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 KNOWLEDGE ECOLOGY INTERNATIONAL AND UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES, SUPPORTING AFFIRMANCE

KRISTA L. COX
KNOWLEDGE ECOLOGY INTERNATIONAL
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20002
(202) 332-2670
Counsel for Amici Curiae

CERTIFICATE OF INTEREST AND ENTRY OF APPEARANCE

Counsel for the amici curiae, Knowledge Ecology International and Universities Allied for Essential Medicines, certifies the following:

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

   Knowledge Ecology International (KEI)
   Universities Allied for Essential Medicines (UAEM)

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:

   Same as above.

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:

   Neither KEI nor UAEM appeared in the trial court. Before this court, KEI and UAEM are represented by:

   Krista L. Cox
   Knowledge Ecology International
   1621 Connecticut Ave. NW, Suite 500
   Washington, DC 20002
   (202) 332-2670
   krista.cox@keionline.org

Dated: June 15, 2012

_____
Krista L. Cox

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BRIEF OF *AMICI CURIAE* KNOWLEDGE ECOLOGY INTERNATIONAL AND UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES IN SUPPORT OF PLAINTIFFS-APPELLEES

INTEREST OF *AMICI CURIAE*

Knowledge Ecology International ("KEI") is an international nonprofit organization that searches for better outcomes and new solutions to management of knowledge resources, particularly in the context of social justice. KEI is drawn to areas where current business models and practices fail to adequately address social needs or where there are opportunities for substantial improvements. Among other areas, KEI has expertise in access to medicines and medical technologies.

KEI has concerns about the impacts of the present case because of the far-reaching consequences for the future of innovation, patent law and public health. As an advocate of new incentives and financing models for innovation, and the proponent of mechanisms for stimulating investments and promoting innovation outside the patent regime, KEI encourages the Federal Circuit to fully consider the alternatives, particularly in cases where patent rewards may not be appropriate.

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, 14565.) 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

Pursuant to paragraph four (4) of this Court's order, dated April 30, 2012, stating that briefs of *amici curiae* may be filed without consent and leave of court, *amici* file this brief. This brief is limited to fifteen (15) pages and otherwise complies with Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29.

Neither KEI nor UAEM has any 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 *amici curiae*, KEI and UAEM, contributed money to the preparation and submission of this brief

INTRODUCTION

Patents-at-issue involve two human gene sequences, known as BRCA1 and BRCA2, which play a critical role in determining susceptibility to breast cancer. Patents-at-issue are based on federally funded research conducted at the University of Utah ("UT"). UT obtained ownership over the patents-in-suit by exercising its rights under the Bayh-Dole Act.

Exclusive licensee, Myriad Genetics, prevented others from developing additional genetic testing. Defendants-Appellants also prohibited independent verification of the accuracy of its tests, despite known failure rates, and used their monopoly to stifle further research on the genes, including for specific mutations more prevalent in minorities. As the exclusive rights holder, Defendants-Appellants can therefore block patient access to better testing and second-opinions.

Isolated DNA represents products of nature and should not receive patent protection. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The process of isolation relies on application of well-understood scientific principles. Even where a gene's entire function has not yet been discovered, patents remove the gene from the public domain, hindering research that depends on collective understanding. DNA patents create exclusive rights with unknown breadth, impeding new discoveries. As a result, patents on DNA have a "blocking" effect and represents "unnecessary toll booths on the road to discovery." Alan E. Guttmacher, et. al, *Genomic Medicine—A Primer*, 347 NEW. ENG. J. MED. 1512, 1514 (2002).

KEI and UAEM believe that the patents-in-suit contravene the constitutional rationale of the patent system and the Defendant-Appellants' monopoly over the BRCA1/2 genes have, in fact, led to a decrease in information concerning these genes and impeded the progress of science. In light of the foregoing facts, KEI and UAEM file as *amici curiae* in support of Plaintiffs-Appellees.

I. THE GOAL OF THE PATENT SYSTEM IS TO ENCOURAGE PROGRESS AND EXCLUDES PRODUCTS OF NATURE, LAWS OF NATURE, NATURAL PHENOMENA AND ABSTRACT IDEAS.

The Constitution sets forth the rationale to create laws permitting inventors to have a limited monopoly: to "promote the Progress of Science and useful Arts." U.S. CONST., art. 1, § 8, cl. 8. While the Patent Act creates a quid-pro-quo for the purpose of advancing scientific progress, the "embarrassment of an exclusive patent" is justified only because such monopolies serve the "benefit of society." *Graham v. John Deere Co.*, 383 U.S. 1, 7-10 (1966) (*quoting* Thomas Jefferson).

