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, PhD, WENDY CHUNG, MD, PhD, HARRY OSTRER, MD, DAVID LEDBETTER, PhD, STEPHEN WARREN, PhD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, 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 AARP, CANAVAN FOUNDATION, CLAIRE ALTMAN HEINE FOUNDATION, FACING OUR RISK OF CANCER EMPOWERED, MARCH OF DIMES FOUNDATION, NATIONAL ASSOCIATION FOR PSEUDOXANTHOMA ELASTICUM, AND OVARIAN CANCER NATIONAL ALLIANCE AS *AMICI CURIAE* IN SUPPORT OF APPELLEES

JOHN L. HENDRICKS
MEGAN M. O'LAUGHLIN
JOHN T. TOWER
HITCHCOCK EVERT LLP
Counsel for Amici Curiae
750 North St. Paul Street, Suite 1110
Dallas, Texas 75201
(214) 953-1111
jhendricks@hitchcockevert.com

June 15, 2012

CERTIFICATE OF INTEREST

Counsel for *amici curiae* AARP, Canavan Foundation, Claire Altman Heine Foundation, Facing Our Risk of Cancer Empowered, March of Dimes Foundation, National Association for Pseudoxanthoma Elasticum, and Ovarian Cancer National Alliance certifies the following:

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

AARP, Canavan Foundation, Claire Altman Heine Foundation, Facing Our Risk of Cancer Empowered, March of Dimes Foundation, National Association for Pseudoxanthoma Elasticum, and Ovarian Cancer National Alliance

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 of the stock of the party or amicus curiae represented by me are:

There are none

4. 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:

Barbara A. Caulfield
Michael J. Malecek
Stephen C. Holmes
Mark D. Shtilerman
Dewey & LeBoeuf LLP

John L. Hendricks
Megan M. O'Laughlin
John T. Tower
Hitchcock Evert LLP

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U.S. DEP'T OF HEALTH & HUMAN SRVS., SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, & SOCIETY, GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON ACCESS TO GENETIC TESTS (2010) 12

I. STATEMENT OF INTERESTS OF *AMICI CURIAE*

This brief is filed pursuant to the April 30, 2012 Order permitting briefs of amici curiae without consent and leave of court. No party's counsel authored the brief in whole or in part, and no party, party's counsel, or person—other than the amici curiae, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief.

AARP is a nonpartisan, non-profit organization dedicated to addressing the needs and interests of people age fifty and older. Access to affordable health care is particularly important to the older population, which has higher rates of chronic and serious health conditions. Gene sequence patents significantly elevate the cost of genetic testing, inhibit the development of better diagnostic testing, and prohibit diagnosis and treatment based on second medical opinions.

Canavan Foundation is a non-profit organization with the mission to provide funding for research efforts to find an effective therapy for, raise awareness of, and to help avoid Canavan disease through carrier screening and prenatal testing. Despite efforts to sponsor low cost screening for potential carriers of Canavan's disease, a doctor and hospital who patented the relevant gene have prevented the group's efforts to provide free or inexpensive screening programs.

Claire Altman Heine Foundation (CAHF) is a non-profit organization dedicated to establishing pan-ethnic carrier screening for Spinal Muscular Atrophy

(SMA)—the number one genetic killer of children under two. In CAHF's experience, the use of patent rights relating to the gene responsible for SMA has reduced access to SMA carrier screening.

Facing Our Risk of Cancer Empowered (FORCE) is a non-profit organization whose mission includes providing people with information and resources to determine whether they are at high risk for breast and ovarian cancer due to family history or genetic predisposition.

March of Dimes Foundation is a non-profit organization dedicated to improving the health of babies by preventing birth defects, premature birth and infant mortality. March of Dimes' mission and research are adversely affected by patents on gene sequences.

National Association for Pseudoxanthoma Elasticum (NAPE) is a non-profit organization and the original Pseudoxanthoma Elasticum (PXE) patient support group in the United States, committed to providing education for afflicted individuals and families. NAPE opposes gene patents because they interfere with research and development of diagnostic and therapeutic tools.

Ovarian Cancer National Alliance (OCNA) is a non-profit organization and the foremost advocate for women with ovarian cancer in the United States. OCNA opposes gene patents because such monopolies impede research on ovarian cancer and restrict access to genetic testing for the disease.

