In *Classen*, the Federal Circuit affirmed the district court’s judgment that U.S. Patent No. 5,723,283, which related to immunization methods, and associated compositions, for substantially preventing or reducing the symptoms of an infectious disease and chronic immune mediated disorder, was invalid under 35 U.S.C. § 101 for lack of patentable subject matter.⁸³

77. 545 F.3d 943 (Fed. Cir. 2008), *aff’d*, *Bilski v. Kappos*, No. 08-964,130 S. Ct. 3218 (2010).

78. *Id.* at 954.

79. See generally Kelsey I. Nix, *Federal Circuit Raises the Bar for Business Method Patents*, METROPOLITAN CORP. COUNS., Jan. 2009, at 27 (discussing the implications of *Bilski* on business method patents); Carol J. Williams, *Supreme Court; A Fresh Patent Manual Sought; Inventors Insist Their Innovations Deserve Protection, Even if They’re not Mechanical*, L.A. TIMES, Feb. 24, 2009, at C1 (discussing implications on the business community from *Bilski*); Brad Stone, *A Patent Ruling May Be Revisited*, N.Y. TIMES, Mar. 10, 2008, at C5 (discussing implications for business method patents from future outcome of *Bilski*).

80. 304 Fed. App’x 866 (Fed. Cir. 2008), *vacated*, 130 S. Ct. 3541 (2010).

81. 581 F.3d 1336 (Fed. Cir. 2009), *vacated*, 130 S. Ct. 3543 (2010).

82. Brian P. Murphy & Daniel P. Murphy, *Bilski’s “Machine-or-Transformation” Test: Uncertain Prognosis for Diagnostic Methods and Personalized Medicine Patents*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 755, 769–73 (2010) (discussing Federal Circuit’s decisions in *Classen* and *Prometheus*).

83. *Classen Immunotherapies, Inc.*, 304 Fed. App’x at 866.

The Federal Circuit applied its machine-or-transformation test to reach this conclusion.⁸⁴

In *Prometheus*, the Federal Circuit reversed and remanded the district court's summary judgment that U.S. Patents No. 6,355,623 and No. 6,680,302, which related to methods for calibrating the proper dosage of thiopurine drugs used for treating both gastrointestinal and non-gastrointestinal autoimmune diseases, were invalid for patent ineligibility under 35 U.S.C. § 101.⁸⁵ The Federal Circuit determined that the methods of treatment claimed in the patents in suit squarely fell within the realm of patentable subject matter because they transformed an article into a different state or thing, and this transformation was central to the purpose of the claimed process.⁸⁶ The Federal Circuit concluded that the transformation is of the human body following the administration of a drug and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined.⁸⁷ The Federal Circuit did not view the disputed claims as merely claiming natural correlations and data-gathering steps.⁸⁸ The asserted claims, in the Federal Circuit's view, were in effect claims to methods of treatment, which are always

84. *Id.*

85. *Prometheus Labs.*, 581 F.3d at 1339 (internal citations omitted) (“The patents claim[ed] claimed methods for calibrating the proper dosage of thiopurine drugs, which are used for treating both gastrointestinal and non-gastrointestinal autoimmune diseases. These drugs include 6-mercaptopurine (‘6-MP’) and azathiopurine (‘AZA’), a pro-drug that upon administration to a patient converts to 6-MP, which are used to treat inflammatory bowel diseases (‘IBD’) such as Crohn’s disease and ulcerative colitis. 6-MP is broken down by the body into various 6-MP metabolites, including 6-methyl-mercaptopurine (‘6-MMP’) and 6-thioguanine (‘6-TG’) and their nucleotides. The patents involv[ed] measurements of these two metabolites. Drugs that deliver 6-TG are widely used for their cytotoxic and immunosuppressive properties. Although drugs such as 6-MP and AZA have been used for years to treat autoimmune diseases, non-responsiveness and drug toxicity may complicate treatment in some patients. To that end, the patents claim[ed] methods that seek to optimize therapeutic efficacy while minimizing toxic side effects. As written, the methods typically include two separately lettered steps: (a) ‘administering’ a drug that provides 6-TG to a subject and (b) ‘determining’ the levels of the drug’s metabolites, 6-TG and/or 6-MMP, in the subject. The measured metabolite levels are then compared to pre-determined metabolite levels, ‘wherein’ the measured metabolite levels ‘indicate a need’ to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize efficacy of treatment. In particular, according to the patents, a 6-TG level greater than about 400 picomole (‘pmol’) per 800 million red blood cells or a 6-MMP level greater than about 7000 pmol per 800 million red blood cells indicates that a downward adjustment in drug dosage may be required in order to avoid toxic side effects. Conversely, according to the patents, a 6-TG level of less than about 230 pmol per 800 million red blood cells indicates a need to increase the dosage to ensure therapeutic efficacy.”).

