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,

Plaintiff,

-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,

Defendant.

No. Civil Action No. 09-4515 (RWS)

ECF Case

DECLARATION OF JOHN J. DOLL

I, John J. Doll, hereby declare that:

1. I reside in Maryland.

2. I served as the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office during the change of administration (January 2009 to August 2009). As the Acting Under Secretary, I advised the President, the Secretary of Commerce, and the Administration about all intellectual property matters. As Acting Director, I administered the laws of granting Patents and Trademarks, and the day-to-day management of the $2.1 billion Agency for over 9,600 employees. I developed and articulated Administration positions on all Patent, Trademark and Copyright issues, both domestic and foreign while promoting strong Intellectual Property policy globally, including strategies to thwart the theft of U.S. Intellectual Property around the world. *See* Curriculum Vitae (Exhibit 1)

3. I was the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office (November 2008 to September 2009). In this capacity, I assisted the Under Secretary in developing and promoting Administration positions on all Patent, Trademark and Copyright issues domestically and internationally. I also served as the Chief Operating Officer in planning, measuring and improving the mission performance and achievement of the Agency. I was responsible for maintaining and growing domestic and international leadership roles in Intellectual Property Rights policy by strengthening Intellectual Property protection. I was also responsible for providing customers with the highest levels of quality and service in all aspects of Agency operations.

4. In 2005 I was appointed as the Commissioner for Patents by the Secretary of Commerce. In this capacity from August 2005 to October 2009, I served as the Chief Operating Officer for all aspects of patent related operations, planning and policy with the mission of properly applying the patent laws and regulations of the United States in the examination of patent applications. I oversaw a budget of $1.3 billion and a staff of over 7000 employees. I was responsible for Patent's strategic planning and execution, budget formulation and execution, information technology systems, staffing, employee development, labor management relations, customer outreach, congressional relations, public advisory committee relations, and patent policy formulation.

5. Prior to my appointment as Commissioner for Patents, I served as the Acting Commissioner for Patents from April 2005 to August 2005. I was appointed by the Under Secretary of Commerce for Intellectual Property and the Director of the United States Patent and Trademark Office to perform the duties of the Commissioner for Patents until the Secretary of Commerce appointed a new Commissioner for Patents. Prior to and during this appointment, I served as the Deputy Commissioner for Patent Resources and Planning from January 2005 to August 2005. I was responsible for the formulation and execution of the $1.3 budget as well as strategic planning for the Patent Office.

6. Before my appointment as Acting Commissioner, I served as the Director or Deputy Director of three different Patent Examination Technology Centers from August 1992 to August 2005. I was responsible for all patent examination issues in the chemistry, pharmaceutical, biotechnology and design art areas. During my tenure, from March 2004 to January 2005, I served as the Special Assistant to the Under Secretary and Director of the United

States Patent and Trademark Office from March 2004 to January 2005. In this capacity, I provided technical, examination and legal advice on all Patent related issues.

7. From September 1974 to August 1992, I was a Patent Examiner, Supervisory Patent Examiner, and Quality Assurance Examiner. I examined and supervised the examination of patent applications encompassing pharmaceuticals, herbicides, pesticides, dyestuffs, inorganic chemistry, hydrometallurgy, zeolite catalysts, buckministerfullerenes, proteins, and peptides.

8. I have been honored on multiple occasions for my service at the United States Patent and Trademark Office. Among my honors, I received the Department of Commerce Bronze Medal for examination and supervisory accomplishments; a second Bronze Medal for the implementation of Patent Application Location and Monitoring (PALM) system; a Department of Commerce Silver Medal for the development of automated examiner office action tools; the Vice Presidential Hammer Award for establishing the Biotechnology Customer Partnership; a Department of Commerce Gold Medal for implementation of the Image File Wrapper system.

9. I received my Master of Science in Physical Chemistry in 1974 from The Pennsylvania State University. I received my Bachelor of Science in Chemistry and Physics in 1971 from Bowling Green State University.