Congress has wide latitude in creating patent laws, but it "may not overreach the restraints imposed by the stated constitutional purposes." *John Deere Co*., 383 U.S. at 6. The Constitution serves as a grant of power, but also a limitation: "This qualified authority . . . is limited to promotion of advances in the useful arts." *Id*. at 5. Congress cannot permit patents that "remove existent knowledge from the public domain, or to restrict free access to materials already available." *Id.* at 5. The Court recently reaffirmed this limitation in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___ (2012) (slip op.). *See infra* Part I.C.

In light of the *Prometheus* decision, past precedent, and the constitutional rationale for the patent system, the lower court decision should be affirmed. Patents-in-suit, as basic tools of scientific work, represent products of nature and are not patent eligible.

A. Products of Nature, Laws of Nature and Natural Phenomena, Such as the Claims-At-Issue Are Not Patent-Eligible Under Section 101 of the Patent Act

In applying Section 101 of the Patent Act, the Supreme Court has repeatedly held three specific types of claims as categorically removed from patent eligibility including "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); *Funk Bros. Seeds Co. v. Kalo Co.*, 333 U.S. 127 (1948). The Supreme Court has provided the following factors for patent eligibility in line with these exclusions and a product may not be patented where it: (1) is the direct product of natural law; (2) is not markedly different from a naturally occurring form; or (3) preempts all uses of a natural product. *See Chakrabarty*, 447 U.S. at 303; *Funk Bros*, 333 U.S. at 130-32 (1948); *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972).

Within this framework, courts have explicitly excluded a number of specific products from patentability including wood pulp and paper pulp, *Am. Wood Paper v. Fiber Disintegrating Co.*, 90 U.S. 566 (1874), purified uranium, *In re Marden*, 47 F.2d 957 (C.C.P.A. 1931), purified vanadium, *In re Marden*, 47 F.2d 958 (1931), purified tungsten, *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928), and vitamin C purified from lemon juice, *In re King*, 107 F 2d 618 (C.C.P.A. 1939). Naturally occurring substances and those identified solely

through purification have been excluded from patentability. Such substances, even when remixed or artificially created, do not fall under the scope of patent eligibility

In the present case, Defendants-Appellants claim protection for purified or isolated DNA, but the extraction does not change its character as a product of nature. The contention that the claims-at-issue exhibit useful properties does not negate the fact that these nucleic acids are not markedly different from those found in nature. Mere breaking of covalent bonds to isolate the BRCA1/2 genes does not change the nature of the DNA. The limitation of our patent system is necessary to ensure that the purpose of the patent regime is fulfilled, that is to promote the progress of science and prohibit roadblocks to future research and development.

B. Where Patent Protection Improperly Preempts All Other Uses, Progress of Science Is Hindered

In addition to excluding products of nature, natural phenomena and abstract ideas, the Supreme Court has held that patents may not be granted where the effect would be "to remove existent knowledge from the public domain, or to restrict free access to materials already available." *Graham v. John Deere Co*., 383 U.S. 1, 6 (1966). Preemption is an important factor in determining the scope of patentability under Section 101 of the Patent Act, *see Bilski v. Kappos*, 130 S.Ct. 3218 (2010) and complete field preemption is evidence of a patent claim that has been drawn on ineligible subject matter. *See O'Reilly v. Morse*, 56 U.S. 62 (1854); *Corning v. Burden*, 94 U.S. 780 (1854); *but see Diamond v. Diehr*, 50 U.S. 175 (1981).

Monopolies preventing all others from creating the same effect or process by any other means forecloses all other uses and demonstrates complete field preemption. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853). Such foreclosure discourages scientific progress and contravenes the very policy of the Patent Act and constitutional rationale for our intellectual property system. *See id.* at 175.

The patents-in-suit completely preempt the use of the patents in the field of genetic testing and identification, therefore evidencing claims drawn on ineligible subject matter. Patent protection over the BRCA1/2 genes completely forecloses and preempts all other uses. DNA patents are difficult, if not impossible, to invent around. *See* Isabelle Huys, et. al., *Legal Uncertainty in the Area of Genetic Diagnostic Testing*, 27 NATURE BIOTECHNOLOGY 903, 907 (2009). The BRCA1/2 patents thus completely foreclose research on any effects of these DNA sequences and scientists cannot conduct research on the naturally occurring gene.

Additionally, patents-in-suit preempt development of new BRCA1/2 related genetic tests as well as tests for those not directly related to BRCA1/2 sequences. 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. The broad description of the claims-at-issue could give Defendant-Appellants control over diagnostic testing on diseases for which they performed no research or work.