86. *Id.* at 1347.

87. *Id.*

88. *Id.* at 1349.

transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.⁸⁹

In particular, the Federal Circuit found that when administering a drug such as AZA or 6-MP, the human body necessarily underwent a transformation.⁹⁰ The Federal Circuit emphasized that drugs do not pass through the body untouched without affecting it.⁹¹ According to the Federal Circuit, “[t]he fact that the change of the administered drug into its metabolites relies on natural processes does not disqualify the administering step from the realm of patentability.”⁹²

The Federal Circuit opined that “transformations operate by natural principles,” but the transformation in this case was “the result of the physical administration of a drug to a subject to transform—*i.e.*, treat—the subject, which is itself not a natural process.”⁹³ The Federal Circuit thus concluded that “the administering step was not merely data-gathering but a significant transformative element of Prometheus’s claimed methods of treatment that was sufficiently definite to confine the patent monopoly within rather definite bounds.”⁹⁴

The Federal Circuit admonished that “a further requirement for patent-eligibility was ensuring that the involvement of the transformation in *Prometheus*’s claimed process was not merely insignificant extra-solution activity.”⁹⁵ The Federal Circuit further indicated that “[a] subsequent mental step d[id] not, by itself, negate the transformative nature of prior

89. *Id.* at 1348.

90. *Id.* at 1346.

91. *Id.*

92. *Id.*

93. *Id.* Indeed, the Federal Circuit noted that “[it] is virtually self-evident that a process for a chemical or physical transformation of *physical objects or substances* is patent-eligible subject matter.” *Id.* (quoting *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008), *aff’d*, *Bilski v. Kappos*, 130 S. Ct. 3218. (2010)).

94. *Id.* at 1346–47. The Federal Circuit recognized that while Mayo was “correct that not all of the asserted claims contain the administering step . . . , the determining step, which [was] present in each of the asserted claims, [was] also transformative and central to the claimed methods. *Id.* Determining the levels of 6-TG or 6-MMP in a subject necessarily involve[d] a transformation, for those levels cannot be determined by mere inspection,” the Federal Circuit found. *Id.* at 1347.

95. *Id.* at 1347. The Federal Circuit determined that “[w]hile it [was] true that the administering and determining steps gather useful data, it [was] also clear that the presence of those two steps in the claimed processes [was] not ‘merely’ for the purpose of gathering data. Instead, the administering and determining steps [were] part of a treatment protocol, and they [were] transformative” *Id.* “[T]he administering step provide[d] thiopurine drugs for the purpose of treating disease, and the determining step measure[d] the drugs’ metabolite levels for the purpose of assessing the drugs’ dosage during the course of treatment,” *Id.*

steps.”⁹⁶ Thus, according to the Federal Circuit, the claims “cover[ed] a particular application of natural processes to treat various diseases, but transformative steps utilizing natural processes [were] not unpatentable subject matter.”⁹⁷

While the *Prometheus* case supported the patent eligibility of medical treatment methods that incorporate a transformative step, the viability of medical diagnosis methods remained questionable pending Supreme Court review of the Federal Circuit’s *Bilski* decision.⁹⁸

