No. 2010-1406

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

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BRIEF FOR THE BIOTECHNOLOGY INDUSTRY ORGANIZATION, THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, AND THE COALITION FOR 21ST CENTURY MEDICINE AS AMICI CURIAE IN SUPPORT OF APPELLANT

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CERTIFICATE OF INTEREST

Counsel for the Biotechnology Industry Organization, the Association of University Technology Managers, and The Coalition for 21st Century Medicine certifies the following:

1. The full name of every party or amicus represented by us are:

   Biotechnology Industry Organization

   Association of University Technology Managers

   The Coalition for 21st Century Medicine

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 us 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 us are:

   None

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

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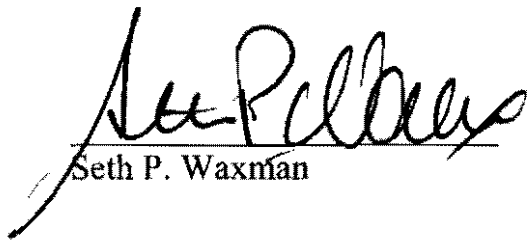
Dated: June 15, 2012



Seth P. Waxman

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STATEMENT OF INTEREST[1]

The Biotechnology Industry Organization ("BIO") is the country's largest biotechnology trade association, representing over 1100 companies, biotech centers, and academic institutions. The Association of University Technology Managers ("AUTM") is the largest association of university technology transfer professionals. The Coalition for 21st Century Medicine represents companies, professionals, and patient advocacy groups interested in state-of-the-art diagnostic techniques.

ARGUMENT

This Court previously concluded that the claimed isolated genomic DNA and cDNA molecules in this case are patentable compositions of matter. Nothing in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), changes the framework for that analysis or the principles that informed this Court's decision. The composition of matter claims therefore remain patent eligible under 35 U.S.C. § 101. Method claim 20 also easily survives review, because it involves the use of a transformed cell that itself would be patent eligible.

I. ISOLATED DNA MOLECULES REMAIN PATENTABLE AFTER *MAYO*

Mayo focused on the relationship between laws of nature and methods, and the framework it applied is designed to police the line between ideas and patent

[1] No counsel for a party authored this brief in whole or part. No party, and no person other than BIO and its members, contributed towards the preparation or submission of this brief. Myriad Genetics is a member of The Coalition for 21st Century Medicine, but took no part in the Coalition's decision to join BIO's brief.

eligible methods applying such ideas. The decision did not alter the proper framework for analyzing manufacture or composition of matter claims, which continue to be governed by *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), and earlier decisions. Had the Supreme Court intended to upset this settled precedent, it would have said so. This Court should therefore reject any invitation to stretch *Mayo* beyond its intended scope.[2]

A. *Mayo* Does Not Apply To Manufacture Or Composition Of Matter Claims

Mayo must be read in the context of the particular method claims that the Supreme Court examined. *See Mayo*, 132 S. Ct. at 1294 ("Our conclusion rests upon an examination of the particular claims before us[.]"). The first of those claims, and the one on which the Court focused, covered a process that involved the administration of a drug and the measurement of a metabolite, with two "wherein" clauses stating what certain levels of the metabolite "indicate[]." *Id.* at 1295. As construed, the claim did not require any change in treatment or other action based on the information in the "wherein" clauses. *See id.* at 1296. The Court therefore concluded that "the 'wherein' clauses simply tell a doctor about the relevant natural laws," *id.* at 1297, and that, taken together, "the three steps [in

[2] Even if *Mayo* had undermined *Chakrabarty* (which it did not), this Court would still be bound to follow *Chakrabarty* until the Supreme Court expressly overruled it. *See Rodriguez de Quijas v. Shearson/Am. Express, Inc.*, 490 U.S. 477, 484 (1989).

claim 1] simply tell doctors to gather data from which they may draw an inference in light of the correlations," *id.* at 1298.

