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

DECLARATION OF JOSEPH STRAUS

I, Joseph Straus, hereby declare that:

1. I am currently at the Max-Planck-Institute for Intellectual Property, Competition and Tax Law, Munich, as a Director Emeritus.

2. I studied law at the University of Ljubljana, Slovenia, receiving a law-diploma in 1962. I continued my studies at the University of Munich, Germany, receiving first a certificate in German private and public law in 1963 and a doctorate of juridical science in 1968. In 1986, I attained habilitation at the University of Ljubljana. I was awarded the honorary grades of a Doctor Honoris Causa by the University of Ljubljana in 2001 and by the University of Kragujevac, Serbia, in 2003.

3. From 1968 until 1977, but partly already before, I was in private practice. Since 1977, I have practiced at the Max-Planck-Institute for Foreign and International Patent, Copyright and Competition Law in Munich, which was renamed in 2002 as the Max-Planck-Institute for Intellectual Property, Competition and Tax Law. At that Institute, I was first the Head of the Department primarily responsible for patents and I have been a Director there since 2001 until my retirement as of end of 2008.

4. Between 2001 and 2004, I was the Managing Director of the Institute. Until the end of 2008, I was also the Chair of the Managing Board of the Munich Intellectual Property Law Center ("MIPLC"), which I co-founded in 2003. My main area of interest is patent law, and in particular, the field of chemical and biotech inventions.

5. The academic positions that I currently hold include Nominated Full Professor for Intellectual Property Law, University of Ljubljana (since 1986); Professor of Law, University of

Munich, where I have taught patent law since 1990; and Marshall B. Coyne Visiting Professor of International and Comparative Law, George Washington University School of Law, Washington D.C., where I teach a course on chemical and biotechnology related patents. Additionally, I am a Visiting Fellow at the Hoover Institution, Stanford University. I am also an Honorary Professor of several universities including Tongji University, Shanghai and Huazhong University for Science and Technology, Wuhan, China.

6. During my career, I have held a number of other academic positions and have been a Visiting Professor at several establishments including Cornell Law School, Ithaca, New York (1989-1998); Toronto University (Spring 2005), Renmin University, Beijing (Spring 2005); and George Washington University, Washington D.C. (2001-2004).

7. I act or have acted as consultant to over ten international organizations and national state authorities including the Organization for Economic Cooperation and Development ("OECD"), World Intellectual Property Organization ("WIPO"), the World Bank, the United Nations Industrial Development Organization, the European Commission, the European Patent Office, the Swiss Intellectual Property Institute, the German Government as well as the Swiss Government and the German Parliament. As an expert on the protection of biotechnological inventions, I have testified before the Committee on Legal Affairs and Citizen's Rights of the European Parliament, before the Committee on Legal Affairs of the German Parliament (Bundestag), and before a Special Committee of the Austrian Parliament.

8. Over my career, I have held positions in several committees or advisory bodies of international governmental as well as non-governmental organizations, including the Advisory Board of the WIPO Worldwide Academy; the Standing Advisory Committee before the

European Patent Organization ("SACEPO"); the Advisory Board of the Research Fund of the European Patent Office; the Programme Committee of the International Association for the Protection of Industrial Property (Chair, 1997-2006); the Intellectual Property Rights Committee of the Human Genome Organization (Chair 1995-2006); and the International Association for the Advancement of Teaching and Research in Intellectual Property (President, 1993-1995). At present, I am the Vice-president of the German Association for the Protection of Industrial Property and Copyright ("GRUR") and Chair of the Law Section of the Academia Europaea.

