No. 2010-1406

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

and

MYRIAD GENETICS, INC.,

Defendant-Appellant,

and

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

Defendants-Appellants

Appeal from the United States District Court for the Southern District of New York,
in case no. 09-CV-4515, Senior Judge Robert W. Sweet

BRIEF FOR UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES, SUPPORTING AFFIRMANCE

KRISTA L. COX
UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES
2625 Alcatraz Ave, #180
Berkeley, CA 94705
(510) 868-1159
Staff Attorney for Amicus Curiae

CERTIFICATE OF INTEREST AND ENTRY OF APPEARANCE

Counsel for the amicus curiae, Universities Allied for Essential Medicines, certifies the following:

1. The full name of every party or amicus represented by me is:

   Universities Allied for Essential Medicines

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   Not applicable

3. All parent corporations and any publicly held companies that own 10 percent or more in stock of the party or amicus curiae represented by me is:

   None

4. The names of all law firms and the partners or associates who appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

   UAEM did not appear in the trial court. Before this court, UAEM is represented by:

   Krista L. Cox
   Universities Allied for Essential Medicines
   2625 Alcatraz Ave., #180
   Berkeley, CA 94705
   (510) 868-1159
   krista.cox@essentialmedicine.org

Dated: December 6, 2010

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Krista L. Cox

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INTEREST OF *AMICUS CURIAE*

Universities Allied for Essential Medicines ("UAEM") is an international nonprofit organization for university students advocating increased innovation and access to medicines and other health-related technologies. UAEM works to promote affordable global access to essential medicines developed from university research. More than one quarter of all gene patents are assigned to universities, and nearly two thirds of all gene patents are the result of publicly funded research. (A168, A14565.) Accordingly, UAEM is particularly concerned with the negative impact of gene patents on the public's ability to afford and utilize essential medical diagnostics and treatments for widespread disease prevention.

AUTHORITY TO FILE

All parties have consented to the filing of this amicus brief by UAEM. As a result, in accordance with Federal Rule of Appellate Procedure 29(a), no motion for leave to file has been submitted with this brief.

UAEM has no commercial interest in the parties to this action. No part of this brief was authored by a party's counsel nor did any party or a party's counsel contribute money that was intended to fund preparation or submission of this brief. No person, other than the amicus curiae, UAEM, contributed money to the preparation and submission of this brief.

INTRODUCTION

The patents-in-suit are based on research performed at the publicly funded University of Utah ("UT"), using federal funding from the National Institute for Environmental Health Sciences ("NIEHS"), a subdivision of the National Institutes of Health ("NIH"). UT obtained ownership over the patents-in-suit gene sequences by exercising its rights under the Bayh-Dole Act.

The patent claims-at-issue are directed to two human genes—BRCA1 and BRCA2—that play a critical role in determining an individual's susceptibility to breast cancer. Isolated genes are solely a product of nature, and thus should not be patented. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The process of isolating a gene requires only the application of well-understood scientific principles. (A2443-45.) Research universities and UAEM members implement these scientific principles worldwide and on a daily basis. *Id*. The claims-at-issue do not use any novel approach that could be the basis for the patents.

Even when a gene's entire function has not yet been discovered, gene patents remove the gene from public domain, therefore stifling the competitive biotechnology research upon which collective understanding, innovation, and development of treatments depend. A recent study on the effects of gene patents found a thirty-percent drop in subsequent scientific development outcomes for a genetic disease after a patent was granted on the targeted gene. (A7062-65.)

Respected scientists including NIH Director, Francis Collins, and UAEM Advisory Board Member, Dr. John Sulston, have cautioned that gene patents place "unnecessary toll booths on the road to discovery." Alan E. Guttmacher & Francis S. Collins, *Genomic Medicine—A Primer*, 347 NEW. ENG. J. MED. 1512, 1514 (2002); *See also* (A2446-48.).

Knowledge of a gene's purpose and the existence of mutations are critical facts researchers use to develop new diagnostic and treatment methodologies. The essential first steps to making such discoveries involve the identification and characterization of the gene. UAEM is deeply troubled that the BRCA patent claims-at-issue remove essential facts from the realm of public use, particularly when the discovery of those facts was funded by the public, and took place at a public university. The removal of these facts from the public commons dramatically restricts the ability of future university researchers to develop new clinical tests and novel pharmaceuticals.

