UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASSOCIATION FOR MOLECULAR PATHOLOGY; AMERICAN COLLEGE OF MEDICAL GENETICS; AMERICAN SOCIETY FOR CLINICAL PATHOLOGY; 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; KATHLEEN RAKER,

Plaintiffs,

-against-

UNITED STATES PATENT AND TRADEMARK OFFICE; MYRIAD GENETICS; 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.

No. 09 Civ. 4515 (RWS)

ECF Case

DECLARATION OF DR. PHILIP R. REILLY

I, Philip R. Reilly, hereby declare that:

I. EDUCATION AND BACKGROUND

1. I currently hold the position of Venture Partner at Third Rock Ventures in Boston, Massachusetts. Third Rock Ventures is a venture capital company whose mission is to create transformational life science companies through close collaboration with members of the scientific and business communities. My qualifications, experience, and a list of my publications are set forth in my *curriculum vitae*, attached hereto as Exhibit 1.

2. I am Adjunct Professor of Law at Suffolk University School of Law in Boston, Massachusetts where I teach a seminar in Biomedical Policy and Law. I previously held teaching positions at Cornell University, Tufts University School of Medicine, Harvard Medical School, and Brandeis University. I am a member of the Board of Trustees of Cornell University.

3. I am trained in and have been board certified in both internal medicine and clinical genetics. I have also been a member of the Massachusetts Bar since 1973.

4. I received my J.D. in 1973 from Columbia University in New York, New York and practiced as an attorney from 1975 to 1977 at the law firm of Powers & Hall in Boston, Massachusetts. For a number of years thereafter, I had a part-time practice at Powers & Hall.

5. I received my M.D. in 1981 from Yale University in New Haven, Connecticut and completed my internship and residency in the Department of Medicine at Boston City Hospital in Boston, Massachusetts. From 1982 to 1983, I was a Professor of Law at the University of Houston. Between 1983 and 1985, I completed my residency. Thereafter, I became a Staff Physician and then, ultimately, Executive Director of the Eunice Kennedy Shriver Center for Mental Retardation, Inc., which was at the time affiliated with Massachusetts General Hospital, in Waltham, Massachusetts.

6. From 2000 to 2006, I was Chairman of the Board and CEO of Interleukin Genetics, Inc. in Waltham, Massachusetts. During the same time, I was also Director of Clinical Genetics. Interleukin Genetics was then and still is a publicly traded company with a focus on developing DNA-based risk assessment tests and preventative and therapeutic products to reduce or ameliorate those risks.

7. I chaired the social issues committee of the American Society of Human Genetics during the 1990's. I also served for three years on the Board of Directors of the American

Society of Human Genetics. In my capacity as chair of the social issues committee, I authored or co-authored numerous position papers on important public policy issues related to human genetics that were adopted by the American Society of Human Genetics.

8. I was president of the American Society of Law and Medicine and Ethics (at the time, including about 3,000 members) in 2002 and 2004. I also served on its Board of Directors.

9. In the 1990's, I was heavily involved in advising leading companies in developing and/or commercializing gene-based diagnostics and therapeutics, including diagnostic tests. This was a time when the field of biotechnology was rapidly developing and a period when many genes were being associated with risk for disease. In particular, many companies turned to me for advice regarding the ethical and legal issues they needed to consider in connection with the new gene based diagnostic tests they were creating. Such companies included, for example, Myriad Genetics, Genzyme Corporation, Collaborative Research, Inc., and Vivigen, Inc. for which I served as a member of the Board of Directors. I further advised biotechnology companies such as Millennium Pharmaceuticals, Inc., GlaxoSmithKline, and Pharmacia.

