2010-1406

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD, ARUPA GANGULY, PHD, WENDY CHUNG, MD, PHD, HARRY OSTRER, MD, DAVID LEDBETTER, PHD, STEPHEN WARREN, PHD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, and KATHLEEN RAKER,

Plaintiffs-Appellees,

—v.—

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

—and—

MYRIAD GENETICS, INC.,

Defendant-Appellant,

—and—

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of the University of Utah Research Foundation,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
IN CASE NO. 09-CV-4515, SENIOR JUDGE ROBERT W. SWEET.

BRIEF OF *AMICI CURIAE*, INFORMATION SOCIETY PROJECT AT YALE LAW SCHOOL SCHOLARS IN SUPPORT OF PLAINTIFFS-APPELLEES

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INTEREST OF *AMICI CURIAE*[1]

Amici are scholars with the Information Society Project at Yale Law School (ISP)[2]: Wendy Seltzer, a Senior Fellow at the ISP, writes on law and technology of free expression and user innovation, including digital copyright, software patent, and information privacy. She founded and leads the Chilling Effects Clearinghouse, exploring legal threats to online expression at https://www.chillingeffects.org/; Margot Kaminski, Research Scholar in Law and Executive Director of the ISP, writes on privacy, information politics and First Amendment issues; Priscilla Smith, Senior Fellow of the ISP, Jennifer Keighley, Resident Fellow of the ISP, and Genevieve Scott, Resident Policy Fellow of the ISP, research and write on reproductive rights, with a particular focus on information policy and new technologies.

SUMMARY OF ARGUMENT

The grant of a patent is a narrowly tailored exception to our free market system, a "carefully crafted bargain" designed to strike a balance between the avoidance of monopolies that stifle competition and the need to encourage innovation. *Bonito*

[1] By Order issued April 30, 2012, this Court authorized the filings of amicus briefs in this case without consent of either party. No counsel for a party authored this brief in whole or in part, and no person or entity other than *amici* and their counsel made any monetary contribution toward the preparation or submission of this brief.
[2] The ISP is an intellectual center addressing the implications of new information technologies for law and society, guided by the values of democracy, human development, and social justice. The Fellows participate in this case in their personal capacity; titles are used only for purposes of identification.

Boats, Inc. v. Thunder Craft Boats, 489 U.S. 141, 146 (1989). Because "imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy," *Id.* at 150, the "stringent requirements for patent protection seek to ensure that ideas in the public domain remain there for the use of the public." *Id.*. This is especially true for "[p]henomena of nature, though just discovered, . . . as they are the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). In reaffirming *Gottschalk* in its recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), the Supreme Court emphasized this "concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature." *Id.* at 1301; *id.* at 1294 (unanimously invalidating patents that risked "inhibiting [the] use [of underlying natural laws] in the making of further discoveries.").

In this brief, *Amici* show that the patents here upset patent law's careful balance. First, the evidence establishes that the promise of a patent was unnecessary to incentivize research on the BRCA genes in the first place. Second, Myriad's monopoly on the information contained in Breast Cancer Susceptibility Genes 1 and 2 (hereafter "BRCA 1/2) has inhibited and continues to inhibit innovation in the field of medical research on breast cancer and other diseases by

preventing researchers from using products of nature to make further advances.[3] Specifically, the BRCA 1/2 patents limit multiplex and full genome testing, as well as research on the relationship between BRCA 1/2 and other genetic diseases. As a result of obtaining a patent on a product of nature, Myriad has a "double monopoly" on genetic testing of the BRCA genes that dissuades Myriad from engaging in additional research, charging reasonable prices, and cross-licensing technology. Accordingly, this Court should invalidate the patents at issue.

ARGUMENT

I. The Court's Recent Decision in *Mayo* Emphasizes the Importance of Maintaining the Patent System's Balance Between Incentivizing Research and Encouraging Innovation.