The district court properly found the BRCA patent claims-at-issue to be invalid, and UAEM urges the Court to uphold that decision. The invalidation of the BRCA patent claims removes an unwarranted bottleneck limiting other researchers from additional innovation and discovery. By upholding the district court's decision, this Court can liberate the BRCA genes from exclusive control as the scientific community continues to discover their complexities. Retaining these

invalid gene claims will create exclusive rights with unknown breadth and significance, which will impede the creation of novel products and the discovery of additional effects.

The BRCA1/2 gene patents are especially onerous. Defendants-Appellants obtained an exclusive license for the patents-at-issue and they have used those patents to prevent others from developing additional tests for the presence of mutations in the BRCA genes. Defendants-Appellants have also resisted others' attempts to independently verify the accuracy of BRCA1/2 tests, despite a study reported in the Journal of the National Cancer Institute which found Defendants-Appellants' test failed to find up to twenty percent of known BRCA1 mutations. Steve Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. NAT'L CANCER INST. 2, 80 (2002). In addition to the failure to find up to twenty-percent of known mutations, one study found that the test had a twelve percent error rate in correctly finding the mutations. Tom Walsh, et. al., *Spectrum of Mutations in BRCA1, BRCA2, CHECK2, and TP53 in families at High Risk of Breast Cancer*, 295 JAMA 1369, 1386 (2006).

In addition, Defendants-Appellants have used their patent-monopoly to stifle continuing research on specific BRCA mutations that are more prevalent in minority groups. Defendants-Appellants' test has a higher rate of error for women of non-European ancestry than those of a Caucasian background. (A1059; A3205-

06.) However, women who receive a questionable result from Defendants-Appellants' test for the cancer-causing version of BRCA genes, cannot obtain a second opinion based on a different BRCA genetic test as Defendant-Appellants are the exclusive provider of all BRCA tests. (A160; A2652; A2772; A2937-38; A2982-83; A3037-38; A3065 A3072-73; A3077.) This concern is especially troubling when the sole test available for BRCA1/2 mutations by Myriad is shown to be flawed. Steve Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. NAT'L CANCER INST. 2, 80 (2002).

Defendants-Appellants' hoarding of the BRCA1/2 genes for pecuniary benefit is particularly evident from its original exclusion of six co-scientist contributors at NIEHS from the patents-in-suit. (A143-44.) Only after NIH maintained that its scientists conducted some of the most important work leading up to the sequencing of the gene did Myriad agree to include the names of the NIEHS researchers as inventors on its patent application and deserving of (as of 2005, yet unpaid) royalties. *Id*.

UAEM believes that the BRCA gene patents now controlled by Myriad fail to promote the progress of science embedded in the Constitutional rationale of the Patent Act. Myriad's monopoly over research on these naturally occurring genes has not led to greater knowledge of the BRCA1/2 genes, but has instead led directly to a *decrease* in information concerning these genes because further

research results cannot be made publicly available due to Myriad's issuance of cease-and-desist letters to scientists and decision to preclude all research into these genes. Myriad's monopoly over the BRCA 1/2 genes has therefore impeded the progress of science. (A163; A2672-74; A7271-73).

UAEM's members are committed to ensuring that the public receives the benefits of the research performed at our universities, particularly research conducted with the use of public funds. UAEM members conduct research and pursue careers in medicine and public health, and the claims-at-issue hinder research, medical training, and collaboration within the scientific community by preventing access to these building-block scientific facts. Moreover, Defendants-Appellants' monopoly increases costs of the research and treatment of genetic diseases. The BRCA gene patents thus limit access to essential information which stands as the foundation to further genetic research by universities.

In light of the foregoing facts, UAEM files as *amicus curiae* in support of Plaintiffs-Appellees.