In the Supreme Court's view, this bare recitation of an idea combined with what the Court deemed to be insignificant steps placed the claim squarely within the contours of prior decisions prohibiting the preemption of abstract ideas or principles. The Court accordingly emphasized its prior statement that "'[p]ost-solution activity that is purely 'conventional or obvious' … cannot transform an unpatentable principle into a patentable process.'" *Mayo*, 132 S. Ct. at 1299 (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)). The Court also cited *Bilski v. Kappos*, 130 S. Ct. 3218, 3230 (2010), and *Diamond v. Diehr*, 450 U.S. 175, 191-192 (1981), for the proposition that "[t]he prohibition against patenting abstract ideas cannot be circumvented by … adding insignificant postsolution activity." *Mayo*, 132 S. Ct. at 1294 (internal quotation marks omitted).

This framework for analyzing *method* claims that effectively do nothing more than recite a law of nature was already in place when this Court issued its panel decision, but it did not affect this Court's analysis of Myriad's *composition* claims—and rightly so. It makes no sense, for example, to ask whether a claim directed to a composition of matter (such as a molecule) merely "append[s] conventional steps" to a law of nature, natural phenomenon, or abstract idea. *Mayo*, 132 S. Ct. at 1300. Compositions of matter do not have "steps"; they have

physical form and can be claimed without regard to the manner in which they are made or used. The Supreme Court, in keeping with this distinction, has analyzed the patent eligibility of manufacture and composition of matter claims under an approach created specifically for that purpose that focuses on whether the claimed invention has different characteristics and uses from any naturally-occurring analogue. *See Chakrabarty*, 447 U.S. at 309-310; *Funk Bros. Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127, 131 (1948). Applying that framework, this Court concluded that isolated DNA and cDNA molecules are patentable subject matter because human involvement has given them both different form and enlarged utility. *See AMP v. USPTO*, 653 F.3d 1329, 1351-1354 (Fed. Cir. 2011) (Lourie, J.); *id*. at 1361-1366 (Moore, J.).

Nothing in *Mayo* implies that this Court should now abandon the Supreme Court's own framework for analyzing composition of matter claims. Indeed, if the Supreme Court had believed that *Mayo* governed manufacture/composition of matter claims as well as process/method claims, it presumably would have addressed *Chakrabarty* and *Funk Brothers* not just in passing but also in its "consideration of the controlling precedents." *Mayo*, 132 S. Ct. at 1298. The complete omission of *Chakrabarty* and *Funk Brothers* from that section of the Court's opinion, *see id.* at 1298-1301, strongly implies that the Court did not

consider, and its *Mayo* decision does not "control[]," the analysis of manufacture or composition of matter claims.

Mayo also included no discussion of the key statutory language interpreted in *Chakrabarty*. The Supreme Court stated in *Chakrabarty* that the question before it was "a narrow one of statutory interpretation" that required the Court to determine whether the claimed "micro-organism constitute[d] a 'manufacture' or 'composition of matter' within the meaning of the statute." *Chakrabarty*, 447 U.S. at 307. The Court noted that the term "manufacture" refers to materials given "new forms, qualities, properties, or combinations," while "composition of matter" means "all compositions of two of more substances" or "composite articles." *Id*. at 308 (internal quotation marks omitted). The Court further noted that because Congress had modified these already "expansive terms" with the word "any," it "plainly contemplated that the patent laws would be given wide scope." *Id*. The language of Section 101 thus demonstrates that the broad scope of patent-eligible subject matter effectively includes anything with physical form that has been given new form, properties, or utility by man. *Id*. at 309.

The Supreme Court's subsequent discussion of Section 101's limits does not discard this careful textual analysis in favor of a free-floating "product of nature" exception. To the contrary, the Supreme Court specifically "cautioned that courts 'should not read into the patent laws limitations and conditions which the

legislature has not expressed.'" 447 U.S. at 308. Thus, to the extent a product of nature in its unaltered natural form is not patentable subject matter, it would only be because the complete absence of human involvement might prevent the product from being considered a "manufacture" or "composition of matter" within the meaning of the statute. That text has not changed since *Chakrabarty* and was not addressed, let alone reinterpreted, in *Mayo*. *Mayo* accordingly provides no basis for abandoning this Court's panel decision.

