

Lessons from the European Union: The Need for a Post-Grant Mechanism for Third-Party Challenge to U.S. Patents

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I. INTRODUCTION

Over the past year and a half the European Patent Office (EPO) has revoked or significantly narrowed claims contained within four patents issued to an American biotechnology company. The patents at issue claim mutations in BRCA1 and BRCA2 genes associated with breast and ovarian cancer, methods for utilizing those mutations in diagnosis, and specific diagnostic kits.¹ The patents were originally granted to Myriad Genetics, Inc., a corporation located in Salt Lake City, Utah. Full shares in the existing BRCA1 and BRCA2 patents were sold and reassigned to the University of Utah Research Foundation in November 2004.² While Myriad Genetics no

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1. The patents are Method for Diagnosing a Predisposition for Breast and Ovarian Cancer, Eur. Patent No. EP0699754 (filed Nov. 8, 1995) (issued Jan. 10, 2001); 17q-Linked Breast and Ovarian Cancer Susceptibility Gene, Eur. Patent No. EP0705902 (filed Nov. 8, 1995) (issued Nov. 28, 2001); Mutations in the 17q-Linked Breast and Ovarian Cancer Susceptibility Gene, Eur. Patent No. EP0705903 (filed Nov. 8, 1995) (issued May 23, 2001); and Chromosome 13-linked Cancer Susceptibility Gene BRCA2, Eur. Patent No. EP0785216 (filed Dec. 17, 1996) (issued Jan. 8, 2003). The most recent opposition determination was handed down by the EPO on June 29, 2005. See Press Release, European Patent Office, Patent on “Breast Cancer Gene 2” Patent Maintained in Amended Form After Public Hearing (June 29, 2005) [hereinafter Patent on Breast Cancer Gene 2], http://www.european-patent-office.org/news/pressrel/2005_06_29_e.htm.

2. See Press Release, Institut Curie, Assistance Publique-Hôpitaux de Paris & Institut Gustave-Roussy, Another Victory for Opponents of Patents Held by Myriad Genetics: European Patent Office Rejects the Essential Points of BRCA1 Gene Patents (Jan. 31, 2005) [hereinafter Another Victory],

longer owns the patents, the corporation has retained exclusive licensing rights.³ Various hospitals, research laboratories, researchers, scientists, physicians, patient organizations, and humanitarian nonprofit organizations across Europe mounted challenges to the patents through a legal opposition procedure set out in European patent law.⁴ Opponents argued that these four patents violated numerous patentability requirements of the EPO and interfered with public health and research activities in a manner explicitly prohibited by multilateral European treaties and patent law.⁵

These recent legal decisions in Europe have serious implications for the United States because Myriad Genetics and hundreds or even thousands of other patent holders have laid claim to large tracts of human genetic material by securing U.S. patents. As a policy, both the U.S. and European patent offices routinely grant patents that claim human genetic material, although it is still openly debated whether genetic material is even patentable subject matter under existing patent law.⁶ In addition to legal arguments that genetic material is not patentable, many also argue that as a policy matter genetic material should not be patentable because of the detrimental effect on health care and research.⁷ Due to this increasing uncertainty and unrest regarding the validity of patents covering genetic material, it is imperative that the

<http://www.curie.fr/upload/presse/myriadpatents310105.pdf>. The patent EP0699754 was granted to both Myriad Genetics, Inc. and the U.S. Department of Health & Human Services. The University of Utah Research Foundation and the U.S. Department of Health & Human Services filed a joint notice of appeal with the EPO against the May 2004 decision to revoke that patent in its entirety. *Id.*

3. *See id.*

4. *See* Press Release, Institut Curie, European-Wide Opposition Against the Breast Cancer Patents (Sept. 26, 2002), http://www.curie.fr/upload/presse/europeanoppmyriad_sept02_gb.pdf.

5. *See* Press Release, Institut Curie, Against Myriad Genetics' Monopoly on Tests for Predisposition to Breast and Ovarian Cancer, the Institute Curie Is Initiating an Opposition Procedure with the European Patent Office (Sept. 12, 2001), http://www.curie.fr/upload/presse/myriadopposition6sept01_gb.pdf.

