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, 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 *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF REVERSAL, BUT IN SUPPORT OF NEITHER PARTY

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October 29, 2010

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* American Intellectual Property Law Association certifies the following:

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

AMERICAN INTELLECTUAL PROPERTY
LAW ASSOCIATION

2. The name of 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 represented by me 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:

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
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AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES, RULES, AND REGULATIONS

LITERATURE

STATEMENT OF INTEREST OF *AMICUS CURIAE*

The American Intellectual Property Law Association ("AIPLA") is a national bar association of nearly 16,000 members engaged in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. AIPLA members represent both owners and users of intellectual property.

In accordance with Federal Rule of Appellate Procedure 29(a), AIPLA has obtained the consent of all parties to file this amicus brief.[1]

QUESTIONS PRESENTED

1. Under Section 101 of the Patent Act, are purified, isolated DNA molecules—transformed in structure and function from native DNA at great cost through significant human effort that identified them as being associated with an

[1] After reasonable investigation, the AIPLA believes that: (a) no member of its Board or Amicus Committee who voted to prepare this brief on AIPLA's behalf, or any attorney in the law firm or corporation of such a board or committee member, represents a party to this litigation; (b) no Counsel or other representative of any party to this litigation participated in the authorship of this brief; and (c) no one other than the AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief. Some committee members or attorneys in their respective law firms or corporations may represent entities that have an interest in other matters that may be affected by the outcome of this litigation.

increased risk of certain cancers—ineligible for patent protection as mere "products of nature?"

2. Under Section 101 of the Patent Act, are methods of diagnosing certain types of cancer by comparing purified/isolated DNA molecules to see if identified anomalies have occurred, ineligible for patent protection as covering nothing more than scientific principles or abstract mental steps?

3. Do potential customers and their related associations have standing to bring a declaratory judgment action to invalidate patents in order to allow third parties to sell potentially infringing products and services that the potential customers may wish to purchase?

PRELIMINARY STATEMENT

This case presents a deceptively simple question regarding the scope of patent protection under 35 U.S.C. § 101: Are purified/isolated DNA molecules derived from the human genome that have new, medically significant utilities, and methods for using them, patent-eligible subject matter? Anything but simple, however, are the legal issues raised by those questions and the ramifications of the District Court's decision. At stake are significant medical and economic interests of individuals and industries alike.

Patent protection, in large part, drives the American economy.[2] Patent protection for purified/isolated DNA molecules and the diagnostic and screening methods that employ them as biological tools encourages medical advances that benefit all of humanity. It provides economic incentives to the biotechnology industry to make the significant investments that are necessary to research and develop critical new healthcare options, such as personalized medicine, which tailors medical treatments to patients based on genetic factors. These results are in keeping with the Constitutional mandate that the patent laws are delegated to Congress "To promote the Progress of Science and useful Arts." Art. I, § 8, cl. 8.

As Abraham Lincoln observed, "The patent system . . . added the fuel of *interest* to the *fire* of genius."[3] Due in no small part to the incentives provided by patent protection, the biotechnology industry holds great promise for making inroads against diseases such as cancer that have eluded effective treatments for generations, despite the dedicated effort of the medical, scientific, and other

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[2] *See* George Elliott, *Basics of US Patents and the Patent System*, 9(3) APPS J. E317, E317 (2007); Roger W. Ferguson, Jr., Vice Chairman, Fed. Reserve Bd., Remarks at the 2003 Financial Markets Conference of the Federal Reserve Bank of Atlanta (Apr. 5, 2003) (transcript *available at* http://www.federalreserve.gov/BoardDocs/speeches/2003/20030407/default.htm); *see also* A Report to the Secretary of Commerce: The Advisory Commission on Patent Law Reform 187 (Aug. 1992).

[3] Abraham Lincoln, Second Lecture of Discoveries and Inventions (Feb. 11. 1859), *in* 3 The Collected Works of Abraham Lincoln 356, 363 (Roy B. Basler et al. eds., 1953).

interested communities. The ripple effects of strong patent protection for such technologies include stimulating the economy and providing jobs in the biotechnology industry.

These are the interests that the District Court's decision minimized and effectively ignored. That decision threatens more than just the members of the biotechnology industry whose business depends on purified/isolated DNA molecule patents. The District Court's rationale could extend to other industries, and threatens to undermine the Patent Code's Constitutional mandate—to promote the progress of science and the useful arts.

SUMMARY OF ARGUMENT

The patents-in-suit cover biological tools and methods of using them that allow health care practitioners to identify individuals at significant risk of breast and ovarian cancer, tailor existing treatment options to ensure the highest likelihood of therapeutic success, and develop new anti-cancer treatments specifically designed to combat these devastating diseases. These real-world medical advances are exactly the type of inventions that the Patent Laws and the policy behind them are designed to incentivize and protect.

