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Facilitating Patient Access to Patent-Protected Genetic Testing

IN MARCH 2010, A NEW YORK FEDERAL DISTRICT COURT granted summary judgment invalidating a number of biotechnology patents directed to the *BRCA1* and *BRCA2* human breast cancer genes.¹ One of the most highly publicized patent disputes in recent memory, *Ass'n for Molecular Pathology (AMP) v. United States Patent and Trademark Office (USPTO) and Myriad Genetics, Inc.* (hereinafter *Myriad*)² pits patient care advocates against the patent-owning biotechnology industry.³ The *Myriad* decision is now under review by the U.S. Court of Appeals for the Federal Circuit, which will likely reverse the district court and confirm the patent-eligibility of the claimed isolated genes.⁴

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* Professor, University of Pittsburgh School of Law; Visiting Professor, spring 2010, University of Kentucky College of Law. I thank Professor Lawrence Sung, Professor Patricia Campbell, and the staff of the University of Maryland School of Law Journal of Business & Technology Law for inviting me to participate in their April 2010 symposium, "The Future of Genetic Disease Diagnosis and Treatment: Do Patents Matter?" I welcome comments by e-mail to mueller2@pitt.edu.

1. See *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office and Myriad Genetics, Inc.*, 702 F. Supp. 2d 181, 185–86 (S.D.N.Y. 2010) (as amended Apr. 5, 2010) ("[T]he challenged patent claims are directed to (1) isolated DNA containing all or portions of the *BRCA1* and *BRCA2* gene sequence and (2) methods for 'comparing' or 'analyzing' *BRCA1* [sic] and *BRCA2* gene sequences to identify the presence of mutations correlating with a predisposition to breast or ovarian cancer.").

2. *Id.*

3. See Timothy Caulfield, *Human Gene Patents: Proof or Problems?*, 84 CHI.-KENT L. REV. 133, 139–40 (2009) (discussing "social trade-off inherent in the patent system" in the biotechnology context and public concern over patient access to clinically useful technologies).

4. The Federal Circuit has previously upheld the validity of gene patents. See, e.g., *In re Deuel*, 51 F.3d 1552, 1560 (Fed. Cir. 1995). See also *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991). These decisions applied qualitative patentability criteria such as nonobviousness under 35 U.S.C. § 103 and disclosure compliance under 35 U.S.C. § 112. However, the Federal Circuit has not previously confronted a *Myriad*-type challenge to the patent-eligibility of gene patents under 35 U.S.C. § 101, most likely because § 101 qualification was taken as a given by the parties and not raised as an issue on appeal in the court's earlier cases.

Neither the Federal Circuit nor the U.S. Supreme Court should prohibit the patenting of genetic material through judicial decision,⁵ such a drastic change in patent law requires due deliberation by Congress.⁶ Despite the critical importance to society of facilitating patient access to genetic testing, dismantling patent protection for this important technology is not the right approach; instead, modifying approaches to licensing gene patents is.⁷

Since the 1980s, the USPTO has granted more than 20,000 patents claiming isolated DNA molecules, almost 4,000 of which claim isolated human DNA encoding proteins.⁸ Based on the likelihood that the USPTO will continue its past practice of granting such patents, a Department of Health and Human Services (HHS) Advisory Committee extensively studied patient access concerns stemming from restrictive licensing of some gene patents.⁹ Rather than eliminating the grant of such patents, the Committee has proposed that patient access be facilitated through statutory exemptions from patent infringement liability.¹⁰ Specifically, the proposed exemptions would allow unlicensed use of gene patents for research and diagnostic, but not therapeutic, purposes.¹¹

5. *See infra* Part I.

6. *See infra* Part I.

7. *See infra* Part II.

8. *See* Remarks of David Kappos, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, BIO International Convention (May 3–6, 2010), *available at* <http://www.ipwatchdog.com/2010/05/04/kappos-talks-patent-reform-and-gene-patents-at-bio-convention/id=10382/> (May 4, 2010). *See also* Statement of Q. Todd Dickinson, Under Secretary of Commerce for Intellectual Property & Director of the U.S. Patent & Trademark Office before the Subcommittee on Courts and Intellectual Property, Committee on the Judiciary, U.S. House of Representatives (July 13, 2000), at 3:

Over the past twenty years, many patent applications have been filed that are drawn to subject matter relating to genes. The filing rate of applications relating to genes has dramatically increased in the past few years. Currently, over 20,000 applications relating to genes are pending before the USPTO. Since the first gene related applications were filed, approximately 6,000 patents have issued which are drawn to full-length genes from human, animal, plant, bacterial and viral sources. Of these 6,000 patents, over 1,000 are specifically drawn to human genes and human gene variations that distinguish individuals.

9. SECRETARY'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOCIETY, U.S. DEP'T OF HEALTH & HUM. SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS (2010) [hereinafter SACGHS Report], *available at* http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf.

10. SACGHS Report, *supra* note 9, at 94.

11. *See id.* at 97. The Committee calls the proposed exemption from infringement liability for gene-based diagnostic testing a “narrowly tailored exemption [permitting] the holders of patents on genes to continue to enforce their exclusive rights to therapeutic uses of the claimed molecules, thereby preserving the incentive such patents create for the development of therapeutics” and

I support the Committee's proposed scheme, but suggest that it be modified to provide remuneration to the patent owner in the case of diagnostic use. In Part I of this essay, I explore the district court's decision in *Myriad* and conclude that it should not stand.¹² In Part II, I describe the HHS Advisory Committee's recommendations for facilitating access to patented genetic testing and offer a modification of the Committee's proposed framework.¹³

I. THE DISTRICT COURT'S SUMMARY JUDGMENT OPINION IN *MYRIAD*

The patents challenged by AMP, the American Civil Liberties Union (ACLU), and other plaintiffs claimed both breast cancer gene-related products and processes.¹⁴ The March 29, 2010 decision of the Southern District of New York, authored by Judge Robert W. Sweet, invalidated both types of claims.¹⁵ This essay focuses exclusively on the debate concerning the patent-eligibility of the product (i.e., composition of matter) claims, setting aside the question of the process claims' patent-eligibility under the Supreme Court's recent decision in *Bilski v. Kappos*.¹⁶

Judge Sweet's discussion of the product claims in *Myriad* began in a promising vein, citing Judge Giles Rich's classic guidance in *In re Bergy*.¹⁷

asserts that the proposed exemption for research on or with genes "is designed to permit research that can generate insights into disease, genetic tests, and therapeutics." *Id.*

12. *See infra* Part I.

