

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2010-1406

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 AMICUS CURIAE JAMES D. WATSON
IN SUPPORT OF NEITHER PARTY**

Matthew J. Dowd
James H. Wallace, Jr.
WILEY REIN LLP
1776 K Street NW
Washington, DC 20006
(202) 719-7000
Attorneys for Amicus Curiae James D. Watson

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Association of Molecular Pathology v. USPTO

No. 2010-1406

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) James D. Watson certifies the following (use "None" if applicable; use extra sheets if necessary):

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

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: James D. Watson

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are: None

4. [X] The names of all law firms and the partners or associates that 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: Matthew J. Dowd; James H. Wallace, Jr.; Wiley Rein LLP

June 15, 2012 Date

Matthew J. Dowd Signature of counsel
Matthew J. Dowd Printed name of counsel

Please Note: All questions must be answered cc: All principal counsel of record

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INTEREST OF AMICUS CURIAE JAMES D. WATSON

James D. Watson is the co-discoverer of the double helix structure of deoxyribonucleic acid (“DNA”). For this discovery, he and his colleague, the late Francis Crick (along with the late Maurice Wilkins for related work), were awarded the Nobel Prize in Physiology or Medicine in 1962. *See* James D. Watson, *The Double Helix* (1968).

Throughout his career, Dr. Watson has been at the forefront of recombinant DNA research and advances in genetic engineering. From 1956 until 1976, Dr. Watson was on the faculty of Harvard University, leading the effort to focus the biology department on the then-emerging field of molecular biology. Starting in 1968, Dr. Watson was the director of Cold Spring Harbor Laboratory (“CSHL”). From 1994 to 2004, he served as the president of CSHL, and from 2004 until 2007, he was CSHL’s chancellor. Dr. Watson is now Chancellor Emeritus of CSHL.

Of particular pertinence to the present appeal is Dr. Watson’s role in the Human Genome Project. In 1988, Dr. Watson was appointed Associate Director for Human Genome Research of the National Institutes of Health (“NIH”) and, in 1989, Director of the National Center for Human Genome Research at the NIH. In these positions, Dr. Watson lead the public effort to sequence the human genome.

Given the significance of the issue at hand, Dr. Watson wishes to write directly to the Court.

ARGUMENT

I. BECAUSE HUMAN GENES ARE UNIQUE AND CONVEY INFORMATION ABOUT THE ESSENCE OF BEING HUMAN, THEY SHOULD NOT BE PATENTED

I have read through the various opinions issued in this case.¹ Although the opinions admirably describe the scientific details of DNA and human genes, what the Court misses, I fear, is the fundamentally unique nature of the human gene. Simply put, no other molecule can store the information necessary to create and propagate life the way DNA does. It is a chemical entity, but DNA's importance flows from its ability to encode and transmit the instructions for creating humans. Life's instructions ought not be controlled by legal monopolies created at the whim of Congress or the courts.

Even before DNA's structure was revealed, many scientists recognized the importance of a cell's chromosomes (which are composed of DNA) to the propagation of life. In 1944, Erwin Schrödinger, a Nobel Prize-winning physicist, wrote a small book titled *What Is Life?* In it, he reasoned that chromosomes were the genetic information bearers. Schrödinger thought that, because so much information must be packed into every cell, the information must be compressed into "hereditary code-script" embedded in the molecular fabric of the

¹ I have also read the Supreme Court's decision in *Mayo v. Prometheus*, although its opaqueness must leave many attorneys wondering if it adds anything at all to the issue of whether human genes ought to be patented.

chromosomes. At the time, this was an untested hypothesis; most biologists thought that proteins would be identified as the bearers of genetic instruction. Eventually, chemical techniques advanced, and scientists confirmed that the chromosomes contained our genes.

As it turned out, the secret to DNA's ability to create life is its double helical structure, along with its information-coding sequences. Francis Crick and I published the first correct structure of DNA in 1953. J.D. Watson & F.H.C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 *Nature* 737 (1953).² The double-helical structure epitomized elegance in simplicity. From a chemical perspective, DNA is little more than two strands of a nucleotide polymer wound together in a double helix formation. The nucleotide polymer consists of various sequences of A, T, G, and C bases. The helical structure has two strands, one complementary to the other.