10. In preparing this Declaration, I reviewed and considered the Plaintiffs' Statement of Material Facts ("SMF"); Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment ("Memo"); Dr, John Sulston's and Dr. Myles Jackson's Declarations; the Utility Examination Guidelines (66 Fed. Reg. 1092 (January 5, 2001)); United States Patent Nos. 5,747,282 ("the '282 patent"); 5,837,492 ("the '492 patent"); 5,693,473 ("the '474 patent"); 5,710,001 ("the '001 patent"); 5,753,441 ("the '441 patent"); 6,033,857 ("the '857 patent"); 5,709,999 ("the '999 patent"), (collectively "Myriad patents").

THE USPTO ADMINISTERS THE LAWS ENACTED BY CONGRESS

11. The U.S. Patent and Trademark Office ("USPTO" or the "Office") is an administrative agency charged with examining applications for patent. The USPTO issues a patent if the application meets the statutory requirements of Title 35 United States Code, Title 37 Code of Federal Regulations and the procedures of the Manual of Patent Examining Procedure ("MPEP"). The USPTO must apply the laws Congress has enacted and the Federal Circuit and the Supreme Court have interpreted.

12. On October 17, 1994, Commissioner Bruce Lehman conducted a public hearing in San Diego on the patenting of biological inventions before the USPTO. Public Hearing on the Patenting of Biotechnological Inventions before the United States Patent and Trademark Office (Oct. 17, 1994), located at http://www.uspto.gov/web/offices/com/hearings/biotech/biotrans.html (Exhibit 2). The purpose of the public hearing was to obtain input from the industry in connection with the Office's review of its examining procedures to ensure that examination was of sufficiently high quality, and that the USPTO was responsive to the industry's needs.

13. The recurrent theme of the testimony received from industry representatives at that hearing, sometimes referred to as "the San Diego Massacre," was that the USPTO applied a more stringent and uneven standard for biotechnology inventions, and that we were "killing the industry" by not issuing patents for biotechnology inventions. Mostly, the complaints related to uneven examination standards, peer review rather than legal review of patent applications, and that a special higher standard for patentability (in particular, utility) was being applied to biotechnology inventions.

14. In response, the USPTO issued utility examination Guidelines to address the concerns aired at the public hearing. Utility Examination Guidelines, 60 Fed. Reg. 36263 (1995) (reproduced in MPEP § 706.03(a)(1) (July 1998) (hereafter "1995 Utility Guidelines")) (Exhibit

3). The Guidelines are not law or substantive rules. Rather, the Guidelines define the procedures to be followed by Office personnel in their review of patent applications for compliance with 35 USC § 101. The legal analysis supporting the Guidelines articulated the basis for the procedures that were established.

15. In February of 1995, I was asked to be the Director of the Patent Examination Technology Center 1800, which examined patent applications claiming biotechnological inventions. Shortly after taking the position, I was told of a backlog of unexamined applications in Group 1800 relating to "ESTs" ("**e**xpressed **s**equence **t**ags"). An EST is a short fragment of a cDNA that represents a portion of an expressed gene. Patenting "anonymous" EST fragments was controversial. There was a concern that patents on ESTs without knowledge of the function of the gene, could potentially dominate or preclude a patent to those who later deciphered the structure of the full length gene and the function of the gene. The Technology Center was holding the EST applications and not examining them since they were unsure how to properly apply the patent laws and regulations to EST applications claiming, sometimes, thousands of ESTs in a single application. Thus, there was a moratorium on examination of these applications.[1]

16. After I was briefed on the EST applications, it was apparent that the examination of EST applications presented some unique examination issues. I began discussions with the Office of the General Counsel and the Solicitor's Office to determine the appropriate examination procedures for EST applications and to get the examination of these applications started.

[1] Plaintiffs' expert, Jackson, is incorrect when he states that ESTs were easy to patent in the mid-1990s (Jackson Declaration, p. 11, n.13). Patents on ESTs were not issued during this time period, and ultimately, patentability of ESTs without knowledge of function of the corresponding gene product was denied by the Federal Circuit (In re Fisher, 421 F.3d 1365 (1995)).

17. A team from the Office of the General Counsel, including the Solicitor's Office, and the Technology Center convened and studied the law on patent eligibility of DNA molecules and the criteria that would be required to address the concerns about ESTs. The results showed that utility was the main issue that needed to be addressed. The USPTO also consulted with various groups, including Pharmaceutical Research and Manufacturers of America ("PhRMA") and Biotechnology Industry Organization ("BIO"), and agencies, including the National Institutes of Health ("NIH"), the Department of Commerce ("DOC"), and the Office of Management and Budget ("OMB"), to develop a framework for examining DNA EST patent applications.