13. *See infra* Part II.

14. *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office and Myriad Genetics, Inc.*, 702 F. Supp. 2d 181, 220 (S.D.N.Y. 2010) ("[T]he sole task of this Court is to resolve whether the claimed compositions and methods constitute statutory subject matter or fall within the judicially created products of nature exception to patentable subject matter.").

15. *Id.* at 232 (holding composition claims invalid); *id.* at 237 (holding method claims invalid).

16. *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010). The Court in *Bilski* held that patent application claims to a method of fixing commodity costs by hedging weather and market risks were not patent-eligible subject matter under 35 U.S.C. § 101 because the claims were drawn to an "abstract idea." The facts of *Bilski* did not involve composition of matter (or other product) claims, and it would seem illogical to characterize a tangible, isolated DNA sequence as an abstract idea.

Nevertheless, one judge of the Federal Circuit has raised *Bilski's* potential applicability to the *Myriad* dispute by writing that "[j]ust as the patentability of abstract ideas would preempt others from using ideas that are in the public domain . . . , so too would allowing the patenting of naturally occurring substances preempt the use by others of substances that should be freely available to the public." *Intervet Inc. v. Merial Ltd.*, No. 2009-1568, slip op. at 4 (Fed. Cir. Aug. 4, 2010) (Dyk, J., concurring in part and dissenting in part).

17. 596 F.2d 952, 960 (C.C.P.A. 1979) (describing "three doors" to obtaining a patent); *id.* at 960-61 (stating that "the questions of whether a particular invention is novel or useful are

that 35 U.S.C. § 101 statutory (i.e., patent-eligible) subject matter issues must be distinguished from § 102 (novelty) and § 103 (nonobviousness) issues.¹⁸ But the district court took a wrong turn when it interpreted *Bergy*'s guidance to distinguish away the leading purified products of nature decision, *Parke-Davis & Co. v. H.K. Mulford Co.*,¹⁹ as involving merely novelty rather than statutory subject matter issues.²⁰

questions wholly apart from whether the invention falls into a category of statutory subject matter”).

18. *Id.* at 960 (discussing the need for “separate keys to open in succession the three doors of sections 101, 102 and 103”). All statutory references herein are to sections of the U.S. Patent Act, 35 U.S.C. (2010).

19. 189 F. 95 (C.C.S.D.N.Y. 1911) (L. Hand, J.), *aff'd*, 196 F. 496 (2d Cir. 1912). Judge Sweet's *Myriad* opinion recalls his own appearance as a government lawyer before Judge Hand. *Myriad*, 702 F. Supp. 2d at 225 n.46 (stating that “[a]lthough Judge Hand once turned his back on the author of this opinion arguing before him on behalf of the Government, his opinion in *Parke-Davis* deserves careful review but brings to mind that oft repeated adage ‘Quote Learned, but follow Gus’”) (citing James Oakes, *Personal Reflections on Learned Hand and the Second Circuit*, 47 STAN. L. REV. 387, 389 n.17 (1995)).

20. Judge Learned Hand's opinion in *Parke-Davis* considered whether the claimed composition (isolated adrenalin) was a patentable “composition of matter,” stating:

Nor is the patent only for a degree of purity, and therefore not for a new “composition of matter.” As I have already shown, it does not include a salt, and no one had ever isolated a substance which was not in salt form, and which was anything like Takamine's. Indeed, Sattler supposes it to exist as a natural salt, and that the base was an original production of Takamine's. That was a distinction not in degree, but in kind. But, even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.

Parke-Davis, 189 F. at 103. *See also* *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 160–62 (4th Cir. 1958) (sustaining § 101 validity of composition claims to “[vitamin] B(12)-active compositions derived from . . . specified fermentates” against challenge that claims recited unpatentable “products of nature,” and citing *Parke-Davis* as illustrating principle that “where the requirements of the [Patent] Act [(i.e., novelty, utility, and nonobviousness)] are met, patents upon products of nature are granted and their validity sustained”).

Judge Hand's opinion in *Parke-Davis* is recognized as the foundational case for the patent-eligibility of purified and isolated products of nature, which differ from their corresponding natural products “not merely in degree of purity, but in degree of kind.” Lauren Nowierski, *A Defense of Patenting Human Gene Sequences Under U.S. Law: Support for the Patenting of Isolated and Purified Substances*, 26 CARDOZO ARTS & ENT. L.J. 473, 483 (2008) (analyzing *Parke-Davis* and observing that “[t]he jurisprudence that developed following *Parke-Davis* primarily relied on Judge Hand's decision to support the patentability of extracted, isolated, and purified ‘products of nature’ that meet the other statutory requirements of patentability”). *See also* 1-1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.02[9] (2010) (commenting that “there is a long line of cases that hold that mere purification of known materials does not result in a patentable

The district court's opinion went further astray by placing unjustified reliance on two inapposite Supreme Court decisions from the 1930s/1940s, *American Fruit Growers, Inc. v. Brogdex Co.*²¹ and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*²² Both of these decisions are off point, for they dealt with novelty or nonobviousness (earlier expressed as an elusive requirement for "invention") rather than patentable subject matter issues.²³ *American Fruit Growers* inexplicably relied on 19th century tariff cases to decide what is a patentable "manufacture" under the Patent Act.²⁴

Turning to more pertinent Supreme Court precedent from 1980, *Diamond v. Chakrabarty*,²⁵ the *Myriad* district court extracted a single phrase: that the bacteria genetically engineered by Dr. Ananda Chakrabarty possessed "markedly different characteristics" than those found in nature.²⁶ Judge Sweet elevated that three-word description to *the* test for qualifying

product," but citing *Parke-Davis* as recognizing an exception to the purity rule when "the new pure compound differs 'in kind' rather than merely 'in degree' from the old compound").