II. SUMMARY OF ARGUMENT

In its April 30, 2012 Order, this Court invited briefing on the applicability of the Supreme Court's decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) to Myriad's isolated DNA claims and to method claim 20 of the '282 Patent (U.S. Pat. No. 5,747,282).

In *Mayo*, the Supreme Court clarified that patent eligibility may not be based on elements that "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field." *Id.* at 1299. In this case, Myriad's claims describe nothing more than a natural sequence of nucleotides isolated from the human genome. "Isolated DNA" is a well-understood and conventional format for DNA used in scientific research and clinical medicine. The process of isolation does not alter the natural sequence or any of the structural or functional properties by which DNA is scientifically defined or described in the claims. *Mayo* read in conjunction with *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) compels the conclusion that merely isolating portions of the human genome does not sufficiently alter the natural properties of DNA to qualify it as patentable subject matter.

In addition, the Court in *Mayo* emphasizes "a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature." *Mayo*, 132 S. Ct. at 1301. Myriad's claims for isolated DNA entirely preempt any

use of those genetic coding sequences and thereby inhibit any further research or innovation relating to them.

Myriad's claim 20 of the '282 Patent is closely analogous to the method claims at issue in *Mayo*, and the Supreme Court's explanation for their invalidity applies with equal force to Myriad's remaining method claim.

III. IN LIGHT OF *MAYO*, MYRIAD'S ISOLATED DNA CLAIMS ARE NOT PATENT ELIGIBLE SUBJECT MATTER

In *Mayo*, the Supreme Court reaffirmed its prior teaching that patent eligible subject matter under § 101 is limited by exclusions for natural phenomena, laws of nature and abstract ideas. It reiterated the rationale for these exclusions:

> "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.

Mayo, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

With these fundamental concerns in mind, the Supreme Court held *Mayo's* patent claims invalid because they effectively do nothing more than describe natural phenomena, i.e. correlations governed by natural laws. The Court determined that steps such as administering an amount of the drug, determining the metabolite concentration, and inferring the need for a change in dosage, contributed nothing inventive to the correlations governed by nature that lay at the core of the claimed invention. "[A] process that focuses upon the use of a natural

law [must] also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Id.* at 1294 (citing *Parker v. Flook*, 437 U.S. 584, 594 (1978)). Focusing on the absence of an "inventive concept," the Court concluded that well-known procedures for administering and determining contributed nothing of ingenuity to the claims.

A. Myriad's isolated DNA claims are not patentable because they describe nothing more than DNA sequences that occur naturally

In its previous review of this case, the majority found that Myriad's isolated DNA claims were patentable subject matter by virtue of being "isolated" from their natural environment of the human genome. *Ass'n for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011). According to the majority's opinion, isolation required the breaking of covalent bonds at each end of a gene segment and thereby resulted in a composition having "markedly different characteristics" from the characteristics of the same sequence of nucleotides occurring in the larger genome. *Id.* at 1352. Although this Court relied on the language of *Chakrabarty*, it deviated significantly from the analytic approach taken by *Chakrabarty* and its predecessor, *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), both of which make clear that function must also be considered.

In *Funk Bros.*, the Supreme Court acknowledged that the claimed composition of bacteria was new and useful, but concluded that "[i]t is no more

than the discovery of some handiwork of nature and hence is not patentable." *Id.* at 131. Significantly, the Court did not address the structural characteristics of the composition in determining whether it was a product of nature as opposed to a human manufacture. Instead, the Court observed:

> The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

Id. Under a similar analysis, the Supreme Court in *Chakrabarty* held that patent claims for a genetically enhanced bacterium capable of decomposing oil more effectively was a human manufacture, and therefore fell within subject matter patentable under § 101. In reaching this decision, the Court said nothing about chemical structural differences in explaining how the claimed bacteria were markedly changed. Instead, it differentiated the claimed subject matter by observing that it had a petroleum degrading capability "which is possessed by no naturally occurring bacteria." *Chakrabarty*, 447 U.S. at 305. The analysis in both cases turns on an assessment of whether the claimed invention describes any performance advantage beyond those inherent in the natural components.

If *Funk Bros*. and *Chakrabarty* guide away from a narrow concern with structural chemical differences in assessing patent eligibility of biological technology, *Mayo* reinforces the view that changes incidental to the isolation and purification of natural material do not render it patentable.