As soon as Francis and I deciphered the structure, we immediately understood its significance. With a hint of more to come, we wrote in our article that “[i]t has not escaped our notice that the specific pairing we have postulated immediately suggests a possible copying mechanism for the genetic material.” The double helix structure confirmed DNA's role as the genetic carrier and created

² At the time, we were in a tight race with Linus Pauling (soon to be a Nobel laureate in chemistry). Fortunately for us, Pauling concluded that DNA was a triple helix—an erroneous conclusion ironically based on a chemical error.

the possibility of almost limitless information storage. The various sequences of bases could be translated by a cell's machinery, and that information would be used to create new proteins for the cell.³

Later scientists discovered that certain DNA sequences controlled the expression of other genes. One of the earliest discovered of these control sequences was the "TATA box." The TATA box contains the core DNA sequence 5'-TATAAA-3' or a similar variant. Specific proteins can bind to this sequence, which promotes the transcription of other specific genes. Extracted from the chromosome, a nucleic acid molecule having the TATAAA sequence has little, physically inherent value. Its significance arises because that sequence is useful information to the cell's genetic machinery. The TATAAA sequence leads to the expression of genes that affect the cell and ultimately our human experience.

The terminology of DNA underscores DNA's informational role in life. In a living cell, DNA is used to make RNA, and then RNA is used to make polypeptides, *i.e.*, protein. The first step—DNA to RNA—is called *transcription*. The second step—RNA to proteins—is called *translation*. Both words connote the conveyance of information. The information encoded by a human gene is first

³ Amusingly, after I gave my first presentation of our DNA structure in June 1953, Leó Szilárd, the Hungarian physicist and inventor of the nuclear chain reaction, asked whether I would patent the structure. That, of course, was out of the question.

transcribed into RNA (DNA and RNA are similar molecules, thus similar languages, so the genetic information is merely *transcribed* from one format to another). Then, the genetic information is translated from RNA into protein. (RNA and protein are different biochemical “languages,” hence *translation*). The entirety of the DNA machinery focuses on transferring and utilizing the genetic information.

When cells replicate, they make copies of the genetic code for the progeny cells. New strands of DNA are synthesized in a process analogous to the way scribes of years past would copy legal documents. Just as scribes would copy legal documents word by word, a cell copies the DNA molecule letter by letter (A, G, T, or C). And just as scribes proofread their work, the DNA polymerase—the enzyme that replicates DNA—has a built-in proofreading mechanism. But as with all proofreading, the system is not perfect, and errors occur. “Typographical” errors with DNA replication can lead to genetic mutations—which can cause devastating diseases or can lead to evolutionary improvements.

To this day, we continue to learn how human genes function. We estimate that humans have approximately 22,000 genes. We have yet to fully understand the functions of all human genes, but this lack of understanding is further reason

that scientists should be permitted to experiment on human genes free from any threat of patent infringement.

The social history of human genes also reveals DNA's informational uniqueness. In the early part of the twentieth century, many in society believed that the answers to all of society's ills resided in the human genome. From that belief grew the eugenics movement—an ill-fated movement founded on an incomplete understanding of genetics.

Even the legendary Supreme Court justice Oliver Wendell Holmes misunderstood the role of genes in human development. In the landmark case of *Buck v. Bell*, 274 U.S. 200, 207 (1927), Justice Holmes expressed a view about genetics that prevailed during his time:

It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. . . . Three generations of imbeciles are enough.

We now know that many factors affect a person's mental acuity, genes being some of them. But Justice Holmes and other supporters of the eugenics movement could not appreciate, at that time, the precise role of the human gene.

In years to come, with the right advances in genetic engineering, we may well be able to treat or rectify mental disabilities and physical diseases which today are deemed incurable. Such hope is all the more reason that scientific research on human genes should not be impeded by the existence of unnecessary patents.

More importantly, we would not want one individual or company to monopolize the legal right to the beneficial information of a human gene—information that should be used for the betterment of the human race as a whole.