18. Through this process, the USPTO refined its procedures for examining all inventions including biotechnology inventions to require a specific, credible and substantial utility for DNA molecules claimed. This was done to ensure that patents did not issue on DNA molecules without a proper disclosure of utility satisfying 35 USC § 101. These criteria were published in the revised Guidelines. Revised Interim Utility Examination Guidelines, 64 Fed. Reg. 71440 (December 21, 1999) (hereinafter "1999 Interim Guidelines") (Exhibit 4). The Utility Examination Guidelines that were released in 2001 (Utility Examination Guidelines, 66 Fed. Reg. 1092 (January 5, 2001) (hereinafter "2001 Utility Guidelines") (Exhibit 5)) were based on the 1999 Interim Guidelines. The USPTO incorporated these Guidelines into the MPEP. U.S. Pat. & Trademark Off., MPEP § 2107 (8th ed. 2001) (Exhibit 6).

19. In order to explain our position regarding the examination of patent applications relating to DNA molecules to the public, I worked with the Office of Public Affairs, the Office of the General Counsel including the Solicitor's Office, and the Technology Center, and wrote an

article published in Science. Doll, J.J., 1998, "The Patenting of DNA" *Science* 280: 689-690 (Exhibit 7).

20. During the evolution of the Examination Guidelines, several of the plaintiffs and plaintiffs' experts in this action participated in the commentary and expressed their concern with the possible impact of patents granted for DNA-related inventions, particularly with respect to ESTs. [Association for Molecular Pathology, Debra Leonard, Wayne W. Grody, Mark E. Sobol, The American College of Medical Genetics, David H. Ledbetter]. A number of the participants commended the USPTO's approach since it addressed their major concern in that the Guidelines would prevent the patenting of DNA molecules where the function of the gene product was unknown. *See* Letter from R. Rodney Howell, President, American College of Molecular Genetics to Commissioner, USPTO (March 20, 2000), *available at* http://www.uspto.gov/web/offices/com/sol/comments/utilguide/acmg.pdf (Exhibit 8); Letter from Debra G.B. Leonard, President, Association for Molecular Pathology to Commissioner, USPTO (March 17, 2000), (hereinafter "AMP Letter"), *available at* http://www.uspto.gov/web/offices/com/sol/comments/utilguide/amp.pdf (Exhibit 9).

21. The only remaining concern expressed was whether patents in this area were in the public interest (AMP Letter ¶ 3) – an issue mirrored in the plaintiffs' complaint. *See* Plaintiffs' Complaint, ¶¶ 2, 81-101. This is a policy issue that can only be addressed by Congress, not the courts and not the USPTO.

22. I will now explain what criteria were used to assess patentability of biotechnological inventions, in particular for DNA molecules, and how the USPTO applied them.

ISOLATED DNA MOLECULES ARE PATENT ELIGIBLE SUBJECT MATTER

23. New areas of technology do not create the need for a whole new specialized area of patent law. The patent statutes and regulations are the same for all inventions regardless of whether they are genes, semiconductors, computers, pesticides or doorbells. Neither the Congress nor the courts have indicated that patent law should be changed with the introduction of genetic technology or any other specific technologies. Had Congress wanted the USPTO to apply different standards to different technologies, I believe Congress would have expressly done so.

24. The same patentability analysis has always been applied by USPTO regardless of the technology. The laws have consistently remained the same through every new class of inventive effort because they established a patent regime that has worked well.

25. As I pointed out in my Science article, in many ways, Plaintiffs' arguments resemble those voiced 30 to 40 years ago when polymer chemistry was an emerging technology. At that time, it was argued that patents on the building blocks of basic polymers would devastate the industry. In fact, no such disaster occurred. For example, the issuance in 1965 of a basic patent broadly claiming a vulcanizable copolymer of aliphatic mono-olefins and unsaturated bridged-ring hydrocarbons (*i.e.*, ethylene-propylene-diene monomer ("EPDM") rubber) did not preclude the later issuing of patents to different inventors for several copolymers of this type (Exhibit 7 ¶ 3-4).

26. Isolated or purified DNA molecules are chemical compositions that are eligible for patent protection under 35 USC § 101 as compositions of matter. They are not naturally occurring substances and they are not just information.