That policy is, as it should be, blind to the raw materials from which significant technological advances spring. Indeed, precedent has long held that isolating and purifying naturally occurring biological substances—such as

adrenaline or prostaglandins—to give them different characteristics and uses transforms them into protectable "compositions of matter" or "manufactures" under 35 U.S.C. § 101. The District Court, however, misapplied or disregarded those precedents in favor of an unprecedented test that focuses on a shared "essential characteristic" of the claimed subject matter and the native source from which it was derived. But neither the Supreme Court nor this Court has endorsed such a test. Courts instead have recognized that the key to patent eligibility of inventions derived from natural substances is structural and functional transformation.

Under the proper test—which focuses on differences, not similarities—the grant of summary judgment was improper. Myriad presented substantial evidence that the product claims at issue are directed to purified, isolated BRCA1/2 DNA molecules that have been, through human ingenuity, transformed from their natural state to possess a different structure and new function. Drawing all reasonable inferences in favor of the non-movant Myriad, there are at least genuine issues of material fact that preclude summary judgment.

The District Court further erred in ruling the method claims unpatentable. Each of the claimed methods inextricably depends on the Myriad inventors' novel purified/isolated DNA molecules and involves substantial physical and chemical transformations. Nevertheless, the District Court ruled that all of the method

claims were invalid as claiming mere scientific principles, and as failing to satisfy the "machine or transformation test" set forth by the Federal Circuit in *Bilski*. But now applying the Supreme Court's subsequent guidance from *Bilski*, the District Court's judgment that Myriad's method claims are invalid as mere abstract mental processes should not stand.

Finally, the District Court erred in finding that potential customers for BRCA genetic testing, and their related healthcare organizations, had standing to bring a declaratory judgment suit. Myriad never sought to enforce its patents against them or similarly situated entities, and those parties have taken no concrete steps to practice or induce infringement of the patented subject matter. Accordingly, the facts show that they lack declaratory judgment standing under "all the circumstances."

ARGUMENT

The claims at issue fall into two categories: methods of using purified/isolated DNA molecules to diagnose increased risks of cancer by looking for well-characterized anomalies or to identify new cancer treatments, and the purified/isolated DNA molecules themselves. As explained below, both the compounds and their methods of use should be patentable under Section 101 for reasons of precedent and policy.

In Sections I and II, *infra*, AIPLA sets out the reasons that isolated DNA is meant to be patentable as a matter of policy and law, and in Section III, AIPLA shows how that impacts method claims where the essential new information in the method is the isolated DNA itself and its correlation with quantifiable cancer risks. The business and real world harms caused by the District Court's decision are discussed in both Sections I and IV, and Section V explains how the District Court has attempted to set policy instead of deferring to Congress. Finally, Section VI discusses the standing issue, analyzing how the District Court erred.

I. The Claimed Purified/Isolated DNA Molecules Are the Kind of Inventions that the Patent Laws Are Intended to Protect

Congress envisioned Section 101 as broad, flexible, and adaptable to new technologies and advances in knowledge. *Bilski v. Kappos,* 130 S. Ct. 3218, 3225 (2010). "Congress took this permissive approach to patent eligibility to ensure that 'ingenuity should receive a liberal encouragement.'" *Id.* (*citing Chakrabarty,* 447 U.S. at 308 (*quoting* 5 The Writings of Thomas Jefferson 75-76 (H. Washington ed., 1871))). In keeping with that directive, each advance—from the Industrial Age through the Information Age and beyond—has been spurred on and rewarded

by robust patent protection.[4] And in every age, the ultimate beneficiary has been the public.[5]

First, and most immediately, the public benefits from the innovation itself, whether it be the proverbial "better mousetrap" or a breakthrough in advanced medical science (such as the miracle breast cancer treatment tamoxifen that has saved millions of lives). Second, the public has benefited in terms of the economic prosperity this country has enjoyed for generations, thanks in large part to the role patents have played in inspiring entrepreneurship, putting investment capital in the hands of innovators, and stimulating employment. The company that takes the risk of discovering, testing, and bringing to market a novel lifesaving product at the cost of hundreds of millions of dollars should be permitted to seek exclusive rights to the invention for a limited period to recoup its enormous investment, fund additional research, and expand its business.[6]

Third, patents make innovation contagious. The fundamental quid pro quo of the patent grant is the requirement that inventors fully disclose their inventions so their knowledge, insights, and achievements become available to everyone, especially to competing innovators, who can then use the patent disclosure to push

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[4] Elliott, *supra* note 2, at E317.
[5] *Id.*
[6] *Id.*

the frontiers of science even further.[7] Once the patent term expires, all are free to enjoy, commercialize, and improve the claimed inventions. One need only to look to societies with weak patent systems—and to their stagnant economies—to appreciate how critically important it is for U.S. patent protection to remain as robust as possible in every field of science and technology.[8]