9. In 1999, I was elected Katz-Kiley Fellow of the Houston Law Center, Houston. In 2000, I was awarded the "Science Award 2000" of the Foundation for the German Science (Stifterverband für die Deutsche Wissenschaft) as the first non-scientist. In 2005, I was awarded the "Commander's Cross" of the Order of Merit of the Federal Republic of Germany (Großes Verdienstkreuz des Verdienstordens der Bundesrpublik Deutschland). From 2003-2006, I was selected as one of the 50 most influential people in intellectual property by the Journal "Managing Intellectual Property" and was made a Member of Honour of the International Association for the Protection of Industrial Property ("AIPPI") in 2006. I was inducted into the Intellectual Asset Management Magazine IP Hall of Fame in 2007. In that same year, I was also given the Venice Award for Intellectual Property for commitment to the promotion of intellectual property culture.

10. I am the author or co-author of some 300 publications in the field of intellectual property. A full list of my publications is provided in **Ex.** A. Details of the various advisory and academic positions I have held during my career is set out in the bibliography which is provided at **Ex.** A.

11. In the past, I have provided expert opinions in connection with various patent disputes in

Germany, Europe, the United States of America, Japan and Brazil for a great number of companies, including U.S., Europe and Japan based companies.

12. At present, I am acting as Consultant to a number of companies, however, entirely unrelated to the case at hand and to the parties involved.

13. In view of the subject matter at hand, I may in particular emphasize the following:

14. In 1985, I co-authored (with Prof. F.K. Beier und St.R. Crespi) a study published by OECD, entitled "Biotechnology and Patent Protection – An International Review," which was translated into French, German and Japanese language and which presented the very first study in the area of patenting biotechnological inventions at an international level. Also, in 1985, I prepared a study for WIPO entitled "Industrial Property Protection of Biotechnological Inventions. Analysis of Certain Basic Issues," (WIPO Document BIG/281), which was translated into French, German and Spanish language and which served as the basis for deliberations of a Special Committee of WIPO on the Protection of Biotechnological Inventions.

15. Between 1986 and 1988, I served as consultant to the European Commission in the preparation of the first draft for a Directive on the legal protection of biotechnological inventions. I was the sole drafter of the Explanatory Memorandum to that document. Later on, I assisted the EC Commission in the deliberations with the EU Council and testified before the Committee on Legal Affairs and Citizen's Rights of the European Parliament in the last hearing before adoption of the European Directive 98/44/EC (the "EU Directive"); **Ex.** B.

16. From 1995 to 2006, I was the Chair of the Intellectual Property Rights Committee of the Human Genome Organization ("HUGO"), whose members at that time were *inter alia* Professors Rebecca Eisenberg (Michigan State University), Eric Lander (MIT), Sir John Sulston

(Cambridge), David Cox (Stanford). In this capacity, I was co-responsible for a number of statements on issues of patentability of human DNA sequences, which were adopted and published by HUGO's Council.

17. It should be noted that in 1997, when I was acting as Chairman of HUGO's IPR Committee, we issued a statement on patenting issues related to the early release of raw sequence data ("HUGO 1997 Statement"). *See* **Ex.** C. This statement embodied the principles we adopted in the organization, and particularly set out to inform the scientific and legal community that HUGO did *not* oppose the "patenting of useful benefits derived from genetic information." **Ex.** C. Quite the contrary, HUGO was in favor of patenting isolated DNAs with a known function. What HUGO opposed was patents on express sequence tags ("EST")[1] which had no known function or utility. The United States adopted this standard, which has been the state of the law since *Fisher*. *See In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) (affirming the USPTO's refusal to grant a patent on ESTs with unknown function or utility). I note that, Sir Sulston, Plaintiffs' declarant, contrary to the positions he has taken in this case (*See*, *e.g.*, Sulston Decl. ¶¶ 37-38.), was indeed not only a member of HUGO at this time, but also a signatory of the 1997 HUGO Statement.

18. Between 2004 and 2006, I chaired an OECD Expert Group which in 2006 successfully developed detailed principles and best practices for the licensing of genetic inventions in order to ensure that therapeutics, diagnostics and other products and services employing genetic inventions are made readily available on a reasonable basis.