In its recent decision in *Mayo*, the Supreme Court struck down a process patent claim that threatened to "inhibit further discovery by improperly tying up the future use of laws of nature." 132 S. Ct. 1289, 1294. The Court cautioned against patenting claims "so abstract and sweeping as to cover both known and unknown uses" of patented subject matter (*id.* (*citing Gottschalk v. Benson*, 409 U.S. 63, 67-68 (1972)), finding that "upholding the patents would risk disproportionately tying

[3] *BRCA1* and *BRCA2* "belong to a class of genes known as tumor suppressors. Mutation of these genes has been linked to hereditary breast and ovarian cancer." National Cancer Institute Fact Sheets, *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, (Mar. 29, 2009), *http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA* .

up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." *Id.* at 1294. As the Court explained,

> … even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are the "the basic tools of scientific and technological work." (*citing Benson*, 409 U.S. at 67). And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a [patent] …forecloses more future innovation than the underlying discovery could reasonably justify.

Id. at 1301. Just as Prometheus' patents set forth laws of nature, *id.* at 1296 (the relationships between concentrations of certain metabolites in the blood and the effect or ineffect of a dosage of a drug), so too Myriad's patents are based on the recognition of existing relationships in nature, the nucleotide sequence on a strand of DNA.[4] Just as Prometheus' patents threatened "to inhibit the development of more refined treatment recommendations…that combine Prometheus' correlations with later discovered features of metabolites, human physiology, or individual patient characteristics,"[5] so too here the tradeoff that normally occurs in the patent system is undermined.[6] Myriad's patents prevent the use of natural phenomenon to conduct additional research, discover other natural relationships, and develop

[4] Stiglitz Decl. ¶ 25 (describing patented information as "the very instructions inside each of our cells that determine what proteins are produced.").
[5] *Mayo*, 132 S. Ct. at 1302 ("[t]he presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible").
[6] Stiglitz Decl. at. ¶¶ 10, 12, 25.

innovations in disease treatments that could save lives. As in *Mayo*, Myriad's patents create an "acute danger" because they do not confine their reach, resulting in extreme limits on invention and research. *Id.* at 1301-1302. As in *Mayo*, Myriad's patents foreclose more future innovation than Myriad's underlying discovery can "reasonably justify." *See id.*

II. Myriad's Patents Were Unnecessary To Incentivize the Identification of the BRCA 1/2 Genes.

In its report entitled *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (hereinafter "SACGHS report"), the Secretary's Advisory Committee on Genetics, Health and Society concluded that patents are not necessary to ensure that genetic tests come to market,[7] finding significant evidence that most gene discoveries are in fact not patent-driven.[8] Advances in genetics have been and continue to be funded significantly by the publically financed human genome project and U.S. federal funds.[9] SACGHS reported no

[7] Dep't of Health & Human Serv., SACCHS report at 26 (April 2010), *available at* http://oba.od.nih.gov/oba/sacghs/ reports/SACGHS_patents_report_2010.pdf.
[8] *Id.* at 2.
[9] *Id.* at 26; Ledbetter Decl. ¶ 13 , Aug. 20, 2009; *See also* Cho Decl.¶ 22, Aug. 17, 2009 (study showing 67% of US gene patents on genetic diagnosis were for discoveries funded by the U.S. government) (*citing* Schissel, A., Merz, JF, Cho, MK., *Survey Confirms Fears About Licensing of Genetic Tests*, 402 Nature 118 (1999); *see also* Cho Decl. ¶¶ 17, 23, Aug. 17, 2009 ("majority of patented gene discoveries were supported by the federal government.")).

cases in which possession of exclusive rights was necessary for the development of a particular genetic test, including both common and rare genetic diseases.[10] This case proves the point. As the District Court Opinion discusses at length, the discovery of the BRCA 1/2 gene patents received significant federal funding through the National Institutes of Health, and was made possible by the use of known sequencing techniques[11] and the scientific contributions of various teams of researchers, including those staunchly opposed to patenting the BRCA 1/2 genes.[12]

III. Rather Than Encouraging Innovation and Scientific Progress, Myriad's Patents Stifle Advances in Medical Testing.

The patents in this case prevent research into relationships between the BRCA genes and other cancers as well as other genetic diseases, delaying the discovery of life-saving information about breast cancer, ovarian cancer, and other diseases causing significant harm to thousands of Americans each year. These limitations on innovation are not a normal consequence of the patent system; they are a consequence of the overextension of the patent system to cover the discovery of

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[10] SACGHS report at 2.