The considerable public interest is not well served by a decision that would curb patent protection as the horizons of science have expanded inward, to human biology, as part of a new age of innovation—the biotech age.[9] Unfortunately, the District Court's decision denying patent protection for the purified, isolated BRCA DNA molecules and related methods categorically curtails patent protection for the biotechnology industry, which depends on patents to attract the investment capital needed to fund further discoveries.[10] The average estimated investment required for developing a biologic treatment can reportedly exceed $1 billion, and is still

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[7] Melissa Wetkowski, *Unfitting: Gene Patent Limitations Too Tight for United States' Biotechnology Innovation and Growth in Light of International Patenting Policies,* 16 Sw. J. Int'l L. 181, 204 (2010).
[8] *Id.* at 198.
[9] *See generally* Gregory Ellis, *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents,* 15 Rich. J. L. & Tech. 1 (2009).
[10] Henry Grabowski, *Pharmaceuticals: Politics, Policy and Availability: Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 Geo. Pub. Pol'y Rev. 7, 9 (2003).

rising.[11] In denying patent protection for Myriad's inventions—and by extension jeopardizing existing and future patents across the biotechnology industry—the District Court's ruling will have a profound negative impact if allowed to stand.

This is not an empty prediction. In 2000, a White House spokesman erroneously suggested that the United States and Great Britain would restrict gene patents. Due to that statement, stocks of two relevant companies dropped 25% - 30%.[12] Even when President Clinton and Prime Minister Blair attempted to correct the false report, the NASDAQ plunged to its second steepest dive ever.[13] These types of patents, thus, are a vital and dynamic part of the economic engine that drives the American high-technology economy.

The District Court's decision to entertain this unusual patent challenge and then to effectively abolish patents on isolated genes represents a step backwards. Underlying the challengers' hostility toward gene patents is the visceral reaction

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[11] *See* Tufts Center for the Study of Drug Development, Research Milestones: Drug Policy and Strategy Analyses to Inform R&D and Strategic Planning Decisions, *available at* http://csdd.tufts.edu/research/research_milestones (referring to a 2006 study that estimated the average cost of developing a new biotechnology product as $1.2 billion); Press Release, Tufts Center for the Study of Drug Development, *Rising Clinical Trial Complexity Continues to Vex Drug Developers* (May 5, 2010), *available at* http://csdd.tufts.edu/news/press_releases (discussing increasing costs).

[12] *Clinton/Blair Gene Patent Announcement Draws Reaction*, BIOTECH Patent News (Mar. 1, 2000), *available at* http://www.allbusiness.com/business-finance/equity-funding-stock/497481-1.html.

[13] Tom Reynolds, *Genome Data Announcement Fuels Stock Plunge, Misunderstanding*, 92(8) J. Nat'l Cancer Inst. 594, 594-97 (2000).

that one's personal genetic makeup—how nature makes us who we are—ought not to be the intellectual property of for-profit enterprises. But patents on purified/isolated DNA molecules and methods of using them do not confer upon Myriad "ownership" rights of anyone's genetic heritage.[14] The patent claims cover only molecules that have been extracted and significantly altered relative to native genomic DNA, after great effort and ingenuity by the inventors. The utility of those extracted, isolated, and purified DNA molecules lies in their ability to improve the health and longevity of humanity.

No legal or factual basis exists for excluding from patent-eligible subject matter purified/isolated DNA molecules that have a host of therapeutic, diagnostic, and prognostic applications. The patents here assist medicine by explaining how to detect cancer and other genetic anomalies; they are not part of an effort to stymie medicine by patenting the essence of humanity. Accordingly, the subject matter is worthy of patent protection.

II. The Claimed Purified/Isolated DNA Molecules Fall Within the Broad Scope of Section 101

The Supreme Court has recognized only a few narrow exceptions to patent-eligible subject matter under Section 101: claims directed solely to laws of nature,

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[14] James Guillo, *Genomic Research and Accessibility Act: More Science Fiction than Fact,* 8 Nw. J. Tech. & Intell. Prop. 292, 298 (2010) ("Since DNA must be isolated from the genome to qualify for patentability, it is impossible for any corporation or university holding a patent on a gene to own any person's DNA.").

natural phenomena, and abstract ideas. *Bilski*, 130 S. Ct. at 3225 (*citing Chakrabarty*, 447 U.S. at 309). Those exceptions do not "give[] the Judiciary *carte blanche* to impose other limitations that are inconsistent with the text and the statute's purpose and design." *Id.* at 3226. Thus, the so-called "products of nature" exception—the only impediment to Section 101 raised by the District Court—has been, and should be, narrowly drawn and should not apply here to exclude Myriad's important inventions. *See In re Bergy*, 596 F.2d 952, 976 (C.C.P.A. 1979) ("We were thinking of something preexisting and merely plucked from the earth and claimed as such, a far cry from a biologically pure culture produced by great labor in a laboratory and so claimed."). Section 101 embraces products that are derived from naturally occurring sources—and sharing some of the sources' properties or qualities—but that are nonetheless different from them in some structural and functional manner as a result of human effort and ingenuity. *See, e.g.*, *Chakrabarty*, 447 U.S. at 309-10 ("a product of human ingenuity 'having a distinctive name, character [and] use'") (*citing Hantranft v. Wiegmann*, 121 U.S. 609, 615 (1887)); *Am. Fruit Growers, Inc. v. Brogdex,* 283 U.S. 1, 11 (1931) ("giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery") (citation omitted). Had the District Court followed this principle, derived from controlling precedents, it would not

have concluded that Myriad's invention falls outside the broad scope of patent-eligible subject matter under Section 101.