[1] An EST (Expressed Sequence Tag) is a short sequence of the complementary DNA that was expressed by the full-length gene.

19. I have reviewed the following documents: Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment; Plaintiffs' Rule 56.1 Statement of Material Facts; Declaration of Sir John E. Sulston, Ph.D. of August 17, 2009; Declaration of Myles W. Jackson of August 18, 2009; and 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"), (collectively "Myriad patents"); *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (January 5, 2001), **Ex.** D ("2001 Guidelines"); Decision of June 6, 2007 of the Opposition Division in connection with the EP 0 705 903 patent (granted May 23, 2001), **Ex.** E; Board of Appeal Decision T 0666/05 of November 13, 2008 in connection with the EP 0 705 903 patent, **Ex.** F; Board of Appeal Decision T 1213/05 of September 27, 2007 in connection with the EP 0 705 902 (granted November 28, 2001), Ex. **G**; Straus et al., "Genetic Inventions and Patent Law – An Empirical Survey of Selected German R & D Institutions," Published by Max Planck Institute for Intellectual Property, Competition and Tax Law, Munich 2004, **Ex.** H; Walsh *et al.*, 2005, *Science*, "View from the Bench: Patents and Material Transfers," 309:2002-03, **Ex.** I ("Walsh 2005").

I. ISOLATED NUCLEIC ACID PATENTS – A EUROPEAN PERSPECTIVE

A. SCIENTIFIC BACKGROUND

20. Genes are to be understood as fundamental physical and functional units of heredity. Genes are located in a particular position on a particular chromosome. Genes encode specific functional products, such as a protein or RNA molecule. Genes are of double nature: On the one hand, they are chemical substances or molecules. On the other hand, they are physical carriers of information, *i.e.*, where the actual biological function of this information is coding for proteins. Thus, inherently genes are multifunctional.

21. Since the completion of the raw sequence of the human genome not only do we know that we only have some 20,000–25,000 genes, but also that some 40 per cent of the gene products are alternatively spliced. Therefore, genes encode for more than one protein, depending on the combination of exons read in an open reading frame, or even depending on the direction in which the exons are read. Thus, many genes are rendered multifunctional based on this splicing mechanism. Moreover, DNA molecules as physical carriers and information are multifunctional under another important aspect: they hybridize to other DNA molecules, a property I would like to describe as an actually non-biological function. Thus, by virtue of this property, DNA molecules can be used, for instance, as DNA probes, and diagnostic markers.

B. WHAT CONSTITUTES AN INVENTION IN THE CASE OF ISOLATED NUCLEIC ACID PATENTS - A COMPARATIVE ANALYSIS WITH OTHER PRODUCT INVENTIONS

22. Generally, product inventions relate to: synthetic molecules produced in a lab; chemical substances isolated from natural environment; and DNA molecules of human origin, respectively. I will discuss whether essential differences exist between these different forms of chemical compounds, and secondly, if there are such differences, whether they require different legal treatment.

1. Synthetic Molecules

23. Synthetically produced new chemical substances are molecules of an arbitrary formula. They are new in an absolute sense and are in principle without an actual biological function. Such molecules are producible in arbitrary – unlimited variations. Finding a first surprising property, for instance a therapeutic effect, of such new, *i.e.*, not pre-existing molecule, even if routinely produced or detected, justifies patent protection. In other words, the essence of the

invention is in "making the absolutely new substance available" to the public. The substance made available, in combination with the disclosure of the surprising therapeutic effect, opens up an entire new field for further research. Third parties can search for, for instance, further therapeutic uses, or they can experiment with the disclosed new formula, for instance, by adding, exchanging or deleting protection groups, in order to achieve other useful effects. To my understanding, in such circumstances "absolute" protection is justified and in line with the spirit and purpose of patent law. Without the new molecule and its "invented" property, others could not embark on further research.

