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 OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

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October 28, 2010

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The Association for Molecular Pathology v. USPTO

2010-1406

CERTIFICATE OF INTEREST

Counsel for the *Amicus Curiae* Intellectual Property Owners Association certifies the following:

1. The full names of every party or amicus represented by me is:
   Intellectual Property Owners Association

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: **NONE**

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

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

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INTEREST OF AMICUS CURIAE

The Intellectual Property Owners Association ("IPO") submits this brief as *amicus curiae* pursuant to Fed. R. App. P. 29 and Rule 29 of this Court. All plaintiffs and defendants have consented to the filing of this brief.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in U.S. intellectual property rights. IPO's membership includes more than 200 companies and over 11,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the USPTO and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.

INTRODUCTION

IPO submits this brief to address two issues of vital importance to the proper functioning of the patent system: 1) how immediate and substantial must a controversy be in order to create declaratory jurisdiction standing sufficient to challenge the validity of a patent and 2) whether isolated DNA qualifies as patentable subject matter under 35 USC § 101. IPO's views on these two issues

are: 1) plaintiffs do not have standing to bring a declaratory judgment action for invalidity under the facts of this case; and 2) isolated DNA qualifies as patentable subject matter under 35 USC § 101. IPO expressly declines to take any position, however, regarding whether the particular patent claims at issue in this case satisfy all the conditions for patentability.

SUMMARY OF ARGUMENT

IPO believes that the declaratory judgment plaintiffs lack standing to challenge the validity of the patents in suit because: (1) Myriad has not directed any action toward the plaintiffs that would create an actual controversy of sufficient immediacy and reality to warrant declaratory judgment jurisdiction; (2) Myriad's actions from over ten years ago are not of sufficient immediacy to create a justiciable controversy between the parties in this case; and (3) the plaintiffs' mere formations of intent to potentially engage in undefined conduct that may or may not infringe any particular claim of the patents at some unspecified time in the future do not amount to "meaningful preparation" to conduct infringing activity. As a result, there is no substantial controversy in the present case of sufficient immediacy and reality to warrant declaratory judgment jurisdiction. Indeed, if the facts of this case provide adequate foundation for standing, then nearly anyone might seek to file a declaratory judgment action to challenge the validity of any

patent -- a result that would place a heavy burden on patent owners and on the already overburdened judicial system.

IPO also believes that claims directed to isolated DNA constitute patentable subject matter under 35 U.S.C. § 101. The standard for patent eligibility was enunciated by the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), to include "anything under the sun made by man." The Supreme Court has never overruled this standard and has never promulgated a categorical exclusion from patent eligibility for products derived from nature. Under this controlling Supreme Court precedent, claims to isolated DNA are patentable under Section 101.

If the standard for patentable subject matter applied by the District Court were adopted, it could render broad categories of important inventions patent-ineligible, including most biologic drugs, antibodies, antibiotics, hormones, metabolites, proteins, and genetically-modified organisms and food. This in turn would have a devastating effect on the viability of large portions of the biotechnology, pharmaceutical and other industries, industries that are built upon the availability of valid and enforceable patent protection for the fruits of their costly and risky research efforts.

ARGUMENT

I. There Is No Standing Here Sufficient to Establish Declaratory Judgment Jurisdiction

Under the circumstances of this case, there is no substantial controversy of sufficient immediacy and reality to support declaratory judgment jurisdiction because: (1) Myriad has not directed any action toward the plaintiffs that would create an actual controversy between the parties in this case; (2) Myriad's actions from over ten years ago are not of sufficient immediacy to create an actual controversy between the parties; and (3) the plaintiffs' mere formations of intent to potentially engage in unspecified conduct that may or may not infringe any particular claim of the patents-in-suit at some undefined time in the future do not amount to "meaningful preparation" to conduct infringing activity that would give rise to a justiciable controversy between the parties.

1. Myriad has not directed any action toward the plaintiffs that would create an actual controversy of sufficient immediacy and reality to warrant declaratory judgment jurisdiction.

"Although *MedImmune*[*Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007),] clarified that an injury-in-fact sufficient to create an actual controversy can exist even when there is no apprehension of suit, [*MedImmune*] did not change the bedrock rule that a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the [patentee]*." *Prasco, LLC v.*

Medicis Pharm. Corp., 537 F.3d 1329, 1339 (Fed. Cir. 2008) (emphasis in original); *see also SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007) (declaratory judgment jurisdiction "will not attach without some affirmative act by the patentee"). The plaintiff in *Prasco* alleged that the patentee had caused it "to suffer an actual harm -- namely, 'paralyzing uncertainty' that [the patentee] [would] bring an infringement suit against [the plaintiff]." *Prasco*, 537 F.3d at 1338. However, this Court held that "paralyzing uncertainty" or a subjective fear of suit did not amount to a harm caused by the patentee that would create an actual controversy of sufficient *immediacy* and *reality* to warrant declaratory judgment jurisdiction. *Id*. Because there was no evidence that the patentee had planned to assert its patents against the plaintiff or even believed that the plaintiff had engaged in infringing conduct, this Court concluded that there was no harm caused by the patentee of sufficient immediacy and reality to show an actual controversy between the parties, despite the fact that the patentee had an established history of enforcing its patent rights through litigation and had even sued the declaratory judgment plaintiff in the past. *Id*. at 1341-42.

