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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

UNIVERSITY OF UTAH RESEARCH FOUNDATION et al., Plaintiffs, v. AMBRY GENETICS CORPORATION, Defendant.	**[PROPOSED] BRIEF OF THE AMERICAN CIVIL LIBERTIES UNION, AMERICAN CIVIL LIBERTIES UNION OF UTAH FOUNDATION, INC., PUBLIC PATENT FOUNDATION, ASSOCIATION FOR MOLECULAR PATHOLOGY, BREAST CANCER ACTION, AND AARP AS AMICI CURIAE IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** Case No. 2:13-cv-00640-RJS Case No. 2:13-cv-00643-RJS
UNIVERSITY OF UTAH RESEARCH FOUNDATION et al., Plaintiffs, v. GENE BY GENE, LTD., Defendant.	

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INTEREST OF AMICI[1]

The American Civil Liberties Union ("ACLU") is a nationwide, nonprofit, nonpartisan organization with over 500,000 members dedicated to protecting the fundamental rights guaranteed by the Constitution and the laws of the United States. Its Women's Rights Project, founded in 1972 by Ruth Bader Ginsburg, works to advance gender equality and to address civil liberties concerns affecting women and girls. The ACLU of Utah Foundation is a regional affiliate of the ACLU. These cases, which arise under patent law, raise concerns regarding freedom of scientific inquiry and implicate important constitutional values embodied in the Patent Clause and the First Amendment. They will also have a major impact on access to genetic testing that many women seek in order to make life-changing medical decisions regarding breast and ovarian cancer screening, treatment, and prevention. These cases are, therefore, of significant concern to the ACLU and its membership in Utah and throughout the country.

The Public Patent Foundation ("PUBPAT") is a not-for-profit legal services organization affiliated with the Benjamin N. Cardozo School of Law. PUBPAT achieves its mission of protecting freedom in the patent system by representing the public interest against undeserved patents and unsound patent policy. PUBPAT has argued for sound patent policy before the Supreme Court, various Courts of Appeals and District Courts, Congress, the U.S. Patent & Trademark Office (PTO), and many other national and international bodies. PUBPAT is a leading provider of public service patent legal services and advocate for comprehensive patent

[1] Amici state that no counsel to a party authored this brief, in whole or in part, and that no person or entity other than amici and their counsel have made a monetary contribution to the preparation or submission of this brief.

reform. These cases will have a significant effect on the public interest represented by PUBPAT, which includes ensuring that publicly beneficial competition is not improperly enjoined.

The Association for Molecular Pathology ("AMP") is an international not-for-profit professional association representing over 2,000 physicians, doctoral scientists and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Since its founding in 1995, AMP members have been involved in every aspect of molecular diagnostic testing: administration and interpretation of molecular diagnostic tests, research and development, and education. As the only professional association dedicated solely to molecular pathology, AMP has an interest in this matter because these cases will have a great impact on the provision of and innovation in genetic testing. AMP members regularly report that they were forced to stop providing testing services and are reluctant to develop new tests that could directly benefit patients due to enforcement of improper patents relating to genes, such as the claims at issue in these cases.

Founded in 1990, Breast Cancer Action ("BCAction") is a national, grassroots advocacy and education organization working to end the breast cancer epidemic. BCAction receives no funding from any corporation that manufactures any products linked to breast cancer, including pharmaceutical and medical companies. As the watchdog of the breast cancer movement, BCAction believes that Myriad's monopoly on examination of the BRCA genes through its patents creates unacceptable barriers to research and testing, endangering the health of its members and the public. If Myriad is successful in enjoining other laboratories from offering BRCA genetic testing, patients will have no way of confirming test results they receive, and

Myriad will be allowed to maintain its control over BRCA data. BCAction is also concerned that Myriad is able to charge a high price for its test, placing testing out of reach for many.

AARP is a nonpartisan, nonprofit organization with a membership, dedicated to addressing the needs and interests of people age fifty and older. AARP seeks through education, advocacy, and service to enhance the quality of life for all by promoting independence, dignity, and purpose. In its efforts to promote independence, AARP works to foster the health and economic security of individuals as they age by attempting to ensure the availability of quality and economical health coverage. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Access to affordable health care is particularly important to the older population, which has higher rates of chronic and serious health conditions. The results of genetic testing may help to diagnosis a variety of diseases enabling treatment to be tailored to individual genetic variations. Patents such as those present in this case significantly elevate the cost of genetic testing, interfering with diagnosis and treatment based on second medical opinions.

Amici ACLU and PUBPAT represented the twenty individual and organizational plaintiffs who challenged Myriad Genetics' patents in the litigation resulting in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) [hereinafter, the "*AMP* litigation"], including the Association for Molecular Pathology and Breast Cancer Action. AARP filed amicus briefs in that litigation. Thus, *amici* are well-positioned to inform this Court about the issues raised and decided in the *AMP* litigation and the public interest at stake in invalidating patents that create monopolies on genetic information, which the U.S. Supreme Court has held is a law of nature.

STATEMENT OF THE CASE

These cases arise in the aftermath of a unanimous Supreme Court decision invalidating patent claims held by Myriad Genetics that created a monopoly on clinical testing of the BRCA1 and BRCA2 genes. Despite the clear message sent by that ruling, Myriad continues to seek to maintain its monopoly by asserting other patent claims that, under prevailing precedent, clearly cover laws and products of nature and thus are invalid. Its lawsuits against Ambry Genetics and Gene by Gene ("Defendants"), laboratories that began or will begin offering genetic testing of the two genes, are Myriad's latest attempts to control access to people's genetic information.

In 2009, twenty plaintiffs – including associations of pathologists and geneticists with over 150,000 members, researchers, genetic counselors, breast cancer and women's health groups, and patients – filed a lawsuit challenging patents related to the BRCA1 and BRCA2 genes controlled by Myriad and the University of Utah Research Foundation. The lawsuit sought a judgment declaring fifteen claims in seven patents to be invalid under Section 101 of the Patent Act, on the grounds that they impermissibly claimed products of nature, laws of nature, and abstract thought. Other invalidity and unenforceability criteria were not at issue because the *AMP* plaintiffs sought a ruling on the issue of patentable subject matter, the threshold validity consideration for courts. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010). Nine of the claims were directed to "isolated DNA," five of the claims to methods of screening the BRCA1 or BRCA2 genes by analyzing or comparing genetic sequences, and one claim to a method of screening potential therapeutics. These claims were chosen because Myriad asserted these patents on the genes and basic methods of gene screening when sending cease-and-desist letters to other laboratories that were conducting testing. Gaede Decl. Ex. B (Ganguly Decl. Exs.