[11] *Ass'n for Molecular Pathology et. al v. USPTO,* 653 F.3d 1329, 1373 (Fed. Cir. 2011) (Bryson, J. concurring in part and dissenting in part) (95a); *Ass'n for Molecular Pathology et. al. v. USPTO*, 702 F. Supp.2d 181, 201-202 (S.D.N.Y. 2010) (155a-156a).

[12] Stiglitz Decl. ¶ 26, Jan. 19, 2010; *Ass'n for Molecular Pathology et. al.,* 702 F. Supp.2d at 201-202 (154a-158a) (*citing* Jeff M. Hall et al., *Linkage of Early-Onset Familial Breast Cancer to Chromosome 17q21*, 250 Science 1684 (1990); Richard Wooster, et. al, *Identification of the Breast Cancer Susceptability Gene BRCA 2*, 378 Nature 789-92 (1995)).

scientific fact, creating a monopoly on the "basic tools" of scientific research. *Benson,* 409 U.S. at 67. Given the fundamental nature of the information contained in a human gene, it is unsurprising that the BRCA 1/2 patents on human genes have retarded innovation and stifled competition. *See Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329, 1373 (Fed. Cir. 2012) (Bryson, J. concurring in part and dissenting in part) ("[Myriad's claims] are not directed to patentable subject matter, and if sustained…will likely have broad consequences…even though Myriad's contribution to the field is not remotely consonant with such efforts.").

By threatening litigation and sending cease and desist notices,[13] Myriad prevents researchers at top academic institutions from researching alternative and less costly means of testing for mutations in the BRCA 1/2 genes.[14] In addition, because of its patents, Myriad controls all test data in the United States, but fails to make this data readily available to researchers, limiting their ability to conduct research on breast cancer, ovarian cancer, and other cancers and diseases.[15]

[13] Myriad aggressively enforces its patent against private research labs, nonprofits research institutions, and universities. *Ass'n for Molecular Pathology et. al.,* 702 F. Supp.2d at 204-206 (163a-166a); SACGHS report at 33.
[14] Ledbetter Decl. ¶¶ 13, 16, Aug. 20, 2009.
[15] Swisher Decl. ¶¶ 14, 15, 19, Aug. 19, 2009.

A. **Myriad's** Patents Place Limits on Multiplex and Full Human Genome Testing.

Myriad's patents directly interfere with researchers' ability to investigate complex diseases. In most cases, rather than associating a single gene with a given disease, multiple genes play a causative role.[16] For example, autism is associated with more than ten different genes.[17] Similarly, BRCA 1/2 may be associated with, and serve as a predictor for, cancers other than breast or ovarian cancer, and even other diseases.[18] "Multiplex testing" is a recent innovation in genetic testing which allows researchers to simultaneously test multiple genetic markers[19] or to simultaneously test for multiple conditions.[20] Screening may eventually be done by affordable whole-genome sequencing, including newborn screening.[21]

However, multiplex testing of multiple genes raises concerns that it will violate multiple patents.[22] The number of patents protecting genes spread among various

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[16] Ledbetter Decl. ¶ 24, Aug. 20, 2009.
[17] *Id.*
[18] *Id.* at ¶ 25.
[19] SACGHS report at 49.
[20] *Id.*
[21] *Id.* (*citing* The President's Council on Bioethics, *The changing moral focus of newborn screening: an ethical analysis by the President's Council on Bioethics. Chapter Three: The Future of Newborn Screening* (2008)).
[22] *Id.* (*citing* D Nicol, *Navigating the molecular patent landscape*, 18 Expert Opinion on Therapeutic Pat. 461, 468 (2009); S Soini, S Aymé, & G Matthijs, *Patenting and licensing in genetic testing: ethical, legal and social issues*, 16 Eur. J. of Human Genetics S10, S12 (2008); TJ Ebersole, MC Guthrie, & JA Goldstein, *Patent pools as a solution to the licensing problems of diagnostic genetics* 17 Intellectual Property & Technology Law Journal 6 (2005)).