By the 1970s, the public’s perception of DNA had reached its nadir. Far from being viewed as the vindicator of the wrongfully accused—as the public sees it today—recombinant DNA technology was considered by many to be inherently dangerous. Indeed, various interest groups wanted to ban recombinant DNA research.⁴ Ironically, this hysteria seemed to begin after I participated in the first scientific discussions exploring whether proposed regulations on DNA research were necessary (at the Gordon Research Conference of Nucleic Acids in June 1973). Unfortunately, the initial ruminations mutated into full-fledged proposed restrictions, issued from the Asilomar Conference in February 1974. Later, as the hysteria increased, the National Institutes of Health (“NIH”) enacted regulations governing recombinant DNA technology. The public discourse reached such a fevered pitch that, in the summer of 1976, the Cambridge City Council declared a three-month moratorium on recombinant DNA research in the city of Cambridge—and therefore at Harvard University and the Massachusetts Institute of Technology.

⁴ I describe much of this history in one of my books. *See* James D. Watson & John Tooze, *The DNA Story: A Documentary History of Gene Cloning* (1981).

I, of course, did not favor these restrictions. At one point, I had to defend recombinant DNA research from the attacks of the actor Robert Redford, who, along with the Environmental Defense Fund, raised money to stop experiments with recombinant DNA. *See* James D. Watson, *The Nobelist vs. The Film Star: DNA Restrictions Attacked*, Washington Post, May 14, 1978, at D1. Eventually, reason and objectivity prevailed, and scientists were free to conduct their recombinant DNA research without absurd regulations.

My point with this overly brief and incomplete history of recombinant DNA research is to illustrate how the major controversies associated with human genes have arisen because human genes are much more than chemical compounds. The myopic viewpoint thinks of a human gene as merely another chemical compound, composed of various bases and sugars. But history and science teach us otherwise. A human gene, which is a product of nature, is useful because it conveys vital information. The human genome's ability to be our instruction book on life distinguishes it from other chemicals covered by the patent laws. No other molecule carries the information to instruct a human zygote to become a boy or a girl, a blonde or brunette, an Asian, African, or Caucasian.

II. THE HUMAN GENOME PROJECT WAS INTENDED TO BENEFIT ALL, NOT JUST SELECT COMPANIES

In addition to understanding the uniqueness of human DNA, I hope that an awareness of the Human Genome Project's history will guide the Court to the

correct decision that human genes, as products of nature, should not be patented. The Human Genome Project was started not to increase the profits of select companies but to expand our understanding of the human genome and make this information available to all scientists.

The genesis of the Human Genome Project dates to the mid-1980s, when the dual technological advances of recombinant DNA and computers opened the door to deciphering the human genome. In June 1986, I organized a special session at Cold Spring Harbor Laboratory to discuss the beginnings of what would become the Human Genome Project. At that time, the U.S. Department of Energy had also begun to focus on sequencing the genome. Other eminent scientists joined the early effort, including Bruce Alberts, Sydney Brenner, and David Botstein. Eventually, we published our report (from the National Academy of Sciences) making the case for sequencing the human genome. With the support of James Wyngaarden, then-head of NIH, and many others, the Human Genome Project became reality.

In May 1988, I was appointed Associate Director for Human Genome Research of NIH (and later, in 1989, became NIH's Director of the National Center for Human Genome Research). In these positions, my role was to oversee a multimillion dollar budget and to organize what had become an international effort to map the human genome. The United States was directing the project and carried

out half of the work, while the rest was done mainly in the United Kingdom, France, Germany, and Japan.

Even at the early stages of the project, we were concerned about the issue of patenting human genes. Most, although not all, eminent scientists recognized that human genes should not be monopolized by patents. I believed at the time—and continue to believe—that the issue of patenting human genes went to the very crux of whether the information encoded by human DNA should be freely available to the scientific community. Some twenty years ago, I explained that patenting human genes was lunacy, and I was not a lone voice.

Sadly, and to the detriment of scientific research, my view did not control the policy decisions of NIH, which had filed for numerous patents covering human genes. Even more egregious were the types of patents being filed on human genes. Many of NIH's patents described only small portions of a gene. For example, in June 1991, an NIH official had urged Craig Venter, who at the time was working at NIH, to file patent applications on several hundred new DNA sequences, even though, in many instances, neither Venter nor NIH had any inkling of what those sequences did. The following year, Venter listed over 2,000 more sequences in his patent applications, still having no clue about the function of those sequences.