27. Isolated or purified DNA molecules are chemical compositions that possess physical, chemical and structural properties that differ from their naturally occurring counterpart

genes. In their natural state, genes are chemically bonded into long strands of nucleotides that make up chromosomes. Genes do not float around in cells as separate entities; one cannot simply reach into a cell and pull a gene out of the body. It requires research and discovery to identify, isolate or synthesize and sequence a gene from the vast run of nucleotides on a chromosome. There is no roadmap as to where the genes are located on a chromosome or what function the gene products have.

28. Isolating or purifying a gene is not simply copying its information into another format. The isolated DNA is chemically, physically and structurally different from the gene in the body. Just like any other chemical composition, DNA contains various groupings of atoms. DNA specifically contains carbon, hydrogen, nitrogen, oxygen and phosphorous atoms that are bonded in a manner that determines its properties, just as the properties of any chemical composition are determined by the atoms that comprise it and the manner in which they are bonded. Even if the information in an isolated DNA molecule is the same as its genomic counterpart, it would not preclude the isolated DNA from being patent eligible subject matter.

29. A critical aspect of any chemical compound is its inherent chemical, physical and structural properties, such as chemical reactivity, catalytic properties, and biological interactions. This is also true of DNA. An isolated DNA has a different number of atoms of various elements that are bonded in a manner that is distinct from the gene sequence found in the body. As a result, an isolated DNA has properties, functions and utilities that the gene in the body does not have. For example, the isolated DNA, but not the naturally occurring gene, can be used as a diagnostic probe, molecular marker, or source primer.

30. The Plaintiffs contend that genetic sequences are information and should not be patentable. SMF ¶¶ 48-49, 59, 65, 96, 114. The Plaintiffs fail to see that the inherent

information contained in a composition of matter is not what is patented in a composition of matter claim. What is patented is the composition of matter itself and the patent excludes others from making using selling or importing the patented invention which includes all of chemical, physical, structural and informational properties for that specific composition of matter.

31. A DNA molecule is a chemical composition that is composed of structural units called nucleotides. A nucleotide consists of an phosphate, a deoxyribose sugar, and one of four bases: Adenine (A), Thymine (T), Cytosine (C), and Guanine (G). The letters are just assigned to the nucleotides so that a DNA molecule may be more easily depicted. This system is analogous to the chemical formulas used for describing other chemical compounds. For example, the chemical formula for water is H_2O, where "H" represents a hydrogen atom, "2" represents the number of hydrogen atoms present in the compound, and "O" represents an oxygen atom. The recitation of a chemical formula in a claim does not mean that the inventor is patenting the chemical formula – it is the chemical composition of matter is being patented. So analogously, when a nucleotide sequence is recited in a claim, the inventor is not claiming the sequence, but the DNA molecule as a chemical composition.

32. As the Plaintiffs acknowledge, cDNAs are not natural forms of DNA that are found in the human body. They are synthesized by reverse transcribing mRNA in a laboratory. SMF ¶ 62. They are chemical compositions of matter that are chemically, physically and structurally different from naturally occurring genes.

33. For example, cDNAs are not the same as the gene sequence in the body – they lack the introns that are present in the naturally occurring gene. Even if we assume for argument's sake that a sequence of a cDNA was identical to a DNA sequence in the body, the cDNA would be a very small part of a chromosome's huge string of nucleotides present in the

body, and thus would have totally different properties than any naturally occurring composition of matter. Thus, Plaintiffs are wrong when they claim that "[t]he sequence of a cDNA … is identical to that in the body." SMF ¶¶ 62, 63.

34. Plaintiffs incorrectly conclude that genes and their mutations are unpatentable because they are manifestations of laws of nature. SMF ¶¶ 73, 81. Every composition of matter ever patented can be said to embody the inherent laws of nature dictated by the chemical, physical and structural properties of that particular chemical combination of atoms – this does not render those compositions unpatentable. Determining specifically which nucleotides on a chromosome relate to a gene of a specific function and which variations of that gene indicate a predisposition to a specific disease is certainly a discovery which is patent eligible under § 101. Claims covering isolated DNA molecules with a specific, substantial and credible utility, and methods using them to screen, analyze, or diagnose are patent eligible.