In *Mayo*, the Court questioned whether: "the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?" *Mayo*, 132 S. Ct. at 1297. The correlative question in this case is whether the process of isolating DNA and the attendant changes that occur at the terminal ends of an isolated gene make it different *enough* to *transform* it in any defining way. Based on the Supreme Court's reasoning in *Funk Bros.*, *Chakrabarty* and now *Mayo*, the answer is "no." Isolating a natural substance is not an inventive step. As this Court recognized in *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007), "isolation of interesting compounds is a mainstay of the chemist's art," and that "[i]f it is known how to perform such an isolation doing so 'is likely the product not of innovation but of ordinary skill and common sense.'" *Id*. at 1302 (citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007)). Secondly, the structural change that occurs as a consequence of isolation—breaking covalent bonds—has no bearing on what DNA is or does. Such changes do not alter the claimed or defining *properties* of DNA. It is not *enough* to identify slight molecular differences in the ends of a complex polymer chain if such differences bear no relationship to any change in the properties claimed or any inventive concept or solution to a problem. In this case, the patent claims describe a sequence of nucleotides or amino acids without regard to miniscule differences in

molecular characteristics of terminal points. Such differences are irrelevant to the structure of the nucleotide sequence or coding function that defines DNA.

B. There are no "marked differences" in structure or function between cDNA and native DNA that qualify cDNA as a patentable invention

Although the U.S. Department of Justice (DOJ) has argued for a distinction between "isolated DNA" and complimentary DNA (cDNA), none of Myriad's claims for DNA sequences are limited to cDNA. Moreover, Myriad has not asserted or consented to such a narrow interpretation of its claims and the district court in this case did not find that any of the claims were so limited. Nevertheless, the DOJ has argued that cDNA falls on the side of human artifacts and is patent eligible subject matter. Amici disagree for the following reasons:

"[N]aturally occurring cDNAs, known as 'psuedogenes,' exist in the human genome and are structurally, functionally, and chemically identical to cDNAs made in the laboratory." *Ass'n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 198 (S.D.N.Y. 2010) (citing Mason Supp. Decl. ¶¶ 18-21 (A7023-24); Nussbaum Decl. ¶¶ 41-42 (A6974-75)). In a laboratory, cDNA can be generated "using routine, standard techniques." Mason Supp. Decl. ¶¶ 18-19 (A7023-24). Similar to the pre-solution steps in *Mayo*, this conventional process adds no change that would alter the defining properties of a genetic sequence. Moreover, other than catalyzing natural mRNA with an enzyme, the process of reverse transcription is an entirely natural process that requires no human ingenuity. The fact that the

essence of DNA—the encoding sequence—is obtained through human initiative does not transform what is natural and inherent in the sequence of nucleotides or bring about any new capabilities.

> There are many things well known and valuable in medicine or in the arts which may be extracted from...substances. But the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.

American Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566, 593-94 (1874).[1]

C. Myriad's isolated DNA claims wholly preempt the use of natural phenomena and thereby impede scientific and medical innovation

For over 150 years, courts have disallowed patent claims that impede future innovation by preempting or broadly covering natural phenomena or natural laws: "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." *Mayo*, 132 S. Ct. at 1301; *see O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-20 (1854).

Gene sequence patents afford a monopoly on a basic source of information that is necessary for innovation in the field of applied genetics. Such patents

[1] *See also Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884) (finding artificial alizarine derived from a precursor substance and having the same properties as those found in natural alizarine was not patentable); *Ex parte Latimer*, 1889 Dec. Comm'r Pat. 123 (finding purified pine needle fiber not patentable).

preempt *any* use of a natural product—the gene—because they cannot be designed around; any alteration of the sequence precludes the purpose—to correspond identically with a native human gene or portion thereof. Specifically, gene sequences that correspond to a likelihood or susceptibility to a disease are *necessary* to use for any genetic diagnostic, testing, or personalized treatment for that disease. Consequently, a patent claiming a genetic sequence will stifle any uses of that sequence for research, diagnosis and treatment.