2, 3); Nussbaum Decl. ¶¶ 19-20; Tait Decl. ¶¶ 40-42. The decision to focus on these claims was by no means a concession that any of Myriad's other claims is valid.

The district court held all of the challenged claims to be invalid under Section 101. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010). The court found that "isolated DNA" is a product of nature and embodies a law of nature because isolated DNA is not markedly different from DNA as it exists in the body. *Id.* at 227-32. The court also found the five method claims related to screening genes were invalid because they covered abstract thought – comparing or analyzing two genetic sequences. *Id.* at 232-37. Moreover, the court held that even if these method claims included steps such as "isolating" and "sequencing" DNA, they would still fall. "Even if the challenged method claims were read to include the transformations associated with isolating and sequencing human DNA, these 'data-gathering step[s]'. . . are not 'central to the purpose of the claimed process.'" *Id.* at 236 (citations omitted). The court recognized that "[t]he essence of what is claimed is the identification of a predisposition to breast cancer." *Id.*

Myriad appealed and the U.S. Court of Appeals for the Federal Circuit rendered a split decision. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011). Judges Lourie and Moore, each relying on different reasoning, held that isolated DNA is patent-eligible, while Judge Bryson dissented. All three judges held that cDNA is patent-eligible, *id.* at 1350, 1364, 1373, although Judge Bryson specifically found that claim 6 of the '282 Patent, which he considered to be claiming cDNA, was not patent-eligible. *Id.* at 1378-79 (Bryson, J., dissenting). All three judges agreed that the five screening method claims

were invalid, *id.* at 1355-57, and that the therapeutic screening method claim was valid under Section 101. *Id.* at 1357-58.

Following *AMP* plaintiffs' petition, the U.S. Supreme Court vacated the judgment and remanded for further consideration in light of its recent decision in *Mayo v. Prometheus*, 132 S. Ct. 1289 (2012). *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) (mem.). Upon remand, the Federal Circuit issued a similar ruling to its first, with each judge reaching the same conclusions as before. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012). Of significance to the current litigation, the judges held that *Mayo* reaffirmed their prior holding as to the five claims on screening methods that involved "comparing" or "analyzing" sequences. The Federal Circuit noted *Mayo* found that the steps of "administering" a drug and "determining" the drug's metabolite levels, combined with the "wherein" clauses correlating the metabolite levels with drug efficacy, "were not sufficiently transformative of what was otherwise a claim to a natural law. . . . That holding governs Myriad's claims to methods of 'comparing' and 'analyzing' DNA sequences." *Id.* at 1335. It concluded that the methods could be accomplished by mere inspection, as the claims did not have "any other putatively transformative step," but did not address the question of whether claims with any such step would be valid. *Id.*

AMP plaintiffs petitioned a second time for Supreme Court review, which was granted, and Myriad did not cross-petition as to the method claims. Thus, only the isolated DNA claims were before the Supreme Court. The Federal Circuit's affirmance of the district court judgment striking the five method claims therefore stands as the law of the case, as does its ruling on the other method claim. *See, e.g.*, *Arizona v. California*, 460 U.S. 605, 618 (1983).

On June 13, 2013, the Court issued a 9-0 decision invalidating Myriad's patents on isolated genomic DNA. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2107. The Court began its discussion highlighting its longstanding precedent prohibiting the patenting of products and laws of nature. "[T]hey are the basic tools of scientific and technological work that lie beyond the domain of patent protection. . . without this exception, there would be considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'" *Id.* at 2116 (internal citations omitted).

The Supreme Court then concluded that Myriad's patents on isolated DNA "fell squarely within the law of nature exception." *Id.* at 2117. The "isolation" of the genes did not create an invention, because what Myriad had patented was the "genetic information encoded in the BRCA1 and BRCA2 genes." *Id*. at 2118. "[I]ts claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule." *Id.* Moreover, "the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents 'were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach.'" *Id.* at 2119-20 (quoting *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 202-03). The Court also ruled that cDNA is not a product of nature, with an important caveat: "except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA." *Id.* at 2119. The Court stated that it was not expressing an opinion on whether patents on cDNA satisfy other statutory requirements of patentability, citing to sections 102, 103, and 112 of the Patent Act. *Id.* at 2119 n.9.

Scientists, medical professionals, patient advocates, and others hailed the ruling as a victory for science and public health that lifted a major barrier to the progress of personalized medicine. *See, e.g., Statement by NIH Director Francis Collins on U.S. Supreme Court Ruling on Gene Patenting*, Nat'l Inst. of Health, U.S. Dep't of Health & Human Servs. (June 13, 2013) (the ruling "represents a victory for all those eagerly awaiting more individualized, gene-based approaches to medical care"); Press Release, Am. Med. Ass'n, AMA Welcomes an End to Human Gene Patents (June 13, 2013), http://www.ama-assn.org/ama/pub/news/news/ 2013/ 2013-06-13-end-to-human-gene-patents.page ("[t]he U.S. Supreme Court's unanimous rejection of patenting human genes is a clear victory for patients that will expand medical discovery and preserve access to innovative diagnosis and treatment options"); *Clinton: SCOTUS Myriad Genetics Decision 'Terrific'*, Bloomberg Law (June 14, 2013), http://about.bloomberglaw.com/ videos/clinton-scotus-myriad-genetics-decision-terrific (former President Clinton predicting the decision will "generate untold thousands of jobs in this country").