6. *See* Jordan Paradise, *European Opposition to Exclusive Control over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 133-34 (2004); *see also* Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 370 (2002).

7. *Id.* at 147-50.

United States develop an opposition procedure that gives third parties the ability to mount substantive challenges to claims contained within issued patents. Not only would such an opposition procedure necessarily expand society's role in promoting innovative scientific advancements, it would also strengthen the patent system by submitting patents to review and potentially eliminating patents that do not measure up to federal patent law. Additionally, an opposition procedure would serve as a check on individual patent examiner decisions and cut down on expensive civil litigation by providing an alternative forum for would-be patent infringers. This Article will focus on the recent legal developments in Europe and suggest that they serve as a wake-up call for the creation of a similar procedure of post-grant review in the United States. While I will address the need for an opposition procedure in the United States through the lens of certain patents claiming genetic sequence information, this system of legal challenge would apply across all subject matters and fields of technology.

II. CONTROVERSY OVER PATENTS CLAIMING MUTATIONS IN BRCA1 & BRCA2

A. EUROPEAN PATENT LAW

The authority and substantive grounds for filing a legal challenge with the EPO are found in the European Patent Convention (EPC)⁸ and Directive 98/44/EC of the European Parliament and Council of the European Union (Directive).⁹ The EPC is a multilateral patent treaty among European Union member states and various other European nations. It provides for a type of legal procedure called an "opposition" that allows third parties to challenge the validity of a granted patent within nine months of the date of issuance.¹⁰ The opponent must identify specific claims within the patent that he or she believes fail to meet patentability requirements that bear on the validity of an invention.¹¹ After formal oppositions

8. Convention on the Grant of European Patents (European Patent Convention), Oct. 5 1973, 1065 U.N.T.S. 255 [hereinafter EPC], *available at* <http://www.european-patent-office.org/legal/epc/>.

9. Council Directive 98/44, On the Legal Protection of Biotechnical Inventions, 1998 O.J. (L 213) 13 (EC) [hereinafter Directive].

10. EPC, *supra* note 8, at arts. 99-123.

11. *Id.* at art. 100. An opposition may only be filed on the grounds that:
(a) the subject-matter of the European patent is not patentable within

are filed with the EPO, the Opposition Division (OD), consisting of a panel of three patent examiners, holds public hearings on the matter and renders a decision applying current law as set forth in the EPC.¹² The EPC establishes basic requirements for patentability, including that the invention is novel, involves an inventive step, is susceptible of industrial application,¹³ and sufficiently discloses the invention so that it can be carried out by a person skilled in that art.¹⁴ Significant to the recent legal challenges, it also provides that “discoveries, scientific theories and mathematical methods” are not patentable subject matter,¹⁵ “diagnostic methods” performed on the human body are not inventions for purposes of patentability,¹⁶ and, as a policy determination, inventions contrary to public morality are not patentable.¹⁷

The Directive was promulgated as a means to address legal protections specifically for biotechnological inventions. It contains the same basic patentability requirements as the EPC and provides explicit applications of the EPC to biotechnological inventions. For example, the Directive states that the simple discovery of one of the elements of the human body, which includes “the sequence or partial sequence of a gene,” does not qualify for patent protection;¹⁸ however, it may be patentable if the sequence is isolated from the human body or produced by means of a technical process and is adequately disclosed.¹⁹ The Directive also reiterates the morality provision

the terms of Articles 52 to 57; (b) the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art; (c) the subject-matter of the European patent extends beyond the content of the application as filed, or, if the patent was granted on a divisional application or on a new application filed in accordance with Article 61, beyond the content of the earlier application as filed.

Id.

12. *Id.* at arts. 101-02.

13. *Id.* at art. 52(1) & 56. As a comparison, this industrial application requirement is parallel to the U.S. utility requirement and inventive step is parallel to the U.S. nonobviousness requirement. See U.S.C. §§ 101, 103 (2000).