2. Chemical Substances Isolated from the Natural Environment

24. In case of chemical substances isolated from the natural environment, the assessment is similar, although such substances are "new" only in the sense of not being previously available to the public. For example, Lovastatin, a cholesterol lowering agent was isolated from *Monascus rubber* and various species of *Aspergilus terreus*, a microorganism. In such microorganisms, Lovastin's function by no means is lowering cholesterol. Thus, Lovastatin, and many other natural products, in their natural environment, in principle, typically have no actual biological function or use. Alternatively, the function of the chemical substance as "isolated" is distinct from that as it exists in nature. Moreover, such substances are available in unlimited numbers in nature. Thus, a finding of a first surprising property, such as lowering the blood cholesterol level in the case of Lovastatin, justifies for the very same reason the same treatment as in the case of synthetically produced new chemical molecules. Once the formula of Lovastatin was disclosed, the research in the entire area of the class of statins was opened up and eventually ended in inventing a great number of other new cholesterol-lowering agents.

3. DNA Molecules

25. As indicated above, human genes are biochemical substances as well as physical carriers of information. They have one or more related or unrelated actual, pre-determined biological function(s). They code for various proteins, for instance receptors, structural or regulatory proteins, etc. They are available – producible – only in limited numbers. The actual goal of research in this area is aimed at identifying and deciphering their actual nucleotide sequences, *i.e.*, the exact location and sequence of the gene, in order to find and exploit its actual and pre-determined biological function(s). This information can be used to make primers and probes for use in diagnostics.

26. Once the actual nucleotide sequences, *i.e.*, the exact location and sequence of the gene, is identified and deciphered, the focus of the invention should be shifted from the "making available" of the DNA, to finding the surprising property(ies), function(s). The identification of a specific open reading frame of a gene will involve "inventive" activity. Thus, "making available of the sequence" is playing the same role as in the case of synthetic molecules and chemical substances isolated from their natural environment. Isolation of such DNA molecules can thus constitute an invention fulfilling all the patentability requirements and deserving "absolute" protection.

II. A UNIFORM WORLD-WIDE APPROACH TO PATENTING ISOLATED NUCLEIC ACIDS

27. Although the appropriateness of granting patents on isolated DNA and other isolated nucleic acids continues to be publicly debated, the position of the official patent authorities in OECD has been clear and consistent for some time. From the standpoint of patent offices in Europe, especially the European Patent Office ("EPO"), genetic material is not seen as a special

case requiring treatment different from chemical compounds and other products. This view is shared by the patent offices of the United States and Japan. Common ground between the EPO, the United States Patent and Trademark Office ("USPTO") and the Japanese Patent Office ("JPO") has already been reached with respect to patents on isolated nucleic acids.

28. Mere determination of a DNA sequence is not enough for patentability. But, where the inventor is the first to identify a gene and its useful function, to isolate and clone the nucleic acid of the gene and thereby make synthetic copies of the nucleic acid that are available for use in diagnosis or therapy, patent offices world-wide accept that this is the kind of invention for which a patent can be granted.

III. THE EUROPEAN APPROACH

29. Patenting of biotechnology inventions, including patenting DNA molecules corresponding to genes, has been contentious and involved, at times, heated public debate. All of such discussions influenced the debate concerning the implementation of the EU Directive of the European Parliament and the Council on the legal protections of biotechnological inventions. The EU Directive 98/44/EC was adopted in July 1998 after a tense and controversial debate.

30. According to the EU Directive, assuming that a DNA sequence is novel, *i.e.*, not previously publicly known or used, and that other criteria for patentability are met (*i.e.*, industrial applicability ~ utility, non-obviousness, sufficient disclosure), the isolated substance of the DNA itself is patentable. To be precise, the claims concern not the sequence as abstract information, but a molecule which has a defined chemical structure (as nucleotide sequence) and function. This type of product claim will often be qualified in some respect, *e.g.*, by the limitation of "isolated" or "purified", especially if the substance exists in nature.