On June 28, 2010, the U.S. Supreme Court issued its decision in *Bilski v. Kappos*,⁹⁹ regarding the propriety of the Federal Circuit’s new exclusive machine-or-transformation test for patent eligibility under 35 U.S.C. § 101.¹⁰⁰ The Court affirmed the Federal Circuit judgment that Bilski’s business method was unpatentable as an abstract idea,¹⁰¹ but held:

“[T]he machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under §101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible ‘process.’”¹⁰²

The Court eschewed a categorical rejection of business methods as patentable subject matter, but admonished that inventions that might have involved a useful, concrete, and tangible result under *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*¹⁰³ may not be patent eligible

96. *Id.* at 1348. “[W]hen viewed in the proper context, the final step of providing a warning based on the results of the prior steps [did] not detract from the patentability of Prometheus’s claimed methods as a whole.” *Id.* “The data that the administering and determining steps provided for use in the mental steps was obtained by steps well within the realm of patentable subject matter” in the Federal Circuit’s view. *Id.* “The addition of the mental steps to the claimed methods thus [did] not remove the prior two steps from that realm.” *Id.*

97. *Id.* at 1349 (citations omitted) (“Moreover, the claims [did] not preempt natural processes; they utilize[d] them in a series of specific steps Regardless, because the claims [met] the machine-or-transformation test, they [did] not preempt a fundamental principle The inventive nature of the claimed methods stem[med] not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of transformative steps comprising particular methods of treatment.”).

98. See, e.g., Peter A. Jackman & Michelle K. Holoubek, *Fine-Tuning the Test for Patent-Eligibility*, 43 MD. B.J. 30, 33 (2010) (discussing the potential impact on medical diagnostic techniques in anticipation of the Supreme Court’s decision in *Bilski*).

99. 130 S. Ct. 3218 (2010).

100. *Id.* (en banc) (reviewing 545 F.3d 943 (Fed. Cir. 2008)).

101. *Id.* at 3231.

102. *Id.* at 3227.

103. 149 F.3d 1368 (Fed. Cir. 1998).

now.¹⁰⁴ The Court otherwise left to the Federal Circuit any refinements to the test for patent eligibility.¹⁰⁵ In so doing, the Court allayed many fears that extant and future patent rights would be greatly undermined or extinguished.¹⁰⁶

In view of the *Bilski* decision, the Court on June 29, 2010, remanded to the Federal Circuit the appeals in *Classen*¹⁰⁷ and *Prometheus*¹⁰⁸ for further consideration consistent with the Court's holdings in *Bilski*.¹⁰⁹ The Federal Circuit's September 1, 2010 supplemental briefing order in *Prometheus*

104. *Bilski*, 130 S. Ct. at 3231. (citations omitted) (“[N]othing in today’s opinion should be read as endorsing interpretations of §101 that the Court of Appeals for the Federal Circuit has used in the past.”).

105. *Id.* at 3227–29 (citations omitted) (“Section 101 is a ‘dynamic provision designed to encompass new and unforeseen inventions.’ A categorical rule denying patent protection for ‘inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law’ . . . [T]here are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age. . . . [T]he machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals. . . . In the course of applying the machine-or-transformation test to emerging technologies, courts may pose questions of such intricacy and refinement that they risk obscuring the larger object of securing patents for valuable inventions without transgressing the public domain. . . . [I]n deciding whether previously unforeseen inventions qualify as patentable ‘process[es],’ it may not make sense to require courts to confine themselves to asking the questions posed by the machine-or-transformation test. Section 101’s terms suggest that new technologies may call for new inquiries. . . . It is important to emphasize that the Court today is not commenting on the patentability of any particular invention, let alone holding that any of the above-mentioned technologies from the Information Age should or should not receive patent protection. This Age puts the possibility of innovation in the hands of more people and raises new difficulties for the patent law. With ever more people trying to innovate and thus seeking patent protections for their inventions, the patent law faces a great challenge in striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles. Nothing in this opinion should be read to take a position on where that balance ought to be struck.”).