As a consequence of its patents, Myriad gained the *exclusive right* to perform genetic testing and research on the BRCA1 and BRCA2 genes in the United States. But, when one party such as Myriad controls all testing of a gene sequence, it has no incentive to develop further knowledge of gene mutations affecting the risk of breast cancer or improve the quality of testing. Indeed there are several scientific studies that demonstrate the significant limitations of Myriad's test.[2] According to one study published in 2006, the test Myriad employs to detect breast cancer risk does not take into account significant possible

[2] *See* Maurizia Dalla Palma et al., *The Relative Contribution of Point Mutations and Genomic Rearrangements in BRCA1 and BRCA2 in High-Risk Breast Cancer Families*, 68 Cancer Research 7006, 7011 (2008) (finding 8% of non-Ashkenazi Jewish test subjects carried a BRCA mutation not detectable by Myriad's standard test); Allison W. Kurian et al., *Performance of BRCA1/2 Mutation Prediction Models in Asian Americans*, 26 J. Clinical Oncology 4752, 4754-56 (2008) (finding that the models used by Myriad underestimate the prevalence of BRCA1/2 mutations among Asian American women by a full 50%).

mutations of the gene that correlate with a susceptibility to breast cancer. Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. Am. Med. Ass'n 1379, 1379-1388 (2006). In the study, researchers sampled DNA from 300 members of high-risk families that had received negative test results from Myriad. *Id.* The researchers used six methods to search DNA for breast cancer gene mutations, and found that 12% of the patients studied carried rearrangements of BRCA1 or BRCA2 that were not included in Myriad's array. *Id.*[3]

Despite this and other empirical evidence that Myriad's test is deficient and often produces ambiguous results even with the mutations it checks, Myriad, as a result of its DNA sequence patents, remains in sole control of how or whether any new research on the BRCA genes will be conducted and/or incorporated into the tests that it offers.

Myriad's patents provide but one example of the adverse effects on innovation of patents that preempt natural phenomena. In April 2010, the U.S. Department of Health and Human Services issued the Secretary [of Health and Human Services]'s Advisory Committee on Genetics, Health, and Society, Report

[3] The number of missed mutations may be even higher. According to Institute Curie geneticist Dr. Dominique Stoppa-Lyonett, Myriad's test may miss up to 20% of the expected BRCA1 mutations. Steve Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. Nat'l Cancer Inst. 80, 80 (2002).

on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests (2010) [hereinafter "SACGHS"]. The report found that research in the field of genetics has already begun to suffer as a consequence of gene patents. "Patents are already hindering the development of multiplex tests. Laboratories utilizing multiplex tests are already choosing not to report medically significant results that pertain to patented genes for fear of liability." SACGHS at 3. As a consequence of their chilling effects on genetic research, the existence and enforcement of gene patents discourage the development of better quality testing methods. "Neither sample sharing nor competition is possible when an exclusive-rights holder prevents others providing testing. As a result, significant concerns about the quality of a genetic test arise when it is provided by a patent protected sole provider." SACGHS at 4.

Perhaps most directly and immediately of concern to the groups who submit this brief, the practice of patenting human genetic material has already proven to increase the costs of diagnostic procedures, restrict patient access to existing genetic testing and preclude the availability of better tests and of second opinions of the often ambiguous results of current testing methods. *See* SACGHS at 1-6.

IV. MYRIAD'S CLAIM FOR "COMPARING" CELL GROWTH RATES IS DIRECTED TO PATENT INELIGIBLE NATURAL LAWS

The district court held claim 20 of the '282 Patent invalid because it is directed to the abstract mental processes of the scientific method itself. According

to the district court, "the essence of the claim, when considered in its entirety, is the act of comparing cell growth rates and concluding that 'a slower growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.'" *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 237. This analysis is consistent with the Supreme Court's analysis in *Mayo*.

A. The Claimed Steps Add Nothing of Significance to the Natural Laws

Claim 20 is directed to three main steps: (1) growing two transformed eukaryotic host cells with altered BRCA1 genes, one in the presence of a compound and one in the absence of the compound; (2) determining the rates of growth for each of the host cells; and (3) comparing the growth rates of the host cells. The claim further indicates that "a slower rate of growth of the host cell in the presence of the compound is indicative of a cancer therapeutic."

The growing step (1) is analogous to the "administering" step of the *Prometheus* claims—a step that simply told doctors to provide thiopurine drugs to patients as they had previously. *Mayo*, 132 S. Ct. at 1297. In the present case, the growing steps do no more than direct a scientist to grow eukaryotic host cells, a process that was known and routinely performed. *See* '282 Patent Col. 27 Lns. 41-52 (acknowledging that "propagation of mammalian cells [which are a type of eukaryotic host cells] in culture is per se well known.").