ARGUMENT

I. THE DISTRICT COURT PROPERLY EXERCISED ITS DUTY TO DETERMINE PATENT ELIGIBILTY

Article 1, Section 8, Clause 8 of the U.S. Constitution allows Congress to create laws to promote the progress of science and useful arts by allowing inventors to have a limited monopoly over their discoveries. U.S. CONST., art. 1, §

8, cl. 8. The Patent Act creates a quid-pro-quo for the express purpose of advancing the "Progress of Science and useful Arts." However, the "embarrassment of an exclusive patent" is a special legal privilege justified only because such "monopolies of invention" serve the "benefit of society." *Graham v. John Deere Co.*, 383 U.S. 1, 7-10 (1966) (*quoting* Thomas Jefferson). The Court has repeatedly held: "Congress may not authorize the issuance of patents whose effect is to remove existent knowledge from the public domain, or to restrict free access to materials already available." *John Deere Co.*, 383 U.S. at 5. By creating monopolies that prohibit all others from creating the same effect or process by any means whatsoever, a patent discourages scientific progress in contravention of the avowed language policy of the Patent Act. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853)

Not all discoveries are eligible for patent protection. The claims-at-issue restrict access to basic tools of scientific research and thus "impede rather than promote the Progress of Science and the useful Arts." *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office.* 702 F.Supp.2d 181, 219 (S.D.N.Y. 2010) (09 Civ. 4515) (*quoting Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.,* 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting) (quotation marks omitted)). The district court properly found these claims to be invalid under 35 U.S.C. § 101, and that decision should be affirmed.

II. PRODUCTS OF NATURE, LAWS OF NATURE, NATURAL PHENOMENA, AND ABSTRACT IDEAS ARE NOT ELIGIBLE FOR PATENT PROTECTION

While the Court has consistently recognized that Title 35 must be broadly interpreted to accomplish Congress' design of encouraging innovation, three specific types of claims have been categorically removed from the scope of patent protection: "the laws of nature, physical phenomena, and abstract ideas." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *see also, Diamond v. Diehr*, 450 U.S. 175, 185 (1981). Further, in determining patent eligibility, the Supreme Court has eschewed bright line tests, instead providing the lower courts with boundary-setting factors for patent eligibility: (1) a claim may not reach to a product of nature when the claimed substance is the direct product of a natural law; (2) a product that is not markedly different from a naturally occurring form cannot be patented; and (3) a claim that preempts all uses of a natural product reaches too far and is not patent eligible. *See Chakrabarty*, 447 U.S. at 303; *Funk Brothers Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127, 130-32 (1948); *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972).

A. The District Court Properly Concluded That Claims-at-Issue Are Directed to Pure Products of Nature.

Constitutional limits on patentability traditionally applied to all inventions, including those made in the biological arts. *Chakrabarty*, 447 U.S. 303 (1980). The Court has held that certain objects created solely by operation of natural law,

unaided by the hand of man, are not patentable and "must be free to all mankind" in order to encourage innovation. *Id*. at 312-13 ("a new mineral or plant discovered in the wild would not be patent eligible"). Despite this well-established rule, many inventors have unsuccessfully attempted to circumvent the prohibition on patenting naturally occurring objects by arguing the antiquation of the fundamental principles of patent law. *See e.g., O'Reilly v. Morse*, 56 U.S. 62 (1853); *American Fruit Growers, Inc. v. Brogdex Co*., 283 U. S. 1 (1931); *Bilski v. Kappos*, 545 F. 3d 943 (2010).

Defendants-Appellants attempt to circumvent the rule prohibiting patents on products of nature by concealing the simple fact that the BRCA1/2 genes are a product of nature beneath a veil of intentionally convoluted technical language. However, the district court properly cut through these obfuscations to reach the obvious and undisputed conclusion that human genes are products of nature.

Defendants-Appellants argue that the unique dual nature of genetic molecules should be ignored when construing their claims and ask the Court to ignore the information concerning the structure of proteins stored within nucleic acids. However, as the district court properly noted, the nature of the information storing and transmitting in nucleic acids is critical to properly construe the claims-in-suit as a whole. (A215 "Myriad's focus on the chemical nature of DNA, however, fails to acknowledge the unique characteristics of DNA that differentiate

it from other chemical compounds.") Myriad's claim is analogous to "taking a hardback book written by someone else, publishing it in paperback and then claiming authorship because the binding is different." (A2445.)