106. See Joe Mullin, *After ‘Bilski,’ All Eyes on Life Sciences Patent Cases*, RECORDER, Sept. 27, 2010, at 3 (asserting Supreme Court’s ruling in *Bilski* did not drastically change intellectually property law); Joe Mullin, *Patent Litigation Weekly: Post-Bilski, Some Things Still Don’t Merit a Patent*, CORP. COUNS., Oct. 1, 2010, at 115 (stating that *Bilski* did little not drastically alter the state of intellectual property law).

107. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 Fed. App’x 866 (Fed. Cir. 2008), *vacated*, 130 S. Ct. 3541 (2010).

108. *Prometheus Labs. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009).

109. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 130 S. Ct. 3541 (2010); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, No. 09-490, 2010 U.S. LEXIS 5537, at *1 (U.S. June 29, 2010).

suggests that the Federal Circuit will remain consistent with its pre-*Bilski* disposition of the appeal.¹¹⁰

The Court's holding in *Bilski* notwithstanding, the continued viability of medical diagnosis method claims, which could be viewed as mere correlations of data relating to natural phenomena that would not satisfy the machine-or-transformation test,¹¹¹ is questionable. In addition, the patent claims to medical diagnosis methods submitted pre-*Bilski* may require amendments to achieve patent eligibility under 35 U.S.C. § 101 as presently interpreted by the USPTO following Federal Circuit precedent.¹¹²

V

On March 29, 2010, in *Association of Molecular Pathology v. U.S. Patent & Trademark Office*,¹¹³ Judge Robert Sweet of the U.S. District Court for the Southern District of New York granted summary judgment invalidating seven U.S. patents, which related to the BRCA1 and BRCA2 genes associated with breast cancer that are owned or licensed to Myriad Genetics.¹¹⁴ The decision was a shock to the medical technology industry.¹¹⁵ If *Bilski* had dealt medical technology patent rights a glancing blow, *Myriad* was a head-on tackle.

110. *Prometheus Labs. v. Mayo Collaborative Servs.*, No. 08-1403, 2010 U.S. App. LEXIS 19159 (Fed. Cir. Sept. 1, 2010) (nonprecedential order) (available at http://www.ca9c.uscourts.gov/images/stories/opinions-orders/2008-1403_new.pdf).

111. See Memorandum from Robert W. Bahr, Acting Assoc. Comm'r For Patent Examination Policy to the Patent Examining Corps of the USPTO (June 28, 2010) [hereinafter *USPTO Memorandum*] (providing guidance on machine-or-transformation test's role post-*Bilski*); Murphy & Murphy, *supra* note 82, at 767-69 (2010) (arguing that machine-or-transformation analysis confuses the issue of whether a medical diagnosis process is patent eligible).

112. *USPTO Memorandum*, *supra* note 111. See Gregory J. Carlin, *Prometheus Gets Delivered Again: Vacated and Remanded by the Supreme Court in the Wake of Bilski*, MCKEON, MEUNIER INTELL. PROP. L. NEWS (Jul. 7, 2010), <http://www.m2iplaw.com/news/supreme-court-impacts-medical-diagnostics-patent-claims> (last visited Nov. 1, 2010).

113. 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

114. *Id.* at 211-12 (referring to U.S. Patents No. 5,693,473; No. 5,709,999; No. 5,710,001; No. 5,747,282; No. 5,753,441; No. 5,837,492; and No. 6,033,857).

115. See e.g., Andrew Pollack, *After Patent on Genes Is Rejected, Taking Stock*, N.Y. TIMES, Mar. 31, 2010, at B1 ("The decision invalidating the gene patents stunned many lawyers who follow such issues."); *Pigs Fly: Federal Court Invalidates Myriad's Patent Claims*, GENOMICS L. REP., (Mar. 30, 2010), <http://www.genomicslawreport.com/index.php/2010/03/30/pigs-fly-federal-court-invalidates-myriads-patent-claims/> (calling the decision a "jaw-dropping summary judgment ruling"); W. Edward Ramage, *The Aftermath of 'Myriad Genetics'*, LAW.COM, (June 1, 2010), <http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1202458973843> ("The recent ruling in [*Myriad*] has created more than a few ripples in the biotech industry.")