B. The Supreme Court's Decision To Grant, Vacate, And Remand Does Not Imply That *Mayo* Applies To Composition Of Matter Claims

The Supreme Court's decision to grant, vacate, and remand (GVR) in this case likewise does not indicate that the Court believed that *Mayo* applies to manufacture or composition of matter claims. As this Court has recognized, a GVR is a regular consequence of an intervening Supreme Court decision and means simply that the court of appeals should consider the effect, if any, of the Supreme Court's decision on the particular case, not that the court of appeals' judgment was incorrect. *E.g.*, *Hughes Aircraft Co. v. United States*, 140 F.3d 1470, 1473 (Fed. Cir. 1998) ("Vacatur and remand by the Supreme Court, however, does not create an implication that the lower court should change its prior determination."); *see also, e.g.*, *Gonzalez v. Justices of Mun. Ct. of Boston*, 420 F.3d 5, 7 (1st Cir. 2005).

The proceedings in *Chakrabarty* and its companion case, *In re Bergy*, are instructive. Both cases involved manufacture/composition of matter claims, and both were originally decided by the Court of Customs and Patent Appeals before the Supreme Court issued its decision in *Flook*, which involved a process claim and applied essentially the same framework later applied in *Mayo*. *See In re Bergy*, 596 F.2d 952, 956 (C.C.P.A. 1979). The Supreme Court vacated and remanded *Bergy* in light of *Flook*.[3] The CCPA then considered whether *Flook* applied to manufacture and composition of matter claims. Judge Rich, writing for the majority, held that *Flook*'s analysis was "inapplicable" because "*Flook* was concerned only with the question of what is a 'process' under § 101," while *Bergy* and *Chakrabarty* "involve[d] only the construction of the terms 'manufacture, or composition of matter.'" *Id.* at 965.

In *Chakrabarty*, the Supreme Court subsequently reviewed and affirmed Judge Rich's decision. Like Judge Rich, the Supreme Court declined to stretch the framework designed for method/process claims to cover manufacture and composition of matter claims. It did not, for example, dissect the claimed microorganism into its individual components—all of which were naturally occurring—and ask whether the *techniques* used to combine them into a non-

[3] Rather than wait for a similar GVR order to issue in *Chakrabarty*, the CCPA granted a motion to recall the mandate so that *Chakrabarty* could be consolidated with *Bergy* and reconsidered on the same schedule. *See Bergy*, 596 F.2d at 957.

naturally occurring microorganism were novel. The Court instead analyzed the microorganism as a whole and concluded, based on its interpretation of the terms "manufacture" and "composition of matter," that the microorganism was a patent-eligible manufacture or composition of matter because it was created by man and had different characteristics and uses from any naturally-occurring analogue. 447 U.S. at 309-310. *Chakrabarty* thus confirmed that it would have been error for the CCPA to change its analysis based on the Supreme Court's post-*Flook* GVR—just as it would be error for this Court to abandon *Chakrabarty* and the reasoning of its own prior decision based on the Supreme Court's post-*Mayo* GVR.

C. An Overbroad Reading of *Mayo* Would Have Far-Reaching Negative Consequences

The policy arguments presented in *Mayo* also do not warrant a change of direction in this case. For the reasons discussed in amici's original brief, any consideration of policy overwhelmingly favors this Court's earlier determination that isolated genomic DNA and cDNA molecules are patentable subject matter. Numerous empirical studies have refuted the claim that patents on isolated DNA or cDNA molecules "inhibit future innovation," *Mayo*, 132 S. Ct. at 1301 or "impede the flow of information," *id*. at 1305.[4] Arguments about stifling research also