21. 283 U.S. 1, 11 (1931) (invalidating patent claiming fresh fruit having rind impregnated with borax to provide mold resistance on ground was not a patentable "article of manufacture"). The *American Fruit Growers* Court asserted, without citation to authority, that

[a]ddition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange, fit only for the same beneficial uses as theretofore." *Id.* at 11–12. Scholars have observed that "[t]he presence or absence of a 'new or distinctive form, quality or property' is an issue properly relevant to the statutory standards of novelty and nonobviousness.

See CHISUM, *supra* note 20, at § 1.02[3][a].

22. 333 U.S. 127, 132 (1948) (invalidating patent claiming mixture of mutually non-inhibitive strains of bacteria that advantageously helped various legume plants extract nitrogen on ground of invention or discovery). The *Funk Bros.* Court opined that "[e]ven though [the claimed discovery] may have been the product of skill, it certainly was not the product of invention." *Id.* The *Funk Bros.* decision is "perhaps best viewed as an interpretation of the nonobviousness or 'invention' requirement." See CHISUM, *supra* note 20, at § 1.02[7][b].

23. See *supra* notes 21–22 and accompanying text (discussing novelty, nonobviousness and requirements for "invention" under the Patent Act).

24. *Am. Fruit Growers, Inc.*, 283 U.S. at 12 (citing *Hartranft v. Wiegmann*, 121 U.S. 609, 613, 615 (1887)) (finding that there was no patentable "manufacture" of shells on grounds that there was no transformation "into a new and different article, having a distinctive name, character, or use from that of a shell").

25. 447 U.S. 303 (1980).

26. See *Ass'n for Molecular Pathology v. Myriad*, 702 F. Supp. 2d 181, 223 (S.D.N.Y. 2010) (as amended Apr. 5, 2010) (quoting *Chakrabarty*, 447 U.S. at 310) (contrasting the bacterium at issue with the bacterial mixture at issue in *Funk Bros.*, stating "the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own . . .").

an isolated genetic product under § 101, stating that “[t]he question thus presented by Plaintiffs’ challenge to the composition claims is whether the isolated DNA claimed by Myriad possesses ‘markedly different characteristics’ from a product of nature.”²⁷ Judge Sweet found that it did not.²⁸

The *Myriad* district court’s opinion misinterpreted *Chakrabarty*.²⁹ The primary focus of *Chakrabarty* was not on the degree of difference between Chakrabarty’s genetically engineered bacterium and *bacillus* bacteria as they existed in nature.³⁰ Rather, the Supreme Court emphasized that the latter were nature’s handiwork, while the former would not have existed but for Chakrabarty’s intervention and ingenuity in manipulating the DNA.³¹ Accordingly, the § 101 analysis for gene patents should focus on *who* or *what* (i.e., whether human or nature) produced the claimed subject matter.³² The “degree of difference” question speaks to novelty under § 102 and/or nonobviousness under § 103.

Myriad filed its notice of appeal in the Federal Circuit in June 2010,³³ but the gene patenting controversy crystallized by the *Myriad* litigation

27. *Id.* at 227–28.

28. *Id.* at 229.

In light of DNA’s unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA ‘markedly different.’ This conclusion is driven by the overriding importance of DNA’s nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form. The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature.

Id.

29. *See infra* notes 30–32 and accompanying text.

30. *See Chakrabarty*, 447 U.S. at 309–10 (comparing genetically engineered bacterium to bacteria that existed in nature and holding the former patentable subject matter as “a product of human ingenuity”).

31. *Id.*

[Chakrabarty’s] claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use. . . . [Chakrabarty] has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.

Id.

32. *See generally* U.S. Patent Act, 35 U.S.C. § 101 (2010).

33. Myriad Defendants’ Notice of Appeal, *Ass’n for Molecular Pathology v. Myriad*, S.D.N.Y. (June 16, 2010) (No. 4515).

could well continue beyond the Federal Circuit's review.³⁴ Judge Sweet invited Supreme Court interest by quoting Justice Breyer's dissent from the dismissal of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Labs., Inc.*,³⁵ that "sometimes *too much* patent protection can impede, rather than 'promote the Progress of Science and useful Arts . . .'"³⁶ Because the Supreme Court's recent decision in *Bilski* was limited on its facts to the patentability of process or method claims under § 101 and did not (at least directly) address the patentability of composition of matter claims,³⁷ the legitimacy of patenting so-called purified products of nature (such as isolated and purified genetic material) remains an issue ripe for Supreme Court adjudication.³⁸

If the Court granted certiorari in *Myriad*, the Justices would undoubtedly consider carefully the guidance of their expansive 1980 decision in *Chakrabarty*, which held that genetic material removed from its native state (in that case, in the form of a genetically modified bacterium) was statutory subject matter under § 101.³⁹ The Court's more recent holding in *J.E.M. Agricultural Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.* would also be relevant.⁴⁰ The Court in *J.E.M.* held that plants are

34. See John Schwartz & Andrew Pollack, *Cancer Genes Cannot be Patented*, *U.S. Judge Rules*, N.Y. TIMES, Mar. 30, 2010, at B0 (stating that *Myriad* could have far-reaching implications impacting the future of medicine). See also Marisa Noelle Pins, *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, 396 (2010) ("Several lawyers expect the ruling to be overturned, or at the very least 'an important Supreme Court showdown' to ensure [sic].").

35. 548 U.S. 124 (2006) (Breyer, J., dissenting from dismissal of writ of certiorari).

36. *Id.* at 126 (Breyer, J., dissenting from dismissal of writ of certiorari) (quoting U.S. CONST. art. I, § 8, cl. 8).

37. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) ("The present case involves an invention that is claimed to be a 'process' under § 101."); *Id.* at 3221 ("The machine-or-transformation test . . . is not the sole test for deciding whether an invention is a patent-eligible 'process.'"); *Id.* at 3222 (rejecting *Bilski*'s patent application under Court's precedents on the unpatentability of "abstract ideas" and declining to further define "what constitutes a patentable 'process'").