10. I have served as a member of several advisory boards, including the SmithKline Beecham Genomics Advisory Board, and was Chair of the SmithKline Beecham Clinical Genetics, Ethics and Public Policy Advisory Board. From about 1995 to 2000, I was a member of the Clinical Advisory Board of Myriad Genetics. I assisted Myriad in identifying ethical considerations related to the *BRCA1* and *BRCA2* genetic tests that were developed, and played an important role in developing Myriad's patient consent forms. It was my experience during those years that the entire scientific and clinical team at Myriad showed deep concern for the best interest of patients. For example, Myriad tried to ensure that as many patients as possible had

access to the test. Importantly, Myriad also strived to ensure that patients were given the results of their genetic tests in a responsible and compassionate manner.

11. For several years, I was an advisor to the Biotechnology Industry Organization ("BIO"). BIO is well-regarded and the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide. In my capacity as an advisor, I helped to develop a number of position statements for BIO including in areas such as genetic testing.

12. I am an author of numerous peer-reviewed academic articles and books on topics such as the ethical, legal, and social issues related to genetics. From the 1990's to about 2003, I was frequently a public speaker on the topic of genetics, the future of medicine, and bioethics. I have given approximately 500 speeches on these topics during my career.

13. In my capacity as CEO at Interleukin Genetics, I became familiar with the workings of the United States patent system. I was also involved in drafting or reviewing some of the company's patent applications.

14. I keep apprised of the literature regarding the impact of United States intellectual property law and policy on the development and commercialization of science and technology, particularly with respect to biotechnology.

II. BASIS OF OPINION

15. In preparing this declaration, I have been provided and considered the following: (1) the Complaint filed in connection with this proceeding; (2) Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment; (3) Plaintiffs' Rule 56.1 Statement of Material Facts; (4) the Declaration of Dr. Mildred Cho, dated August 17, 2009 ("Cho"); (5) Cho, MK *et al.*, 2003, Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services, *J. Mol. Diagnostics* 5(1):3-8 (cited in paragraph 11 of the Cho Declaration) (Exhibit 2; "Cho

2003"); (6) Merz and Cho, 2005, What are gene patents and why are people worried about them?, *Community. Genet.* 8(4):203-08 (Exhibit 3; "Merz and Cho"); (7) Declaration of Dr. Wendy Chung, dated July 30, 2009 ("Chung"); (8) BIO 2009 Member Survey: Technology Transfer and the Biotechnology Industry, located at http://bio.org/ip/techtransfer/PDF.TECH.TRANSFER.PRESENTATION.10.25.pdf (last printed on December 11, 2009) (Exhibit 4; "BIO Survey"); (9) The Economic Impact of Licensed Commercialized Inventions Originating in Research, 1996-2007: Final Report to the Biotechnology Industry Organization, September 3, 2009, located at http://www.bio.org/ip/techtransfer/BIO_final_report_9_3_09_rev_2.pdf (last printed on December 11, 2009) (Exhibit 5; "BIO Study"); (10) Walsh et al., 2005, "View from the Bench: Patents and Material Transfers" *Science* 309:2002-03 (Exhibit 6; "Walsh"); and (11) Bremer *et al.*, August 14, 2009, The Bayh-Dole Act and Revisionism Redux, Patent, Trademark & Copyright Journal (Exhibit 7; "Bremer").

III. PATENTS PROVIDE THE ESSENTIAL INCENTIVE FOR THE DEVELOPMENT AND COMMERCIALIZATION OF NEW TECHNOLOGIES

16. Patents provide a *bona fide* net social benefit. First, patents are essential in obtaining capital investment in the development and commercialization of technological breakthroughs. Second, patents encourage the sharing of technological advances through the disclosure requirements of the applicable patent laws and regulations, thus enabling the public to take advantage of these developments after the patents expire.