Almost immediately, several laboratories announced that they would begin offering BRCA genetic testing. Andrew Pollack, *After DNA Patent Ruling, Availability of Genetic Tests Could Broaden*, N.Y. Times, June 14, 2013, at A16. That reaction was unsurprising. Many laboratories are fully capable of providing BRCA testing, want to offer such services to their patients, but were unable to do so until the ruling struck down Myriad's monopoly on the genes. Matloff Decl. ¶¶ 6-7; Ledbetter Decl. ¶¶ 14, 27, 29; Cho Decl. ¶¶ 12-14, 16; Leonard Decl. ¶ 21; Tait Decl. ¶ 40. And many patients seek to understand their BRCA genetic information in order to make informed medical decisions, but were unable to access the BRCA testing they needed

through Myriad or were given inconclusive results. Morris Decl. ¶¶ 4-9; Matloff Decl. ¶¶ 8-11; Swisher Decl. ¶¶ 78, 80-81, 90-93, 97.

Plaintiffs before this Court (hereinafter referred to as "Myriad")[2] sued Defendants, two of the laboratories, and now move for a preliminary injunction to stop their testing of the BRCA genes. Myriad asserts six method claims and four claims on primers in its motion.[3] The method claims all involve comparing a sequence from a patient sample to a reference sequence. A representative method claim is claim 8 of the '441 Patent:

> The method of claim 1 wherein a germline nucleic acid sequence is compared by amplifying all or part of a BRCA1 gene from said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids.

And claim 1 of the '441 Patent, to which claim 8 refers, reads:

> A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA

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[2] The University of Utah Research Foundation, Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc., and Myriad Genetics, Inc. are plaintiffs. University of Pennsylvania and HSC Research and Development Limited Partnership have expressed discomfort with their involvement in the suit. Fiona Glisson & Harry Cooperman, *Penn Joins Two Genetic Patent Infringement Lawsuits*, The Daily Pennsylvanian, July 31, 2013, *available at* http://www.thedp.com/article/2013/07/penn-joins-two-genetic-patent-infringement-lawsuits (quoting Susan Phillips, Senior Vice President of the University of Pennsylvania Health System as saying, "It is a matter of law, not a matter of choice. We did not seek out this lawsuit. You can call the Hospital of Sick Children in Toronto and they would feel the same way."); Press Release, Hospital for Sick Children, SickKids in the News: Myriad Genetics Lawsuit (July 19, 2013), *available at* http://www.sickkids.ca/FYI/SickKids-in-the-news-myriad.html. Poignantly, two of the plaintiffs in the *AMP* litigation were geneticists who worked at the University of Pennsylvania. In 1998, the BRCA genetic testing they offered to the National Cancer Institute and other laboratories was shut down following cease-and-desist letters and litigation filed by Myriad. Gaede Decl. Ex. B (Ganguly Decl. ¶¶ 4-10).

[3] *Amici* focus on the method claims as analyzed under Section 101 and the Constitution in this brief. *Amici* agree that, for the reasons stated by Defendants in their opposition brief, the asserted primer claims are also invalid under the Patent Act.

> from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject.

Claim 1 of the '441 Patent was invalidated by the Federal Circuit in the *AMP* litigation under Section 101. *Ass'n for Molecular Pathology*, 689 F.3d at 1333-35. Thus, the question presented to this Court is whether a preliminary injunction should issue based on method claims that add routine, additional steps – such as "amplifying" using an unspecified set of primers and "sequencing" – to what is undoubtedly unpatentable subject matter.

SUMMARY OF ARGUMENT

Despite the unanimous rulings in *Mayo* and *AMP*, Myriad continues to aggressively defend its monopoly on examining the BRCA genes, pointing to patent claims that were not the subject of the previous suit but are clearly invalid under those decisions and the Federal Circuit's earlier ruling.[4] From the start, Myriad touted itself as a "genetic information business," and with these suits, continues to pursue a business model that depends on exclusive access to patients'

[4] Myriad is also asserting a patent claim that was at issue in the *AMP* litigation, claim 6 of Patent '282. Complaint at 6, Myriad Genetics, Inc. v. Ambry Genetics, No. 2:13CV00640 (D. Utah July 9, 2013); Complaint at 6, Myriad Genetics, Inc. v. Gene by Gene Ltd., No. 2:13CV00643 (D. Utah July 10, 2013). That claim is invalid pursuant to the Supreme Court's holding that cDNA is a product of nature when it consists of nucleotides that comprise genomic DNA short enough to contain no intervening introns. *See Ass'n for Molecular Pathology*, 132 S. Ct. at 2119. Claim 6 of Patent '282 claims any nucleotide sequence containing 15 or more nucleotides from SEQ. ID NO:1, and 15 nucleotide (and longer) sequences from SEQ. ID NO:1 are found throughout genomic DNA. *See, e.g.*, Jeffrey Rosenfeld & Christopher E. Mason, *Pervasive Sequence Patents Cover the Entire Human Genome*, 5 Genome Med. 27 (2013) (showing that 15-nucleotide sequences of BRCA1 match at least 689 other genes). It therefore covers short sequences of genomic DNA that contain no intervening introns. While claim 6 is not part of Myriad's preliminary injunction motion, the fact that it was asserted in the complaints illustrates Myriad's willful disregard of Supreme Court precedent.

BRCA1 and BRCA2 sequences. Kevin Davies & Michael White, *Breakthrough: The Race to Find the Breast Cancer Gene* 166 (1996) (quoting Myriad's April 1994 press release).

The method claims asserted by Myriad are invalid under Section 101 because they claim laws of nature and abstract thought. As the Federal Circuit recognized in the *AMP* litigation, claims on screening for a BRCA mutation by comparing or analyzing a patient's sequence against a reference sequence cover a mental process. *Ass'n for Molecular Pathology*, 689 F.3d at 1334. The addition of routine, data-gathering steps such as "amplifying" and "sequencing" does not alter the ultimate conclusion that these claims seek to monopolize a law of nature – whether a patient has a BRCA1 or BRCA2 mutation or not – and medical professionals' ability to examine it. Under *Mayo*, these claims cannot withstand Section 101 scrutiny, and Myriad cannot use these claims to monopolize all analysis of the two genes. Such a result, moreover, would be in conflict with the First Amendment and Patent Clause of the U.S. Constitution.