Unlike the patentee in *Prasco*, the patentee in *SanDisk*: (i) met with the declaratory judgment plaintiff; (ii) presented an infringement analysis that identified, on an element-by-element basis, how the plaintiff's products infringed

specific claims of 14 different patents; (iii) liberally referred to the plaintiff's "present, ongoing infringement"; (iv) gave the plaintiff a ~300 page packet of materials showing detailed reverse engineering documentation and claim charts illustrating how the plaintiff's multiple products infringed the 14 patents; and (v) demanded that the plaintiff license its patents. *SanDisk*, 480 F.3d at 1382. Even though the patentee stated that it "[had] absolutely no plan whatsoever to sue [the plaintiff]," this Court nevertheless held that the patentee's affirmative actions directed toward the plaintiff had created an actual controversy between the parties sufficient immediacy and reality to warrant declaratory judgment jurisdiction. *Id.* at 1382-83.

In contrast to the patentee in *SanDisk,* Myriad has not taken *any* affirmative action toward the plaintiffs that would create an actual controversy of sufficient immediacy and reality to warrant declaratory judgment jurisdiction. Like the plaintiffs in *Prasco*, there is no evidence that Myriad either (i) had any plans to assert its patents against any of the plaintiffs or (ii) had any knowledge that any of the plaintiffs were even considering engaging in any type of infringing activity with respect to the claims at issue. Instead, the plaintiffs merely allege that "[a]s a result [of Myriad's conduct], researchers are chilled from engaging in research on BRCA1/2 as well as research on other genes that may interact with BRCA1/2." *Ass'n for Molecular Pathology, et al. v. U.S. Patent and Trademark Office*, 669

F.Supp.2d 365, 381 (S.D.N.Y. 2009). But the plaintiffs have also acknowledged that "Myriad has permitted some scientists to conduct pure research on BRCA1/2." *Id*. Therefore, the type of "chill" the plaintiffs have alleged in this case is the same sort of "paralyzing uncertainty" and fear of an infringement suit described in *Prasco* that does not amount to an actual controversy of sufficient immediacy and reality to warrant declaratory judgment jurisdiction. *Prasco*, 537 F.3d at 1338.

2. When considering "all the circumstances," Myriad's actions from over ten years ago are not of sufficient immediacy to create a justiciable controversy between the parties in this case.

A. Ten year old cease-and-desist letters are not of sufficient immediacy to create a justiciable controversy between the parties.

The goal of the Declaratory Judgment Act in patent cases is to prevent situations where a patentee "attempts extra-judicial enforcement with scare-the-customer-and-run tactics… [where] competitors…[are] rendered helpless and immobile so long as the patent owner refuse[s] to grasp the nettle and sue." *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1346 (Fed. Cir. 2005) (citations omitted). But the record in this case shows that Myriad has not attempted anything of the sort. Indeed, the *only* evidence of *any* action that Myriad has directed to *any* of the plaintiffs named in this case are (1) the May 29, 1998 and August 26, 1998 cease-and-desist letters to Dr. Kazazian, and (2) the May 21, 1998 cease-and-desist letter to Dr. Ostrer. *Ass'n for Molecular Pathology*, 669 F.Supp.2d at 378-79.

However, these decade-old letters should not be considered to be sufficiently immediate to show a justiciable controversy, particularly when there is no evidence that Myriad has taken any other actions against these two plaintiffs in at least 10 years. *See, e.g., Sierra Applied Sciences, Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1374 (Fed. Cir. 2004) (four year old letter not sufficiently immediate to warrant declaratory judgment jurisdiction); *Cygnus Therapeutics Systems v. ALZA Corp.*, 92 F.3d 1153, 1159 (Fed. Cir. 1999) (five year old threat not sufficiently immediate to warrant declaratory judgment jurisdiction). Furthermore, the 1998 letters should be afforded no weight with respect to determining whether a justiciable controversy exists with respect to the claims of the 5,837,492 and 6,033,857 patents because the '492 and '857 patents issued well after the 1998 letters. *See, e.g., Prasco*, 537 F.3d at 1341 (patentee's prior enforcement of *different* patents against the plaintiff insufficient to create a real and immediate controversy regarding the patents-in-suit).