patent holders and assignees, thus far 20% of the human genome,[23] has led to a "patent thicket," "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."[24] Because of the thousands of patents claiming gene molecules or methods of associating a gene with a phenotype, developing multiplex testing, parallel sequencing and whole-genome sequencing will depend upon the acquisition of multiple rights or licensees to patents on genes, which will likely be prohibitively expensive and complex under current law.[25]

A recent study performed by the Centre for Intellectual Property Rights and the Centre for Human Genetics in Belgium confirms that 64% of patents relating to genetic testing will be difficult to invent around.[26] Patents on human genes are often difficult to interpret. For example, claim six of Myriad's patent on the BRCA 1 gene sequence is so broad that it includes at least 4% and as much as

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[23] K. Huang & F. Murray, *Does Patent Strategy Shape the Long-Run Supply Of Public Knowledge? Evidence From Human Genetics*, 52 Acad. of Mgmt. J. 1193 (2006).

[24] *Ass'n for Molecular Pathology*, 653 at 1379-1380 (Bryson, J. concurring in part and dissenting in part) (citing SACGHS Report 49-62 (2010) ("Broad claims to genetic material present a significant obstacle to the next generation of innovation in genetic medicine—multiplex test and whole-genome sequencing."); SACGHS report at 51 (*citing* C Shapiro, *Navigating the patent thicket: cross licenses, patent pools, and standard setting*, 1 Innovation Pol'y and the Econ. 119 (2001)).

[25] *See Ass'n for Molecular Pathology*, 653 F.3d at 1380 (Bryson, J. concurring in part and dissenting in part); SACGHS report at 51-52.

[26] SACGHS report at 15-16 (*citing* I. Huys, et al., *Legal uncertainty in the area of genetic diagnostic testing*, 27 Nature Biotechnology 903 (2009)).

100% of the genes in the human genome.[27] Patent claims that are difficult to circumvent can only be evaded after "a substantial investment of money and time, as well as a large amount of inventiveness."[28] Even if many of those patents are ultimately found to be invalid for anticipation or obviousness, the costs associated with litigating the scope of the patents is prohibitive.[29] As the SACGHS report discusses, under the standard set out in *eBay v. MercExchange, L.L.C.*, a multiplex developer faces the risk of an injunction and will not learn if that injunction will issue until after lengthy and expensive litigation.[30]

The Association of Genetic Counselors concurs that exclusive licenses and patents will "hinder the cost-effectiveness of genetic testing, particularly when analysis of multiple genes or the entire genome is necessary to assess the risk or existences of a disease."[31] As multiplex testing and whole-genome sequencing progress as medical tools, thickets of gene patents will discourage the development of advanced tests and their application to medicine.[32] If more than one gene is patented, researchers are prevented from developing a comprehensive, cost-

[27] Mason. Supp. Decl. ¶¶ 3-6, Jan. 19, 2010.
[28] SACGHS report at 16.
[29] *Id.* at 51-52 (*citing* Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 Hou. L. Rev. 1059, 1076-1080 (2008)).
[30] *Id.* at 53 (lack of clarity regarding how *ebay* will be applied has chilling effect on research) (*citing eBay v. MercExchange, L.L.C* ., 547 U.S. 388 (2006)).
[31] NSGC, *Position Statement on Human Gene Patenting* (2010). http://www.nsgc.org/Advocacy/PositionStatements/tabid/107/Default.aspx.
[32] SACGHS report at 62.