[4] *See, e.g.*, Huys et al., *Legal Uncertainty in the Area of Genetic Diagnostic Testing*, 27 Nature Biotech. 903, 909 (2009) (evidence does "not point to the existence of a wide patent thicket in genetic diagnostic testing"); FTC, *Emerging Health Care Issues* 32 (2009) (problem of "hindering follow-on innovation" "has

overlook the protection provided to researchers under 35 U.S.C. § 271(e)(1) and the common law research exception. *See* BIO/AUTM Br. 32. Moreover, concerns that claims to isolated DNA molecules are unduly "preemptive" cannot be substantiated or resolved without examining what activities actually infringe such claims, something that has been strikingly absent from plaintiffs' case. For example, it is highly questionable whether typical patents on isolated DNA molecules would even be infringed by existing sequencing techniques and emerging techniques such as whole genome sequencing, because such techniques do not require isolation of the gene being sequenced.[5]

Patents on isolated DNA molecules are critical to encouraging innovation and feature prominently in a number of biotechnology success stories. BIO/AUTM Br. 20-27. Any erosion of patent protection would threaten this

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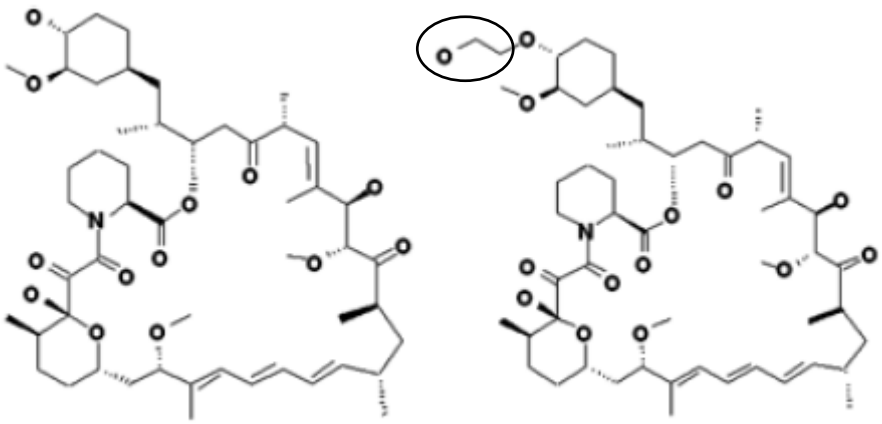
yet to materialize"); Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 Nature Biotech. 1091, 1093 (2006) ("[E]mpirical research suggests that the fears of widespread anticommons effects that block the use of upstream discoveries have largely not materialized."); Adelman & DeAngelis, *Patent Metrics*, 85 Tex. L. Rev. 1677, 1681 (2007) ("The existing empirical studies find few clear signs that the patenting of biotechnology inventions is adversely affecting biomedical innovation."); Walsh et al., *Patents, Material Transfers and Access to Research Inputs in Biomedical Research* 3 (Sept. 20, 2005) ("patenting does not seem to limit research activity significantly").

[5] *See, e.g.*, Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. Rev. 563, 580 (2012); Price, *Unblocked Future: Why Gene Patents Won't Hinder Whole Genome Sequencing and Personalized Medicine*, 33 Cardozo L. Rev. 1601, 1618-1623 (2012).

innovation and the reliance interests of the industry. The USPTO has issued patents on compositions or compounds isolated from nature for more than 100 years. As early as 1873, Louis Pasteur received U.S. Patent 141,072 claiming "yeast, free from organic germs of disease." "There are now thousands of patents with claims to isolated DNA, and some unknown (but certainly large) number of patents to purified natural products or fragments thereof." *AMP*, 653 F.3d at 1367 (Moore, J.). Reversing course at this point would disrupt the long-settled, investment-backed expectations of businesses that rely on such patents.