Judge Sweet based his conclusions that the composition of matter patent claims were not directed to patentable subject matter on the fact that the claimed “isolated DNA” was not “markedly different” from the corresponding DNA found in nature.¹¹⁶ Judge Sweet focused on the expert testimony that genes are multifunctional with a dual nature as a chemical molecule as well as an information repository.¹¹⁷ In his view, the nucleotide sequence was the defining characteristic of both native and isolated DNA, and therefore, he concluded that the primary biological function of isolated DNA was the same as that of the corresponding native DNA.¹¹⁸ In so doing, he discounted Myriad’s arguments that the differences between native and isolated DNA as chemical molecules should be the crux of the patentable subject matter inquiry.¹¹⁹ Moreover, Judge Sweet abruptly dismissed concerns over the impact of his decision on the biotechnology industry as unfounded.¹²⁰ In addition, Judge Sweet embraced the Federal Circuit’s *Bilski* and *Prometheus* holdings to invalidate the method claims of the Myriad patents.¹²¹

Although the public reaction to the *Myriad* ruling has been mixed, the element of surprise seemed shared among all.¹²² For patient advocacy groups and medical practitioners, the decision lends credence to the notion that patent exclusivity for medical prevention, diagnosis and treatment has been based on tenuous distinctions from the public domain and other “lawyer’s trick[s].”¹²³ For industry members and their patent attorneys, the

116. *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 232.

117. *Id.* at 228.

118. *Id.* at 229.

119. *Id.* at 228 (“Myriad’s focus on the chemical nature of DNA, however, fails to acknowledge the unique characteristics of DNA that differentiate it from other chemical compounds.”).

120. *Id.* at 228 n.51.

121. *Id.* at 233–37.

122. See *supra* note 115; see also Mildred Cho, *Patently Unpatentable: Implications of the Myriad Court Decision on Genetic Diagnostics*, TRENDS IN BIOTECHNOLOGY, 2010, at 1–4 (“Even to longtime observers of patent law, this decision came as a shock because it questions long-held practices in the writing and granting of gene patents.”).

123. *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 185 (footnote omitted) (“The claims-in-suit directed to ‘isolated DNA’ containing human *BRCA1/2* gene sequences reflect the USPTO’s practice of granting patents on DNA sequences so long as those sequences are claimed in the form of ‘isolated DNA.’ This practice is premised on the view that DNA should be treated no differently from any other chemical compound, and that its purification from the body, using well-known techniques, renders it patentable by transforming it into something distinctly different in character. Many, however, including scientists in the fields of molecular biology and genomics, have considered this practice a ‘lawyer’s trick’ that circumvents the prohibitions on the direct patenting of the DNA in our bodies but which, in practice, reaches the same result.”)

decision represents an indefensible departure from decades of precedent as well as a significant undermining of established investment-backed expectations.¹²⁴

Now on appeal before the Federal Circuit, *Myriad* raises the question whether Judge Sweet was correct in his characterization of genomic fragments and synthetic polynucleotides as mere physical embodiments of the laws of nature that should be precluded from patentable subject matter.¹²⁵ While many commentators expect the Federal Circuit to reverse the trial court on either substantive or procedural grounds,¹²⁶ perhaps we are in store for further surprises. Indeed, Judge Timothy Dyk of the Federal Circuit, in dissent from the majority in *Intervet Inc. v. Merial Ltd.*,¹²⁷ seemed to be sympathetic to Judge Sweet's reasoning.¹²⁸ Precedent notwithstanding, only history will reveal whether Judge Sweet was simply the first to say the Emperor has no clothes.¹²⁹