A. Purified/Isolated DNA Molecules Are Patent-Eligible Subject Matter

The purified/isolated DNA molecules disclosed and claimed in Myriad's patents are new chemical compounds that do not exist in nature and have been adapted for new uses as diagnostic tools and probes. Armed with knowledge resulting from the use of the claimed purified/isolated DNA molecules in the claimed methods, cancer patients can determine whether or not to undergo certain medical procedures, and healthy individuals can opt for preventative techniques that may ward off the onset of cancer. Thus, Myriad's claimed purified/isolated DNA molecules are essential health care tools that were made possible by the insight, ingenuity, and effort of the named inventors. Section 101 permits the patenting of such useful industrial tools, assuming the remaining gatekeeper requirements of novelty, nonobviousness, and adequate description are met. *Bergy,* 596 F.2d at 956.[15]

[15] An analogous situation occurred in *Bergy* where the court recognized that the discovery of a biologically pure culture provided the indispensable element that made the claimed process new and nonobvious. "Without the culture, the process does not exist," Judge Rich observed. 596 F.2d at 968. The same can be said here: without the claimed DNA, the diagnostic method does not exist.

Undisputed evidence demonstrates that the claimed purified/isolated DNA molecules are not only structurally altered relative to native genomic DNA but are also functionally distinct to enable new uses that have significant ramifications in the medical community. Indeed, the District Court acknowledged that the claimed purified/isolated DNA molecules are chemical compounds (A184;A215), and that there are profound chemical differences between a full-length chromosome or a gene thereof and the claimed purified/isolated DNA molecules:

- Excising a relatively small portion from the intact genomic DNA requires breaking covalent chemical bonds (A126 n.11 (DNA held together by covalent bonds); A137 (gene is a small portion of the entire genome));

- The purified/isolated DNA molecules lack a vast number of the chemical moieties (nucleotides) that make up the full-length genome (A127;A137;A185).

Simply put, the claimed purified/isolated DNA molecules are much smaller and do not have the same three-dimensional structural and chemical complexity of the larger genomic DNA.

Moreover, by divorcing the claimed purified/isolated DNA molecules from native chromosomes, the inventors introduced fundamental structural changes that render them incapable of performing in exactly the same fashion as they do in the human body. For example, genomic DNA is "packaged" with proteins that modulate the structure and function of DNA to form complex structures known as

chromosomes. A125-26. In isolated, purified form, however, the claimed BRCA DNA molecules can no longer perform as nature intended.[16] Conversely, the absence of proteins associated with the claimed purified/isolated DNA molecules enables new uses that translate into tangible medical benefits. Thus:

- The "purification of native DNA" accomplished by Myriad's invention results in "the absence of proteins and other nucleotide sequences" that makes the purified/isolated DNA molecules of Myriad's patents different from native DNA molecules (A225);

- The differences between the purified/isolated DNA molecules of Myriad's patents and native DNA molecules are "required for [the] DNA to be useful for the cited purposes" claimed in Myriad's patents (*id.*);

- Purified/isolated DNA can be used as tools for practical applications that native DNA cannot be used for (A128-29).

Furthermore, the District Court recognized that isolating and purifying DNA to impart these functional and structural differences required skill, hard work, and ingenuity. A123;A125 n.9;A146.

Under the proper standard, then, the excision and purification of a relatively short DNA segment derived from the full-length native genome results in new

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[16] Certain of the claims recite nucleotides of much shorter length than the full gene and therefore cannot possibly encode a full-length BRCA protein. A174;A221. Such molecules are, for this reason as well, chemically and functionally distinct from native genomic DNA. Similarly, claimed DNA molecules lacking intron sequences are also chemically and functionally different from native BRCA genes. A220.

structural and functional characteristics that allow for new practical applications. This qualifies the claimed purified/isolated DNA molecules as patent-eligible subject matter, just as the inventors' activities in *Chakrabarty* and *Bergy* made those inventions patentable.

B. The District Court's Erroneous "Shared Essential Characteristic" Test

Notwithstanding its recognition of substantial differences, the District Court approached the Section 101 inquiry by identifying a characteristic of native DNA that it deemed "essential"—its ability to store biological information—and then determined that the claimed subject matter retained that "essential characteristic." *See, e.g.*, A95-96;A215-210;A225. In so doing, the District Court changed the focus from a "different characteristics" test to a "shared essential characteristic" test.