An overbroad application of *Mayo* would have implications not just for patents on isolated DNA molecules, but for innumerable other patents claiming medically and industrially useful compounds that are isolated or derived from natural sources. Many novel chemicals are created through the application of known techniques to create a new and useful manufacture or composition of matter. An overbroad reading of *Mayo* that evaluated the patent-eligibility of a composition of matter based not on the claimed matter, but on whether *the techniques used to make it* are "routine," "conventional," or "well-understood," would anomalously make patentability turn on something other than the claimed invention. It could also invite unproductive attempts to divide molecules into their constituent parts, creating a new and uncertain inquiry that would redirect the patent-eligibility analysis away from the claimed product as a whole. For example,

would the patent eligibility of isolated rapamycin (below left)[6] turn on the novelty of the techniques used to isolate it, rather than on the fact that once it is given that new form by the hand of man, it has a vastly expanded range of utility? *See infra* pp. 12-13. Similarly, would the patent eligibility of a particular rapamycin derivative (below right) turn on whether the limited portion of the chemical structure with no analogue in nature (circled) is "well-known" or "conventional"? Neither approach would accurately capture the inventor's important contribution—yet, under an overbroad reading of *Mayo*, structural claim limitations, such as "purified" (left) or "ethoxylated" (right), could be wrongly dismissed as lacking an "inventive concept."



Extending *Mayo* to manufacture and composition of matter claims could also make it nearly impossible to patent a manufacture or composition of matter

[6] Majumder & Sellers, *Akt-regulated pathways in prostate cancer*, 24 Oncogene 7465, 7470 fig. 3 (2005), *available at* http://www.nature.com/onc/journal/v24/n50/pdf/1209096a.pdf.

without also patenting a new method of manufacture. This unprecedented result would improperly divert research incentives away from the use of established techniques to create novel and useful substances and, ironically, place a premium on patenting upstream research tools over downstream discoveries.

Reliable patent protection is critical to the discovery, disclosure, and commercialization of new and useful compositions of matter that are isolated or derived from natural sources. Among the many success stories:

- Amgen's patent on the isolated DNA molecule for erythropoietin, U.S. Patent No. 4,703,008, has been critical in protecting its therapeutic, Epogen®, which virtually eliminated the need for blood transfusions to treat anemia. *See* BIO/AUTM Br. 20.

- Sirolimus, also known as rapamycin, is a macrocyclic compound produced by the bacterium *Streptomyces hygroscopicus* NRRL 5491, which was first discovered in a soil sample from Easter Island. The inventor disclosed the discovery, deposited a sample of the bacterium, and applied for and obtained a patent on purified sirolimus as a novel antifungal and antibiotic compound. *See* U.S. Patent 3,929,992. Others then built on the discovery and disclosure of sirolimus to make new discoveries and create important products. The compound was subsequently developed, for example, as a powerful immunosuppressant for clinical use, and today RAPAMUNE® (sirolimus) is used to prevent organ

rejection in kidney transplant patients. Sirolimus was also found to display cytostatic (antiproliferative) activity outside the immune system, and coronary stents with sirolimus-eluting coatings, such as Cordis's CYPHER® Stent, were developed to prevent endothelial growth around the newly-placed stent. Semisynthetic derivatives of sirolimus, such as the one depicted on page 11 above have also been developed in an effort to use sirolimus's cell growth-arresting properties to treat cancer.

- Muromonab-CD3, a monoclonal antibody derived from mice, is used to prevent transplant rejection by suppressing the human immune system, and was created using standard immunization and hybridoma techniques. The inventors patented the resulting antibody, muromonab-CD3, which corresponds to the antibody produced naturally by immunized mice. *See, e.g.*, U.S. Patent 4,361,549. After further investment and clinical trials, muromonab-CD3 became the first monoclonal antibody approved by the FDA, and it was commercialized as Orthoclone OKT3®.

- The inability of some livestock to digest phytate in grain causes environmental pollution from fecal phosphate. Inclusion of the enzyme phytase in animal feed significantly reduces this problem. Progress in this area has been facilitated by the invention of a phytase enzyme from the microbe *E. coli* and patent protection of isolated DNA. *See* U.S. Patent 6,190,897.