17. The net social benefit provided by patents is especially striking for patents in the life sciences arena. Numerous biotechnology-based clinical applications, especially, gene-based applications, would not be available today without patents. There are many diagnostic tests based on patented isolated DNA molecules or methods of detecting mutations therein. Examples

of such tests include the DNA tests for cystic fibrosis (a severe lung disease) which are based on the *CFTR* gene, and for Fragile X syndrome (a leading cause of inherited mental retardation), which is based on the *FMR1* gene. There are today many other DNA based diagnostic tests secured by patents. Similarly, there are many therapeutic products based on patented isolated DNA molecules or their recombinant protein products, including recombinant erythropoietin ("EPO") to treat anemia, and recombinant human granulocyte colony-stimulating factor ("G-CSF") to treat cancer patients receiving chemotherapy and bone marrow transplants.

18. The patent system is essential to attract investors. Without the incentive provided by the patent system, investors would be much less likely to invest in new and potentially life-saving technologies. Patents, through the promise of a limited period of market exclusivity, provide investors with an opportunity to recoup their initial investment and ultimately, derive commercial benefit therefrom.

19. Indeed, Dr. Mildred Cho has recognized that "[p]atents are clearly seen as a necessary stimulus for the infusion of venture and risk capital in the bio-technology industry . . .." Merz and Cho at p. 6.

20. As Venture Partner of Third Rock Ventures, my work includes the analysis and valuation of intellectual property portfolios and, most importantly, patent portfolios in the life sciences sector. I have come to understand that intellectual property protection is essential to biotechnology and pharmaceutical companies that must invest up to hundreds of millions of dollars in research and development over many years to bring their diagnostic and therapeutic products to market. Patents enable these companies to acquire the capital needed for diagnostic and drug development testing by providing a necessary period of market exclusivity.

21. In the case of genetic testing companies, the limited period of exclusivity provided by a patent is almost always required to secure sufficient capital needed to establish testing capability on a clinical scale. As CEO of Interleukin Genetics, I personally found this to be the case.

22. I recently reviewed a survey published in 2009 by BIO of 150 biotechnology member companies in the therapeutic and diagnostic healthcare industry. (*See* Exhibit 4, BIO Survey). The survey revealed that the majority of companies (61%) stated they generally in-license projects that are in the pre-clinical or Phase I stage of development, and thus still require substantial R&D investment and commercialization risk by the licensee (*See* Exhibit 4, BIO Survey at 13). A substantial majority (77%) of the respondents without approved products indicated that they expect to spend 5-15 years and over $100 million developing a commercial product (*See* Exhibit 4, BIO Survey at 25, 28). These expenditures far exceed most initial research funding by the federal government.

23. The net social benefit of the patent system accrues both to the biotechnology sector and to the patients it hopes to serve. This is true with regard to patents related to isolated DNA molecules.

IV. PATENTS PROMOTE INFORMATION DISCLOSURE

24. The patenting of human isolated DNA molecules is not in conflict with the notion that science would advance more rapidly if researchers are allowed to take advantage of free access to knowledge. Part of the *quid pro quo* of the patent system is that inventors, in exchange for a limited period of patent exclusivity, must provide a sufficient description of the patented invention so that others may improve upon it.

25. Moreover, patents do not necessarily operate as an absolute monopoly. Although a patent grants the right to exclude others from making, using, and selling or importing into the

United States the patented invention for a limited term, the patent holder must still respect the intellectual property rights of third parties in the same field of the invention. Thus, the patentee may not be able to practice the invention covered by the patent without a license from the third party.

26. In addition, the patent system promotes more disclosure than otherwise might occur if, for example, trade secrets were the only means to exclude competitors, at least in the commercial sector. For example, one of the most well-known products sold throughout the world is Coca-Cola (or "Coke"). It is generally known that although various formulas have been introduced since the 1880's, the various formulas have and still are protected by trade secrets. This period of time far exceeds the limited period of market exclusivity that a patents can provide.

V. THE PATENT SYSTEM WORKS AS THE FOUNDING FATHERS INTENDED

27. The Constitution recognizes the need "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." United States Constitution, Article 1, Section 8, clause 8.