I expressed my objections to NIH management, but to no avail. To me, it was clear that the goal of the Human Genome Project was to map and publish the

human genome sequence for the scientific community. As the then-leader of the project, I felt a particular obligation to do what I could. In my view,

[t]he Human Genome Project is much more than a vast roll call of As, Ts, Gs, and Cs: it is as precious a body of knowledge as humankind will ever acquire, with a potential to speak to our most basic philosophical questions about human nature, for purposes of good and mischief alike.

James D. Watson, *DNA: The Secret of Life* 172 (2003). In 1992, I publicly opposed NIH's decision to patent human genes. As a result, I was left with no choice and was forced to resign from NIH that year. Patenting human genes was not necessary to complete the Human Genome Project. Indeed, the international effort was proceeding on schedule without any need to file patent applications on human genes.

Less than fifteen years after its start, the Human Genome Project, along with Celera Genomics, achieved success. On June 26, 2000, President Bill Clinton and Prime Minister Tony Blair announced that the two groups had finished a working draft, which was published for the public in February 2001. Gaps in the rough draft were filled in by 2003—fifty years after Crick and I published the structure of DNA. Scientists have used the data to estimate that humans have about 22,000 genes—in some sense a surprisingly small number compared to other organisms.

The Human Genome Project was a multi-agency, international effort. It was funded in large part by taxpayer money, and the primary expectation was that the

information derived from the sequenced human genes would be available for all scientists to use. Unfortunately, a decade later, private companies are still trying to unnecessarily restrict access to human genes and the information encoded in those genes. This situation burdens all of society. Other scientists involved in the Human Genome Project continue to warn about the harms caused by patenting human genes. For instance, John Sulston, who received the 2002 Nobel Prize in Physiology or Medicine, headed the British effort of the Human Genome Project. He has explained that “many human genes have patent rights on them and this is going to get in the way of treatment unless you have a lot of money.”⁵

III. PATENTS ON HUMAN GENES ARE NOT NECESSARY, BUT IF THEY ARE GRANTED, COMPULSORY LICENSES SHOULD BE REQUIRED TO ENSURE FAIR ACCESS

As a third point, lawyers and judges misunderstand scientific research when they contend that patent protection is necessary to encourage scientists to discover human genes. A scientist does not—and should not—expect to obtain a legal monopoly controlling the information encoded by human genes. And the average scientist should not expect a windfall simply for revealing the sequence of DNA bases that encode various genes. Research on human genes is one of those rare endeavors which should be—and is done—with the understanding that, although

⁵ See Alok Jha, *Human Genome Project Leader Warns Against Attempts to Patent Genes*, *The Guardian*, June 24, 2010, at <http://www.guardian.co.uk/science/2010/jun/24/human-genome-project-patent-genes>.

inventions based on those genes may later be commercialized, the genes themselves are to be employed for the maximum benefits of humankind.

Consider also whether a biotechnology or pharmaceutical company derives major revenue of human genes. From what I have seen, the answer is generally no. Most biotechnology and pharmaceutical companies do not derive substantial revenue from selling or licensing human genes. Rather, their primary revenue source is much more likely their selling pharmaceuticals or actual research tools. We should not be overly concerned that banning patents on human genes will cause a detrimental loss of revenue.

Additionally, researchers are developing new medical diagnostic tools which often rely on the use of multiple genes. For instance, investigators at the University of Washington have developed parallel gene sequencing methods for identifying of inherited mutations in breast and ovarian cancer genes. *See Tom Walsh, et al., Detection of Inherited Mutations for Breast and Ovarian Cancer Using Genomic Capture and Massively Parallel Sequencing, 107 Proceedings of the National Academy of Science USA 12,629 (2010).* This group's approach uses multiple genes, not just the specific BRCA1 and BRCA2 genes in the Myriad patents, to estimate cancer risk.

If each of the human genes used in a new multi-gene assay are subject to patents, I fear that useful tests requiring multiple human genes will be

unnecessarily delayed, become prohibitively expensive, or, worse yet, never be made available to patients at all. For a new assay using hundreds of human genes, the sea of patents and patent applications would create hundreds, if not thousands, of individual obstacles to developing and commercializing the assay. The best way, in my view, to resolve this problem is to eliminate the unnecessary patenting of human genes.