- The growing field of biofuels requires enzymes to break down the energy-rich carbohydrates of plants. Industrial biotechnology companies have invented a glucoamylase enzyme from the fungus *Trichoderma reseii* that efficiently releases glucose sugars from carbohydrates, allowing for better production of biofuels such as ethanol. *See* U.S. Patent 7,413,887.

These examples are but a small fraction of the many important inventions derived from nature that might never have been made without the promise of patent protection.[7] They illustrate that the stakes of this case extend far beyond the diagnostic use of human DNA or the practices of a single company, and that any discussion of policy must consider the impact on new and emerging research regarding non-human DNA, therapeutic proteins, agriculture, food safety, and industrial and environmental biotechnology. *See* BIO/AUTM Br. 21-24. They also show that, far from suppressing downstream research, patent protection on a molecule such as sirolimus can speed the pace of innovation by encouraging the inventor to disclose the invention and make it available to other researchers. The

[7] *See, e.g.*, U.S. Patent 6,083,733 (claiming isolated heat and alkaline-resistant enzyme from New Zealand hot spring bacterium for use in paper production); U.S. Patent 6,589,772 (claiming isolated bacterial culture useful in processing low grade metal ores under extremely acidic conditions); U.S. Patent 7,923,234 (claiming isolated DNA encoding bacterial acid-stable thermotolerant hemicellulases for use in biofuel production); U.S. Patent 7,960,505 (claiming isolated bacterial protein as a meat preservative); U.S. Patent 8,106,013 (claiming isolated peptide from scorpion venom for treatment of cystic fibrosis).

expiration of the original sirolimus patent also provides a reminder that patents last for only a limited time, while the information they disclose lasts forever.

Finally, these examples demonstrate that the individuals and companies responsible for these and other inventions have invested billions of dollars in reliance on the long-standing recognition that the fruits of their research are patent-eligible subject matter. If there is to be any change in the law, it should and must come from Congress, not from the overreading of a case, like *Mayo*, that never addressed the issue.

II. THE METHOD OF CLAIM 20 IS PATENTABLE SUBJECT MATTER

To the extent the Court revisits Claim 20, the issue need not detain it long. The first step in Claim 20 involves "growing a transformed eukaryotic host cell containing an altered BRCA1 gene." This step alone easily distinguishes Claim 20 from the claims in *Mayo*, because the transformed host cell is itself novel (and, indeed, patented) and use of that transformed cell in the presence of a suspected therapeutic therefore cannot be the type of "well-understood, routine, conventional activity already engaged in by the scientific community." *Mayo*, 132 S. Ct. at 1298.

CONCLUSION

This Court should reaffirm the panel's decision holding that Myriad's isolated DNA claims and method claim 20 cover patentable subject matter.

Dated: June 15, 2012

Respectfully submitted,

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I hereby certify that on this 15th day of June, 2012, I caused two copies of the Brief for Amicus Curiae Biotechnology Industry Organization, Association of University Technology Managers, and The Coalition for 21st Century Medicine to be sent by overnight commercial carrier and electronic mail to each of the following:

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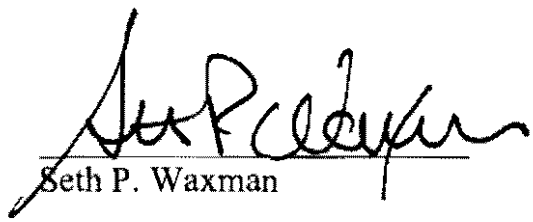
CERTIFICATE OF COMPLIANCE

Counsel for Amicus Curiae Biotechnology Industry Organization and Association of University Technology Managers hereby certifies that:

1. The brief complies with the page limit in this Court's request for supplemental briefing; and

2. The brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Office Word 2003 in a proportionally spaced typeface: Times New Roman, font size 14.

Dated: June 15, 2012



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