No legal basis exists for arbitrarily and categorically excluding such DNA-derived inventions from the scope of Section 101 on the ground that they share a characteristic with the native, naturally occurring DNA from which they are derived. *See Bergy*, 596 F.2d at 975. Furthermore, a "shared essential characteristic" test is untenable. Some similarity between the product derived from nature and its native source is unavoidable; it therefore becomes all too easy to focus on one shared characteristic, while ignoring all the other differences, even salient, fundamental differences. More importantly, it violates a core patent law

principle: the claimed subject matter must be evaluated *as a whole*. *Bilski*, 130 S. Ct. at 3230 (*citing Diamond v. Diehr*, 450 U.S. 175, 188 (1981)). Indeed, the District Court's focus on biological information ignores the language of the product claims, which are directed to chemical compounds, not abstract biological information.

The CCPA in *Bergy* was not troubled by the fact that the invention in that case was a living organism derived from "nature" that presumably retained some of its natural characteristics and capabilities. On the contrary, the court rejected any categorical exclusion of living matter from patent-eligibility:

> [W]e see no Legally significant difference between active chemicals which are classified as "dead" and organisms used for their Chemical reactions which take place because they are alive. Life is largely chemistry.

Bergy, 596 F.2d at 975. Here, too, there is no legally significant difference between chemicals that store biological information and those that do not. By selectively assigning dispositive importance to one shared characteristic of the claimed purified/isolated DNA molecules and discounting all the differences, the District Court adopted precisely the rationale that *Bergy* rejected. Furthermore, the fact that this shared characteristic may contribute to the utility of the claimed subject matter is legally irrelevant to the Section 101 inquiry. *See Bergy*, 596 F.2d at 975 (holding that there is no reason to exclude bacteria from the scope of

Section 101 on the sole ground that it is alive, noting "[i]t is because it is alive that it is useful").

Finally, reversing the District Court's grant of summary judgment will not result in a multitude of non-meritorious patents on isolated genes. First, each particular isolated, purified DNA molecule must meet the PTO's stringent utility requirement that an applicant identify a specific, substantial, and credible utility for any newly discovered gene. *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) ("Guidelines"). Second, an invention must be novel under 35 U.S.C. § 102. Finally, an invention must also be nonobvious under 35 U.S.C. § 103. In short, the bar for obtaining patents on purified/isolated DNA molecules is the same as for other types of inventions.

III. The Method Claims Disclose Patent-Eligible Subject Matter

Myriad's purified/isolated DNA molecules are the indispensable tools that animate each of the claimed methods and allow the diagnostic comparisons or identification of new therapeutic agents to be made. Without them, the diagnostic and cancer therapeutic screening methods for those diseases would not be possible. *See Bergy*, 596 F.2d at 968. Nevertheless, the District Court ruled that all of the method claims at issue are invalid as claiming mere scientific principles, and as failing to satisfy the "machine or transformation test" set forth by the Federal Circuit in its *Bilski* decision.

Since the District Court's ruling, of course, the Supreme Court issued its *Bilski* decision, and in so doing, clarified the foundational principles for analyzing method claims that may embrace or entail the use of scientific principles, mathematical formulas, or other abstract concepts. Applying the Supreme Court's guidance from *Bilski* and prior decisions, the District Court's judgment that Myriad's method claims are invalid cannot stand.

A. Myriad's Methods Are Not Merely Abstract Ideas or Scientific Principles

In *Bilski*, the Supreme Court held that "[t]he machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible 'process.'" *Bilski,*130 S. Ct. at 3227. While recognizing that test as an "important clue" and "useful tool" in appropriate cases, the Court relied on its decisions in *Gottschalk v. Benson,* 409 U.S. 63 (1972), *Parker v. Flook,*437 U.S. 584 (1978), and *Diehr* to resolve the issue of whether Bilski's method for hedging investment risk fell within the scope of Section 101. *Benson* and *Flook* establish that mere abstract ideas are not patentable. But in *Diehr*, the Supreme Court tempered that prohibition, explaining that while an abstract idea, law of nature, or mathematical formula could not be patented, "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." 450 U.S. at 187. Thus, diagnostic method claims that "do not preempt natural processes; [but instead] utilize them in a series of specific steps"

are patent-eligible subject matter. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1349 (Fed. Cir. 2009), *cert. granted, vacated, and remanded*, 130 S. Ct. 3543 (2010).

Applying the *Benson, Flook,* and *Diehr* trilogy to Myriad's method claims, it is apparent that those claims embrace neither mere abstract ideas nor attempts to limit an abstract idea to a particular technological environment. Rather, even if the claimed methods *invoke* scientific principles, such as the correlation between certain DNA sequences and susceptibility to disease, Myriad's methods *apply* such principles in a series of transformative acts that rely upon novel diagnostic or screening tools, *i.e.*, the claimed purified, isolated BRCA DNA molecules.