28. A historical example of the success of the patent system comes from the area of federally funded research. In 1980, in response to concerns about U.S. competitiveness in the global economy, Congress enacted the Bayh-Dole Act.

29. In 1980, Congress enacted Bayh-Dole to address concerns regarding barriers to commercial development affecting non-governmental entities such as universities and small business firms. Some of the stated objectives of the Act include: (1) utilization of inventions arising from federally supported research or development; (2) to promote collaboration between commercial entities and nonprofit organizations, including universities; and (3) to promote the

commercialization and public availability of inventions made in the United States by United States industry and labor. 35 U.S.C. § 200.

30. As reported in the BIO Survey discussed above, the vast majority of the surveyed biotechnology companies license technology from universities (76%) (Exhibit 4, BIO Survey at 17). Moreover, half of the companies surveyed reported that they were founded on the basis of obtaining an in-licensing agreement (Exhibit 4, BIO Survey at 28).

31. Patents also have a significant and positive influence on the United States economy. A 2009 study released by BIO illustrates the importance of university-industry research and development partnerships based on in-licensing of patents. (*See* Exhibit 5; BIO Study). The study reports that university-licensed products commercialized by industry created more than 279,000 new jobs across the United States during the 12-year period between 1996 and 2007 (*See* Exhibit 5, BIO Study at p. 8). Further, the study states that "[w]ithout accounting for product substitution effects, we estimate that over the period 1996 to 2007, university licensing agreements based on product sales contributed at least $47 billion and [possibly] as much as $187 billion to the U.S. GDP. A moderately conservative estimate based on 5% royalty rates yields a total contribution to GDP for this period of more than $82 billion." (Exhibit 5, BIO Study at p. 32).

32. In a 2009 article published by Bremer and colleagues the authors concluded that "[r]eams of objective data exist supporting the conclusion that the Bayh-Dole Act greatly improved the commercialization of federally-funded research . . . and that the public sector-private sector partnerships which were generated under the [Bayh-Dole] Act are essential both to the well being and the competitive position of the United States." (Exhibit 7, Bremer Article).

33. It is my understanding that the University of Utah Research Foundation, an owner or part-owner of at least some of the patents at issue in this case, obtained federal funding in connection with *BRCA1* and *BRCA2* research. I further understand that Myriad, the exclusive licensee of the patents at issue in this case, developed and commercialized its breakthrough diagnostic tests through the investment of a significant amount of venture and risk capital. The *BRCA1* and *BRCA2* story is just one of the many positive examples of the impact of the Bayh-Dole Act.

34. Further, I believe that the incentives of the patent system were instrumental in Myriad's discovery of the correct *BRCA1* and *BRCA2* sequence and characterization of its true structure, which has enhanced *BRCA1* and *BRCA2* research by its disclosure to the public.

35. Finally, from my experience in industry, post-invention development costs far exceed pre-invention and research expenditures. In the case of the *BRCA1* and *BRCA2* genes, for example, although the U.S. Government may have granted millions of dollars in the initial research that led to the patents at issue in this case. Myriad almost certainly spent far more in development and commercialization in order to bring its groundbreaking sequencing tests rapidly to the market.

36. Given the immense importance of the existing patent portfolio to the biotechnology industry, it would be far wiser to have any important policy shifts be made prospectively by Congress after sustained public debate. I believe that the policy arguments are better left to the parts of government where they are better addressed—in Congress and in the U.S. Patent and Trademark Office.

VI. PATENTS ON ISOLATED DNA PROMOTE RESEARCH AND ADVANCE CLINICAL DEVELOPMENT

37. Plaintiffs have voiced the concern that gene patents impede scientific research and clinical development by creating an atmosphere of apprehension of patent infringement in the research community. Underlying such concern appears to be the assumption that such patents cover the genes as they are found in the human body.

38. Patents such as the patents-in-suit have served to advance research and the practice of medicine and benefit patients. I am not aware of any credible evidence that Myriad's patents impede or have impeded basic research.