14. EPC, *supra* note 8, at art. 83.

15. *Id.* at art. 52(2(a)).

16. *Id.* at art. 52(4).

17. *Id.* at art. 53(a).

18. Directive, *supra* note 9, at art. 5(1).

19. *Id.* at art. 5(2).

contained within the EPC.²⁰

1. Opposition History

The opposition to the first of the four patents issued by the EPO, EP0699754, was filed September 6, 2001, by the French Institut Curie, a cancer research center and hospital, and was widely supported by the public, including the French Ministers for Research and Health²¹ and the European Parliament.²² In early October 2001, the Assistance Publique-Hôpitaux de Paris, a publicly-owned hospital, and the Institut Gustave-Roussy, a nonprofit, private cancer treatment center, filed a formal statement of opposition with the EPO.²³ An opposition was also filed at this time by the Belgian Human Genetics Society, Belgian and Dutch human genetics centers, and German, Dutch, and British genetics societies.²⁴ On February 22, 2002, the Institut Curie, the Assistance Publique-Hôpitaux de Paris, and the Institut Gustave-Roussy filed a joint opposition to EP0705903.²⁵ The Belgian Ministries of Health, Social Affairs, and Scientific Research, the Dutch Ministry of Health, the German league against cancer, and Greenpeace Germany also filed statements of opposition at that time.²⁶

Joint statements of opposition to patent EP0705902 were formally filed on August 27, 2002, by the Institut Curie, the Assistance Publique-Hôpitaux de Paris, and the Institut Gustave-Roussy. At the same time, a joint opposition was filed by the Belgian Society of Human Genetics, the Belgian and Dutch human genetic centers, German, Dutch, Czech, Austrian, Swiss, British, and Finnish genetics societies, the Greek National Center for Scientific Research, the Swiss Institute for Applied Cancer Research, and patient associations in the Netherlands and Belgium.²⁷ The Swiss Social Democrat

20. *Id.* at art. 6(1).

21. See Press Release, Institut Curie, The Key Dates (Sept. 26, 2002) [hereinafter The Key Dates], <http://www.curie.fr/upload/presse/keydates.pdf>.

22. See *id.*

23. See *id.*

24. See *id.*

25. See *id.*

26. See *id.*

27. See The Key Dates, *supra* note 21; see also Press Release, Institut Curie, European-Wide Opposition Against the Breast Cancer Patents (Sept. 26, 2002), http://www.curie.fr/upload/presse/europeanoppmyriad_sept02_gb.pdf.

Party, Greenpeace Germany, the Dutch and Austrian Health Ministers, and an individual German doctor also filed notices of opposition to EP0705902.²⁸ Opponents to the fourth patent, EP0785216, included the Institut Curie, the Assistance Publique-Hôpitaux de Paris, the Institut Gustave-Roussy, the Belgian Society of Human Genetics, and sixteen additional organizations across Europe, most of which had also opposed the previous patents.²⁹

2. Opposition Decisions

Following three separate opposition proceedings, one of the patents, EP0699754, has been revoked in its entirety,³⁰ and three, EP0705902, EP0705903, and EP0785216, have been significantly limited in their scope through amendments and revocation of individual claims.³¹ The latest opposition procedures resulted in an amendment limiting EP0785216 to a single claim.³² To date, appeals have been filed for three of the four decisions.³³

a. EP0699754

The first BRCA1 patent, EP0699754, was revoked in its entirety by the OD after two days of opposition procedures in Munich, Germany on May 17 and 18, 2004.³⁴ The OD cited a number of grounds for the revocation, including improper extension of subject matter by amendment of claims,³⁵ lack of

28. See The Key Dates, *supra* note 21.

29. See European Patent Office, Oral Proceedings Before the Opposition Division, Application No. 96 309 211.9, Facts and Submissions, Sept. 12, 2005.

30. See Press Release, Institut Curie, Assistance Publique-Hôpitaux de Paris & Institut Gustave-Roussy, The European Patent Office Has Revoked the Myriad Genetics Patent (May 21, 2004), http://www.curie.fr/upload/presse/190504_gb/pdf.