Because the 1998 letters are so old and even pre-date some of the patents in this case, and because the record shows that Myriad has taken no action against Drs. Kazazian and Ostrer regarding the letters in over 10 years, the letters should be given very minimal (if any) weight in determining whether a justiciable controversy exists between Myriad and Drs. Kazazian and Ostrer regarding the claims of the patents at issue here. Additionally, the 1998 letters should be given

no weight in determining whether a justiciable controversy exists between Myriad and the other plaintiffs (*i.e.*, the other researcher plaintiffs, the organization plaintiffs, and the non-researcher doctors and their patients), because the 1998 letters were not directed at them. *See, e.g., Innovation Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1381-82 (Fed. Cir. 2010) (patentee's past conduct directed at others insufficient to create justiciable controversy between patentee and plaintiff when patentee had not directed conduct at the plaintiff); *Prasco,* 537 F.3d at 1341, n. 10 (same).

B. Myriad's litigation against third parties that concluded over ten years ago does not amount to conduct of sufficient immediacy to create a justiciable controversy between the parties in this case.

In *Innovation Therapies,* the patentee had an established history of enforcing its patent rights. 599 F.3d at 1381-82. However, this Court agreed with the district court that the patentee's "history of litigation against others, and general propensity to enforce its legal rights, did not establish an actual controversy between [the patentee] and [the plaintiff]" because: (i) the patentee had not seen the plaintiff's supposedly infringing product; (ii) the plaintiff had not sold any supposedly infringing products; (iii) the patentee had not accused the plaintiff of infringement; and (iv) the patentee had not threatened to sue the plaintiff for infringement. *Id*. In affirming the district court's dismissal of the declaratory judgment action, this

Court explained that prior litigation is one circumstance to be considered under the "all the circumstances test," but a patentee's prior litigation against third parties without some action directed to the plaintiff does not create a justiciable controversy between a declaratory judgment plaintiff and a patentee. *Id*. at 1382.

The patentee in *Prasco* also had an established history of enforcing its patent rights through litigation and had even sued the declaratory judgment plaintiff in the past. 537 F.3d at 1341. But even though the patentee had actually sued the plaintiff for patent infringement in the past, this Court nevertheless affirmed the district court's dismissal of the declaratory judgment action. *Id*. at 1342. Considering "all the circumstances," this Court placed "minimal weight" on the patentee's prior litigation history because: (i) the patentee's suit against the plaintiff for different patents was not sufficient to "create a real and immediate controversy" regarding the four patents at issue in the declaratory judgment action; and (ii) the patentee's prior suit against a third party "[had] no relevance to whether there [was] a case or controversy with [the plaintiff], as [the plaintiff] was not a party to the prior suit." *Id*. at 1341 n.10.

Like the plaintiffs in *Innovative Therapies* and *Prasco*, Myriad's history of litigation should be given "minimal weight" under the circumstances. Indeed, similar to *Innovative Therapies*, the record here shows that Myriad has not evaluated any of the plaintiffs' planned activities to determine whether those

activities would infringe any particular claim of the patents at issue, Myriad has not accused any of the plaintiffs of presently infringing the patents at issue, and Myriad has not threatened to sue any of the plaintiffs for infringement. And just like *Prasco*, Myriad's suits against third parties during the late 1990's are not relevant to whether there is a case or controversy between Myriad and the plaintiffs in this case because none of the named plaintiffs in this case were parties to the prior suits.

Thus, even though Myriad has a general history of enforcing its patent rights, there is no evidence of record that Myriad planned to assert its patents against any of the plaintiffs named in this case, and there is no evidence that Myriad even knew that any of the plaintiffs in this case had any desire to engage in infringing conduct. Because there is no evidence that Myriad has taken any affirmative action toward the plaintiffs that would create an actual controversy of sufficient immediacy and reality, there is no justification for declaratory judgment jurisdiction under the circumstances of this case.

3. The plaintiffs' mere formations of intent to engage in undefined conduct that may or may not infringe any particular claim of the defendants' patents at some unspecified time in the future do not amount to "meaningful preparation" to conduct infringing activity.

"If a declaratory judgment plaintiff has not taken significant, concrete steps to conduct infringing activity, the dispute is neither 'immediate' nor 'real' and the

requirements for justiciability have not been met." *Cat Tech LLC v. Tubemaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008); *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1348-49 (Fed. Cir. 2007). Although the declaratory judgment plaintiff need not actually engage in infringing activity to create a controversy, "there must be a showing of 'meaningful preparation' [to conduct infringing activity]." *Cat Tech*, 528 F.3d at 881.

In *Benitec*, this Court determined that the requirements for a justiciable controversy had not been met in part because the plaintiff had not engaged in "meaningful preparation" to conduct infringing activity even though the plaintiff had (i) negotiated with a potential customer multiple times over a period of months, (ii) entered into a confidentiality agreement with the potential customer, and (iii) planned to commence work "shortly" to manufacture infringing products. *Benitec*, 495 F.3d at 1348-49. In declining to find "meaningful preparation" to conduct infringing activity, this Court reasoned that the plaintiff "merely 'expects' to begin work 'shortly'" and that "to allow such a scant showing to provoke a declaratory judgment suit would be to allow nearly anyone who so desired to challenge a patent." *Benitec*, 495 F.3d at 1349. The plaintiffs in this case have made even fewer preparations to conduct infringing activity than the plaintiffs in *Benitec*.