38. *Cf. Intervet Inc. v. Merial Ltd.*, No. 2009-1568, slip op. at 3 (Fed. Cir. Aug. 4, 2010) (Dyk, J., concurring in part and dissenting in part) ("Neither the Supreme Court nor this court has directly decided the issue of the patentability of isolated DNA molecules. Although we have upheld the validity of several gene patents . . . none of our cases directly addresses the question of whether such patents encompass patentable subject matter under 35 U.S.C. § 101. Although the U.S. Patent and Trademark Office . . . believes that at least some of these patents satisfy section 101 . . . thus far the question has evaded judicial review.").

39. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (holding that respondent's genetically modified bacterium qualified as patentable subject matter).

40. 534 U.S. 124 (2001).

potentially protectable under § 101 utility patents,⁴¹ despite the fact that alternative forms of protection are also available under the plant-specific statutes (i.e., the Plant Patent Act of 1930⁴² and the Plant Variety Protection Act of 1970).⁴³ Notably, the *J.E.M.* Court relied on *Chakrabarty* in “declin[ing] to narrow the reach of § 101 where Congress has given us no indication that it intends this result,”⁴⁴ and described § 101 as “a dynamic provision designed to encompass new and unforeseen inventions.”⁴⁵

If it were to consider *Myriad*, the Supreme Court would also need to weigh the significant reliance interests of gene patent owners.⁴⁶ Such interests are far more vested than those of business method patent holders. The USPTO has issued thousands of patents on isolated genetic material since the 1980s,⁴⁷ pre-dating any significant trend toward patenting business methods.⁴⁸ The agency’s position is that isolated and purified genetic sequences are potentially patentable.⁴⁹ More than thirty years after the Supreme Court’s decision in *Chakrabarty*, the U.S. Congress has not acted to legislatively overrule the Court’s holding that genetically engineered life forms are patent-eligible under § 101.⁵⁰ In the meantime,

41. *Id.* at 127.

42. 35 U.S.C. §§ 161–64 (2006).

43. 7 U.S.C. §§ 2401–2582 (2006).

44. *J.E.M.*, 534 U.S. at 145–46.

45. *Id.* at 135.

46. See *Ass’n for Molecular Pathology v. Myriad*, 702 F. Supp. 2d. 181, 185 (S.D.N.Y. 2010) (noting that the case’s resolution “deeply concern[s],” *inter alia*, patent holders). See also Roger D. Klein, & Maurice J. Mahoney, *Labcorp v. Metabolite Laboratories: The Supreme Court Listens, but Declines to Speak*, 36 J.L. MED. & ETHICS 141, 147 (2008) (noting Myriad has placed great reliance on gene-related patent protection).

47. See *supra* note 8 and accompanying text.

48. The Federal Circuit’s 1998 *State Street Bank* case is generally considered to be the decision that opened the door to the filing of large numbers of business method patent applications in the USPTO. *State St. Bank and Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).

49. USPTO, Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (“[A]n inventor’s discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.”).

50. See Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 477 (2003) (noting that Congress has not overruled *Chakrabarty*’s holding).

the U.S. biotech industry has become the world's leader; the availability of patent protection has undoubtedly contributed to this success.⁵¹

The § 101 statutory subject matter inquiry should not be used as a blunt instrument to cabin patenting of isolated genetic material.⁵² Other provisions of the Patent Act, as interpreted in recent Supreme Court and Federal Circuit decisions, already act as difficult (if not insurmountable) qualitative obstacles to obtaining patents on isolated genetic material.⁵³ For example, the Supreme Court's 2007 decision in *KSR v. Teleflex*⁵⁴ is widely viewed as having raised the bar for satisfying the § 103 requirement of nonobviousness across all technologies.⁵⁵ Interpreting *KSR* in the genetic context, the Federal Circuit's 2009 decision in *In re Kubin*⁵⁶ signaled that "classical" biotechnology inventions (i.e., claims to isolated genes that encode particular proteins) may now be routinely characterized as "obvious to try" in the *KSR* sense, and hence obvious under § 103.⁵⁷

51. See Lila Fei, *The Role of the Private Sector in Biotechnology: Research and Development*, 12 HEALTH MATRIX 357, 363–64 (2002) (noting that patent protection is critical for the biotech industry's large profits).

52. See Utility Examination Guidelines, 66 Fed. Reg. 1093 (Jan. 5, 2001) (refusing to consider excluding isolated genetic material from patentability). See also Julian David Forman, Case Comment, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 659 (2002) (noting that "[s]ubject matter does not seem like a particularly useful doctrinal tool for evaluating biotechnology patents").

53. See, e.g., *KSR Intern. Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007) (forbidding patenting when the claimed invention would have been obvious to a person having ordinary skill in the art); *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc); *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (recognizing significant "obviousness" hurdle for gene patents); *In re Fisher*, 421 F.3d 1365, 1373 (Fed. Cir. 2005) (stating that a patentable invention must meet a standard of substantial utility).

54. *KSR*, 550 U.S. at 398.

55. See R. Mark Halligan, *Trade Secrets v. Patents: The New Calculus*, 2 No. 6 LANDSLIDE 10, 2 (2010) (noting that *KSR* decision is illustrative of trend towards more restrictions on patents); Rubin L. McGrath et. al, *Recent Developments in Patent Law and its Impact on Patent Litigation*, 948 PRAC. L. INST./PAT. 95, 112 (2008) ("[O]bviousness standards that have been distilled from *KSR* appear to have given patent challengers a diverse arsenal from which to attack patents."). See generally Janice M. Mueller, *Chemicals, Combinations, and "Common Sense": How the Supreme Court's *KSR* Decision is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases*, 35 N. KY. L. REV. 281, 281 (2008) (examining *KSR*'s substantial impact on an already complicated § 103 nonobviousness analysis).

56. 561 F.3d 1351 (Fed. Cir. 2009).