Because these claims are invalid under Section 101, a preliminary injunction would harm the public interest. An injunction would also have detrimental effects on patients' access to genetic testing, clinicians' provision of medical care, and researchers' ability to innovate using the basic scientific methods at issue here. Patients and physicians are best served when they may choose from the range of testing options that could and would be provided by Defendants and others, including testing of the multiple genes connected to breast and ovarian cancer risk, lower cost testing, access to confirmatory testing, and testing as part of research studies.

Myriad can continue to offer BRCA1 and BRCA2 testing services to patients in the manner it selects. What it cannot be permitted to do, however, is stop all others from analyzing

people's genetic information, the blueprint for our cells, organs, and bodies which contains significant medical clues about our susceptibility to diseases and responsiveness to treatments.

ARGUMENT

I. Supreme Court Precedent on Section 101 of the Patent Act Prohibits Patent Holders, like Myriad, From Monopolizing Any and All Examination of Genetic Information.

A. Myriad's Method Claims Are Invalid Pursuant to the Decisions in *Mayo* and *AMP*.

Myriad seeks to enforce its claims on comparing two sequences – a mental process, as recognized by the Federal Circuit in the *AMP* litigation – to determine whether a patient's sample contains a BRCA1 or BRCA2 mutation – a law and product of nature. Because Defendants have raised a "substantial question" concerning validity, "the preliminary injunction should not issue." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

The method claims asserted by Myriad in its preliminary injunction motion violate long-established precedent that prohibits the patenting of laws of nature, natural phenomena, products of nature, and abstract ideas. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2116; *Mayo*, 132 S. Ct. at 1293; *Bilski*, 130 S. Ct. at 3225; *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Mayo*, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). This Court has explained repeatedly that "[s]uch discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'" *Chakrabarty*, 447 U.S. at 309 (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127, 130 (1948)). A law of nature does not become a

patentable invention based on utility, novelty, hard work, or the need to recoup investment. *See Ass'n for Molecular Pathology*, 133 S. Ct. at 2118; *Mayo*, 132 S. Ct. at 1303-04.

Mayo described two key factors in determining whether a method is patent-eligible: whether it is based on an inventive concept, and whether the patent ties up the use of the underlying natural phenomena. *Mayo*, 132 S. Ct. at 1289, 1294. These claims fail both tests.

1. The Method Claims Are Not Based on an Inventive Concept.

Mayo explained in depth how a court must analyze a method claim for the existence of an inventive concept. The Court asked, does the claim arise from an "'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself"? *Id.* at 1294 (quoting *Parker v. Flook*, 437 U.S. 584, 594 (1978)). Does it "add enough" or "simply append[] conventional steps, specified at a high level of generality, to laws of nature [or] natural phenomena"? *Id.* at 1300.

In *Mayo*, the Supreme Court found that the claims were not inventive, despite putative transformations that occurred during the administration of a drug and determination of metabolite levels, because nothing of significance was added to the law of nature – the patient's response to a drug. *Mayo*, 132 S. Ct. at 1297. The steps of administering a drug and determining metabolite levels were routine, conventional science. *Id.* at 1297-98. The only addition in the patent claim was the identification by Prometheus of the metabolite levels that indicate drug efficacy. *Id.* at 1297-98. The claims simply "inform a relevant audience about certain laws of nature." *Id.* at 1298.

The method claims at issue here do not cross the Section 101 threshold set out in *Mayo*, because the claims are clearly directed at whether or not a patient has a BRCA1 or BRCA2

mutation, a law of nature. Steps like "amplifying" and "sequencing" are simply routine, preparatory steps that were not invented by Myriad. The patents themselves disclose this fact. *See, e.g.*, the '441 Patent, col. 14, ll. 9-16; col. 17, ll. 20-25.[5] These conventional steps simply allow the technician to gather the data to ascertain the natural phenomenon of whether a patient has a mutation or not and inform the physician and patient accordingly. And for the reasons described by Defendants, the use of simple primers, as laid out in the claim, does not change that conclusion. Defs. Opp'n to Pls. Mot. Prelim. Inj. 41-42, ECF No. 45. The primers were not "invented" by Myriad but instead consist of nucleotide sequences found in the body. In this respect, the method here is even less inventive than the methods set out in Prometheus' claims. Myriad's method claim assesses pure biological facts that do not depend on the administration of a man-made drug for their existence. As in *Mayo*, the amplifying and sequencing steps – while involving arguably trivial transformations – do not render the methods patent-eligible because they are "[p]urely 'conventional or obvious' '[pre]-solution activity.'" *Mayo*, 132 S. Ct. at 1298. Clever draftsmanship – such as adding routine steps such as "amplifying" using primers or "sequencing" – cannot rescue a claim that otherwise falls short of Section 101 scrutiny. The Court's "cases warn us against interpreting patent statutes in ways that make patent eligibility 'depend simply on the draftsman's art' without reference to the 'principles underlying the prohibition against patents for [natural laws].'" *Id.* at 1294 (quoting *Flook*, 437 U.S. at 593).

[5] Numerous scientists laid the groundwork for Myriad's ultimate sequencing of the BRCA1 and BRCA2 genes, including Dr. Mary-Claire King and her team, who identified the locus of the BRCA1 gene and named it. Gaede Decl., Ex. G (Parthasarathy Decl. ¶¶ 10-16); Ledbetter Decl. ¶ 22. Others made significant contributions as well. *See, e.g.*, Kenneth J. Abel et al*., A Radiation Hybrid Map of the BRCA1 Region of Chromosome 17q12-q21*, 17 Genomics 632 (1993).