The district court properly identified the "invention" here as information already naturally carried within the DNA, while also noting that Defendants-Appellants' are in the "genetic information business." The district court properly held the biological information stored in the "genes" on chromosomes 13 and 16, are the products of nature. As a result, Defendants-Appellants have not created anything new, but simply attempted to patent a mere photocopy of naturally occurring information. Therefore, the court properly held that the long-standing prohibition on patenting laws of nature forecloses Defendants-Appellants' claims. (A228.)

The lower court's decision to limit the scope of patents-in-suit is supported by a long line of cases covering patent-eligible subject matter. *Chakrabarty* is distinct from the case at hand; there, the claim was drawn on newly created bacteria different from any other existing organism, and so it was a "product of human ingenuity." *Chakrabarty*, 447 U.S. at 309. Conversely, the court in *Funk Brothers* noted that the invention drawn from a collection of naturally existing bacteria produced "no new bacteria" and "no change in the six species of bacteria." *Funk Brothers*, 333 U.S. at 131. No transformation occurs in Defendants-

Appellants' claims; they involve only the comparison and analysis of two given genetic sequences. (A2479-81; A2574-75.) Accordingly, in the present case, the lower court properly applied the Supreme Court's clear guidance to identify the claims as patent-ineligible because they are directed to preexisting products of nature—the information contained within the BRCA1/2 genes.

B. Patents-in-Suit Improperly Claim a Naturally Occurring Substance.

The courts have consistently found that naturally occurring substances, even when remixed or completely artificially created, are beyond the scope of patent-eligibility. In *Funk Brothers*, a unique mixture of isolated, naturally occurring bacteria was beyond the scope of patent-eligibility despite the unique and beneficial properties afforded by the new mixture. *Funk Brothers*, 333 U.S. at 130-32. There, the Court held: "The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men." *Id*. at 130. Similarly, in *General Electric*, the Federal Circuit found that the creation of "substantially pure tungsten" was ineligible subject matter for patent protection. *General Electric Co. v. DeForest Radio Co.*, 28 F.2d 641, 642 (3d. Cir. 1928). The mere purification and isolation of the natural substance was insufficient to create a markedly different patentable material. *Id*.

Defendants-Appellants' contention that purified nucleic acids exhibit useful properties does nothing to negate the fact that these nucleic acids are not markedly

different than those preexisting in nature. Moreover, the process of purification used by Defendants-Appellants does not create a product that is markedly different than its naturally occurring form. It is clear from the undisputed facts determined by the lower court that many of Defendants-Appellants' patents broadly sweep in products of nature. The key to the patents-in-suit is that the claimed nucleic acids have genetic information indistinguishable from products of nature.

Defendants-Appellants incorrectly rely on *Parke-Davis* to characterize substantially purified nucleic acids as markedly different from natural articles. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911). Instead, the district court correctly noted that the ruling regarded the novelty of the subject matter in question, not its patent eligibility. (A207-09.) Furthermore, the Supreme Court and this Courts' predecessor have rejected the notion that "merely an extracted product without change is patentable." *See Chakrabarty*, 447 U.S. at 310; *Funk Bros.*, 333 U.S. at 130-32; *Am. Fruit Growers*, 282 U.S. at 11. *See also In re Merz*, 97 F.2d 559, 601 (C.C.P.A. 1938); *General Electric*, 28 F.2d at 642.

The claims-at-issue merely restate the natural chemical properties of all nucleic acids and are not drawn on any new properties. Defendants-Appellants' entire model relies on "isolated" and "purified" nucleic acids that carry the same biological information of protein translation as nucleic acids that naturally occur in human cells. Hence, the claims-in-suit are drawn on nucleic acids not markedly

different than products of nature, and thus properly denied patent protection for failing to meet the requirements of 35 U.S.C. § 101. (A228.)

III. CLAIMS-AT-ISSUE IMPROPERLY PREEMPT ALL OTHER USES OF THE UNDERLYING PRINCIPLE

The Supreme Court has held that a process preempting every practical use of a fundamental principle may not be patented. *Gottschalk*, 409 U.S. at 72. There, the patent covered a process performed entirely on a computer, which converted binary-coded decimals into pure binary numbers. Despite the technical complexity of the underlying process, the Court held that to grant a patent for this invention "would preclude any further use of the algorithm." *Id*.