B. Myriad's Methods Use Biological Tools and Depend on Transformations of Biological Materials

Myriad's diagnostic method claims involve detecting, screening, or identifying mutations and alternations in isolated BRCA genes (claim 1 of each of Patent Nos. 5,710,001, 5,709,777, 5,753,441, and 6,033,857) or diagnosing predisposition for breast cancer (claim 2 of the '857 patent) (collectively, "the diagnostic method claims"). Significantly, each of the diagnostic method claims involves the transformative steps of drawing blood or removing a tissue sample from a subject, extracting BRCA DNA or RNA from the biological sample, and detecting alterations in the subject's BRCA nucleotide sequence in order to analyze the BRCA DNA, RNA or cDNA made from an mRNA of the sample. *See, e.g.,*

A699-70; A707-09; A723-25. As described above, the extraction process radically alters the structure and function of the native DNA, creating a new chemical compound that does not exist in nature. Furthermore, the comparison of sequence data is also transformative: such comparisons cannot be made by the naked eye but instead require sophisticated biotechnological methods of sequencing nucleic acids and/or detecting alterations that involve chemical or physical transformation. *See, e.g.,* A700;A707-08.

The remaining method claim at issue, claim 20 of the '282 patent, covers a method for screening potential cancer therapeutics in cells containing an altered BRCA gene. The transformative nature of that method is evident: the administration of a potential cancer therapeutic to a cell that contains an altered BRCA gene involves both the insertion of that gene into a cell and the biological effect of the test agent on cell growth. *See, e.g.*, A602-03.

The transformations effected in all of the method claims at issue are essential to the diagnostic, prognostic, and therapeutic screening functions recited in the claims. Therefore, although the machine or transformation test is no longer the definitive test for evaluating the patentability of processes or methods, as an "investigative tool" and "useful clue" it supports the patent-eligibility of Myriad's "transformative" methods in this case. And it demonstrates that, contrary to the District Court's decision, the claimed methods, viewed as a whole, are not limited

"only to the abstract mental processes of 'comparing' or 'analyzing' gene sequences." A234. Accordingly, like the methods found patentable in *Diehr*, the methods recited in Myriad's method claims entail the *application* of scientific principles to complex and sophisticated scientific and medical/biotechnological processes using specific biological tools. As such, Myriad's method claims describe patent-eligible subject matter.

IV. Affirmance Would Change Settled Law and Disrupt the Expectations of Patent Owners and Inventors

Excluding purified/isolated DNA molecules and diagnostic methods that use them from the scope of Section 101 would displace existing property rights and threaten future investment in new diagnostic and treatment techniques.[17] "[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community."[18] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) (*citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997)). Congressional action is required to change such well-settled rules because "[f]undamental alterations in these rules risk destroying the legitimate expectations of inventors in their property." *Id.*

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[17] Nikos C. Varsakelis, *The Impact of Patent Protection, Economy Openness and National Culture on R&D Investment: A Cross-Country Empirical Investigation,* 30 Res. Pol'y 1059, 1066 (2001); Melissa Wetkowski, *supra* note 7, at 198-99.

[18] Likewise, such changes would prove a disruption to the investment community. Melissa Wetkowski, *supra* note 7, at 198.

Like the doctrine of equivalents issue in *Festo*, the patentability of isolated genes and diagnostic methods is well-settled. Ten years ago, the U.S. Patent and Trademark Office implemented guidelines for issuing gene-related patents. Guidelines at 1092-99. The Patent Office noted then that "[p]atenting compositions or compounds isolated from nature follows well established principles, and is not a new practice." *Id.* at 1093. Just as the Supreme Court warned in *Festo*, "[t]o change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision."[19] 535 U.S. at 739 (quoting *Warner-Jenkinson*, 520 U.S. at 32 n.6). Rather than venturing into territory reserved for the legislature and disrupting the settled expectations of patent owners and inventors, this Court should reaffirm that isolated genes and diagnostic methods that rely upon them are patent-eligible under Section 101.

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[19] In a widely publicized comment, President Clinton noted that the people "with the skills and the experience to draw the line in the right place" were in a position to formulate criteria for patent-eligibility of gene-based inventions. *BIO Praises Clinton Reassurances Regarding Gene Patents and PTO Leadership*, BIOTECH Patent News (Apr. 1, 2000), *available at* http://www.allbusiness.com/technology/538104-1.html. Indeed, the government agency specifically charged with that task, the Patent Office, has in fact already drawn that line in the right place, in its *Utility Examination Guidelines*.