C. *Mayo v. Prometheus* Reaffirms Prior Case Law Regarding Exclusions from Patentability and Emphasizes the Importance of Considering Implications for Further Innovation

In its recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court reaffirmed the "long held" exclusions of the laws of nature, natural phenomena and abstract ideas from patent eligibility. 566 U.S. __ (2012) (slip op. at 1) (citations omitted). Specifically, the Supreme Court reminds, quoting its previous decisions, that "'a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter . . . Such discoveries are 'manifestations of nature, free to all men and reserved exclusively to none.'" *Prometheus* at 1 (*citing Chakrabarty* at 309 (*quoting Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

In refusing to permit patents on those discoveries, the Court notes their status as "basic tools of scientific and technological work" and monopolization of such tools "might tend to impede innovation more than it would tend to promote it." *Mayo v. Prometheus*, 566 U.S. __ (2012) (slip op. at 2) (internal quotations omitted). Citing *Benson*, *Bilski* and *Flook*, the Court noted that permitting patents on natural laws or "basic tools" run the

> danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to 'apply the natural law,' or otherwise forecloses more future invention than the underlying discovery could reasonably justify. *Id.* at 17 (internal citations omitted).

The Court further suggests that the presence of the concern "these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible." *Id.* at 18.

Isolation of DNA involves well-understood and routine activity by researchers and the DNA itself represents a product of nature. The Supreme Court noted that the patents in *Prometheus* involved routine activity and permitting patents "would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." 566 U.S. __ (2012) (slip op. at 4). The Court "has repeatedly emphasized . . . a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature." *Id.* DNA represents the essence of a natural product and its functions represent the laws of nature. Although *Prometheus* involved method patents, the reasoning is relevant and supports affirmance of the denial of patents-at-issue.

II. NON-PATENT MECHANISMS CAN AND SHOULD ENCOURAGE PROGRESS WHERE PATENTS ARE AN INAPPROPRIATE, UNNECESSARY, INSUFFICIENT, OR BURDENSOME REWARD

The most common and superficially appealing justifications for liberal standards on patentability are those that assert, without evidence, that patents are necessary to protect and reward investments for new products. This false argument is belied both by known shortcomings of patents as incentives, and growing proliferation of non-patents mechanisms to stimulate research and development.

In certain areas of innovation, patents do not provide adequate incentives and other mechanisms to reward innovation are needed. Also, with respect to the claims-at-issue, patent protection can effectively block further research and development, and discourage investments.

A report by an advisory committee of the Department of Health and Human Services concluded gene patents were not necessary to provide incentives for research or development of clinical testing. Dep't of Health & Human Serv., Sec'y's Advisory Comm. On Genetics, Health, and Soc'y, *Gene Patents and Licensing Practices and Their Impact on Patient Access* (2010), *available at* http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf. This report noted that gene patents harmed patient access to genetic testing and denied quality assurance tests. *Id*. Because patents provide a burdensome incentive in the case of isolated-DNA or human genes, other mechanisms should be explored.

A wide range of non-patent incentives exist to encourage research and discovery. Mechanisms to protect, reward and induce investment into innovation across broad sectors often take the place of patent incentives.[1] Great flexibility exists to design these alternative forms of incentive outside of the patent system.

[1] Although several alternative incentive mechanisms are discussed herein, *amici* do not necessarily endorse each of these alternatives, particularly in the manner in which some have been implemented. This discussion of alternatives serves as examples of the great range of incentives that currently exist outside of the patent system or those that have been proposed.

Trade secret protection, for example, while having their own shortcomings in terms of limiting access to knowledge, are used to promote investments in new medical products, including for medical diagnostic and biotechnology drugs. Iraj Daizadeh, et. al., *A general approach for determining when to patent, publish, or protect information as a trade secret*, 20 NAT. BIOTECH at 1053-54 (2002).

Furthermore, there exist a wide range of new *sui generis* forms of intellectual property used in parallel to the patent system, often when patents are unavailable. One type of *sui generis* protection that has become quite common is the application of time limited exclusive rights to rely upon test data used to register new drugs or vaccines. Food, Drug and Cosmetics Act, New Drugs, 21 U.S.C. §355. These rights include 5 years of test data protection for new chemical entity pharmaceutical products, and 12 years of test data protection for new biologic drugs. *Id*. Like trade secrets, exclusive rights over test data for pharmaceuticals may have their own shortcomings, including ethical concerns, but presently serve as a mechanism to promote investments in clinical test data. Another non-patent right is the marketing exclusivity granted for the development of new "orphan" drug indications, or to reward investments in clinical trials for pediatric patents. Internal Revenue Code, Clinical testing expenses for certain drugs for rare diseases or conditions, 26 U.S.C. §45C. The U.S. Government gives a 50 percent tax credit for investments in clinical trials for orphan drugs, and