For over one-hundred-fifty years, the Court has found that complete field preemption, in any area, is evidence of a patent claim drawn on ineligible subject matter. *See O'Reilly v. Morse*, 56 U.S. 62 (1854) (invention claiming all uses of electro magnetism [sic] was patent-ineligible as it precluded all possible uses of a field); *Corning v. Burden*, 94 U.S. 780 (1854) (chemical process or physical acts must confine the patent-monopoly within rather definite bounds); *but see Diamond v. Deihr*, 50 U.S. 175 (1981) (computer programmed to use the Arrhenius equation to control a process for curing rubber was patent eligible as it did not preclude any other use of the Arrhenius equation). Regardless of the underlying technology, patents that preclude any other use of a field are suspect. *Deihr*, 50 U.S. at 187-88.

In the present case, the lower court correctly identified the field-at-issue to be a test for the presence of BRCA1/2 genes. The claims-at-issue cover the entire field of use for BRCA1/2 genes and, under the principle of complete field preemption, are drawn on patent ineligible subject matter.

A. The BRCA Claims-at-Issue Prevent Further Life-Saving Research.

Gene patents have resulted in negative effects on the progress of research and biotechnology. A recent study found that thirty-percent of clinical laboratories reported voluntarily stopping development on a test for a haemochromatosis-related gene once a patent was issued for it. Matthew Herder, *Patents & The Progress of Personalized Medicine: Biomarkers Research as Lens*, 18 Ann. Health L. 187, 209-211 (2009). Another study, conducted by Dr. Mildred Cho, found that fifty-three percent of laboratory directors in the United States decided not to develop a new clinical test because of a gene patent or license, and sixty-seven percent believed that gene patents decreased their ability to conduct research. (A2672-73.)

In this case, several medical researchers cited Defendants-Appellants' patents as hindering or completely barring their research on breast cancer. (*See, e.g.,* A2650; A2753; A2775; A2813; A2828; A2848-50; A2887-91; A2934-36; A2978-81; A3022; A3035-36.) Unlike many other patents, the patents-in-suit are essentially impossible to invent around. *See* Isabelle Huys, et. al., *Legal*

Uncertainty in the Area of Genetic Diagnostic Testing, 27 Nature Biotechnology 903, 907 (2009) (describing Myriad Patent 6,033,857 as a "blocking patent" and claims 1-8 as "almost impossible to circumvent.") The claims-at-issue are especially detrimental to breast cancer research because unlike pharmaceutical patents, the BRCA1/2 patents completely foreclose research on any effects of the BRCA1/2 genes. (A153; A2448-49; A2646-49; A2652-53; A2672-75; A2775-78; A2937-39; A2980-83; A3037-39; A3068; A3080; A3085.) With the claims-at-issue, researchers cannot conduct any research, innovation, or development of the naturally occurring gene. For example, as a result of the patents, researchers cannot develop more efficient or expansive tests that cover mutations that Defendants-Appellants have not yet identified. (A39; A2649-50; A3068; A3080; A3085.)

The Department of Health and Human Services established a commission to study the effects of gene patents on medical research and patient access to genetic tests. *Sec'y's Advisory Comm. On Genetics, Health and Soc'y, Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic* Tests (2010*)* at 16, *available at* http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf ("SACGHS"). SACGHS found stirring evidence that gene patents can harm genetic research by hindering vital follow-up

projects. *Id*. at 17. Patents-in-suit were found to have led directly to a decrease in information available to the public of these breast cancer genes. (A163.)