39. Isolated and purified DNA molecules are chemically, structurally, and functionally different from genes in their native states as they exist in the human body.

40. Thus, the notion that genes and their mutations, alterations, or variations are naturally occurring substances that should not be patented is misplaced. Genes as they are found in the human body are not patentable subject matter.

41. Data cited to support the notion that patents impede research or diagnostic test development is at best inconclusive. This conclusion is echoed in part by an article co-authored by Dr. Mildred Cho. In the article, the authors conclude that "[l]ittle is known about how gene patents are being used and whether they are having a net beneficial or detrimental effect on scientific research and commercial product development." (Exhibit 3, Merz and Cho at p. 6). The authors also state that "[t]here is little evidence that early fears about gene patenting placing substantial restraints on research and clinical medicine have come to fruition." (Exhibit 3, Merz and Cho at Abstract, p. 1).

42. Further, in a 2005 article published in the journal *Science*, John P. Walsh and colleagues report the findings from a survey conducted on 414 biomedical researchers in

universities, government, and nonprofit institutions to determine the effect of patents on biomedical research and material transfers. (Exhibit 6, Walsh at p. 2002). The researchers found that "few academic bench scientists currently pay much attention to the others' patents." *Id.* Moreover, of the "32 respondents who were aware of relevant IP, four reported changing their research approach and five delayed completion of an experiment by more than one month. No one reported abandoning a line of research. Thus, of 381 academic scientists . . . none were stopped by the existence of patents, and even modifications or delays were rare." *Id.*

43. The sheer volume of scientific publications on BRCA1/2 genes and their gene products belies the purported impediment in basic research. On December 10, 2009, I performed a search using the term "BRCA1" in the PubMed database[1] which retrieved almost 7,000 references. A similar PubMed search conducted using the term "BRCA2" retrieved over 4,000 references.

44. Moreover, the *BRCA1* and *BRCA2* patents at issue in this case do not appear to have impeded clinical research. A search on the website ClinicalTrials.gov[2] on December 19, 2009 using the term "BRCA1" retrieved 77 clinical trials that have been completed, are ongoing, or are actively recruiting subjects. Using the search term "BRCA2," 58 clinical trials were retrieved that have been completed, are ongoing, or are actively recruiting subjects.

45. From my experience, the sharing of research tools was not inhibited by IP protection. For example, during my tenure as Executive Director at the Eunice Kennedy Shriver Center for Mental Retardation, an institute that focused on neuroscience research, the scientists

[1] PubMed at the website pubmed.org is a free search engine for accessing citations, abstracts and some full text articles on life sciences and biomedical topics. PubMed is maintained by United States National Library of Medicine at the National Institutes of Health.

[2] ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world. It is a service provided by the National Institutes of Health.

with whom I had the privilege to work routinely acquired valuable substances, materials, and information under material transfer agreements from both academe and industry.

46. I note that in her declaration, Dr. Cho concludes that "patents on genes used for clinical diagnostics inhibit the conduct of research to further the development of improvements to genetic tests." Cho ¶ 24. I strongly disagree. I would be curious to see how Dr. Cho herself would reconcile her statement quoted above with her own article published just a few years ago, which states that "[t]here is little evidence that early fears about gene patenting placing substantial restraints on research and clinical medicine have come to fruition." (Exhibit 3, Merz and Cho at p. 6).

47. Moreover, I note that the surveys conducted by Dr. Cho and cited in her declaration included many clinical geneticists who were involved in or overseeing genetic testing laboratories that were intended to generate a profit. Thus, many of these geneticists charge for genetic testing themselves. For example, in her 2003 article, Dr. Cho and colleagues performed a telephonic survey of all laboratory directors in the United States who were members of the Association for Molecular Pathology ("AMP") or who were listed on the GeneTest.org website. (Exhibit 2, Cho 2003 at p. 3). I further note that AMP is a plaintiff in the present proceeding. I believe that the study was biased towards individuals or laboratories many of whom stand to gain should the patents at issue become invalidated.