The researcher plaintiffs who claim that they are ready to conduct BRCA1/2 testing fail to explain: (i) whether the testing would infringe any particular claim of Myriad's patents[1]; or (ii) what material steps they have taken in preparation to conduct testing in a way that would infringe any particular claim of Myriad's patents. Moreover, it is unclear whether some of the researchers would actually conduct BRCA1/2 testing. For example, Drs. Hubbard and Kant stated that they would merely "consider" conducting BRCA1/2 testing if the patents were found invalid, and Drs. Ganguly and Kazazian merely have the "desire to consider" conducting testing. *Ass'n for Molecular Pathology*, 669 F.Supp.2d at 371-72. Merely contemplating or desiring to contemplate taking some undefined conduct is simply not sufficient to establish "meaningful preparation" to engage in infringing activity. *See Benitec*, 495 F.3d at 1349.

The non-researcher plaintiffs, including individual patients and their doctors who claim that they would ask the researcher plaintiffs to conduct BRCA1/2 testing, fail to explain: (i) whether the tests conducted by the researcher plaintiffs would infringe any claim of the patents at issue; or (ii) what material steps the researcher plaintiffs may have taken to perform testing in an infringing manner.

[1] The researcher plaintiffs' failure to explain how their intended conduct would infringe any of the 15 distinct claims across the 7 different patents at issue, and the district court's conclusion, without analysis, that the undefined planned conduct would necessarily infringe all the claims at issue is contrary to the requirement that "the existence of a case or controversy [] be evaluated on a claim-by-claim basis." *Jervis B. Webb Co. v. Southern Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984).

Ass'n for Molecular Pathology, 669 F.Supp.2d at 372-76. An intent to ask others to engage in some future undefined conduct that may or may not infringe is too speculative under the facts of this case to amount to a "meaningful preparation" to engage in infringing activity.

Finally, the organization plaintiffs who claim their members are "ready, willing, and able to engage in research and clinical practice involving the BRCA1 and BRCA2 genes if the patents are invalidated," *Ass'n for Molecular Pathology*, 669 F.Supp.2d at 371, do not have standing because, as explained above, their members do not have standing. *See United Food & Commercial Workers v. Brown Group*, 517 U.S. 544 (1996) (an association has standing to sue on behalf of its members only if its members would otherwise have standing to sue in their own right).

It appears that the plaintiffs in this case have expressed at most a vague and unsubstantiated notion of being ready to engage in some undefined conduct that may or may not infringe Myriad's patents at some undetermined time in the future. "[T]o allow such a scant showing to provoke a declaratory judgment suit would be to allow nearly anyone who so desired to challenge a patent," *Benitec*, 495 F.3d at 1349, which is exactly what the plaintiffs have done in this case.

IPO is particularly concerned by the expansion of declaratory judgment jurisdiction represented by the district court's decision. Under the district court's

reasoning, all it takes to bring a declaratory judgment action seeking to invalidate a patent is a statement that the plaintiff intends to practice the patented invention at some point in the future. No concrete showing that the plaintiff's intention to practice the invention is substantial and immediate is required. Under this loose approach, literally anyone might ask any federal court to invalidate any claim of any unexpired patent. If this were the law, it could open the floodgates of declaratory judgment actions. Patentees should not have to bear the expense and burden of such strike suits and the *in terrorem* effect they may have on obtaining and enforcing valid patent protection.

There are more than one million U.S. patents currently in force and the validity of many or most of them could be attacked in U.S. district courts were this low threshold to become law. Software patents, for example, might be attacked by groups or individuals who believe that software should remain "open" and, therefore, unpatented. Opponents of genetically-modified foods could launch attacks on patents in the hopes of discouraging future investment and research in the area. Opponents of research-driven healthcare could attack pharmaceutical patents in order to bring generic drugs to the marketplace more rapidly than through the carefully balanced process set forth by Congress in the Hatch-Waxman Act. Under the district's court approach to declaratory jurisdiction, any corporation, association or individual might attack almost any patent as a form of

protest or to seek leverage against the patentholder. Indeed, the present case appears to be just such a form of social protest against the principle of gene patents, based on nothing more than an unsubstantiated intent or desire to be free of the commercial constraint of well-established patent rights. If such a Pandora's Box of social protest and commercial leverage is to be opened, it should be done so deliberately by Congress, not through a judicial expansion of the declaratory judgment jurisdiction in contravention to established precedent.

In addition to the unnecessary burden on patent holders, a loosening of the showing required for a declaratory judgment action seeking to invalidate a patent would potentially add to the already overburdened dockets of the district courts and this Court. Further, Congress has already provided avenues by which members of the public can seek to invalidate patents, including reexamination and protests. Significantly, Congress could have but has not provided a specific remedy for members of the public to challenge issued patents in Court. There is no call for providing such a remedy by an unwarranted and unwise loosening of the existing standards for declaratory judgment standing. Instead, IPO believes that declaratory judgment jurisdiction should be present where there is a substantial and immediate controversy between the patentee and the declaratory judgment plaintiff concerning the patent or patents at issue.