Congress is considering legislation to grant 5 years of market exclusivity for new antibiotic drugs, that would work as a supplement to or independent of patent protection. *Id*. To simulate R&D in treatments for rare tropical diseases, Congress has created a "Priority Review Voucher," providing for a transferable right to an accelerated consideration of new drug approvals as a reward for registering drugs for treatments like cholera or leprosy. Food, Drug and Cosmetic Act, Priority Review to Encourage Treatments for Tropical Diseases, 21 U.S.C. §360n.

In addition to these mechanisms, a new class to reward investments is under consideration, both internationally and domestically. These systems involve cash innovation inducement prizes to stimulate investments in public health and other areas of public and private interest.[2]

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[2] *See*, *e.g.*, James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519, 1521-24 (2007); James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANNALS HEALTH L. 155 (2009); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes and Research Contracts,* 73 AM. ECON. REV. 691(1983)*;* Burton Weisbrod*, Solving the Drug Dilemma,* WASH. POST *(*Aug. 22, 2003) at A21; T. Kalil*, Hamilton Project and Brookings Institution, Prizes for Technological Innovation* (2006)*;* Bruce G. Charlton*, Mega-Prizes in Medicine: Big Cash Awards May Stimulate Useful and Rapid Therapetic Innovation*, 68 MEDICAL HYPOTHESES 1-3 (2007); L. Brunt. et. al, Inducement Prizes and Innovation (2008); *Selected Innovation and Reward Programs*, KEI RESEARCH NOTES (2008); K. Davidian, Prizes, Prize Culture and NASA's Centennial Challenges (2004); Julien Penin, *Patents versus ex post rewards,* 34 RESEARCH POL'Y 641 (2005); J.G. Morgan, *Inducing Innovation Through Prizes*, 3 INNOVATIONS: TECHNOLOGY, GOVERNANCE, GLOBALIZATION 105 (2008); W.A. Masters, *Prizes for innovation in African agriculture* (2004), http://ww.eart.columbia.edu/cgsd/prizes; Joseph E. Stiglitz, *Scrooge and Intellectual Property Rights: A Medical Prize Fund Could*

The World Health Organization (WHO) has called for new proposals to address

> de-linkage of the costs of research and developments and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries. Global strategy and plan of action on public health, innovation and intellectual property, WORLD HEALTH ASSEMBLY 61.21 (2008).

Such de-linkage includes the awards of prizes. *Id*. at Annex, element 5.3(a). And independent group of experts again endorsed this concept in an April 2012 report. WHO, *Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination: R&D to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*, http://www.who.int/phi/CEWG_Report_5_April_2012.pdf.

This de-linkage concept has found domestic support as well. In the 112th Congress, two bills were introduced in the Senate proposing large cash prizes as an alternative to an exclusive patent monopoly, including S.1137 and S.1138. Medical Innovation Prize Fund Act, S.1137, 112th Cong. (2011); Prize Fund for HIV/AIDS Act, S.1138, 112th Cong. (2011). S.1137 would apply to all prescription drugs, while S.1138 would limit its application to HIV/AIDS drugs.

Improve the Financing of Drug Innovations, 333 BRITISH MEDICAL JOURNAL, 129 (2006); Ron Marchant, *Managing Prize Systems*, 2 KNOWLEDGE ECOLOGY STUDIES (2008); James Love, *The Role of Prizes in Developing Low-Cost, Point-of-Care Rapid Diagnostic Tests and Better Drugs for Tuberculosis* (2008), http://www.keionline.org/misc-docs/Prizes/prize_tb_msf_expert_meeting.pdf.

On May 15, 2012, the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing on S. 1138 and as noted in testimony by Nobel Prize winner, Joseph Stiglitz, the patent system may "have adverse effects on innovation, because the most important input into any research is prior ideas . . . there is a simple way to 'square the circle,' which entails de-linking research and development incentives from drug prices, and that is precisely what S.1138 proposed to do in the context of new medicines to treat HIV/AIDS. It does this through a simple mechanism—prizes." Joseph E. Stiglitz, Testimony to the U.S. Senate HELP Committee, Subcommittee on Primary Health and Aging, Hearing on the High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative, available at http://www.help.senate.gov/imo/media/doc/Stiglitz.pdf.