If, for some reason, patents on human genes are deemed necessary, the next best, albeit imperfect, solution is to require those patent holders to license the patents to other researchers so that scientific progress is not obstructed. This is often called a “compulsory license.” In my view, a compulsory license can establish reasonable access to human genes and genetic information—which is what scientists in general want, had the lawyers and courts not complicated matters. Reasonable access facilitates scientific and social progress.

Compulsory licensing ensures that scientists and researchers will have reasonable access to human genes and genetic information. Compulsory licensing will attenuate the negative consequences of the genetic monopolies created by patents. Implementing a compulsory license protocol will also reduce the risk that a patient is denied access to life-saving medicines and technologies using human genes and the information encoded in the genes.

Finally, I do not suggest that all patents relating to recombinant DNA technology should be abolished. Scientists have developed many new inventions based on recombinant DNA technology. And these inventions have contributed to the progress of science and the success of our nation. But, as I have written before, “[g]ood patents, I would suggest, strike a balance: they recognize and reward innovative work and protect it from being ripped off, but they also make new technology available to do the most good.” James D. Watson, *DNA: The Secret of Life* 122 (2003).

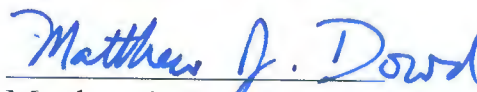
IV. RULE 29(c)(5) STATEMENT

No party’s counsel authored this brief in whole or in part. No party, no party’s counsel, and no other person contributed money that was intended to fund the preparation and submission of this brief.

V. CONCLUSION

For at least the reasons above, Dr. Watson respectfully asks the Court to reconsider its opinion on the patentability of human genes.

Respectfully submitted,



Matthew J. Dowd

James H. Wallace, Jr.

WILEY REIN LLP

1776 K Street, N.W.

Washington, D.C. 20006

Attorneys for Amicus Curiae James D. Watson

Date: June 15, 2012

CERTIFICATE OF SERVICE

I hereby certify that on this day, June 15, 2012, two copies of the foregoing BRIEF OF AMICUS CURIAE JAMES D. WATSON IN SUPPORT OF NEITHER PARTY were served via first class mail on the following counsel for the parties:

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

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

Bruce Vignery
AARP Foundation Litigation
601 E Street, NW
Washington, DC 20049
Counsel for Amicus AARP

Stephen B. Maebius
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 1110
Dallas, Texas 75201
*Counsel for Amici Canavan
Foundation et al.*

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

E. Richard Gold
Faculty of Law, McGill University
3664 Peel Street
Montreal, Quebec H3A 1W9
*Counsel for Amici E. Richard Gold
et al.*

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

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

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

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

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

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)*

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.*

George Kimbrell
International Center for
Technology Assessment
660 Pennsylvania Ave., Suite 302
Washington, D.C. 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

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.*

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

Herbert C. Wamsley
Intellectual Property Owners
1501 M Street
Suite 1150
Washington, D.C. 20005
*Counsel for Amicus Intellectual
Property Owners Association*

Jacqueline Wright-Bonilla
Foley & Lardner LLP
3000 K Street, NW
Suite 500
Washington, D.C. 20007
*Counsel for Amici Rosetta Genomics,
Inc. et al.*

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.

Mark R. Freeman
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Room 7646
Washington, D.C. 20530
*Counsel for Amicus Curiae United
States*

Krista L. Cox
Universities Allied for Essential
Medicines
2625 Alcatraz Avenue
No. 180
Berkeley, CA 94705
*Counsel for Amicus Universities Allied
for Essential Medicines*

James J. Kelley
Eli Lilly & Co.
940 S. East Street
Dock 88
Lilly Corp. Center – Drop Code 1104
Indianapolis, IN 46225
Counsel for Amicus Eli Lilly & Co.

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

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

Andrew Chin
University of North Carolina School of
Law
160 Ridge Road CB# 3380
Chapel Hill, NC 27599
*Counsel for Amici University of North
Carolina School of Law et al.*

Matthew J. Dowd

Dated: June 15, 2012