II. Isolated Human DNA Is Patent-Eligible

1. Controlling Supreme Court Precedent Mandates the Patent-Eligibility of Isolated Human DNA.

The Patent Act defines four classes of inventions that are eligible for patenting: machines, processes, manufactures, and compositions of matter. Isolated human DNA can be considered either a "manufacture" or "composition of matter."

The Supreme Court has spoken, clearly, on the scope of the "manufacture" and "composition of matter" classes in *Diamond v. Chakrabarty*:

> [T]his Court has read the term "manufacture" in § 101 in accordance with its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery."

Chakrabarty, 447 U.S. at 308 (quoting *Am. Fruit Growers, Inc. v. Brogdex Co.,* 283 U.S. 1, 11 (1931)). The Court gave an equally expansive reading to the class "composition of matter":

> "[C]omposition of matter" has been construed consistent with its common usage to include "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."

Id. at 308 (quoting *Shell Development Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957)).

The Court in its *Chakrabarty* decision found no constitutional, philosophical, or jurisprudential infirmities in the choice by Congress to define patent-eligible subject matter broadly. Indeed, the Court cited Thomas Jefferson for the proposition that the patent laws *should* be broadly construed with regard to what is patent-eligible, referencing the first Patent Act (Patent Act of Feb. 21, 1793, § 1, 1 Stat. 319) and Jefferson's exhortation that "ingenuity should receive a liberal encouragement." 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871). The Court noted that this liberality had been a steadfast characteristic of every Patent Act since the first, including the 1952 Act. It was in this context that the Court noted Congress' intent to stay true to Jefferson's vision, citing the Committee Reports for the proposition that statutory subject matter was intended to "include anything under the sun that is made by man." *Chakrabarty*, 447 U.S. at 309.

The Court recognized that the scope of patent-eligible subject matter was not infinite. But the Court was parsimonious in setting forth what was not patent-eligible: "laws of nature, physical phenomena, and abstract ideas" fell into this category, which the Court exemplified as "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter." Similarly, the Court said "[l]ikewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." *Chakrabarty*, 447 U.S. at 309. Notably, the Court did not include "product of nature" in this list.

The Court fashioned a straightforward test of whether a manufacture or composition of matter was patent-eligible: it must demonstrate the hand of man, something that is ”a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Chakrabarty*, 447 U.S. at 309-10 (citing *Hartranft v. Wiegmann,* 121 U.S. 609, 615 (1887)). The Court distinguished *Funk Brothers Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127 (1948), in this regard, where the patentee had discovered only “some handiwork of nature” and thus had discovered something that was not patent-eligible. This is the proper standard for patent-ineligibility. *Anything* that evinces the hand of man is patent-eligible, according to the Court.

2. Isolated Human DNA Is Patent-Eligible Because It Satisfies These Requirements.

Isolated human DNA is patent-eligible because, as disclosed and claimed in the patents-in-suit, it satisfies the requirement in *Chakrabarty* that claimed subject matter show the hand of man. The claimed isolated human DNA does this in several ways.

First, claims to isolated human DNA do not encompass genes as they exist naturally in any cell. *See* USPTO Utility Examination Guidelines, 66 Fed. Reg. 1092-02, 1093 (Jan. 5, 2001). Thus, a patent on isolated human DNA does not implicate any individual’s right to her own genes, since an individual’s genes are

not "isolated" and, therefore, fall outside the scope of the patent claim. Indeed, these claims would not even encompass a recombinant cell containing a copy of either of the isolated human DNAs as claimed, since in that case the human DNA would also not be "isolated."

Moreover, isolated human DNA is properly understood as a manufacture under the Patent Act. Claims to isolated human DNA are conventionally supported by disclosure of enzymatically-generated copies of cellular messenger RNA (mRNA). In isolating the claimed DNA, an inventor typically identifies a cell that expresses a gene, obtains the mRNA from the cell and enzymatically converts it into DNA before it can be isolated. The enzymatic conversion is performed by a viral enzyme called reverse transcriptase that is absent from cells that have not been infected by a virus that produces the enzyme. Significantly, DNA copies of mRNAs encoding isolated human DNA do not exist without human intervention, *i.e.*, prior to their synthesis by a researcher.

Claims to isolated human DNA thus satisfy the *Chakrabarty* requirement that patent-eligible subject matter show the hand of man. Isolated DNAs are a "nonnaturally occurring manufacture or composition of matter - a product of human ingenuity," *Chakrabarty*, 447 U.S. at 310, and thus are eligible for patenting under binding Supreme Court precedent.

III. A Ban on Patenting Isolated Human DNA Would Negatively Impact Research, Technology and Innovation

The district court's decision that isolated human DNA is patent-ineligible is based on an interpretation of the Patent Act having a broader impact than merely the patents-in-suit or similar patents claiming isolated human DNA, but would extend in principle to any patent claim encompassing a "natural product."