V. Moral and Ethical Policy Considerations Are Matters for Congress, Not the Courts

The issues on appeal arise under the Patent Laws, and the policy implicated by those issues should be limited to that underlying the Constitution's Patent Clause—namely, the patent laws must promote the progress of technology with the free and full disclosure of advances in technology, and must reward inventors for their contributions to that progress. The Plaintiffs, however, have invoked additional societal, moral, and ethical issues surrounding the impact of purified/isolated DNA molecule patents. These issues, while important, go beyond the social objective set forth in Article I, Section 8, Clause 8 of the Constitution—to promote the progress of the useful arts—and are reserved for Congress, not the courts. Where Congress has spoken and set forth broad categories of patent-eligible subject matter, the courts should not arbitrarily narrow the scope of the patent laws based on their own balancing of ethical and moral considerations. *See Charkrabarty*, 447 U.S. at 318 ("[U]ntil Congress takes [] action, this Court must construe the language of § 101 as it is.").

The Constitution, the Congress, and the courts recognize that the rewards to society as a whole from encouraging progress in science and technology fully justify the limited exclusionary power of patents. The District Court, however, apparently focused narrowly on whether the particular patents in this case might

help or harm certain segments of the public who claim that they might be adversely affected by the patents' existence.

Societal issues such as the cost of testing, however, should play no part in the Section 101 analysis. While patents covering diagnostic tests may impact cost and accessibility of those tests in some respects during the term of the patents, this is a natural—indeed, even intended—consequence of the Framers' decision to provide patents on inventions and discoveries.[20] To allow such considerations to determine patent eligibility fails to recognize that the patented inventions here are what made the diagnostic tests possible in the first place.[21]

Indeed, there has never been a "medical treatment/diagnostics" exception to Section 101. The Hatch-Waxman Act—which permits patent challenges by manufacturers of low-cost generic drugs—reflects clear Congressional intent that society benefits by permitting patents for new and useful therapeutic inventions, even though doing so may limit the availability of those inventions to patients, researchers, or competitors for a specified time. Similarly, President Obama recently signed the Biologics Price Competition and Innovation Act of 2009 into law, which reflected the sense of the Senate that "a biosimilars pathway balancing

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[20] *See, e.g.*, Lauren M. Dunne, Note, *"Come, Let Us Return to Reason": Association of Molecular Pathology v. USPTO*, 20 DePaul J. Art Tech. & Intell. Prop. L. 473, 475 (2010).

[21] *See generally* R. Stephen Crespi, *Patenting and Ethics—a Dubious Connection*, 85 J. Pat. & Trademark Off. Soc'y 31, 42-43 (2003).

innovation and consumer interests should be established." Patient Protection and Affordable Care Act, Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, Title VII, Subtitle A, § 7001(b) (2010). Significantly, the Act recognized, and did not abrogate or limit, the rights of innovators in biotechnological medical advances. § 7002. Addressing the alleged economic or social impact of Myriad's patents in the context of a patent challenge brought by patients and researchers is to engage in a moral and ethical inquiry that is not the proper subject of the patent statute, but is a matter for the public forum provided by Congress.

VI. The Consumer Parties Lack Standing to Bring a Declaratory Judgment Action for Patent Invalidity

The District Court's apparent consideration of the perceived societal implications surrounding the patentability of Myriad's DNA-related inventions also affected its analysis of the declaratory judgment standing issues for the potential customers of BRCA genetic testing (Ceriani, Limary, Girard, Fortune, Thomason, and Raker) and their related healthcare organizations (Breast Cancer Action ("BCA") and Boston Women's Health Book Collective ("OBOS")) (collectively, "the Consumer Parties").

The court should have granted Myriad's motion to dismiss those parties, none of whom alleged that Myriad threatened an infringement suit or showed any actual, immediate, and substantial controversy with Myriad. The Consumer Parties

assert that they or their members may wish to purchase test services utilizing the Myriad patents' claimed products or methods, from a source other than Myriad and/or at a price lower than that available from Myriad. But Myriad has never threatened any of those parties with an infringement suit, and as mere potential inducers of infringement they have no actual, immediate, or substantial controversy with Myriad. Here, under all the circumstances, there is no controversy, let alone a substantial one, "between [the] parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

The District Court first focused on the presence of "some affirmative act by the defendant relating to enforcement of its patent rights" in applying the "all the circumstances" test. A55. But each of the alleged enforcement acts identified by the District Court was directed to researchers and institutions performing Myriad's patented BRCA gene testing—essentially, Myriad's competitors—not to any conduct by the individuals or organizations among the Consumer Parties. A56-62. The Consumer Parties merely desire to purchase, or refer customers to, BRCA tests from a source other than Myriad, and thus are at best only potential inducers

of others' infringement under 35 U.S.C. § 271(b).[22] The District Court pointed to no evidence showing that Myriad had directed any patent enforcement actions against individual customers or alleged inducers of infringement, and evidence of enforcement actions against Myriad's competitors is irrelevant to the standing of potential inducers. *Cf. Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1341 & n.9 (Fed. Cir. 2008) (enforcement actions against the patentee's competitors are potentially relevant to the declaratory judgment jurisdiction of a case brought by the competitors).