31. Specifically, the approach adopted by the EU Directive is that a nucleic acid corresponding to a complete or part of a gene, even if its structure is identical to that of a natural element, may constitute a patentable invention, if isolated from the human body or otherwise technically produced. **Ex.** B at Article 5(2). Indeed, the natural pre-existence of biological material alone does not constitute a patentability obstacle. **Ex.** B at Article 3(2). The EU Directive established that no patent can cover a substance *in situ* in the human body. Rather, the patent must cover the isolated substance. It is my understanding that the United States Patent and Trademark Office has a similar policy, in that it requires product claims to genetic materials be limited to the purified and isolated material. 2001 Guidelines; **Ex.** D.

32. Apart from the above restriction, an isolated DNA can be claimed as the substance *per se*, without limitation to any particular process of purification or isolation and without any limitation as to its intended use. In patent parlance, this is known as a "product per se" claim and it confers "absolute product protection". Granting "product per se" patents for genetic inventions is consistent with the established practice for new pharmaceuticals and other chemical compounds. The trend in many countries over the years has been to allow such product claims, as against previous more restrictive policies of allowing claims only to the particular chemical processes described in the patent application for making end products. In fact, the World Trade Organization ("WTO") Trade Related Intellectual Property Rights ("TRIPS") Agreement requires patent protection to be available for process and product claims in all branches of technology, without discrimination. TRIPS Agreement at Article 27 (1)).

33. Under the EU Directive, the disclosure of a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention (EU Directive at Recital 23), even if the method of manufacture is indicated. On the other hand,

the industrial applicability of the isolated DNA, in other words its function, has to be specifically disclosed in the patent application as filed. EU Directive at Recital 22, last sentence, Article 5(3). Where the use of a sequence or partial sequence of a gene for making a protein is claimed, the protein or part protein and its function have to be specified. EU Directive at Recital 24. If therapeutic or diagnostic uses are claimed, the disorder to be diagnosed or treated must be specifically indicated. Thus, the European legislator has made the function of a claimed DNA molecule an integral part of the notion of an invention (inventive concept) of a chemical compound invention, at least in this area.

34. Under the EU Directive, protection of a product, which consists of or contains genetic information, *i.e.*, a gene sequence, extends to any product – except man – in which this product is incorporated and in which the genetic information is contained and performs its function. **Ex.** B at Article 9.

IV. MYRIAD'S COMPOSITION OF MATTER CLAIMS COMPLY WITH THE EP PATENT LAWS

35. I reviewed claims 1, 2, 5, 6, and 7 of the '282 patent; claim 1 of the '473 patent; claims 1, 6, and 7 of the '492 patent. These claims all relate to isolated DNA molecules comprising either the *BRCA*1 or *BRCA*2 DNA. For ease of reference, I will refer to such claims as the "isolated DNA" claims.

36. Under the EU Directive, the Implementing Regulations to the European Patent Convention ("EPC") and case law interpretation of it, "isolated and purified" DNA molecules are patent-eligible subject matter. Thus, Myriad's isolated DNA claims are patent-eligible. The European Patent Office ("EPO") and Supreme Courts of the EU Member States, to my knowledge, have never challenged the validity of patents granted by the EPO Boards of Appeal

for "isolated and purified" DNA based on the grounds of their eligibility for patent protection.

37. As I mentioned above, I reviewed the decision of June 6, 2007 of the Opposition Division in connection with the EP 0 705 903 patent; Board of Appeal Decision T 0666/05 of November 13, 2008, confirming the holding of the Opposition Division and maintaining the EP 0 705 903 patent, and the Board of Appeal Decision T 1213/05 of September 27, 2007, maintaining the EP 0 705 902 patent. **Exs.** E-G. It should be noted that all the arguments that Plaintiffs have raised in this case (*see* Plaintiffs' Statement of Material Facts) were also raised during the Opposition Proceedings of these counterpart EP patents. In each case, these arguments were rejected by the Boards of Appeal.