Cases decided after the Supreme Court decision in *Mayo* confirm that methods consisting of routine steps are invalid under Section 101, when they ultimately claim patent-ineligible matter, even when several routine steps are combined together. *See, e.g.*, *CLS Bank Int'l v. Alice Corp. Pty.*, 717 F.3d 1269, 1287 (Fed. Cir. 2013); *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65, 70-73 (Fed. Cir. 2012); *OIP Techs., Inc. v. Amazon.com, Inc.*, No. C-12-1233 EMC, 2012 WL 3985118, at *16-20 (N.D. Cal. Sept. 11, 2012); *Aria Diagnostics, Inc. v. Sequenom, Inc.*, No. C 11-06391 SI, 2012 WL 2599340 (N.D. Cal. July 5, 2012), *vacated and remanded on claim construction grounds*, No. 2012-1531, 2013 WL 4034379 (Fed. Cir. Aug. 9, 2013); *SmartGene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 56-57 (D.D.C. 2012). In *Aria Diagnostics, Inc. v. Sequenom, Inc.*, recently remanded by the Federal Circuit on claim construction grounds, the district court found that combining routine steps in a method to detect fetal DNA did not result in a patent-eligible claim because the patent did no more than combine conventional techniques, such as "amplifying" and "detecting" fetal DNA. No. C 11-06391 SI, 2012 WL 2599340, at *11 (N.D. Cal. July 5, 2012). The court denied Sequenom's motion for a preliminary injunction, finding that Aria Diagnostics raised a substantial question as to whether the patent amounted to "significantly more than a patent upon the natural law itself." *Id.* at *12-13. As in *Aria Diagnostics*, the method claims presented here comprise steps that are conventional, routine, and well-understood and gather data about the law of nature at the heart of the claim. They are not based on an inventive concept.

2. The Method Claims Preempt Basic Scientific Activities and Use of Laws of Nature.

As *Mayo* reaffirmed, a key aspect of the Section 101 analysis turns on whether the patent preempts use of the laws and products of nature. Does the patent "risk disproportionately tying

up the use of the underlying natural laws, inhibiting their use in the making of further discoveries"? 132 S. Ct. at 1294. "[M]onopolization of [basic scientific and technological] tools through the grant of a patent might tend to impede innovation rather than it would tend to promote it." *Id.* at 1293. Thus, the Court's precedents "warn us against upholding patents that claim processes that too broadly preempt the use of a natural law." *Id.* at 1294*; see also Bilski*, 130 S. Ct. at 3231 ("Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea."); *Funk Bros.,* 333 U.S. at 130 ("He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes."); *O'Reilly v. Morse*, 56 U.S. 62, 113 (1853) (The patentee's claim on any machinery or process using electric current to mark characters at a distance "shuts the door against inventions of other persons...."). While every patent forecloses use of what has been patented, the Section 101 preemption inquiry focuses on whether the patent claim authorizes the patentee to foreclose use of natural phenomena or abstract thought.

In the *AMP* litigation, the Supreme Court expressed concern that patents on isolated DNA unduly interfered with scientific activity such as genetic testing. "But isolation is necessary to conduct genetic testing, and Myriad was not the only entity to offer BRCA testing after it discovered the genes . . . [describing Myriad's assertion of patent exclusivity against others] . . . Myriad thus solidified its position as the only entity providing BRCA testing." *Ass'n for Molecular Pathology*, 133 S. Ct. at 2114 (2013). In reaching its unanimous ruling, the Supreme Court clearly sought to ensure that patents on genes, or basic methods such as "isolating," would not stand in the way of scientific and medical activity, such as genetic testing. This concern

applies with equal force to the methods asserted here, where Myriad is enforcing patent claims reciting conventional science to stop others from examining this genetic information.

The Court's decision on this motion will also affect the ability to engage in basic scientific activities regardless of whether the laboratory professional is doing so for the purpose of providing breast and ovarian cancer risk testing for patients. The patent claims that Myriad is asserting are not limited to that context. Any scientist who engages in the basic steps of amplifying part of the BRCA1 gene and sequencing the amplified segment as part of a research study would violate these claims. As a consequence, these patents prevent any scientist from examining or understanding the underlying law of nature – whether a particular BRCA1 gene contains an alteration from the wild-type – and using that law of nature in any way. For that reason, the patents raise the same concerns about patenting a "building-block" that has previously troubled the Supreme Court. *Mayo,* 132 S. Ct. at 1303. The claims undermine the patent system by giving Myriad the right to any innovation based on these routine methods. These patents thus tie up simple screening of people's genes, "foreclose[ing] more future innovation than the underlying discovery could reasonably justify." *Id.* at 1292.

B. Granting a Preliminary Injunction Based on These Patent Claims Would Also Violate the First Amendment and Patent Clause of the U.S. Constitution Because It Would Grant Myriad Exclusive Control Over a Body of Knowledge.

The structure of intellectual property is created by Article I, section 8, clause 8, which covers copyright and patents: Congress has the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. 1, § 8, cl. 8. Like other legislative powers conferred by Article I, the power to award copyrights and patents is limited by the First

Amendment. In copyright, where the potential conflict between copyright law and the First Amendment is more obvious, the Supreme Court has suggested that the First Amendment requires doctrines, like the idea/expression distinction, that are incorporated into the statute. *Eldred v. Ashcroft,* 537 U.S. 186, 219 (2003); *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 556 (1985). *See also Salinger v. Colting*, 641 F. Supp. 2d 250, 255 (S.D.N.Y. 2009), *rev'd on other grounds*, 607 F.3d 68 (2d Cir. 2010); *Maxtone-Graham v. Burtchaell*, 631 F. Supp. 1432, 1435 (S.D.N.Y. 1986). *Cf.* Peter Yun-Hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on Biotechnology Research Tools*, 19 Harv. J.L. & Tech. 79, 98-100 (2005). Although the section 101 doctrine prohibiting patenting of natural phenomena and abstract thought has not been described previously as compelled by the First Amendment, there can be little doubt that patents that give control over an entire body of knowledge would violate the First Amendment. Indeed, the Court's concern about tying up basic scientific and technological tools highlights the priority placed on preventing patents that impede scientific thought and innovation. *Mayo*, 132 S. Ct. at 1293*; see also* Lee, *supra*, at 101-103; Gary L. Francione, *Experimentation and the Marketplace Theory of the First Amendment*, 136 U. Pa. L. Rev. 417, 428 (1987).

For a typical downstream invention, such as a carburetor, others can examine how the new carburetor functions once the patent is published and develop a better carburetor using different materials or methods. But rather than leading to a greater understanding or a better product, the patent claims asserted in this motion exclude others from basic scientific and medical work examining naturally-occurring genes. *See* Stiglitz Decl. ¶¶ 25-26; 34-35.