48. The results obtained through Dr. Cho's telephonic survey published in 2003 at most represent a snapshot of opinions of a 122 laboratory directors at that time. (Exhibit 2, Cho 2003 at p. 3). Dr. Cho was clearly aware of the limitations of her own study. She concluded that "our data do not directly address the question or whether patents and restrictive licensing

practices have affected the cost and quality of genetic tests, or hindered new research." (Exhibit 2, Cho 2003 at p. 8).

49. Based on the above, any concerns that human "gene" patents impede basic scientific and/or clinical research are not supported by the evidence. The sheer amount of research being conducted and the number of scientific articles being published regularly on the *BRCA1* and *BRCA2* genes and their protein products, for example, provide strong evidence that research is not impeded.

VII. PATENTS ON ISOLATED DNA PROMOTE ADVANCES IN MEDICINE AND ENHANCE THE QUALITY OF PATIENT CARE

50. Another concern voiced by Plaintiffs is that "gene" patents impede advancements in medicine and clinical development. Again, Dr. Cho was clearly aware of the limitations of her own study. She concluded that "our data do not directly address the question or whether patents and restrictive licensing practices have affected the cost and quality of genetic tests, or hindered new research." (Exhibit 2, Cho 2003 at p. 8).

51. The reality is quite the opposite. As discussed above, without the promise of a period of market exclusivity provided by patents and the infusion of venture and risk capital derived therefrom, companies that capitalize on innovation simply would not be created. Their products would not be brought to market, to the clinic, and most importantly, to patients. This of course, holds true for companies such as Myriad and its *BRCA1/2* diagnostic tests.

52. Intellectual property is essential to innovation in health care. In my capacity as venture partner, I help to start companies that develop treatments for rare genetic disorders for which there is no adequate current therapy. An example is a company to develop a recombinant protein to treat a rare genetic disorder, namely X-linked hypohidrotic ectodermal dysplasia. The decision to fund this company with significant capital was critically dependent on an assessment

of the quality of the relevant intellectual property. Without the promise of a period of market exclusivity provided by the patent law, this investment would not have been made.

53. Without strong patent protection, the many biotechnology-based medical advances, such as Myriad's *BRCA1/BRCA2* genetic based testing, would not be developed.

54. Yet another concern voice by the Plaintiffs about "gene" patents is that they harm patients by interfering with their ability to get a second opinion and to make informed decisions about their health and medical care. I disagree. Indeed the term "second opinion" is not used properly. In the clinic, the term "second opinion" is used to refer to the interpretation of diagnostic tests and their implications for treatment. It would be quite unusual to have a patient's DNA sequenced a second time in a second laboratory. If, however, there were any doubts regarding the accuracy of the test, re-sequencing with the proper controls would normally be performed by the original provider. The term, second opinion, generally refers to the interpretation of a test result and which therapeutic options to follow based thereon.

55. As an internist and clinical geneticist, it is my understanding that once a patient has his or her genes sequenced, *e.g.*, the *BRCA1* and/or *BRCA2* genes, the patient generally does not get his or her genes re-sequenced. In the absence of any doubts regarding the accuracy of the original test, re-sequencing of the patient's genes would be an unnecessary use of resources.

56. The situation is analogous to a person who obtains an MRI and whose physician then diagnoses a disorder and subsequently recommends a course of treatment. The patient is free to take the MRI images to another physician for a second opinion. Again however, obtaining another MRI just a short time thereafter would be an unnecessary use of resources, and it is unlikely that an insurance plan would cover a second MRI.