38. Indeed, as reiterated by the Board of Appeal, an independent judiciary body, there simply is no bar to the patenting of isolated human DNA. Like plaintiffs in the U.S. case, the opponents in Europe attempted to raise socio-economic consequences of patenting of the claimed subject matter as a basis for denying patentability of Myriad's invention. But, like the Courts in the United States, those in Europe have all repeatedly ruled that isolated nucleic acids such as those claimed in the Myriad patents constitute patent eligible subject matter. Any change in the law is not within the province of the EPO or the national courts of the states parties to the European Patent Convention ("EPC") – neither is it within the province of the U.S. courts. Anyone challenging the Myriad patents would need to access another vehicle – perhaps, the Legislature.

V. EFFECT OF ISOLATED NUCLEIC ACID PATENTS ON BASIC RESEARCH, MEDICAL AND CLINICAL RESEARCH, INNOVATION AND COMMERCIALIZATION

39. While many have criticized the impact of genetic invention patents on access to the information and technologies covered by DNA patents, the available evidence does not suggest a systematic breakdown in the research and development of genetic inventions, once a particular isolated nucleic acid corresponding to a gene is patented. To the extent there are any concerns

regarding the potential for over-fragmentation of patent rights, blocking patents, or abusive monopoly positions, they appear anecdotal and not supported by any actual studies. Below, I summarize the result of two such empirical studies that negate the misconception that biotechnology patents have slowed biomedical research.

A. An Empirical Study in Germany

40. In 2002, the German government commissioned a study on "Genetic Inventions and Patent Law," which I conducted while at the Max Planck Institute for Foreign and International Patent, Copyright and Competition Law. **Ex.** H. The purpose of the German survey was to gain information from an objective viewpoint concentrating on the challenges of potential patentees for patenting genetic inventions and to provide evidence about the licensing practices relating to genetic inventions. Furthermore, the German survey was aimed at elucidating whether specific problems arise from the application of patent law on genetic inventions, in particular from patents on isolated DNA. As I indicated in a presentation, which I offered on the Survey in a January 2002 workshop, entitled "Genetic Inventions, Intellectual Property Rights and Licensing Practices," jointly organized by the OECD and the German Federal Ministry for Education and Research in Berlin, the overall goal of the survey was to verify concerns expressed on negative impact of patents in genomics as set forth in the EU Directive 98/44. Interviews were carried out at 25 institutions, including large pharmaceutical companies, biotech start-ups, clinical institutions associated with universities and other publicly funded research institutes and clinical institutions involved in genetic testing.

41. The survey specifically investigated, *inter alia*, whether there was reluctance to enter particular research fields in which gene related patents have been granted. No such tendency

was observed. Interestingly, the great majority of those interviewed across the entire surveyed group clearly favored the so-called absolute product patent protection of isolated nucleic acids. Those surveyed opposed any discrimination of this area of research and development as compared with the protection which classical chemical inventions enjoy. Of all the groups surveyed, including clinical institutions associated with universities, no specific problems of licensing were reported. Only some of those interviewed indicated a reduced interest for research in further uses of inventions patented for third parties.

42. Indeed, my study showed that all institutions surveyed were able to cope with the patent system ***as is*** in a satisfactory manner. We could not detect any support for a special regime for protecting genetic inventions. It should also be added that for those interviewed, there is a possibility for applying for a compulsory license, available under Section 24 German Patent Act ("GPA") which allows the grant of such a license, if such a license would be in public interest. Alternatively, in cases of a dependent patent claiming an invention, which involves an important technical advance of considerable economic significance in relation to the invention covered by the dominant patent, so-called dependency compulsory license would be available under the GPA. To my knowledge, neither in Germany nor in any other EU Member State a compulsory license has ever been applied for any of Myriad patents.