Most notably, each of the method claims asserted in the motion include what the Federal Circuit found to be a mental step – comparing two genetic sequences. *Ass'n for Molecular Pathology*, 689 F.3d at 1334. This raises the same concern identified in *Mayo* about the claim's inclusion of mental steps; although the wherein clauses in Prometheus' claims were obviously intended to alert the physician to act in a therapeutic setting, the claims were not limited to the therapeutic setting or restricted to action taken as a result of the test levels. *Mayo*, 132 S. Ct. at 1302; *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04CV1200 JAH (RBB), 2008 WL 878910, at *6 (S.D. Cal. Mar. 28, 2008). Likewise, here, the claims asserted by Myriad target the abstract thought of comparing two sequences after performing routine scientific activities but does not direct any subsequent actions. *See* Tait Decl. ¶ 45; Stiglitz Decl. ¶ 34.

The ability to think without constraint is an essential attribute of human autonomy and an essential cornerstone of the First Amendment. *See* Laurence Tribe, *American Constitutional Law* § 12-1 (2d ed. 1988); Thomas Emerson, *The System of Freedom of Expression* 6 (1970). In Justice Harlan's words, "No other approach would comport with the premise of individual dignity." *Cohen v. California*, 403 U.S. 15, 24 (1971). Or, as Justice Brandeis famously stated in an opinion joined by Justice Holmes, the First Amendment protects the "freedom to think as you will and to speak as you think." *Whitney v. California*, 274 U.S. 357, 375 (1927) (Brandeis, J., concurring). Echoing that theme, *Palko v. Connecticut*, 302 U.S. 319, 326-27 (1937), described "freedom of thought and speech" as "the matrix, the indispensable condition, of nearly every other form of freedom." And *Griswold v. Connecticut* said, "The right of freedom of speech … includes not only the right to utter or to print, but the right to … freedom of inquiry,

freedom of thought …." 381 U.S. 479, 482 (1965). *See also United States v. Reidel*, 402 U.S. 351, 355-56 (1971); *Stanley v. Georgia*, 394 U.S. 557, 564-66 (1969);.

There can be no compelling governmental interest in granting an exclusive license on knowledge, abstract ideas or every possible expression of those ideas. Even in copyright, the government does not claim a compelling interest in licensing an idea or every possible expression of that idea. The same First Amendment principles apply to patent law. If, for example, the government decided to encourage innovation in engineering by granting specific universities exclusive rights to study specific fields of engineering, that exclusivity would be unconstitutional. Indeed, the First Amendment is based on the opposite conclusion – that progress is best achieved through a marketplace of ideas, not thought that is strictly controlled.

Yet, Myriad is attempting to use its patents to control the field of scientific and medical work relating to the BRCA1 and BRCA2 genes. The patents prohibit mental comparison and consideration of genetic sequences after performing routine scientific steps. Myriad has already used its exclusive rights to amass an enormous amount of information critical to the health of every American. Matloff Decl. ¶¶ 8, 11; Ledbetter Decl. ¶¶ 25, 35-37, 44; Swisher Decl. ¶¶ 34-36; Nussbaum Decl. ¶¶ 17, 21, 30. Myriad refuses to allow others to obtain the information themselves by performing the basic methods at issue in this litigation, or to share the information with the medical and scientific communities. Ledbetter Decl. ¶¶ 11-12, 25, 29, 36, 38, 44; Matloff Decl. ¶¶ 6, 8, 11; Swisher Decl. ¶¶ 36-38; Nussbaum decl. ¶¶ 19-21; Tait Decl. ¶¶ 50-51. The claims thus give entire control over a body of knowledge and over pure information to Myriad. That, under the First Amendment, is impermissible. *See Ashcroft v. Free Speech Coal.,* 535 U.S. 234, 253 (2002) ("First Amendment freedoms are most in danger when the government

seeks to control thought or to justify its laws for that impermissible end. The right to think is the beginning of freedom . . . .")*; see also* John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. Cal. L. Rev. 1203, 1217-18 (1977) (concluding that "[i]f the first amendment serves to protect free trade in the dissemination of ideas and information, it must also protect the necessary preconditions of speech, such as the production of ideas and information through research.") (footnote omitted).

The serious constitutional violation raised by these patent claims provides an additional reason for the Court to find the claims invalid. The Court should apply the Patent Act to these claims in a manner consistent with constitutional bounds.

II. A Preliminary Injunction Would Severely Harm the Public Interest.

Because Myriad's patents are invalid under Section 101, the public interest is not served by granting the preliminary injunction. *See Abbott Labs. v. Andrx Pharm.*, *Inc*., 452 F.3d 1331, 1348 (Fed. Cir. 2006). While a "court should not be reluctant to use its equity powers once a party has so clearly established his patent rights," *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983), "[t]he converse is also true, that a court should be cautious to use its equity powers when a challenger has so clearly challenged the patent's validity," *Kalipharma, Inc. v. Bristol-Myers Co.*, 707 F. Supp. 741, 757 (S.D.N.Y. 1989).

The public interest should especially weigh against an injunction where the patents are likely to be invalid under Section 101. As the Supreme Court repeatedly has recognized, allowing monopolization of natural phenomena – the basic tools of scientific and technological work – through the grant of a patent might tend to impede innovation more than it would tend to promote it. *Mayo*, 132 S. Ct. at 1293*; see also Lab. Corp. of Am. Holdings v. Metabolite Labs.*,

Inc., 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting). It is particularly vital that a court deny a preliminary injunction where the patents likely claim laws of nature, because scientists will otherwise be barred from innovating using what should properly be in the common domain, for the benefit of the public. The sequences of a person's BRCA1 and BRCA2 genes, "like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none." *Funk Bros.*, 333 U.S. at 130.

Denying an injunction based on public interest in these cases is also appropriate because of the serious, detrimental impact such an order would have on public health. *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547-48 (Fed. Cir. 1995). The Federal Circuit has found that a negative impact on public health is a sound basis for refusing to enter a preliminary injunction. *See Cordis Corp. v. Boston Scientific Corp.*, 99 Fed. App'x. 928, 935 (Fed. Cir. 2004); *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988); *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986). The Federal Circuit affirmed refusals to issue a preliminary injunction where the "strong public interest supports a broad choice" of medical options and concluded that the public interest is harmed when some physicians are denied their choice of medical products due to patent assertion. *Cordis Corp.*, 99 Fed. App'x. at 935-36; *see also Datascope Corp.*, 786 F.2d at 401. The record clearly establishes that allowing Myriad to maintain its monopoly on BRCA genetic testing by granting a preliminary injunction would injure the public health.