The District Court also analyzed whether the Plaintiffs had "undertaken 'meaningful preparation to conduct potentially infringing activity.'" (A55 (quoting *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008)). Here, the District Court stated that the potential customers and associations "may very well understand the precise nature of, and be prepared to take advantage of, the services of a potential infringer were the latter not prevented from offering those services by a third party's assertion of its patent rights." A69. But mere contemplation to purchase products or services not currently on the market is simply too tenuous to

[22] The District Court referred to these customers as "[p]otential contributory infringers" (A69); however, the individuals and their representative associations could not infringe under 35 U.S.C. § 271(c). Those customers do not sell, offer to sell, or import any component of the patented isolated genes or material for use in practicing the patented testing processes—in fact, just the opposite, they pay others to perform the testing.

support any finding of "meaningful preparation." *See MedImmune*, 549 U.S. at 127 (dispute must be real and concrete to support a declaratory judgment claim). There was no showing that potential infringers would indeed offer testing products and services of the quality and at a cost that these potential customers would accept and be ready to purchase.

On the facts before the District Court, it is therefore doubtful that Myriad would succeed in any action against the Consumer Parties for induced infringement, since there has been no showing that they have taken the kind of active steps necessary to encourage the direct infringement of Myriad's patents. *See DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc*) (mere knowledge of any allegedly infringing acts is not enough to establish liability for inducing infringement). The lack of any cause of action by Myriad against the Consumer Parties further highlights that those potential purchasers of non-existent products do not have proper declaratory judgment standing.[23] *See, e.g., Ours Tech., Inc. v. Data Drive Thru, Inc.*, 645 F. Supp. 2d 830, 840 (N.D. Cal. 2009) (Patel, J.) (finding no standing "based on a lack of an underlying cause of

[23] That the individual potential purchasers themselves do not have proper standing also shows that their related healthcare organizations, BCA and OBOS, do not meet the requisite test for associational standing. *See Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977) (requiring, in part, that for proper standing the association's "members would otherwise have standing to sue in their own right").

action that [the patentee] could have brought against [the declaratory judgment plaintiff]").

Distilled to its essence, the District Court believed the Consumer Parties should have the right to sue and invalidate patents covering as-yet non-existent products and services that they might want to purchase if the allegedly invalid patents did not block the potential direct infringers. While the Consumer Parties have a worthy and commendable interest in the outcome of this case, this Court has long held that the public interest in the merits of the patentability issues raised in this case do not confer jurisdictional standing. On the contrary, "[p]ublic policy, of course, dictates dismissal of litigation where there is neither standing nor jurisdiction." *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 884 (Fed. Cir. 1985) (affirming dismissal of declaratory judgment complaint for lack of subject matter jurisdiction, despite appellant's public interest concerns regarding the allegedly fraudulently procured patents).

In its attempt to be sensitive to the social implications of this case, the District Court impermissibly expanded its declaratory judgment jurisdiction to cover an "advisory opinion" for anyone merely expressing the desire to purchase a patented product or utilize a patent method, including non-existent products and services. However, this decision, if affirmed, presents a very real concern for other federal courts and patent holders. The dramatic expansion of federal declaratory

judgment jurisdiction to those without a real and immediate interest in the litigation will open all patents to challenge by anyone asserting a "public" interest. This has never been permitted by the controlling authorities and could not have been the intent of Congress in permitting declaratory judgment actions.

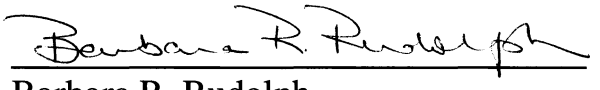
CONCLUSION

AIPLA urges the Court to find that Myriad's claims define patentable subject matter, and to dismiss the Consumer Parties for lack of proper declaratory judgment standing.

Respectfully submitted,

AMERICAN INTELLECTUAL PROPERTY
LAW ASSOCIATION

By its attorneys,



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CERTIFICATE OF SERVICE

I hereby certify that on October 29, 2010, two (2) true and correct copies of the BRIEF FOR *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF REVERSAL BUT IN SUPPORT OF NEITHER PARTY was served upon the following counsel of record by Overnight Courier (Federal Express):

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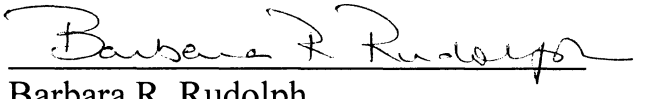
I certify that, pursuant to Federal Rule of Appellate Procedure 29(d) and 32(a)(7)(C)(i), the foregoing brief contains 6966 words as measured by the word processing software used to prepare this brief, excluding the parts of the brief exempted by the Federal Rules of Appellate Procedure 32(a)(7)(B)(iii).

Dated: October 29, 2010

Respectfully submitted,



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