57. See *id.* (affirming USPTO Board's conclusion that claimed genus of isolated nucleic acid molecules encoding Natural Killer Cell Activation Inducing Ligand (NAIL) protein would have been obvious in view of prior art teachings of the NAIL protein and a detailed methodology for cloning genes, with motivation to isolate the claimed NAIL cDNA arising from the importance of NAIL's role in human immune response).

Moreover, the Federal Circuit's recent *en banc* decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*,⁵⁸ confirmed that satisfying the written description of the invention requirement under § 112, ¶ 1 is particularly onerous for biotechnological genus claims where few species have been actually reduced to practice. This results regardless of whether a person having ordinary skill in the art (the "PHOSITA") would have been *enabled* to make and use the entirety of the genus.⁵⁹ *Ariad* also enshrined as *en banc* law that the written description requirement applies to all claims, including originally-filed claims, and not merely those added or amended after filing,⁶⁰ contrary to earlier understandings of the requirement as limited to priority policing.⁶¹

The utility requirement of § 101 is yet another qualitative hurdle to patenting gene-based inventions.⁶² The Federal Circuit held in *In re Fisher*⁶³ that a claimed genetic sequence, part of a larger underlying gene for which no overall structure or function had been established as of the patent's filing date, did not satisfy the utility requirement of § 101.⁶⁴

The cumulative impact of decisions such as *KSR*, *Kubin*, *Ariad*, and *Fisher* means that gene patents are increasingly difficult to obtain.⁶⁵ Those patents already in force may now be at heightened risk of invalidation under

58. 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*).

59. *Id.* at 1345 (stating that "a separate requirement to describe one's invention is basic to patent law The specification must . . . describe how to make and use the invention (i.e., enable it), but that is a different task").

60. *Id.* at 1351 (stating that "[n]either the statute nor legal precedent limits the written description requirement to cases of priority or distinguishes between original and amended claims").

61. *Cf. Id.* at 1350 (disagreeing with *Ariad* Pharmaceutical's contention that court's decision in *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), "constituted a change in the law, imposing new requirements on biotechnology inventions"). See also Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 615 (1998) (asserting that "[t]he [*Regents v. Eli*] Lilly decision may profoundly limit the scope of protection available for new gene inventions . . . [and] represents the latest advance in an ominous trend towards imposition of uniquely heightened patentability requirements for biotechnological inventions.").

62. 35 U.S.C. § 101 (2006). See also Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (noting that § 101 requires patent application to disclose the invention's utility); *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) ("[A]n application must disclose a use which is not so vague as to be meaningless.").

63. 421 F.3d 1365 (Fed. Cir. 2005).

64. See *id.* at 1373, 1379.

65. See *KSR Intern. Co. v. Teleflex, Inc.*, 550 U.S. 398, 427 (2007); *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1358 (Fed. Cir. 2010) (*en banc*); *In re Kubin*, 561 F.3d 1351, 1360–61 (Fed. Cir. 2009); *Fisher*, 421 F.3d at 1379.

these new rules.⁶⁶ The inherent ambiguity of § 101's broadly-phrased categories of patent-eligible subject matter need not be invoked when qualitative doctrines such as nonobviousness, utility, and the disclosure requirements have been much further developed and more finely tuned to deal with gene-based inventions.⁶⁷

II. PROVIDING ENHANCED PATIENT ACCESS TO GENETIC DIAGNOSTIC TESTING WITHOUT ELIMINATING PATENT RIGHTS

Public concern should be redirected from the granting of gene patents themselves, which will likely continue despite Judge Sweet's decision, to greater focus on the restrictive licensing practices applied to some of these patents. *Myriad* illustrates such practices.⁶⁸

Defendant Myriad is the sole U.S. source of full *BRAC* testing,⁶⁹ for which the company reportedly charges about \$3,200.⁷⁰ Myriad, a for-profit corporation, derives 80% of its revenues from its proprietary BRACAnalysis® testing, which it characterizes as “the standard of care in identification of individuals with hereditary breast and ovarian cancer.”⁷¹ Not all insurance plans are accepted.⁷² Importantly, there is no place for a patient to get a second opinion on the genetic testing; no sharing of samples

66. See *KSR*, 550 U.S. at 406 (forbidding patenting when the claimed invention would have been obvious to a person having ordinary skill in the art); *Ariad*, 598 F.3d at 1350 (requiring adequate written description); *Kubin*, 561 F.3d at 1360 (recognizing significant “obviousness” hurdle for gene patents); *Fisher*, 421 F.3d at 1373 (stating that claimed genetic sequences must provide specific, immediate, “real world” benefits).

67. Kristen Osenga, *Ants, Elephant Guns, and Statutory Subject Matter*, 39 ARIZ. ST. L.J. 1087, 1091–92 (2007) (noting that nonobviousness, utility, and adequate description are more practical avenues than § 101 for analyzing patentability of software-related inventions).

68. See *Ass'n for Molecular Pathology v. Myriad*, 702 F. Supp. 2d. 181, 185 (S.D.N.Y. 2010) (providing example of restrictive licensing of BRCA1/2 gene testing technology).

69. See *id.* at 189 (stating that “Myriad is . . . the current exclusive licensee of the patents-in-suit [and] is the sole provider of full sequencing of BRCA1 and BRCA2 genes in the United States on a commercial basis”) (citing Myriad Answer ¶ 28).

70. *Sixty Minutes: Patented Genes* (CBS television broadcast, Apr. 4, 2010), http://www.cbs.com/primetime/60_minutes/video/?pid=DzbFbHN8QAJrs44sVo6h4pHFfblUQfpD.

71. Marketed Products, MYRIAD GENETICS, INC. (2009), <http://www.myriad.com/products/> (describing BRACAnalysis®).

72. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d. at 204 (stating that “[c]urrently, 90% of the tests Myriad performs are covered by insurance at over 90% of the test cost”) (citing Critchfield Decl. ¶¶ 32, 33, 52, 53). See also Complaint at 10, *Ass'n for Molecular Pathology v. Myriad*, 2009 WL 1343027, May 12, 2009 [hereinafter Complaint] (asserting at paragraph 21 that Myriad will not accept insurance coverage from MassHealth, “a Medicaid insurance program for low-income people”).

is permitted to ensure quality of testing.⁷³ Women with the *BRCA1/2* mutation may be making life-altering decisions about whether to have prophylactic mastectomies or hysterectomies without the back stop of a second test run by an entity other than Myriad.⁷⁴ This state of affairs, as alleged in the ACLU's complaint, is simply not acceptable.⁷⁵ However, placing all the blame on the granting of gene patents is not acceptable, either.