First, Myriad's monopoly on testing severely limits the options available to patients for clinical testing. Myriad has prevented full sequencing of these genes by other laboratories, even

when others could do so at lower cost, to confirm results, or to ensure testing quality. Matloff Decl. ¶¶ 6-8; Ledbetter Decl. ¶¶ 14-17, 29; Tait Decl. ¶¶ 40-42; Swisher Decl. ¶ 12, 15. Many women, upon obtaining results from Myriad, wish to get a second opinion before they make life-changing medical decisions, such as obtaining or refraining from prophylactic surgery. Morris Decl. ¶ 5. Women cannot obtain confirmatory testing through other labs except for one small set of mutations. Swisher Decl. ¶¶ 18, 118-21; Matloff Decl. ¶¶ 7-8; Ledbetter Decl. ¶¶ 25, 31-34. Myriad also prevents others from providing testing at a lower price, or for free. Morris Decl. ¶ 4; Leonard Decl. ¶ 28; Matloff Decl. ¶¶ 6, 9-10; Swisher Decl. ¶¶ 12, 123-24. As a result, some patients are unable to access testing due to cost. *See, e.g.*, Swisher Decl. ¶ 91; Matloff Decl. ¶ 10; *see also* Morris Decl. ¶ 7. And Myriad has demonstrated a lack of transparency regarding the analytic sensitivity of its testing. Swisher Decl. ¶¶ 67-68, 88-89, 93; Ledbetter Decl. ¶ 25.

In *Mayo*, the Supreme Court expressed concern about patent claims that "threaten to inhibit the development of more refined treatment recommendations." *Mayo,* 132 S. Ct. at 1302. The same problem is presented here. Myriad is attempting to use its claims on routine methods of screening genes to dictate the standard of care for ascertaining hereditary breast and ovarian risk. This denies both physicians and patients the opportunity to seek out testing options that provide the comprehensive information they need to make major medical decisions. Swisher Decl. ¶¶ 90-93, 100-15, 125-28; Morris Decl. ¶¶ 7-9. For example, Myriad performed tests for thousands of patients over several years that did not identify all clinically significant classes of mutations known to the scientific community and refused requests by others to allow them to offer such testing. Matloff Decl. ¶ 7; Ledbetter Decl. ¶¶ 15-20; Swisher Decl. ¶¶ 78-83. One study found that women with large rearrangement mutations that were not detected by Myriad's

tests, and who were from high risk families, received false negative results 12% of the time. Swisher Decl. ¶¶ 80-81; Ledbetter Decl. ¶¶ 16, 20a. Indeed, Myriad still does not perform rearrangement testing for every patient, charging an additional $700 for large rearrangement testing or BRACAnalysis Large Rearrangement Test ("BART") on top of the $3,340 it charges for the standard "Comprehensive BRACAnalysis," even though national guidelines recommend that patients receive rearrangement testing as part of the standard of care. Swisher Decl. ¶¶ 96-98; Matloff Decl. ¶ 7; *see also* Morris Decl. ¶ 7. Myriad also does not describe the full basis for its interpretation of genetic test results, depriving physicians and their patients of the ability to evaluate the results given. Swisher Decl. ¶ 43; Matloff Decl. ¶ 8; Tait Decl. ¶ 51. Moreover, Myriad's assertion of its patents threatens laboratories that want to include the BRCA1 and BRCA2 genes when clinically assaying the over twenty genes now known to be associated with hereditary risk for breast and ovarian cancer or when using next generation testing methods. *See, e.g.*, Swisher Decl. ¶¶ 101-103; Tait Decl. ¶¶ 40, 42; Ledbetter Decl. ¶¶ 18-20.

Further, because the method claims generically append routine techniques used for screening the BRCA1 and BRCA2 genes to the natural laws governing the relationships between mutations in these genes and the predisposition to breast and ovarian cancer, the claims give Myriad the authority to prevent study of the genes. Myriad's assertion of its patents on the isolated BRCA1 and BRCA2 sequences and basic methods of comparing patients' sequences to reference sequences have stopped and deterred research on the genes. Nussbaum Decl. ¶¶ 19-20; Tait Decl. ¶¶ 40-42; Cho Decl. ¶¶ 15-16. Other gene patents have had the same effect. Over half of all labs surveyed as part of a government-funded study reported "deciding not to develop a new clinical genetic test because of a gene patent or license." Cho Decl. ¶ 10. Another study

found that 46% of surveyed geneticists felt that gene patents had "delayed or limited their research." *Id.* Some geneticists have felt a deep discomfort with conducting research on the two genes because Myriad has sharply limited what it considers to be research and prohibited them from disclosing genetic information to research subjects. Gaede Decl. Ex. B (Ganguly Decl. ¶¶ 4-13); Kimberly Blanton, *Corporate Takeover Exploiting the U.S. Patent System*, Boston Globe Mag., Feb. 24, 2002, at 10 (describing how a Yale researcher's work on breast cancer genes, "once a third of the research in his lab, has been snuffed out by restrictions imposed by a licensing agreement between Myriad and Yale"). And scholars looking closely at gene patents found they had "persistent negative effects on subsequent innovation." Stiglitz Decl. ¶¶ 37-38; Swisher Decl. Ex. L, at 181-83 (Rep. of the Sec'y's Advisory Comm. on Genetics, Health, and Soc'y, Gene Patents and Licensing Practices and their Impact on Patient Access to Genetic Tests (Apr. 2010)). The filing of these infringement actions, which also target basic screening of the BRCA1 and BRCA2 genes, will only further inhibit research.