Prizes may be particularly relevant where products are not patent eligible or where it would be inefficient or harmful to permit enforcement of exclusive rights. Where unrestricted access to basic information or discoveries is critical to progress, patents act as a barrier and do more harm than good. *See* John Sulston, et. al., THE COMMON THREAD (2003); Aaron S. Kesselhein, et. al., *University Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, 293 JAMA 850 (2005).

In the present case, patents are not an appropriate reward for investments in isolation of DNA. Patents in this area are burdensome, foreclosing future research

and development and preempting all other uses, directly contradicting the purpose of patents. More viable incentives should be used to stimulate innovation.

CONCLUSION

The U.S. patent system operates to provide incentives for research and development, but is not without its limits. This case presents questions of fundamental importance to the patent system, future of research and development and public health. Alternative incentive mechanisms exist to induce research and development in areas where a patent monopoly does not provide an appropriate reward. As the Supreme Court noted in its recent decision invalidating a patent in *Mayo v. Prometheus*, 566 U.S. __ (2012), the exclusivity of a patent can "impede the flow of information that might permit, indeed spur, invention," and patents are thus not always appropriate rewards. The reasoning in *Prometheus* applies to the present case and supports affirmance of the lower court decision.

For the above-stated reasons, the Court should uphold the 2010 decision of the district court and find that the USPTO improperly granted the patents-at-issue.

Respectfully submitted,

Dated: June 15, 2012

KRISTA L. COX
KNOWLEDGE ECOLOGY INTERNATIONAL
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20009
(202) 332-2670
krista.cox@keionline.org

CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of June 2012, I caused twelve true and correct copies of the foregoing Brief for Knowledge Ecology International and Universities Allied for Essential Medicines to be delivered to the Court via hand delivery and for two copies to be served upon the following counsel of record listed below via U.S. Postal Service first class 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

Lori B. Andrews
Chicago-Kent College of Law
Illinois Institute of Technology
College of Law
565 West Adams Street
Chicago, IL 60661
Counsel for Amici American medical Association et. al.

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

John L. Hendricks
Hitchcock Evert LLP
750 North St. Paul Street
Suite 110
Dallas, Texas 75201
Counsel for Amici Canavan Foundation et. al.

Larry Frierson
The Law Offices of Larry Frierson
3265 Lake County Highway
Calistoga, CA 94515
Counsel for Amici Cancer Council Australia and Luigi Palombi

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

E. Richard Gold
Faculty of Law, McGill University
3664 Peel Street
Montreal, Quebec H3A IW9
Counsel for Amici E. Richard Gold et. al.

Eileen M. Kane
Penn State Dickinson School of Law
328 Katz Building
University Park, PA 16802
Counsel for Amicus Professor Eileen N. Kane

Erica K. Geroge
Loyola University Chicago School of Law
25 E. Pearson
Chicago, IL 60611
Counsel for Amici Erika R. George and Kali N. Murray

Maxim H. Waldbaum
Schiff Hardin
900 Third Avenue, 23 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

George Kimbrell
International Center for Technology Assessment
660 Pennsylvania Ave., Suite 302
Washingtonn, DC 20003
Counsel for Amici International Center for Technology Assessment et. al.

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

Debra L. Greenfield
UCLA Center for Society and Genetics
Box 957221, 1323 Rolfe Hall
Los Angeles, CA 90095
Counsel for Amici National Women's Health Network et. al.

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

Thomas Kowalksi
Vedder Price PC
1633 Broadway, 47th Floor
New York, NY 10019
Counsel for Protein Sciences Corporation

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

Andrew Chin
University of North Carolina
School of Law
160 Ridge Road, CB #3380
Chapel Hill, North Carolina
27599-3380
Counsel for Amicus Scholars of Biotechnology Patent Law

Francis Pizzulli
718 Wilshire Blvd.
Santa Monica, CA 90401
Counsel for Amicus Southern Baptist Convention

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

Dated: June 15, 2012

_____

Krista L. Cox
Counsel for Knowledge Ecology International et al.

CERTIFICATE OF COMPLIANCE

Counsel for *Amici Curiae* Knowledge Ecology International and Universities Allied for Essential Medicines hereby certifies that:

Pursuant to paragraph four (4) of this Court's order, dated April 30, 2012, this brief is limited to fifteen (15) pages and otherwise complies with Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29. The brief, excluding the portions exempted by Federal Rules of Appellate Procedure 32(a)(7)(b)(iii) and Federal Circuit Rule 32(b), contains 3,508 words.

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 14 point font.

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Krista L. Cox
Counsel for Amici Curiae
KNOWLEDGE ECOLOGY INTERNATIONAL
1621 Connecticut Ave. NW
Suite 500
Washington, DC 20009
(202) 332-2670
krista.cox@keionline.org