35. The USPTO has examined countless applications using the standards I discussed. I searched the USPTO database and found that over the past 29 years, the USPTO has issued some 2,645 patents claiming "isolated DNA." http://patft.uspto.gov/netahtml/PTO/search-adv.htm (search query ACLM/"isolated DNA") (Exhibit 10). Seven of these patents are the Myriad Patents challenged by the plaintiffs.

36. Moreover, I am aware of several patents that are related to genes implicated in different diseases and that have been issued to some of the plaintiffs in this case - Dr. Haig Kazazian 5,407,796, ("Cystic Fibrosis Mutation Cluster")) (Exhibit 11); Dr. Stephen T. Warren (Patents 6,107,025 and 6,180,337 (both entitled "Diagnosis of the Fragile X Syndrome")) (Exhibit 12 and 13); and Dr. David H. Ledbetter (Patent 6,143,504 ("Methods and Compositions for the Diagnosis of Fragile X Syndrome")) (Exhibit 14).

MYRIAD'S BRCA GENE PATENT CLAIMS MEET THE STANDARDS OF § 101

37. I believe that all of the Myriad patent claims in question here meet the requirements for patent eligibility reflected in 35 USC § 101, the Regulations, Guidelines, and the USPTO's practice and procedures set forth in the Manual of Patent Examining Procedure (MPEP) for composition of matter and method claims.

38. Challenged claim 1 of the '473 patent, claims 1 and 2 of the '282 patent, and claims 1,6 and 7 of the '492 patent recite isolated BRCA1/2 DNA molecules. Chemical compositions of matter were patented in these patents, not functionality or information.

39. The utility of the BRCA1/2 composition of matter claims are specific, credible and substantial, thus meeting the elevated utility standard set forth in the 2001 Utility Guidelines. The Myriad patents describe the function of the gene products and discovered the significance of the mutations; these patents are different from the EST patents I discussed earlier.

40. The language of Claim 1 of patents '999, '001, and '441 and Claims 1 and 2 of patent '857 is typical for method claims found throughout thousands of patents for detecting or screening a sample against a normal sample and meet all of the statutory requirements for patentability.

41. The language of Claim 2 of patents '857, patent appears to be the same as thousands of other patented diagnostic claims and meet all of the statutory requirements for patentability.

42. The language of Claim 20 of '282 patent is common for method claims found in thousands of patents for screening drugs using cell culture and meet all of the statutory requirements for patentability.

43. Plaintiffs allege that "[s]ome of Myriad's patents cover mutations that were found by other scientists." SMF ¶ 98. If this is true and if Myriad is not the first true inventor of patented subject matter, there are established procedures to address this concern.[2] However, this is irrelevant to the issue of patent eligibility of the subject matter claimed.

PATENTS PROMOTE RESEARCH AND COMMERCIALIZATION

44. The Plaintiffs express concern that the right to exclude others from using the patented invention will limit the number of other laboratories that can provide the same services as Myriad. SMF ¶¶ 10-12, 87, 139. What the Plaintiffs fail to acknowledge, however, is that the patentee's right to exclude is limited in time, after which the patented invention is donated to the public to freely use. The Constitution expressly permits this quid pro quo contract with the government which the patent system ensures.[3]

45. Patents encourage the sharing of inventions and discoveries by discouraging trade secrets. Without patents and the protections they grant, the world would have less information and many fewer life saving drugs and therapies. More people would have died and there would be less information to use as the basis for future research.

46. Without patents which allow researchers to profit from their discoveries, many discoveries would not have been made. Public funding alone simply could not fund all the research and commercialization that the combination of public and private funding currently accomplishes. Many of the life saving inventions that the world now enjoys would never have been discovered or commercialized if it were not for the potential profits afforded by the temporary exclusive rights granted by the patent system. Undoubtedly, many researchers would

[2] Which party first invented the commonly claimed invention can be determined through an interference proceeding under 35 USC § 135(a).

[3] U.S. Constitution, Article 1, Section 8, Clause 8 clearly states "The Congress shall have the Power to 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."

not have embarked on their research in the first place because they could not afford it or did not have a place to conduct the desired research. Also, the information disclosed in patents provides other researchers with the knowledge and a new starting point to begin research based on the information disclosed in the patent. The discovery and characterization of a gene permits a multitude of other patent possibilities, e.g., diagnostic probes, methods of activating or deactivating, gene splicing, gene replacement therapies, and discovering genes within genes.