1. A Ban on Patenting Isolated Human DNA Would Encompass More Than Human Genes.

While isolated human DNA is the only DNA at issue in this case, a ban on isolated human DNA does not rely wholly on its status as being from a human being. The district court's decision that isolated human DNA is the "physical embodiment of [genetic] information" applies with equal force to isolated DNA from other organisms. Such organisms would include mammals, fish, birds, reptiles, amphibians, plants, and microorganisms. Banning patenting of isolated DNA from all known organisms would have widespread and deleterious effects on human health, nutrition, and progress.

For example, at present there are almost a thousand U.S. patents that claim isolated plant DNA, almost 25,000 U.S. patents on isolated animal DNA, almost 3,000 U.S. patents on isolated bacterial DNA, over 3,000 U.S. patents on isolated viral DNA, and 50 U.S. patents claiming vaccines based on isolated DNA, primarily DNA encoding antigens from viral and other pathogens. If the district

court's ban on patenting isolated human DNA is upheld, it would apply with equal force to these patents as well as the patents on isolated human DNA at issue in this lawsuit. The expected consequences of such a ban would be to make patent-ineligible, and hence unprotectable, such non-human DNAs and the vaccines and other products derived therefrom. Not only would a severe decline in research-driven advances in agriculture, medicine, diagnostics, and therapeutics ensue, but such a ban would also result in a widespread and devastating failure of existing commerce and industry based on present investments made by the public in reliance upon such issued patents.

2. The Vast Majority of Human Therapeutics Are Also "Natural Products" and Hence Patent-Ineligible Under Any Ban on Patenting Isolated Human DNA.

Patents on isolated human DNA also support the development of biologics, *i.e.*, drugs based on "naturally-occurring" human proteins. If the district court's decision that patents on isolated human DNA are directed to patent-ineligible "natural products," then biologics perforce would be patent-ineligible as well. Indeed, proteins like human Blood Clotting Factors VIII and IX, insulin, human growth hormone, erythropoietin, tissue plasminogen activator, and all monoclonal antibodies are "isolated" in substantially homogeneous form, are structurally unchanged from their sources in blood and other bodily fluids, and are less altered

than the isolated human DNAs that are the subject of the claims to isolated human DNA that were invalidated as "natural products" by the district court.

Any number of biologic drugs have been developed that, according to a recent Federal Trade Commission report, "have improved medical treatments, reduced suffering, and saved the lives of many Americans." Federal Trade Commission Report, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," June 2009, *available at* http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf. Biologics are predicted to become the most prescribed drugs over the next decade, to be used in the treatment of diseases such as cancer that have been otherwise incurable throughout human history. Today, such biologics include Enbrel® for treating rheumatoid arthritis; Rituxan® for non-Hodgkin's lymphoma; Remicade® for Crohn's disease, arthritic, ulcerative colitis, and other inflammatory disorders; and Avastin® for colon cancer. In 2008, biologics comprised 39% of drug revenues. Tracy Stanton, *Biologics to top pharma sale by 2014*, FiercePharma, June 18, 2009, http://www.fiercepharma.com/story/biologics-top-pharma-sales-2014/2009-06-18 (last visited Oct. 27, 2010). Biologic drug products are expected to account for 75% of drug revenues by 2014, and additionally include Herceptin® for breast cancer and Humira® for arthritis. Biologics thus treat chronic diseases of aging and are particularly important for the U.S. public as well as the U.S. economy.

Biologics, like other drugs, are cost- and investment-intensive to develop and commercialize, and may in fact be more expensive to develop than conventional therapeutic drugs. Development of a single biologic drug product can take up to 12 years and cost over $1 billion to bring to market. J. Hollingshead & R. Jacoby, "Avoiding no man's land: Potential unintended consequences of follow-on biologics," (2009), *available at* http://www.pharmamanufacturing.com/Media/1001/Deloitte_Biosimilars.pdf. Even the manufacturing facilities required to make biologics are more expensive to build than conventional drug manufacturing plants, being estimated to cost between $400 and $500 million. *Squawkbox* (CNBC television broadcast Aug. 9, 2009) (comments of James Greenwood, President of the Biotechnology Industry Organization BIO), *available at* http://www.cnbc.com/id/15840232?video=1213899782&play=1. Patent protection is necessary to support this level of investment and risk, and its absence can be expected to severely inhibit further development of biologic drugs. Amicus brief on behalf of the Biotechnology Industry Organization, *Bilski v. Kappos,* No. 08-964 (Aug. 6, 2009). Patents on isolated human DNA protect the means for making many of these biologic drugs and their absence if the district court's decision were upheld would negatively impact the ability of such drugs to be developed.

3. Genetic Information Is the Basis for the Coming Era of Personalized Medicine, a Nascent Industry that Requires Patents to Promote Investment and Development.