Finally, a recent study by the Department of Biostatistics and Bioinformatics at Duke University found that some claims of the patents-in-suit would broadly preempt a range of current genetic tests, including tests not directly linked to BRCA1/2 research. Thomas B. Kepler, *et al.*, *Metastatasizing patent claims on BRCA1,* Genomics May 2010. *available at* http://www.elsevier.com /framework_products/promis_misc/kepler_crossman_cook_deegan.pdf (last accessed Dec. 1, 2010). One example is dependent claim 5 of patent-in-suit 5,747,282. This claim broadly covers "an isolated DNA having at least 15 nucleotides of the DNA of claim 1." *Id*. at 2. Although Defendants-Appellants claim the fifteen nucleotides that occur on the BRCA1/2 genes, these nucleotide sequences also occur elsewhere in the genome. *Id.* at 3. Thus, the patents-in-suit give Defendants-Appellants control over diagnostic testing for diseases which they performed no research or work. (A2447.) Researchers and medical professionals around the world routinely sequence Genes and the particular complete field preemption presented by these claims is alarming.

B. The Preclusion of Additional Research by the Claims-at-Issue Detrimentally Affects Patients.

The claims-at-issue preclude scientific research and have a detrimental effect on patient health. SACGHS at 17. While Defendants-Appellants tout their test as

the "gold standard," it competes in a field of just one: its own monopoly. (A157.) This monopoly remains unhealthy for the public; a recent study conducted at the University of Washington found the test had a twelve-percent error rate. Tom Walsh, et. al., *Spectrum of Mutations in BRCA1, BRCA2, CHECK2, and TP53 in families at High Risk of Breast Cancer*, 295 JAMA 1369, 1386 (2006) (12% of the 300 people examined from high risk families had mutations that the Myriad tests missed). This error rate may, in fact, be understated as Defendants-Appellants' monopoly over research on BRCA1/2 has resulted in a great disparity in the effectiveness of their test when applied to women of non-European ancestry. (A1059; A3205-06.)

For patients who must make major life altering decisions based on a single flawed test, such as Plaintiff-Appellee Limary, among others, the issue of total field preemption is not a mere application of patent law theory. (A105-07.) Defendants-Appellants' complete control of the BRCA1/2 genes has prevented researchers, such as Plaintiff-Appellee Dr. Cho, from offering a second opinion on the results of BRCA1/2 tests or from offering lower-cost tests to women who cannot afford the monopolistic and often non-insured pricing of Defendants-Appellants' test. (A2670-75.) Plaintiff-Appellee American Association of Medical Pathologists is deeply concerned that Defendants-Appellants' patents require patients be provided with a knowingly flawed test. As a result, Plaintiffs-

Appellees cannot use their considerable expertise to provide patients with any alternative or validity testing. (A36-46; A1034-36.) UAEM has related concerns that university researchers cannot access and use the basic facts about these genes to enhance the public good through further research and development.

C. Other Nations Have Also Refused to Accept Defendants-Appellants' Patent Claims.

The purpose of the patent system is to encourage innovation by promoting the progress of science and useful arts. U.S. CONST., art. 1, § 8, cl. 8. In analyzing the preemptory effects of Defendants-Appellants' patents, it is useful to compare the experience of researchers and medical doctors under different patent regimes. The European Union, largely in response to the restrictive licensing policies by Defendants-Appellants, prohibit the enforcement of patents that would prevent research. SACGHS at 99. Additionally, individual European nations have refused to honor the enforcement of Defendants-Appellants' patents and allowed market forces to develop less costly tests. (A3207-08.) While market forces foster the development of comprehensive, affordable and less costly BRCA testing in Europe, Canada, and Australia, U.S. patients must rely on an expensive test with an unacceptably high failure rate, especially when it comes to the analysis of the genome belonging to women of color.

CONCLUSION

For over 150 years, the U.S. Supreme Court has held that laws of nature, products of nature, and abstract ideas are ineligible for patent protection. The patent claims by Defendants-Appellants are clearly directed at basic products of nature and therefore ineligible for patent protection. Additionally, they preempt all uses of a natural product.

For the above-stated reasons, the Court should uphold the decision of the district court and find that the USPTO improperly granted the Defendants-Appellants' patent claims.

Respectfully submitted,

Dated: December 6, 2010

KRISTA L. COX
UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES
2625 Alcatraz Avenue, #180
Berkeley, CA 94705
(510) 868-1159
krista.cox@essentialmedicine.org

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of December, 2010, I caused twelve true and correct copies of the foregoing Brief for Universities Allied for Essential Medicines to be mailed to the Court via U.S. Postal Service Express Mail and for two true and correct copies of the Brief to be served upon the following counsel of record listed below via U.S. Postal Service Priority Mail.