124. See, e.g., Cho, *supra* note 122, at 1 (stating that the *Myriad* decision “represents a major challenge to the way USPTO has granted patents on genes”); Aaron S. Kesselheim & Michelle M. Mello, *Gene Patenting—Is the Pendulum Swinging Back?*, 20 NEW ENG. J. MED. 362, 1857–58 (2010) (“Although well-grounded in legislative history and Supreme Court precedent, [Judge Sweet’s] decision flies in the face of years of decision making by the USPTO”); John Schwartz & Andrew Pollack, *Cancer Genes Cannot Be Patented, U.S. Judge Rules*, N.Y. TIMES, Mar. 30, 2010, at B1 (providing input from a patent lawyer, a former biotechnology company head, and a venture capitalist on the *Myriad* decision—that it could “make it harder for young companies to raise money from investors,” “diminish the incentives for genetic research,” and “push more work aimed at discovering genes and diagnostic tests to universities,” respectively).

125. See *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 227, 229, 232 (“[P]urification of a product of nature, without more, cannot transform it into patentable subject matter.”).

126. See, e.g., HOLMAN’S BIOTECH IP BLOG (Mar. 30, 2010), <http://holmansbiotechipblog.blogspot.com/2010/03/in-case-challenging-myriad-gene-patents.html> (“Hopefully the Federal Circuit will intervene, and either reverse the decision, or at least limit its reach.”); Posting of Dennis Crouch, PATENTLYO (Mar. 30, 2010 07:17AM EST), <http://www.patentlyo.com/patent/2010/03/court-essentially-all-gene-patents-are-invalid.html> (“The Federal Circuit is likely to reverse this decision—opening the door to an important Supreme Court showdown.”).

127. 2010 WL 3064311, *9 (Fed. Cir. 2010) (Dyk, J., dissenting).

128. *Id.* at *11 (“[I]n order for a product of nature to satisfy section 101, it must be qualitatively different from the product occurring in nature, with ‘markedly different characteristics from any found in nature.’ It is far from clear that an ‘isolated’ DNA sequence is qualitatively different from the product occurring in nature such that it would pass the test laid out in *Funk Brothers* and *Chakrabarty*. The mere fact that such a DNA molecule does not occur in isolated form in nature does not, by itself, answer the question.”).

129. See HANS CHRISTIAN ANDERSEN, *THE EMPEROR’S NEW SUIT* (1837).

In a particularly crowded field of technology, such as medical technology, the uncertainty over entitlement to patent exclusivity can disqualify otherwise innovative methods and their associated products from access to commercial investment, market entry, and/or post-market entry sustainability.¹³⁰ The oft cited purpose of the patent laws is to promote the progress of the useful arts through the creation of temporary exclusivity rights as an incentive for the prompt, public disclosure of inventions because the patent exclusivity facilitates innovative efforts and encourages investment in such endeavors.¹³¹ These principles apply with equal, if not greater force in the medical technology industry sector, where commercial competition is intense.¹³² Beyond the known beneficial effects today of an enfranchising patent eligibility standard under 35 U.S.C. § 101,¹³³ perhaps a more essential consideration is the maintenance of a patent eligibility test that will continue the promise of patent protection for innovations to come.

The *Bilski* decision and its progeny will open the door to the use of 35 U.S.C. § 101 as an instrument for determining precisely what innovation will be acceptable. In *Chakrabarty*,¹³⁴ the U.S. Supreme Court took the wise approach of interpreting § 101 as broadly inclusive in favor of allowing the other statutory conditions for patentability to more finely monitor what inventions may be patented vis-à-vis the prior art.¹³⁵ A patentable subject matter standard that embraces inclusiveness ensures continuing innovation in new as well as old fields of technology. Tinkering with patent eligibility in hopes of crafting a standard generally applicable to

130. *Ass'n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 211 (S.D.N.Y. 2010) (noting that Myriad claimed it could not have funded its research without the patent protecting the investment).