31. See Another Victory, *supra* note 2.

32. See Press Release, Institut Curie, Assistance Publique-Hôpitaux de Paris & Institut Gustave-Roussy, L'Office Européen maintient le brevet sur le gène BRCA2 réduit à une mutation particulière et sans effet bloquant sur l'activité des laboratoires européens (July 6, 2005), <http://www.curie.fr/upload/presse/brca2-myriad-6-juil-05.pdf>.

33. See EPC, *supra* note 8, at arts. 106-12. These sections provide parties with the right to appeal a decision of the Opposition Division within two months of notification of the decision.

34. See Another Victory, *supra* note 2.

35. See EPC, *supra* note 8, at art. 123(2).

clarity and conciseness,³⁶ insufficient disclosure,³⁷ and lack of inventive step.³⁸

b. EP0705902 & EP0705903

Between January 19 and 26, 2005, the OD heard the opposition to both patents relating to materials and diagnostic methods used to isolate and detect mutations in the human breast and ovarian cancer predisposing gene BRCA1.³⁹ EP0705902 claimed the isolated BRCA1 gene, the corresponding protein, and the use of the BRCA1 gene for therapeutic applications.⁴⁰ The OD determined that the patent holder improperly extended the subject matter by amendment of claims after issuance of the patent.⁴¹ As a result, claims toward diagnostic methods, involving claims to the isolated BRCA1 gene as a chemical molecule, claims to the corresponding protein, claims to conceivable therapeutic applications in gene therapy, drug screening, and transgenic animals, and claims to diagnostic kits were held invalid.⁴² Claims specifically drawn to the nucleic acid probe and to vectors containing BRCA1 sequences were upheld.⁴³

EP0705903 claimed a total of thirty-four mutations in the BRCA1 gene, each with the ability to be used to test for a predisposition to breast and/or ovarian cancer.⁴⁴ The OD determined that there was improper extension of subject matter by amendment of claims⁴⁵ and a lack of clarity and conciseness.⁴⁶ After deliberation, the OD decided that the priority dates applicable to the claimed sequences resulted in considerable restriction of the patent's scope and permitted only a single claim to the 185delAG mutation to remain.⁴⁷ The EP0705903 patent now covers only a 15-30 nucleotide probe

36. *See id.* at art. 84.

37. *See id.* at art. 83.

38. *See id.* at art. 56.

39. *See Another Victory, supra* note 2.

40. *See id.*

41. *See EPC, supra* note 8, at art. 123(2).

42. *See Another Victory, supra* note 2.

43. *See id.*

44. *See id.*

45. *EPC, supra* note 8, at art. 123(2).

46. *See id.* at art. 84.

47. *See Another Victory, supra* note 2.

framing the 185delAG mutation.⁴⁸

c. EP0785216

On June 29, 2005, the OD determined that the amendment of claims contained within EP0785216 by the patent holder met the requirements of the EPC.⁴⁹ However, as a result of the opposition proceedings, this patent was amended to contain a single claim over a nucleic acid sequence asserting a mutation of the BRCA2 gene associated with a predisposition to breast cancer for *in vitro* diagnosis of Ashkenazi Jewish women.⁵⁰ This amended claim has subsequently raised criticism from both the Ashkenazi Jewish community and the European Society of Human Genetics for specifically singling out an entire racial, ethnic, or familial group within a patent claim.⁵¹

III. STATUS OF POST-GRANT OPPOSITION IN THE UNITED STATES

In contrast to patent law in European nations, U.S. patent law does not provide a post-grant mechanism for third parties to challenge patents issued by the United States Patent and Trademark Office (USPTO), aside from the extremely narrow reexamination process.⁵² Reexamination allows a third party to file a request for the USPTO to review an issued patent, but reexamination is limited to grounds that prior art, consisting of patents or printed publications, exists that negates the patentability of the invention.⁵³ It is not until the patent holder initiates an infringement lawsuit that questions regarding the validity of patent claims can be brought as a defense to the alleged infringement.⁵⁴ As a consequence, a significant amount of insufficient or invalid patent claims may