effective test for the full panel of human genes.[33] In the case at hand, the BRCA 1/2 genes prevent researchers from including these genes in tests for other disease predispositions, including other forms of cancer, as well as in tests that simultaneously test for multiple genetic conditions.[34]

B. **Myriad's** Patents Limit Research On BRCA 1/2 and Other Diseases.

The "patent thicket" heavily directs genetic research, forcing researchers to design their business models and research around any gene that has been patented or exclusively licensed.[35] As a result, researchers are unable to provide the public with improved tests for BRCA 1/2[36] or a complete test for any other disease that BRCA 1/2 may be associated with.[37]

Additionally, patents on the BRCA 1/2 genes place severe limits on data sharing. Without competition, Myriad is slow to make research available to other researchers. Myriad has stopped providing data to the Breast Cancer Information Core, a catalogue of all mutations and polymorphisms in breast cancer susceptibility genes whose principle aim is to facilitate the detection and characterization of these genes.[38] Genetic tests often reveal genetic alterations described as "variants of unknown significance" that researchers are unable to

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[33] Ledbetter Decl. ¶ 24, Aug. 20, 2009.
[34] *Id.* at ¶ 25.
[35] *Id.* at ¶ 14.
[36] *Id.*
[37] *Id.* at ¶¶ 24-25.
[38] Swisher Decl. ¶¶ 15, 19, Aug. 19, 2009.

interpret. In order to determine whether these variants are benign or pathogenic, researchers need large datasets, normally pooled from many labs. By hoarding clinical data for the BRCA 1/2 gene, Myriad prevents the greater genetic community from analyzing that data and making life-saving determinations about whether "variants of unknown significance" are benign or a predictor for cancer.[39] Given the limitations set out in *Madey v. Duke University*, academic medical centers and companies fear liability for any infringing acts they commit in the course of experiments to develop a new genetic test.[40] This view is substantiated by Myriad's aggressive threats of litigation for outside testing of the BRCA 1/2.

Finally, studies on the impact of gene patenting on scientific progress and commercialization reveal that gene patents decrease production of public genetic knowledge by 5-17%, a trend that is exacerbated when patents are broad in scope, privately owned, or closely linked to a cancerous disease.[41] All three factors are present in this case. Myriad's patents negatively impact the accumulation of public knowledge of the BRCA 1/2 genes by between 5 and 10%.[42] These results were mirrored in a National Human Genome funded survey of all laboratory directors in

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[39] Ledbetter Decl. ¶ 20, Aug. 20, 2009; Swisher Decl. ¶ 18, Aug. 19, 2009.
[40] *See* SACGHS report at 73 (*citing Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2003); *Embrex, Inc. v. Service Eng'r. Corp.*, 216 F.3d 1343 (Fed. Cir. 2000)).
[41] K. Huang & F. Murray, *Patent Strategy, supra,* at 22.
[42] Murray Decl. ¶ 20, Aug. 20, 2009.

the United States likely to be conducting genetic tests.[43] 53% decided against developing a new clinical genetic test because of a gene patent or license.[44] 67% believe that gene patents result in a decreased ability to perform research.[45] 25% stopped performing a clinical genetic test because of a gene patent or license.[46] 65% of labs that responded reported contact by a patent or license holder regarding the laboratory's potential infringement of a patent by performance of a genetic test, including of the BRCA 1/2 genes.[47] The American Society of Human Genetics similarly report that 46% of respondents felt that patents had delayed or limited their research.[48] Likewise, a study analyzing the sequencing of the human genome by the Human Genome Project and the private firm Celera revealed a 30% reduction in subsequent scientific research and product development as a result of Celera's intellectual property.[49] Though patent law is designed to "expand the

[43] Cho Decl. ¶¶ 9-10, Aug. 17, 2009.
[44] *Id.*
[45] *Id.*
[46] *Id.* at. ¶ 11; Cho, MK et. al., *Effects of Patents and Licenses On The Provision of Clinical Genetic Testing Services*, 5 J. of Molecular Diagnostics 3 (2003).
[47] Cho Decl.. ¶¶ 12-13, Aug. 17, 2009.
[48] *Id.* at ¶ 10 (*citing* Rabino, I., *How human geneticists in US view commercialization of the Human Genome Project*, 29 Nature Genetics 15 (2002)).
[49] Heidi L. Williams, *Intellectual Property Rights and Innovation*, (Nat'l Bureau of Econ. Research, Working Paper No. 16213, 2010), *available at* http://www.nber.org/papers/w16213.

public storehouse of knowledge,"[50] gene patents, and specifically the BRCA 1/2 patents, discourage innovation and research.