Although District Judge Sweet has ruled (and many have argued) that the U.S. government should completely prohibit the patenting of isolated genes,⁷⁶ there are compelling reasons to reject this extreme approach.⁷⁷ Rather than prohibit gene patenting, an alternative strategy aimed at the problem of patient access to patented genetic testing resources would place carefully drawn limits on a patentee's ability to enforce its exclusivity in certain circumstances.⁷⁸ This alternative strategy would involve either an outright exemption from liability for patent infringement, or at least some form of mandatory nonexclusive licensing with remuneration to the patentee.⁷⁹

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

73. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d. at 207 (citations to declarations omitted) (stating that “[p]laintiffs contend that as a result of the patents-in-suit, *BRCA1/2* genetic testing is one of the very few tests performed as part of breast cancer care and prevention for which a doctor or patient cannot get a second confirmatory test done through another laboratory. . . . In particular, women who receive a positive result cannot confirm the lab's findings or *Seek* a second opinion on the interpretation of those results”); Complaint, *supra* note 72, at 27 (asserting at paragraph 90 that “[b]ecause of its patents on the *BRCA* genes, Myriad has the power to bar patients from obtaining testing other than through its laboratory. There are women . . . who have obtained full sequencing from Myriad, who cannot obtain a second opinion on their *BRCA* testing and are compelled to make major medical decisions based on a test that they cannot confirm.”).

74. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d. at 207; Complaint, *supra* note 72, at 27.

75. See Complaint, *supra* note 72, at 27 (asserting that women are forced into making major medical decisions without being able to seek a second opinion).

76. See *Ass'n for Molecular Pathology*, 702 F. Supp. 2d. at 237 (concluding that “the patents issued by the USPTO are directed to a law of nature and were therefore improperly granted”). See also Allen K. Yu, *Why it Might be Time to Eliminate Genomic Patents, Together With the Natural Extracts Doctrine Supporting Such Patents*, 47 *IDEA* 659, 666–73 (2007) (examining the multiple arguments against the patenting of isolated genes).

77. See *supra* Part I.

78. See *supra* Part II.

79. See *supra* Part II.

“fair use” doctrine for patent law.⁸⁰ Most other countries around the world (including most industrialized countries and the world’s leading patent systems—Germany, Japan, and the U.K.) have long included a research use exemption in their domestic patent laws.⁸¹ These patent systems have not fallen apart because of the exemption, nor has innovation in these countries stopped.⁸²

A standard objection to any proposed type of liability exemption is that it would lessen the economic value of patents by reducing their exclusionary power.⁸³ This in turn would reduce the incentives to invent that patent protection offers.⁸⁴ The economic objection should not lightly be brushed aside. Any proposal to alter the patent law liability framework has to be carefully thought out and narrowly defined.⁸⁵ Vested property rights and expectations are at stake.⁸⁶ So as not to unduly disrupt those reliance

80. See, e.g., Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Non-Profit Research and Development*, 56 BAYLOR L. REV. 917 (2004); Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81 (2004).

81. For example, Germany’s patent law provides that “[t]he effects of a patent shall not extend to . . . acts done for experimental purposes relating to the subject matter of the patented invention.” German Patent Act § 11.2 (1980), amended by the Laws of July 16 and August 6, 1998, available at http://www.wipo.int/clea/docs_new/en/de/de081en.html. Japan’s statutes provide that “[t]he effects of a patent right shall not extend to the working of the patent right for the purposes of experiment or research.” Japan Patent Law § 69(1), Law No. 121 of 1959, amended by Law No. 220 of 1999, available at http://www.wipo.int/clea/docs_new/en/jp/jp036en.html. The United Kingdom (U.K.) patent law provides that “[a]n act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if—(a) it is done privately and for purposes which are not commercial; [or] (b) it is done for experimental purposes relating to the subject-matter of the invention.” Patents Act, c. 37, § 60(5) (1977) (Eng.), available at http://www.wipo.int/clea/docs_new/en/gb/gb001en.html.

82. See Kimberly M. Thomas, *Protecting Academic and Non-Profit Research: Creating a Compulsory Licensing Provision in Wake of an Absent Experimental Use Exception*, 7 LOY. L. & TECH. ANN. 97, 108, 111–16 (2007) (observing the patent systems of foreign countries that employ statutory exemptions).

83. See, e.g., Alan Devlin, *Restricting Experimental Use*, 32 HARV. J.L. & PUB. POL’Y 599, 631–32 (Spring 2009); Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2180 (1991).

84. See Karp, *supra* note 83 (“[A] broad experimental use exception, by discouraging inventors from relying on the patent system, would . . . reduce innovative activity in those industries that rely on patent protection.”).

85. Mueller, *supra* note 80, at 919.

86. Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 284 (2008).

interests, legislators should consider implementing any liability exemption (or compulsory licensing scheme) in a prospective-only manner.⁸⁷ Although a prospective implementation would not necessarily address the immediate problem of access to the patented *BRCA1/2* genes, a prospective change in the law would be consistent with the Supreme Court's caution against unfairly discounting the expectations of patent owners who obtained their patents under a different set of rules.⁸⁸

An Advisory Committee on Genetics, Health and Society (hereinafter "SACHGS") provides guidance to HHS Secretary Kathleen Sebelius on a "broad range of policy issues raised by the development and use of genetic technologies [including] the impact of gene patents and licensing practices on access to genetic testing."⁸⁹ The 18-person committee includes a cross-section of notable experts from public sector health departments, private sector genetics companies, health care foundations, academia (medical and legal),⁹⁰ and attorneys in private practice.⁹¹ In April 2010, the SACGHS issued its final report concerning gene patents and licensing practices and their impact on patient access to genetic tests.⁹² Committee members compiled numerous case studies (including the *Myriad* dispute), consulted with experts, and surveyed the literature on gene patenting.⁹³

87. See generally Joseph A. Yosick, *Compulsory Patent Licensing for Efficient Use of Inventions*, 2001 U. ILL. L. REV. 1275, 1301 (2001) (recognizing the importance of advance notice in the context of compulsory licensing).

88. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 739 (2002) (stating that fundamental alterations in rules risk the legitimate expectations inventors hold in their property); *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 n.6 (1997) (stating that changing the rules would "subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision"); *id.* at 41 (Ginsburg, J., concurring) (warning that a new presumption might "unfairly discount the expectations of a patentee who had no notice at the time of patent prosecution that such a presumption would apply").

89. SACGHS Report, *supra* note 9.

90. Leading patent law scholar Professor Rochelle Dreyfuss of NYU Law is a SACGHS member. *Id.* at i.

91. *Id.* at ii.

92. See SACGHS Report, *supra* note 9. An earlier draft was published in February 2010. See SECRETARY'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOCIETY, U.S. DEP'T OF HEALTH & HUM. SERVS., REVISED DRAFT REPORT ON GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS (Feb. 5, 2010), available at <http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Patents%20Report%20Approved%202-5-2010.pdf>.

93. See SACGHS Report, *supra* note 9 (stating the Committee's report is "based on evidence gathered through a literature review and original case studies of genetic testing for 10 clinical conditions as well as consultations with experts and a consideration of public perspectives"). The

The SACGHS report makes a number of important recommendations, but notably does *not* recommend that gene patents be eliminated.⁹⁴ Rather, the Committee recommends that the U.S. patent statutes be amended to create certain limited exemptions from liability for infringing gene patent claims.⁹⁵ The proposed exemptions would apply in two situations: (1) making, using, or selling a test developed under a gene patent for “patient-care purposes”;⁹⁶ and (2) using patented genes in the pursuit of research.⁹⁷ The Committee believes its recommendation for statutory exemption from liability is “the most expeditious and straightforward way of addressing the identified problems and promoting patient access to emerging genetic advances.”⁹⁸

The SACGHS report describes the Committee’s first proposed liability exemption, which would apply when patented genetic tests are offered for “patient-care” (i.e., diagnostic) purposes, as a “narrowly tailored” activity.⁹⁹ In contrast, “therapeutic uses” of patented genes (e.g., gene transfer to treat a genetic disease or disorder) would not be exempted or shielded.¹⁰⁰

case studies were prepared by the Duke University Center for Genome Ethics, Law & Policy. *Id.* at A-1–51.

94. *See id.* at 97–100 (detailing Recommendations 1–6); *id.* at 11 (explaining that report does not explore questions about the legitimacy of granting patents on human genes or the morality of doing so . . .”). While not calling for any broad elimination of gene patents, the Committee does, however,

urge[] the Secretary to use current authority to discourage the seeking, the granting, and the invoking of any patents on simple associations between a genotype and a phenotype,” because such association patent claims “threaten the availability of existing genetic tests and are an anticipated barrier to the development of testing innovations, such as microarrays and whole-genome sequencing.

Id. at 97.

95. *Id.* (“Recommendation 1: Support the Creation of Exemptions from Infringement Liability”).

96. *Id.* (proposing in Recommendation 1(A) “[t]he creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient-care purposes.”).

97. *Id.* (proposing in Recommendation 1(B) “[t]he creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research.”).

98. *Id.*

99. *Id.*

100. *Id.* (“This narrowly tailored exemption [allowing service providers to offer gene-based diagnostic testing for patient-care purposes] permits the holders of patents on genes to continue to enforce their exclusive rights to therapeutic uses of the claimed molecules, thereby preserving the incentive such patents create for the development of therapeutics. Moreover, by preserving the right to patent genes and enforce those patents for therapeutic applications, this exemption maintains the strong incentive patents create for privately funded basic genetic research, which is often ultimately driven by the hope of developing a therapeutic.”).

However, the protected (i.e., non-infringing) activity would include making, using, selling, or offering for sale, a test developed under a gene patent.¹⁰¹

This first proposed recommendation appears to contemplate complete exemption from liability, meaning that there would be no act of infringement and no remuneration due to the patentee, analogous to the operation of fair use in copyright law.¹⁰² The proposed liability exemption would apply to both non-commercial and commercial laboratories.¹⁰³ The 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.¹⁰⁴

It is difficult to know, *ex ante*, whether the Committee's prediction is correct. If commercial genetic testing laboratories are earning profits through the sale of testing services that involve making and/or using patented genes, I contend that some reasonable royalty based on those profit-generating sales ought to flow back to the patentee. The royalty must be set *ex ante* at a reasonable level so as to protect patients from excessively high pricing by the laboratories.

One way to structure this remuneration would be to implement a mandatory licensing scheme for gene patents.¹⁰⁵ The notion of mandatory, government-compelled, or "compulsory" licensing of patents has long been anathema in the U.S., but many other industrialized countries (not only developing countries such as India, Thailand, and Brazil) include compulsory licensing provisions in their domestic patent statutes.¹⁰⁶ The

101. *Id.*

102. See 17 U.S.C. § 107 (2006) (stating that "the fair use of a copyrighted work . . . is not an infringement of copyright"); SACGHS Report, *supra* note 9, at 97 (proposing "an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research").

103. SACGHS Report, *supra* note 9, at 97.

104. *Id.* (stating that "[t]his narrowly tailored exemption [allowing service providers to offer gene-based diagnostic testing for patient-care purposes] permits the holders of patents on genes to continue to enforce their exclusive rights to therapeutic uses of the claimed molecules, thereby preserving the incentive such patents create for the development of therapeutics. Moreover, by preserving the right to patent genes and enforce those patents for therapeutic applications, this exemption maintains the strong incentive patents create for privately funded basic genetic research, which is often ultimately driven by the hope of developing a therapeutic")

105. See Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403, 412 (2005).

106. See, e.g., German Patent Law Act §§ 81–85 (1980), amended by the laws of July 16 and August 6, 1998 (providing for compulsory license proceedings), available at http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=1035 (last visited Aug. 10, 2010). See also

Paris Convention and the TRIPS Agreement permit this.¹⁰⁷ In practice, compulsory licensing provisions are very rarely invoked.¹⁰⁸ Rather, voluntary negotiation over patent licenses proceeds in the shadow of the statutory compulsory licensing provisions.¹⁰⁹ The threat of compulsory licensing encourages patentees to license more widely and on more reasonable terms.¹¹⁰ This type of implicit motivation might go far to solve the problem of restrictive licensing practices by some U.S. gene patent holders.