48. *Id.*

49. See Patent on Breast Cancer Gene 2, *supra* note 1.

50. See Another Victory, *supra* note 2.

51. Nehama Abrahami Keighley, *No Ashkenazi Gene*, NEW SCIENTIST, July 23, 2005, at 21; *Patent Singles Out Ashkenazi Jewish Women*, NEW SCIENTIST, July 9, 2005, at 7; Press Release, European Society of Human Genetics, Geneticists Oppose Singling Out Jewish Women in European Breast Cancer Patent (June 15, 2005).

52. 35 U.S.C. §§ 301-307 (2000). The Director of the USPTO on his or her own initiative may determine whether a substantial new question of patentability is raised. 35 U.S.C. § 303(a). The determination will include an order for reexamination. 35 U.S.C. § 304.

53. 35 U.S.C. § 302.

54. 35 U.S.C. § 282(2)-(3) (2000).

stand despite the fact that they do not meet federal patentability requirements because questions of validity can only be raised as an affirmative defense and because the alleged infringer would rather pay licensing fees in order to avoid drawn-out, expensive litigation.⁵⁵ The American Intellectual Property Law Association reports that these litigation costs can approach approximately \$1.5 million per party.⁵⁶

Many argue that rapid increases in patent applications over the past decade have bombarded the USPTO, resulting in less scrutiny of applications and more patents being issued that are of low quality and questionable legal status.⁵⁷ Since the middle of the 1980s, applications for utility patents at the USPTO have increased approximately 5% per year, from 100,000 per year in 1970-1984 to nearly 330,000 per year in 2001.⁵⁸ The Organization for Economic Development and Cooperation reports that the difference between grant issuance rates for equivalent filing in the United States and Europe has increased from 18% to 40% in the past 20 years,⁵⁹ meaning that the USPTO is issuing patents that would be rejected by the EPO.

A number of recent reports published by both federal government agencies and professional groups advocate increased options for post-grant review.⁶⁰ In its 2003 report, *The 21st Century Strategic Plan*, the USPTO declared that a major priority for the future is to “[m]ake patents more reliable by proposing amendments to patent laws to improve a post-

55. Bronwyn H. Hall & Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System—Design Choices and Expected Impact*, 19 BERKELEY TECH. L.J. 989, 993 (2004).

56. John H. Barton, Policy Forum, *Intellectual Property Rights: Reforming the Patent System*, SCIENCE, Mar. 17, 2000, at 1933 (citing AMERICAN INTELLECTUAL PROP. LAW ASS’N, REPORT OF ECONOMIC SURVEY 1999 tbls.21 & 22 (1999)). These costs have undoubtedly increased in the last six years.

57. *See id.* at 1934.

58. *See* Hall & Harhoff, *supra* note 55, at 995.

59. *See id.* at 998.

60. *See, e.g.*, USPTO, THE 21ST CENTURY STRATEGIC PLAN (2003), http://www.uspto.gov/web/offices/com/strat21/stratplan_03feb2003.pdf; FEDERAL TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>; NATIONAL RESEARCH COUNCIL OF THE NAT’L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY (Stephen A. Merrill, Richard C. Levin & Mark B. Myers eds., 2004).

grant review of patents.”⁶¹ The USPTO has also indicated that a post-grant procedure allowing the public to petition the USPTO to review patent claims would “expand the role of the USPTO in enhancing the integrity of the intellectual property system” and “help assure that those potentially affected by the economic burdens of patents with invalid claims can obtain prompt redress.”⁶² Likewise, the Federal Trade Commission (FTC) recommends that Congress enact such an administrative opposition process to allow for “meaningful challenges to patent validity short of federal court litigation.”⁶³ The FTC recommendation underscores the view that the current presumption of a patent’s validity is inappropriate in light of inadequate USPTO funding and insufficient review time of applications by patent examiners.⁶⁴ The National Research Council of the National Academies also advocates that Congress “should seriously consider legislation” creating an opposition procedure in the United States because the “speed, cost, and design details of this proceeding should make it an attractive alternative to litigation to determine patent validity and be fair to all parties.”⁶⁵