131. U.S. CONST. art. I, § 8, cl. 8 (“The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries. . . .”). See Geoffrey Karyn, *In Defense of Gene Patenting: The Principles of Our Patent System Are Sound and Bring Immense Benefits*, GENETIC ENGINEERING BIOTECH. NEWS (Apr. 1, 2007), <http://www.genengnews.com/gen-articles/in-defense-of-gene-patenting/2052/> (asserting that banning gene patents would risk “shutting down a large part of the industry and creating a major roadblock to progress in patient care and food production”).

132. See *Graham et. al.*, *supra* note 6, at 1277, 1288, 1290 (2009) (finding that patents are more commonly used and considered more important in biotechnology and medical devices sectors as compared to the software and Internet fields).

133. 35 U.S.C. § 101 (2006). See *supra* note 131 and accompanying text.

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

135. *Id.* at 308–09.

past, present, and future technologies, however well intentioned, may bring unforeseeable consequences, including the unfortunate chilling of future innovation.

No readily acceptable solution is available for the patentability of medical technology that involves gene-based inventions and their diagnostic applications.¹³⁶ The controversy may be driven, at least in part, by the absence of a distinction in the patent law between invention and discovery.¹³⁷ The interchangeability of these terms as a matter of patent law defies the common understanding of these two terms where invention tends to suggest the components of labor and ingenuity in the production of something new whereas discovery tends to suggest a component of fortuity in the revelation of something old.¹³⁸

A reinvention of the inventorship standards might serve to decrease the issuance of gene patents.¹³⁹ The patent law jurisprudence uniformly recognizes the element of conception in defining invention.¹⁴⁰ But the

136. See Laurie Axford, *Are Diagnostic Method Claims Patentable?: New Rulings Raise Old Questions*, 2010 EMERGING ISSUES 5134 (“[T]he patentability of diagnostic method claims is still up in the air”); Lawrence M. Sung, *Patent Eligible Medical Technology Post-Bilski*: Prometheus Labs., Inc. and Mayo Collaborative Servs., 2010 EMERGING ISSUES 4810 (“[V]iability of medical diagnosis methods remains questionable post-*Bilski*”); Marisa Noel Pins, Note, *Impeding Access to Quality Patient Care and Patient Rights: How Myriad Genetics’ Gene Patents Are Unknowingly Killing Cancer Patients and How to Calm the Ripple Effect*, 17 J. INTELL. PROP. L. 377, 403, 409 (2010) (pointing out conflicting and unclear provisions of the NIH Best Practices and USPTO’s current Utility Examination Guidelines).

137. See 35 U.S.C. § 101 (2006) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”).

138. See 35 U.S.C. § 100 (2006) (“The term ‘invention’ means invention or discovery.”); Cf. MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY 331, 616 (10th ed. 1996) (defining “discover” as “to make known or visible: expose,” implying something already in existence and defining “invent” as “to devise by thinking . . . to produce (as something useful) for the first time . . .”).

139. See Sean Tu et al., *A Perfect Storm is Brewing Against Personalized Medicine*, 4 BLOOMBERG L. REPS. 8 (2010), available at http://www.foley.com/files/tbl_s31Publications/FileUpload137/6862/foley_lardner_dudas_kiko_tu_wilson_article.pdf (*Stifling of Stimulating – The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcommittee on Courts, the Internet, and Intellectual Property of the House Committee on the Judiciary*, 110th Congress (statement of Professor Lawrence Sung)). See *infra* notes 140–42.

140. 35 U.S.C. § 116 (2006); *Univ. of Pittsburgh v. Hedrick*, 573 F.3d 1290, 1297–98 (Fed. Cir. 2009) (internal citations omitted) (“Conception is the touchstone of inventorship under 35 U.S.C. § 116. It is ‘the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.’ The test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing contemporaneous disclosures. Such corroborating

typical analysis is confined to questioning when these acts might have occurred for purposes of determining who is an inventor or who invented first.¹⁴¹ Little consideration is apparent on whether certain purported acts of invention actually meet these well accepted standards and otherwise constitute inventive acts.¹⁴²