One of the most promising benefits of the elucidation of human genetic sequence information is the development of personalized medicine, the use of genetic information for diagnosing disease propensity and making improved therapeutic choices. C. R. Acharya et al., *Gene Expression Signatures, clinicopathological features, and Individualized Therapy in Breast Cancer*, 299 JAMA 1574-87 (2008); A. Potti et al., *A Genomic Strategy to Refine Prognosis in Early-Stage Non-Small-Cell Lung Cancer*, 355 NEW ENG. J. MED. 570-80 (2006); Sadee & Dai, *Pharmacogenetics/Genomics and Personalized Medicine*, 14 HUMAN. MOL. GENET. R207-14 (2005). Examples of how this technology can be used include pharmacogenomics, defined as "the application of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, and help determine a person's predisposition to a particular disease or condition." The Genomics and Personalized Medicine Act of 2007, S.976, 110th Cong. (2007), *available at* http://www.govtrack.us/congress/bill.xpd?bill=s110-976. Currently, the technology includes detection of enzyme variants for identifying patients susceptible to adverse reactions to the anticoagulant drug coumarin. U.I. Schwarz, *Clinical relevance of genetic polymorphisms in the human CYP2C9 gene*. 33 EUR.

J. CLIN. INVEST. 23-30 (2003). The technology also includes identifying molecular markers for making cancer treatment decisions. J.C. Mansour & R.E. Schwarz , *Molecular Mechanisms for Individualized Cancer Care,* 207 J. AM. COLL. SURG. 250-58 (2008); L.J. van't Veer & R. Bernards, *Enabling personalized cancer medicine through analysis of gene-expression patterns*, 452 NATURE 564-70 (2008).

Development of personalized medicine is thus important for diagnosing diseases, the propensity for developing diseases (including chronic diseases like cancer and diabetes), and making informed and effective treatment decisions. Indeed, researchers have developed a "gene chip"[2] that can be interrogated to detect hundreds of mutations in up to 170 genes relating to drug metabolism. UPI.com, Personalized medicine advancing, http://www.upi.com/Health_News/2009/12/31/Personalized-medicine-advancing/UPI-44821262286609/ (last visited Oct. 27, 2010). Continued development of this technology will depend on patent protection to provide the incentive for investment, which is threatened by the district court's decision invalidating Myriad's patents.

[2] A gene chip, or microarray, is described *inter alia* in Mark Schena, DNA MICROARRAYS: A PRACTICAL APPROACH (Oxford University Press 1999).

4. A Ban on Patenting Isolated Human DNA Would Promote Suppression of Genetic Information Relevant to Diagnostic and Therapeutic Applications.

Banning patents on isolated human DNA and patents on diagnostic uses of genetic information will provide incentives for alternative ways for this technology to be protected. In the absence of patenting, this will most likely involve trade secret protection.

Isolated human DNA and diagnostic methods represent a rare and possibly unique genetic situation: mutations in one or two genes increase a woman's propensity to develop breast or ovarian cancer from 5-10% to 95% (recalling that estimates of breast cancer in the general population are about 1 in 8 (12.5%) (Imaginis.com, Breast Cancer: Statistics on Incidence, Survival, and Screening, http://www.imaginis.com/breasthealth/statistics.asp (last visited Oct. 27, 2010) and, for ovarian cancer, 1 in 62.5 (1.6%) (Imaginis.com, Ovarian Cancer - Introduction, http://www.imaginis.com/ovarian-cancer/intro.asp (last visited Oct. 27, 2010)). While similar "propensity for disease" genes have been identified (*e.g.*, familial adenomatous polyposis. Genetics Home Reference, http://ghr.nlm.nih.gov/condition=familialadenomatouspolyposis (last visited Oct. 27, 2010)), most diseases are the result of several inherited and/or acquired changes in gene structure, expression, or function. Thus, it will be more difficult to determine genetic changes and patterns that reliably indicate an increased

likelihood of developing diseases like diabetes (R. Saxena et al., *Genome-Wide Association Analysis Identifies Loci for Type 2 Diabetes and Triglyceride Levels*, 316 SCIENCE 1331-36 (2007)), cardiovascular disease (M. Kelly et al., *Multiple Mutations in Genetic Cardiovascular Disease: A Marker of Disease Severity?,* 2 CIRCULATION: CARDIOVASCULAR GENETICS 182-90 (2009)), autism (ScienceDaily.com, *Multiple Genes Implicated in Autism; Discovery Could Lead to Drugs Targeting Gene Interactions*, http://www.sciencedaily.com/releases/2009/02/ 090209205049.htm (last visited Jan. 14, 2010)), Parkinson's disease (ScienceDaily.com, *Multiple Genes Implicated in Autism; Discovery Could Lead to Drugs Targeting Gene Interactions*, http://www.sciencedaily.com/releases/2009/02/ 090209205049.htm (last visited Jan. 14, 2010)), Alzheimer's disease (N. Chow et al., *Expression profiles of multiple genes in single neurons of Alzheimer's disease*, 95 PROCEEDINGS OF THE NAT. Acad. of Sci. USA 9620-25 (1998)), immunological disorders (V. Gateva et al., *A large-scale replication study identifies TNIP1, PRDM1, JAZF1, UHRF1BP1 and IL10 as risk loci for systemic lupus erythematosus,* 41 NATURE GENETICS 1228-33 (2009)), asthma (K. Ackerman et al., *Interacting genetic loci cause airway hyperresponsiveness,* 21 PHYSIOL.GENOMICS 105-11 (2005)) and most forms of cancer (W. Jiang et al., *Constructing disease-specific gene networks using pair-wise relevance metric: Application to colon cancer identifies interleukin 8,*