The lack of such a post-grant third-party challenge is problematic because it prevents the larger public from weighing in on the validity of subject matter claimed within a patent. In many respects, it is the public that has information relevant to issues of prior art, especially in the scientific literature, basic research, or prior patents, that the patent examiners at the USPTO may not have the expertise to identify or effectively review while they are assessing a patent application. Uncertainty regarding the validity of patents issued by the USPTO has a variety of negative effects, such as underinvestment in technology because of the presence of patents that may be invalid, abandonment of specific areas of research because of existing patents that may actually be invalid, increased research and health care costs because of licensing fees paid out to patent holders, and costly patent

61. USPTO, *supra* note 60, at 11.

62. USPTO, POST-GRANT REVIEW OF PATENT CLAIMS, <http://www.uspto.gov/web/offices/com/strat21/action/sr2.htm> (last modified Nov. 23, 2003).

63. FEDERAL TRADE COMM’N, *supra* note 60, at 8.

64. *Id.*

65. NATIONAL RESEARCH COUNCIL OF THE NAT’L ACADS., *supra* note 60, at 82.

litigation.

As a means to address these concerns and to remedy the lack of post-grant challenge procedures, the Patent Reform Act of 2005 (H.R. 2795) was recently introduced in the House of Representatives.⁶⁶ This bill is the follow-up to H.R. 5299, introduced in the previous congressional session.⁶⁷ Among other things, H.R. 2795 calls for the establishment of an opposition procedure allowing third parties to initiate a legal challenge to a patent issued by the USPTO within nine months of its issuance on the grounds that it does not fulfill one or more requirements set out in existing U.S. patent law.⁶⁸ The proposal would also allow the filing of an opposition request by an accused infringer within six months of receiving notification that the patent holder has filed claims for patent infringement.⁶⁹ A request for opposition would be required to identify the claims alleged to be invalid and to identify the grounds on which opposition is based for each claim, including any of the requirements for patentability provided in 35 U.S.C. sections 101, 102, 103, 112, and 251(d).⁷⁰ These are the substantive requirements of utility, novelty, nonobviousness, adequate specification of the invention, including a written description of the invention, proper enablement of the invention allowing a person skilled in the art to make and use the invention, definiteness of claims distinctly pointing out the invention, and best mode of constructing the invention as contemplated by the inventor at the time of filing.⁷¹

The introduction of H.R. 2795 has been met largely with support from lawmakers and the legal field, although some individuals caution that the reform measure is getting rushed through Congress without attention to detail.⁷² One criticism of the bill focuses on the structure of the proceedings, in which three administrative patent judges would compose the panel determining patentability as laid out in the opposition request.⁷³ The concern is that the success of such a procedure

66. H.R. REP. NO. 109-2795 (2005).

67. H.R. REP. NO. 108-5299 (2004).

68. H.R. 2795, 109th Cong. § 9 (2005).

69. *Id.*

70. *Id.*

71. See 35 U.S.C. §§ 101, 102, 103, 112, 251(d) (2000).

72. Peter Geier, *Lawmakers Seek Less Expensive Patent System*, N.Y.L.J., Aug. 18, 2005, at 5.

73. H.R. 2795 § 9.

will rely solely on the extent to which individuals and corporations will trust the administrative law judges to fairly arbitrate the patentability matters in front of them and examine the issues rather than deferring to the patent examiners.⁷⁴

IV. CONCLUSION

The recent legal challenges in Europe have intensified the focus on attempts in the United States to create a post-grant opposition procedure. In response to growing domestic and international concerns with patents involving genetic material and general concern with utility patents, it is imperative that the United States adopt an opposition procedure comparable to the patent practices of other industrialized nations. While the proposed legislation may need some adjustments, provisions for opposition procedures laid out in H.R. 2795 are long overdue and would be a welcome improvement to U.S. patent law.

74. Geier, *supra* note 72, at 6.