To the rare extent that compulsory patent licensing provisions *are* actually invoked by applicants for a license, the involvement of government bureaucracy is triggered to determine whether to grant a license, and if so, what its terms should be. The machinery of compulsory licensing disadvantageously displaces bargaining from the marketplace, creates potential delays, requires that the patentee be given due process rights to challenge the government's compulsory licensing decision and terms, and so on.

Another alternative (really just a variant of compulsory licensing) is called a "license of right" scheme.¹¹¹ Certain categories of patents, to be

Yosick, *supra* note 87, at 1277, 1284 (discussing the U.S.'s hostility towards compulsory licensing).

107. See, e.g., German Patent Law Act §§ 81–85 (1980), amended by the laws of July 16 and August 6, 1998 (providing for compulsory license proceedings), available at http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=1035 (last visited Aug. 10, 2010). See also Yosick, *supra* note 87, at 1277, 1284 (discussing the U.S.'s hostility towards compulsory licensing).

108. Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) (noting that "[c]ompulsory licensing is a rarity in our patent system"); Samuel Mark Borowski, *Saving Tomorrow from Today: Preserving Innovation in the Face of Compulsory Licensing*, 36 FLA. ST. U. L. REV. 275, 282 (Winter 2009).

109. See Borowski, *supra* note 108, at 300 n.187 (noting that the value of compulsory licenses is "the inducement of the patentee to agree to reasonable terms").

110. *Id.*; Gregory C. Shaffer & Mark A. Pollack, *Hard vs. Soft Law: Alternatives, Complements, and Antagonists in International Governance*, 94 MINN. L. REV. 706, 781 (2010) (noting the success of South Africa and Brazil in reducing prices charged by pharmaceutical companies on drugs under patent by using the threat of compulsory licensing); Kimberly M. Thomas, *Protecting Academic and Non-Profit Research: Creating a Compulsory Licensing Provision in Wake of an Absent Experimental Use Exception*, 7 LOY. L. & TECH. ANN. 97, 108 (2007) (discussing instances where inventors threatened with compulsory licensing have come to agreements with patent holders to avoid litigation).

111. For example, India's patent laws formerly incorporated a "license of right" for all process patents pertaining to substances capable of being used as medicines or foods. See The Patents Act, No. 39 of 1970, INDIA CODE § 87 (1970) (titled "Certain patents deemed to be endorsed with the words 'Licenses of right,'"), available at <http://indiacode.nic.in>. The United Kingdom's patent laws currently provide that a patent owner may apply to register its patents as available for

determined by the legislature (such as gene patents), would automatically be made available for licensing to all comers for a pre-set statutory royalty rate (that is, some percentage or per-unit amount of the sales made by for-profit testing facilities that provide genetic testing using a patented gene).¹¹² The concept is not very different from the mechanical license in copyright law, which the U.S. has recognized for years to benefit musical work copyright holders.¹¹³ Postponing the implementation of a license of right scheme until a few years of exclusivity have elapsed, rather than immediately after a gene patent issues, would enhance patentee incentives and be consistent with Paris Convention principles.¹¹⁴

Lastly, courts can act to facilitate patient access to patented genetic testing materials even if Congress chooses not to. In the post-*eBay* landscape we now inhabit,¹¹⁵ mandated licensing for a limited category of uses of patented genes should no longer shock or inflame the patent-owning community. Although it seemed virtually impossible ten years ago, U.S. courts in 2010 are denying permanent injunctions against adjudicated infringers and permitting them to continue infringing uses, manufacturing, and sales, in exchange for payment of “ongoing royalties.”¹¹⁶ If courts can

licensing as of right. See Patents Act, §§ 46–47 (1977) (as consolidated 2010) (Eng.), available at http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=1623.

112. See Henrik Holzapfel & Joshua D. Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, 48 IDEA 123, 167 n.187 (2008) (discussing statutory licenses where statutes set notification procedures and royalties).

113. See 17 U.S.C. § 115 (2006) (titled “Scope of exclusive rights in nondramatic musical works: Compulsory license for making and distributing phonorecords”). See also 2 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 8.04[A] (Matthew Bender, Rev. Ed., 2010) (describing the historical basis of the mechanical compulsory license of nondramatic musical works in the 1909 Copyright Act).

114. See Paris Convention for the Protection of Industrial Property art. 5.A.(4), opened for signature Mar. 20, 1883, as amended Sept. 28, 1979, available at http://www.wipo.int/export/sites/www/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf (providing that “[a] compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons”).

115. See *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 394 (2006) (holding that a permanent injunction is not to be automatically awarded in every case in which a patent is found infringed and its validity sustained; a district court’s decision to impose or deny permanent injunction in a patent case should be made only after consideration of traditional equitable principles generally applicable to all types of cases).

116. See *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1315 (Fed. Cir. 2007) (accepting in principle the district court’s award of “ongoing royalty” of \$25 per infringing vehicle that Toyota would sell during remaining life of Paice LLC’s patent on certain hybrid drive train technology, but remanding case to district court for an explanation of how it had arrived at the \$25/car ongoing

fashion such remedies in cases of infringed patents covering, e.g., automotive technology,¹¹⁷ then it is all the more appropriate that they consider doing so in cases involving public health and welfare. The message of *eBay* is that patent rights, like other types of property rights, can no longer be understood to convey an absolute right to exclude others.

royalty); *id.* at 1314 (observing that awarding an ongoing royalty in lieu of an injunction may be appropriate under some circumstances, including patent infringement).

117. *See id.* at 1315.