desmin and enolase 1 as central elements, 2 BMC SYS. BIO. 72, pp. 1-15 (2008)). A critical review of the field concluded that "[g]enetic profiling may have the potential to identify individuals at higher risk of disease depending on the prevalence and heritability of the disease." A.C. Janssens et al., *Predictive testing for complex diseases using multiple genes: Fact or fiction?,* 8 GENETICS IN MED. 395-400 (2006). A separate study on prostate cancer found that "[t]he genetic basis of many common human diseases is expected to be highly heterogeneous, with multiple causative loci and multiple alleles at some of the causative [genetic] loci." D. J. Schaid et al., *Nonparametric Tests of Association of Multiple Genes with Human Disease,* 76 AM. J. HUMAN GENETICS 780-93 (2005)).

As a consequence, it can be expected that most human diseases will involve many genes and vary with race, ethnicity, age, and other variables. S.B. Liggett et al., *A GRK5 polymorphism that inhibits ß-adrenergic receptor signaling is protective in heart failure,* 14 NAT MED. 510-17 (2008). The studies cited herein are but the beginnings of this technology. Absent patent protection, and under the circumstances of multigenic causation (or at least association) of common diseases, the impetus will be to develop and protect this nascent technology using, *inter alia*, trade secret protection. Under these circumstances, innovation in genetic-based diagnostics would be severely limited, since there would be no incentive (indeed, there would be strong *dis*incentives) to disclose the genetic basis of complex

diagnostic assays. This would reduce progress in genetic diagnostics as a direct consequence of the district court's ban on human DNA patenting, since there would be no disclosure of the genetic information as now exists when these relationships are the subject of patent protection.

5. The Consequences of the District Court's Decision Are Not Limited to Isolated Human DNA or Biologic Drugs Produced Therefrom, But Extend to Any "Natural Product."

Despite the district court's attempt to limit the scope of the ban on isolated human DNA as a "natural product," the rationale used by the court could logically be extended to any other invention produced as the result of exploitation of naturally-occurring compounds or substances. These include any naturally-occurring chemical compound, including compounds isolated from petroleum and other sources of organic matter, the products of fermentation by microorganisms, and chemical compounds produced by microorganisms, plants or non-human animals that can be adapted for human use. Taken to its logical conclusion, the district court's "natural products" ban on patent eligibility would extend even to inorganic matter, such as ultrapure silicon used to produce computer microchips, isolated metal products prepared from ore and other natural sources, minerals and glasses produced from silicon and other natural sources, and any other compound produced from any naturally-occurring source. Such a determination would categorically exclude such inventions from patent-eligibility regardless of how

novel, useful and non-obvious such inventions may be. Indeed, the district court's decision would disqualify a number of the inductees in the National Inventors Hall of Fame, including Frederick Banting and his isolation and purification of insulin, George Washington Carver and his isolation of natural products from peanuts, and Robert Gallo and his isolation of the Human Immunodeficiency Virus.

IPO believes such a broad ban is not justified, since there is no other source for these materials *but* nature. Whether materials are "natural" should not determine whether such inventions are patent-eligible, but rather whether the hand of man has been used to invent them.

CONCLUSION

IPO urges this Court to reject the overly loose application of the declaratory jurisdiction standard applied by the district court. Adoption of the district court's approach would potentially open the floodgates and allow almost any vaguely interested party to bring a declaratory judgment case to invalidate any patent. If the threshold for challenging the validity of a patent is to be lowered in such a dramatic fashion, that adjustment should be left to Congress. Instead, declaratory jurisdiction should continue to be based on the existence of a substantial and immediate controversy between the patentee and the declaratory judgment plaintiff concerning the patent or patents at issue.

IPO also believes that this Court should find isolated DNA constitutes patentable subject matter under Section 101 of the patent statute and reject the improper "natural products" test applied by the district court. Maintaining the broad scope of patentable subject matter set forth by the Supreme Court is vital to the continued strength of the U.S. pharmaceutical and biotechnology industries and their continued innovation in the decades to come.

Respectfully submitted,

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APPENDIX

APPENDIX[1]

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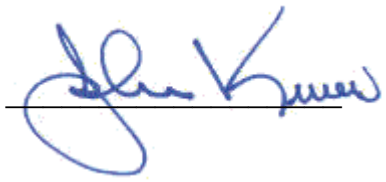

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