Christopher A. Hansen
American Civil Liberties Union
125 Broad Street, 18th Floor
New York, NY 10004
chansen@aclu.org
Counsel for Plaintiffs-Appellees

Gregory A. Castanias
Jones Day
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
gcastanias@jonesday.com
Counsel for Defendants-Appellants

Mary M. Calkins
Foley and Lardner
3000 K Street, N.W., Suite 500
Washington, DC 20007
Counsel for Amicus Alnylam Pharmaceuticals

Barbara R. Rudolph
Finnegan, Henderson, Farabow, Garrett & Dunner
901 New York Avenue, N.W.
Suite 1100
Washington, DC 20001-4413
Counsel for Amicus American Intellectual Property Law Association

Seth P. Waxman
Wilmer Hale
1875 Pennsylvania Avenue, N.W.
Washington, DC 20006
Counsel for Amici Biotech Industry Organization et al.

Erik P. Belt
McCarter & English
265 Franklin Street
Boston, MA 02110
Counsel for Amicus Boston Patent Law Association

Christopher M. Holman
5100 Rockhill Road
Kansas City, MO 64110
Counsel for Amici Christopher Holman et al.

Jennifer Gordon
Baker Botts
30 Rockefeller Center
New York, NY 10112
Counsel for Amicus Croplife International

Maxim H. Waldbaum
Schiff Hardin
900 Third Avenue, 23rd Floor
New York, NY 10022
Counsel for Amicus Fédération Internationale des Conseils en Propriété Industrielle (FICPI)

David S. Forman
Finnegan, Henderson, Farabow, Garrett & Dunner
901 New York Avenue, N.W.
Washington, DC 20001-4413
Counsel for Amicus Genetic Alliance

William G. Gaede, III
McDermott, Will & Emery
275 Middlefield Rd., Suite 100
Menlo Park, CA 94025
Counsel for Amici Genomic Health et al.

J. Timothy Keane
Harness, Dickey & Pierce
7700 Bonhomme Avenue, Suite 400
St. Louis, MO 63105
Counsel for Amici Gilead Sciences et al.

Herbert C. Wamsley
McDonnell, Boehnen, Hulbert & Berghoff
300 South Wacker Drive
Chicago, Illinois 60606
Counsel for Amicus Intellectual Property Owners Association

Brian R. Dorn
Merchant & Gould
80 South 8th Street, Suite 3200
Minneapolis, MN 55402-2215
Counsel for Amicus Kane Biotech

Judy Deleon Jarecki-Black
Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096
Counsel for Amicus Merial Limited

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005
Counsel for Amicus Animal Health Institute

Aaron Stiefel
Kaye Scholer
425 Park Avenue
New York, NY 10022
Counsel for Amicus Novartis Corp.

Kurt G. Calia
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401
Counsel for Amicus Pharmaceutical Research and Manufacturers of America

Jacqueline D. Wright-Bonilla
Foley and Lardner
3000 K Street, N.W., Suite 500
Washington, DC 20007
Counsel for Amici Rosetta Genomics et al.

Mark R. Freeman
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.,
Room 7644
Washington, DC 20530-0001
Counsel for Amicus United States

Ann M. McCrackin
University of New Hampshire
School of Law
2 White Street
Concord, NH 03301
Counsel for Amicus University of New Hampshire School of Law

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Krista L. Cox

CERTIFICATE OF COMPLIANCE

Counsel for Amicus Curiae Universities Allied for Essential Medicines hereby certifies that:

The brief complies with the type-volume limitation of the Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B) because, excluding the exempted portions, it contains 4,045 words as counted by the word processing program used to prepare the brief; and

The brief complies with the typeface requirements of Federal Rule of Appellate Procedure (32)(a)(5) and 32(a)(6) because it has been prepared using Microsoft Office Word 2008 in a proportionally spaced typeface in Times New Roman, font size 14.

Dated: December 6, 2010

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Krista L. Cox