43. Finally, my study also found that patents on research tools, including isolated DNA molecules, have not had a discernible effect on the cost or pace of research in Germany, and the survey results suggested several reasons for this. First, some research tools are staple goods, like enzymes, which can be purchased without declaring their intended use. Second, it is difficult to detect infringement of research tools which are used behind laboratory doors. While end products may be suspected of having been developed using a patented research tool, many

biotechnology companies do not yet have such commercialized products, making it difficult to claim infringement. Third, public research bodies claim that their staff are often unaware of the legal implications of using patented research tools. In short, many groups act as if an "informal research exemption" exists for the use of patented research tools.

B. An Empirical Study in the United States

44. In May 2006, I attended a Conference Organized by the OECD among other organizations entitled "Research Use of Patented Inventions," where I was also a presenter. This conference was organized, in part, to address the concerns in the scientific and legal communities in accessing biotechnology inventions that are protected through the patent system. One presenter of note at this conference was John P. Walsh, associate Professor of Sociology at the University of Illinois, Chicago. *CSIC/OECD/OEPM Conference*, Madrid, Spain, May 18-19, 2006; John P. Walsh, "Roadblocks to Accessing Biomedical Research."

45. Walsh's study consisted of interviews with executives and researchers at biotechnology and pharmaceutical firms and research personnel and administrators at several universities. The objective of the study was to evaluate whether the "tragedy of the anti-commons"[2] is indeed a reality in biomedicine and whether patent rights to certain research tools are retarding innovation. Specifically, Walsh examined the impact of patents and licensing on access to knowledge and material inputs for academic biomedical research; the limitations on subsequent discovery and improvements imposed by assertion of patent on upstream foundational discoveries, such as discovery of genes; and the effect patents on research productivity.

[2] The "tragedy of the anti-commons", a term coined by Heller and Eisenberg (1998), refers to a situation where there are numerous property right claims over the building blocks necessary for research and development.

46. Walsh reported the results from a survey of 1125 academic researchers (including university, non-profits and government labs), which yielded 414 responses (adjusted response rate of 40%).

47. Walsh's results showed that there was little evidence so far of breakdowns in negotiations over patent rights or evidence that biomedical research has slowed as a result of biotechnology patents, including gene patents. Indeed, firms and research organizations in the United States reported "working solutions" which allow them to continue to innovate relatively unimpeded. Solutions included license negotiations where necessary or the avoidance of patent obstacles by working around the claims. Firms also chose to ignore or infringe patents, to challenge patents and litigate, to move offshore or to put innovations in the public domain. Thus, it would appear that access to patented technology has rarely, if ever, been blocked.

48. 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. **Ex.** I at 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.*

49. I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States, that the foregoing is true and correct to the best of my knowledge and believe.

Executed on: December 22, 2004

Joseph Straus

APPENDIX 1

LIST OF EXHIBITS

Exhibit No.	Title
Ex. A	*Curriculum vitae* and Bibliography of Dr. Joseph Straus
Ex. B	European Directive 98/44/EC
Ex. C	HUGO 1997 Statement
Ex. D	*Utility Examination Guidelines*, 66 Fed. Reg. 1092 (January 5, 2001)
Ex. E	Decision of June 6, 2007 of the Opposition Division in connection with the EP 0 705 903 patent (granted May 23, 2001)
Ex. F	Board of Appeal Decision T 0666/05 of November 13, 2008 in connection with the EP 0 705 903 patent
Ex. G	Board of Appeal Decision T 1213/05 of September 27, 2007 in connection with the EP 0 705 902 patent
Ex. H	Straus et al., "Genetic Inventions and Patent Law – An Empirical Survey of Selected German R & D Institutions," Published by Max Planck Institute for Intellectual Property, Competition and Tax Law, Munich 2004
Ex. I	Walsh et al., 2005, "View from the Bench: Patents and Material Transfers," *Science*, 309:2002-03

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