47. Contrary to the clinicians and physicians who complain that gene patents interfere with an individual's ability to make informed health decisions (SMF ¶¶ 7-9, 13, 14, 17, 82, 83), gene patents give people options that may not have been available if not for the exclusive rights granted by patents allowing researchers and companies the opportunity to recover the research and development ("R&D") cost and to possibly return a profit for corporations, shareholders and venture capitalists. Many of the life saving inventions that the world now enjoys would never have been discovered or commercialized if it were not for the exclusive rights granted by the patent system.

48. Myriad might not have spent the monies on the R&D that provided the BRCA1 and BRCA2 information to the world if it were not for the exclusive rights granted by the patent system and the possibility of recovering their R&D costs and to return a profit for their shareholders and venture capitalists. There is nothing of record to suggest that, without Myriad's R&D, the world would have the benefit of the life saving advancements claimed and disclosed in their patents.

49. The Plaintiffs also argue that DNA molecules should not be patentable because DNA patents "can serve as a disincentive to innovation in molecular testing and medicine because they deny access to a vital baseline of genomic information that cannot be 'invented

around.'" SMF ¶¶ 1, 3, 50, 114, 175-192. The Supreme Court captured the overbreadth of this criticism in *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980), "[t]he grant or denial of patents … is not likely to put an end to genetic research … patentability will not deter the scientific mind from probing into the unknown … Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, that is all." Although the new discoveries resulting from the R&D of "inventing around" are a benefit of the patent system, the ability to invent around an invention is not a statutory patentability requirement. That an invention is fundamental to human nature and scientific inquiry does not preclude it from patentability. This issue is not part of the calculus of the patent statutes established by Congress and repeatedly interpreted by the Courts or the guidelines set forth by the USPTO.

50. Many women and men have benefited from the Myriad patented compounds and methods. These benefits probably would not have come about if it were not for Myriad's R&D which is highly likely to have been supported by the profits from their patents. Myriad is using the patent system for exactly what it was intended - to exclude others from making, using, selling and importing their patented invention(s) for a limited time, after which the invention becomes available to the public to freely use.

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

Executed on December 22, 2009

John Doll

John Doll

APPENDIX 1

LIST OF EXHIBITS

Exhibit No.	Title
Exhibit 1	*Curriculum Vitae*
Exhibit 2	Public Hearing on the Patenting of Biotechnological Inventions Before the United States Department if Commerce and Patent and Trademark Office (Oct. 17, 1994), located at http://www.uspto.gov/web/offices/com/hearings/biotech/biotrans.html
Exhibit 3	*Utility Examination Guidelines*, 60 Fed. Reg. 36263 (1995) (reproduced in MPEP § 706.03(a)(1) (July 1998)
Exhibit 4	Revised Interim Utility Examination Guidelines, 64 Fed. Reg. 71440 (December 21, 1999)
Exhibit 5	Utility Examination Guidelines, 66 Fed. Reg. 1092 (January 5, 2001)
Exhibit 6	U.S. Pat. & Trademark Off., MPEP § 2107 (8th ed. 2001)
Exhibit 7	Doll, J.J., 1998, "The Patenting of DNA" *Science* 280: 689-690
Exhibit 8	Letter from R. Rodney Howell, President, American College of Molecular Genetics, USPTO (March 20, 2000), *available at* http://www.uspto.gov/web/offices/com/sol/comments/utilguide/acmg.pdf
Exhibit 9	Letter from Debra G.B. Leonard, President, Association for Molecular Pathology to Commissioner, USPTO (March 17, 2000), *available at* http://www.uspto.gov/web/offices/com/sol/comments/utilguide/amp.pdf
Exhibit 10	http://patft.uspto.gov/netahtml/PTO/search-adv.htm (search query ACLM/"isolated DNA")
Exhibit 11	U.S. Patent No. 5,407,796 (filed Jan. 4, 1991)
Exhibit 12	U.S. Patent No. 6,107,025 (filed May 24, 1991)
Exhibit 13	U.S. Patent No. 6,180,337 (filed Aug. 29, 1991)
Exhibit 14	U.S. Patent No. 6,143,504 (filed Oct. 27, 1999)

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