C. **The BRCA 1/2 Patents Create a "Double Monopoly," Thereby** Undermining The Goals Of The Patent System.

Because a test must match a gene as expressed in the human genome, it is impossible to invent around a genetic patent to create an equivalent, but non-infringing invention.[51] By securing a patent on the genetic information in the BRCA 1/2 genes, Myriad has left no alternative for genetic testing on those genes, creating a powerful "double monopoly."[52] In such an environment, patentees are dissuaded from performing additional research, charging reasonable prices, or cross-licensing technology.[53] In these situations, "[p]rofit maximizing behavior and progress-maximizing behavior" are "at odds."[54]

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[50] SACGHS report at 2.

[51] Andrew S. Robertson, *The Role of Genetic Patents in Genetic Test Innovation and Access*, 9 Nw. J. Tech. & Intell. Prop. 377 at *10 (2011).

[52] Gert Matthijs, *The European Opposition Against the BRCA Gene Patents*, 5 Familial Cancer 95 (2006) ("One cannot invent around the sequence if it is patented because each gene and each gene sequence is unique in its kind."). *See also* Gert Matthijs & Dicky Halley, *European-Wide Opposition Against The Breast Cancer Gene Patents*, 10 Eur. J. of Hum. Genetics 783 (2002) ("[w]hen the uniqueness of the genetic code is combined with the exclusive rights of patents, a truly unbreakable monopolistic right is generated.").

[53] Maureen E. Boyle, *Leaving Room For Research: The Historical Treatment of The Common Law Research Exemption in Congress and the Courts, and Its Relationship To Biotech Law And Policy*, 12 Yale J. L. & Tech. 269 (2010) (*citing* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 6918 (1998)).

[54] *Id.*

This is the precisely the environment created here. Myriad has inflated prices, delayed researchers' access to information, and inhibited the progress of genetic testing. The BRCA 1/2 patents place restrictions on facts of nature that distort the efficient allocation of resources and harm the public health; the tremendous rewards granted to Myriad do not correspond to the social returns.[55] This is indeed one of those instances in which "*too much* patent protection can impede rather than 'promote the Progress of Science and the useful Arts.'" *See Ass'n for Molecular Pathology*, 653 F.3d at 1380 (Bryson, J. concurring in part and dissenting in part) (*citing Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, J., dissenting from dismissal of writ as improvidently granted)).

CONCLUSION

For the foregoing reasons, *amici* respectfully request that the Court invalidate Myriad's patents on the BRCA 1/2 gene sequences.

Respectfully submitted, June 15, 2012

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[55] Stiglitz Decl. ¶¶ 19, 26, Jan. 19, 2010.

CERTIFICATE OF COMPLIANCE

Pursuant to this Court's order of April 30, 2012 and the Federal Rule of Appellate Procedure 29, and Federal Circuit Rule 29, I hereby certify that this brief is 15 pages, excluding the portions of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii), and has been prepared in a proportionally spaced typeface using Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

2010-1406

THE ASSOCIATION FOR MOLECULAR PATHOLOGY V. US PATENT & TRADEMARK OFFICE

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I also certify that the original and eleven (11) copies of this Brief of *Amici* Curiae, Information Society Project at Yale Law School Scholars in Support of Plaintiffs-Appellees were also shipped via Federal Express Next Business Day Delivery to:

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on this 15th day of June 2012.

/s/ Ramiro Honeywell
Ramiro Honeywell