Similarly, the determining step (2) is equivalent to the "determining" step in *Mayo*. In *Mayo*, the "determining" step told the doctor to determine the level of metabolites "through whatever process the doctor or the laboratory wishes to use." *Mayo*, 132 S. Ct. at 1297. In the present case, the '282 Patent does not explain the process beyond stating that "the rate of growth of the host cells is measured," indicating that methods of measuring the rate of growth would be known in the art. *See* '282 Patent Col. 31 Lns. 46-53. Accordingly, these steps instruct the scientists to perform conventional activity to measure growth rates of cells in each environment (*i.e.* the presence or absence of the compound).

The final comparing step instructs the scientists to look at the results of each growth rate measurement. This step is equivalent to comparing metabolite levels with those required by the *Prometheus* claims. A comparison of results is a conventional and routine aspect of scientific testing that is exemplified by the scientific method.

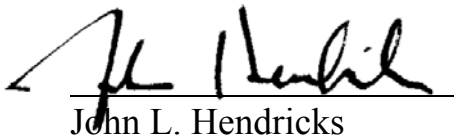
Finally, the wherein clauses in both the *Prometheus* claims and Myriad's '282 Patent claim identify relevant natural laws. In this case, the natural law provided in the wherein clause is the natural correlation between a slower growth rate in the presence of a compound indicating a potential cancer therapeutic.

B. Application of the Scientific Method to a Natural Phenomena is an Abstract Process

Claim 20 is nothing other than the application of scientific method to evaluate natural effects of compounds on the growth rate of host cells. In simple terms, this is a test wherein you (1) prepare a test sample having the hypothesized element (*i.e.*, the compound) and a control sample without the hypothesized element; (2) allow a reactionary process to occur; (3) observe the results of both samples; and (4) draw a conclusion related to the original hypothesis (*i.e.*, whether the compound is indicative of a cancer therapeutic). Applying the scientific method using routine and/or conventional steps does not add any significance to the natural laws and does not make them patentable applications.

V. CONCLUSION

The Supreme Court's *Mayo* decision cautions against a formalistic analysis of subject matter eligibility that would eviscerate exclusions for natural phenomena and laws of nature. Patents on DNA preempt natural phenomena and tie up any use of a foundational tool of biological science. As such, these patents impede innovation. The adverse consequences of such preemption are no longer merely speculative but now well documented. For this and other reasons set forth above, Amici respectfully request that the Court affirm the district court's opinion in light of the Supreme Court's decision in *Mayo*.



John L. Hendricks
Megan M. O'Laughlin
John T. Tower
HITCHCOCK EVERT LLP
750 North St. Paul Street, Suite 1110
Dallas, Texas 75201
(214) 953-1111 Telephone
(214) 953-1121 Facsimile
jhendricks@hitchcockevert.com

Attorney for Amici Curiae
AARP, Canavan Foundation,
Claire Altman Heine Foundation,
Facing Our Risk of Cancer Empowered,
March of Dimes Foundation,
National Association for Pseudoxanthoma Elasticum, and
Ovarian Cancer National Alliance

June 15, 2012

United States Court of Appeals
for the Federal Circuit

ASSOCIATION FOR MOLECULAR v. PTO, 2010-1406

CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr. being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Hitchcock Evert LLP, Counsel for *Amici Curiae AARP, et al.* to print this document. I am an employee of Counsel Press.

On the **15th Day of June 2012**, I served the within **Brief of Amicus Curiae AARP, *et al.*** upon:

Gregory A. Castanias Jones Day 51 Louisiana Avenue, NW Washington, DC 20001-2113 (202) 879-3939 gcastanias@jonesday.com *Counsel for Defendants-Appellants*	Christopher A. Hansen American Civil Liberties Union 125 Broad Street, 18th Floor New York, NY 10017-6702 (212) 549-2606 chansen@aclu.org *Counsel for Plaintiffs-Appellees*

via Express Mail, by causing 2 true copies of each to be deposited, enclosed in a properly addressed wrapper, in an official depository of the U.S. Postal Service.

Additionally, counsel for Amici Curiae known to be appearing at the time of filing will be emailed a copy of this brief.

Unless otherwise noted, 12 copies have been filed with the Court on the same date via hand delivery.

June 15, 2012