Another proposal might be to recast an inventive act as a governing threshold for patent protection, particularly as applied to genomic inventions. This standard does not incorporate the traditional considerations, such as novelty or nonobviousness, in assessing patent eligibility.¹⁴³ Rather, like the requirement of originality in copyright law, this metric considers whether the claimed invention legitimately “owes its origin” to the named inventor, or for that matter, to anyone.¹⁴⁴ This normative proposition contemplates a minimal showing of inventive activity embodied in the conception of an invention in order to qualify for patentability. But to the extent that the conception of the invention cannot fairly be ascribed to an individual, i.e., the named inventor or another, the claimed invention would be deemed to have resulted from a non-inventive act, and thus, be ineligible for patent protection.¹⁴⁵

evidence is taken as a whole; conception of an entire invention need not be reflected in a single source. An inventor need not know that his invention will work for conception to be complete. He need only show that he had the complete mental picture and could describe it with particularity; the discovery that the invention actually works is part of its reduction to practice.”)

141. *See, e.g.,* *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1374–75 (Fed. Cir. 2009); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1374–75 (Fed. Cir. 2009); *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1299–1300 (Fed. Cir. 2007).

142. *See Martek*, 579 F.3d at 1376 (analyzing corroborating evidence of reduction to practice, not conception); *Agilent*, 567 F.3d at 1375 (analyzing “whether the copying party’s specification . . . adequately supported the subject matter claimed by the other party”); *Aventis*, 499 F.3d at 1300 (analyzing prior art status by determining whether the first inventor had “abandoned, suppressed, or concealed” the invention”).

143. *See* 35 U.S.C. §§ 102 & 103 (2006) (novelty and nonobviousness requirements, respectively); DONALD S. CHISUM ON PATENTS §§ 3.01, 5.01 (2010).

144. *Lamps Plus, Inc. v. Seattle Lighting Fixture Co.*, 345 F.3d 1140, 1146 (9th Cir. 2003) (“Original in reference to a copyright work means that the particular work owes its origin to the author. No large measure of novelty is required.” (quoting *N. Coast Indus. v. Jason Maxwell, Inc.*, 972 F.3d 1031, 1033 (9th Cir. 1992)) (internal quotation marks omitted)).

145. *Cf. MEVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 2.01[A]* (“Originality in the copyright sense means only that the work owes its origin to the author, i.e., is independently created, and not copied from other works.”).

CONCLUSIONS

The successful future of medical device innovation depends on the continued support that patent exclusivity facilitates through the incentive to invent and the incentive to invest in innovation. Although industry dynamics regularly adapt to incremental refinements in the law,¹⁴⁶ a sea change like that seen with the recent jurisprudence on patentable subject matter creates immeasurable uncertainty. Without the confidence that investment-backed expectations can be realized, innovation will be retarded. However, the overall societal cost must take into account the immediate benefits that may accrue through open public access to novel medical prevention, diagnosis, and treatment.¹⁴⁷ Unfortunately, these competing interests are difficult to balance because of inadequate information transparency and imperfect valuation metrics for the improvement of the human condition.

146. See e.g., Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1648–51 (2003) (discussing how the software and biotechnology industries have responded differently to changing ‘person having ordinary skill in the art’ standards); Michael J. Malinowski & Maureen A. O’Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163, 180–84 (1996) (tracing genotechnology’s shift from government sector to academia in response to federal policy); see also Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900–2000*, 88 CALIF. L. REV. 2187, 2226, 2228, 2230 (2000) (tracing developments of USPTO, 35 U.S.C. § 116, and Federal Circuit in response to changing industry, and vice versa). Carlin, *supra* note 112 (providing instructions for clients to comply with the Supreme Court’s holding in *Bilski*).

147. Robin Feldman, *The Open Source Biotechnology Movement: Is It Patent Misuse?*, 6 MINN. J. L. SCI. & TECH. 117, 120–22 (2004); Karen Mann, *Gene Patents: A View From the Clinical Laboratory*, 10 EXPERT REV. MOL. DIAGN. 123, 123–24 (2010).