Relatedly, an injunction would allow Myriad to continue to impede our acquisition of greater knowledge about the BRCA1 and BRCA2 genes. Scientists routinely share information about the importance of particular genes and particular gene mutations. Nussbaum Decl. ¶¶ 27-29; Leonard Decl. ¶¶ 27-28. Because Myriad's patents authorized it to maintain a clinical testing monopoly, Myriad gained control over a huge amount of data on the nature and significance of variants in the BRCA1 and BRCA2 genes. For the last several years, Myriad has refused to share that data with the scientific community. Swisher Decl. ¶¶ 34-38; Ledbetter Decl. ¶¶ 35-36; Nussbaum Decl. ¶¶ 27-40. Myriad's conduct flies in the face of the professional ethical standards set out by the American Medical Association, which calls on laboratories, researchers

and providers to publicly share data on genetic variants. Ledbetter Decl. ¶¶ 41, 44, Exs. G and H; Nussbaum Decl. ¶¶ 35-39. Defendants have already committed to sharing the data they obtain. Swisher Decl. ¶ 39; Chao Decl. ¶¶ 62-64. Unless additional labs are able to engage in testing, the scientific community will continue to be stymied in learning more about the genes, particularly about those genetic alterations whose significance is still unknown; these mutations are more likely to occur in patients of African, Hispanic, and Asian descent. Nussbaum Decl. ¶¶ 69-71; Tait Decl. ¶ 51. If Myriad is allowed to control what testing is performed on the BRCA1 and BRCA2 genes, it will not only command the law of nature that is a person's genetic code, but also the laws of nature relating to how these genes function in tandem with other genes and genetic factors and their relationships to diseases other than breast and ovarian cancer – key scientific insights required for the development of personalized medicine. Swisher Decl. ¶¶ 107-10; Tait Decl. ¶¶ 50-51.

Lastly, these patents preclude scientists from engaging in foundational scientific activities that are the first steps toward the development of new drugs, instruments, and treatment methods. Although the genetic testing Myriad offers is a useful service, this value is dwarfed by the potential applications of the claims asserted here to the design of new therapeutics, biomedical devices and instruments, and sequencing technologies. Ledbetter Decl. ¶¶ 19-21, 27, 38; Swisher Decl. ¶ 25; Tait Decl. ¶ 52; Stiglitz Decl. ¶¶ 35-36. Some of these new applications might relate to breast and ovarian cancer, but many will not.[6] Further, such applications are

[6] The BRCA genes have been linked to other cancers, including prostate and pancreatic. *See, e.g.*, Srinath Sundararajan et al., *The Relevance of BRCA Genetics to Prostate Cancer Pathogenesis and Treatment*, 9 Clinical Advances Hematology & Oncology 748 (2011); Kathleen M. Murphy et al., *Evaluation of Candidate Genes MAP2K4, MADH4, ACVR1B and*

likely to involve areas of inquiry untouched by Myriad. Yet, they all are precluded by this method claim if they rely on the basic steps of amplifying part of the BRCA1 gene using simple primers and sequencing the amplified nucleic acids. As in *Mayo*, these claims, unlike a claim on a drug, stand in the way of a scientist who wants to develop innovative applications that also rely on the basic steps of amplifying and sequencing. *See* 132 S. Ct. at 1302-03.

The negative consequences for public health of Myriad's monopoly led the twenty plaintiffs in the *AMP* litigation, including organizations representing over 150,000 medical professionals, geneticists, patients, and patient advocates, to file the *AMP* litigation. The United States filed a brief, opposing patent claims approved by its own Patent Office, stating that "[t]he extent to which basic discoveries in genetics may be patented is a question of great importance to the national economy, to medical science, and to the public health." Brief for United States as Amicus Curiae Supporting Neither Party at 1, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406). Moreover, an additional 89 different organizations and individuals filed 58 amicus briefs in the district court, Federal Circuit, and Supreme Court opposing Myriad's patent claims, and the vast majority of these briefs discussed the detrimental effects on public health. *See, e.g.*, Brief for American Medical Ass'n et al. as Amici Curiae Supporting Petitioners at 8, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398) ("Myriad's exclusive control has led to the misdiagnosis of patients and has precluded the deployment of improved genetic tests."); Brief for Canavan Foundation et al. as Amici Curiae Supporting Petitioners at 6, Ass'n for

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BRCA2 in Familial Pancreatic Cancer: Deleterious BRCA2 Mutations in 17%, 62 Cancer Res. 3789 (2002).

Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398) ("the Federal Circuit's decision authorizes patent practices that will severely compromise efforts in the U.S. to diagnose and treat chronic and life-threatening diseases. The adverse effects of gene patents on science and healthcare are profound and wide ranging.").

The decision on the preliminary injunction motions will not only affect Ambry and Gene by Gene, but will also send a strong message to the larger scientific and medical communities. Many commercial and academic laboratories began or were preparing to offer BRCA1 and BRCA2 testing following the *AMP* Supreme Court decision. Myriad's litigation to maintain its legally invalid monopoly on accessing BRCA1 and BRCA2 genetic information is likely to have a major chilling effect on the willingness of others to engage in testing, as pathologists, geneticists, and laboratories weigh the enormous costs of defending a patent infringement suit.[7] This Court's decision on the preliminary injunction motions will therefore impact whether or not patients and their physicians and genetic counselors have the option of seeking testing from the numerous laboratories that are fully capable and willing to provide clinical testing of these genes and whether scientists can freely engage in research without fear of liability.

[7] *See* Nick Mulcahy & Roxanne Nelson, *BRCA Wars Underway; Senator Wants NIH Action*, Medscape Medical News (July 26, 2013), http:www.medscape.com/viewarticle/808425_2 (describing one laboratory's decision to further investigate whether to offer testing following the filing of these suits); Bradley J. Fikes, *Unanswered Questions with Gene Patent Ruling*, U-T San Diego (July 31, 2013), http://www.utsandiego.com/news/2013/Jul/31/tp-unanswered-questions-with-gene-patent-ruling/ (explaining that Myriad is "well known as happy to litigate" against geneticists); Timothy B. Lee, *Why Are Universities Trying to Limit Access to Breast Cancer Tests*, Wash. Post (July 15, 2013), http://www.washingtonpost.com/blogs/wonkblog/wp/2013/07/15/why-are-universities-trying-to-limit-access-to-breast-cancer-tests/ (raising questions as to whether Myriad's new lawsuits indicate a new type of patent trolling).

CONCLUSION

For the foregoing reasons, Myriad's preliminary injunction motions should be denied.

Respectfully submitted,

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