VIII. TEST RESULTS GENERATED IN RESEARCH LABORATORIES SHOULD NOT BE COMMUNICATED TO PATIENTS

57. Plaintiffs have complained that because of the patents at issue in this case, they are unable to share the results of any genetic testing performed and that this goes against their ethical obligations. In particular, Dr. Chung in her declaration states the following: "[a]s a researcher, I believe I have an ethical responsibility to offer my test subjects access to information about their genes. In order to meet this ethical responsibility, I offer my research subjects the option of finding out their results. As a result of the patents, I can only do that by sending samples to Myriad Genetics to test the sample [*sic*] so I can communicate that information to the patients." Chung ¶14.

58. While I respect Dr. Chung's eagerness to help her "test subjects," Dr. Chung appears to confuse information generated during the course of research with information generated within a legally certified diagnostic laboratory. I believe it would be illegal to provide results of genetic testing for clinical use if the laboratory is not Clinical Laboratory Improvement Amendments ("CLIA")-certified. In order for a laboratory to provide a clinical test result to a patient, it must be CLIA-certified. In addition, New York State, where Dr. Chung operates her research laboratory, imposes additional licensing requirements on DNA testing, which could take, in my personal experience, a year or more to satisfy.

59. It is my impression, based on many years of interacting with academic researchers, that the majority of academic researchers operating laboratories (as opposed to CLIA-certified laboratories) do not believe that they should share test results with subjects outside of the standard clinical setting.

IX. PATENTS SUCH AS THE ONES AT ISSUE ARE CRITICAL TO A NASCENT AND BURGEONING INDUSTRY

60. I believe that the emerging field of personalized medicine promises dramatic improvements in health care. The opportunity to develop new therapies based on the genetic dissection of complex disorders raises the realistic hope for individualized treatment plans.

61. The future of personalized medicine will require understanding the biological and physiological significance of variations in genes like *BRCA1* and *BRCA2*, and designing ways to use them in preventative and therapeutic interventions. By identifying and targeting faulty genes before they wreak havoc in the cells of the human body, medicine has the chance to save countless lives.

62. Patents upon the Myriad inventions, and similar ones, have had and will continue to have a positive impact on clinical practice and research. The granting of patents in this area has not had a negative impact on breast or ovarian cancer research and clinical practice, and clinical practice has not been harmed. To the contrary, patents on these isolated molecular diagnostic tools are important, indeed essential, to create the incentives for the immense effort involved in their discovery, and for the expense involved in bringing them to market. The incentives provided by patents fuel discovery and commercialization in emerging technologies such as medical diagnostics, resulting in social and health benefits for future generations.

The views expressed herein are my own and should not be construed in any way to represent the views of Third Rock Ventures.

Pursuant to 28 USC § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 21, 2009

Philip R. Reilly

LIST OF EXHIBITS

1	*Curriculum vitae*
2	Cho, MK et al., 2003, Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services, J. Mol. Diagnostics 5(1):3-8
3	Merz and Cho, 2005, What are gene patents and why are people worried about them?, Community. Genet. 8(4):203-08
4	BIO 2009 Member Survey: Technology Transfer and the Biotechnology Industry, located at http://bio.org/ip/techtransfer/PDF.TECH.TRANSFER.PRESENTATION.10.25.pdf (last printed on December 11, 2009)
5	The Economic Impact of Licensed Commercialized Inventions Originating in Research, 1996-2007: Final Report to the Biotechnology Industry Organization, September 3, 2009, located at http://www.bio.org/ip/techtransfer/BIO_final_report_9_3_09_rev_2.pdf (last printed on December 11, 2009)
6	Walsh et al., 2005, "View from the Bench: Patents and Material Transfers" Science 309:2002-03
7	Bremer et al., August 14, 2009, The Bayh-Dole Act and Revisionism Redux, Patent, Trademark & Copyright Journal

CERTIFICATE OF SERVICE

This is to certify that on December 23, 2009, a true and correct copy of the foregoing document has been served on all counsel of record via the court's ECF system.

/s/ Brian M. Poissant
Brian M. Poissant