

Nos. 14-1361, -1366

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

IN RE BRCA1- AND BRCA2-BASED HEREDITARY
CANCER TEST PATENT LITIGATION

UNIVERSITY OF UTAH RESEARCH FOUNDATION, THE
TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,
HSC RESEARCH AND DEVELOPMENT LIMITED PARTNERSHIP,
ENDORECHERCHE, INC., AND MYRIAD GENETICS, INC.,

Plaintiffs-Appellants,

v.

AMBRY GENETICS CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court for the Central District of
Utah in consolidated case No. 2:13-cv-00640-RJS, Judge Robert J. Shelby.

**SUPPLEMENTAL BRIEF OF THE AMERICAN CIVIL LIBERTIES
UNION, ASSOCIATION FOR MOLECULAR PATHOLOGY,
BREAST CANCER ACTION, PUBLIC PATENT FOUNDATION,
AND AARP AS *AMICI CURIAE* IN SUPPORT OF APPELLEE**

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September 29, 2014

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

University of Utah Research Foundation, et al., v. Ambry Genetics Corporation
No. 14-1361, -1366

CERTIFICATE OF INTEREST

Counsel for Amici Curiae, American Civil Liberties Union et al., certifies:

1. The full name of every party or amicus represented by me is:
American Civil Liberties Union Foundation, Association for Molecular Pathology, Breast Cancer Action, Public Patent Foundation
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:
Same as above
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the amici curiae represented by me are:
None
4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:
Sandra S. Park; Lenora M. Lapidus
American Civil Liberties Union Foundation

Daniel B. Ravicher
Public Patent Foundation (PUBPAT)

[Please note: Barbara Jones of AARP Foundation Litigation represented additional amicus AARP on the same amici brief]

September 29, 2014
Date

/s/ Sandra S. Park
Signature of counsel
Sandra S. Park

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

University of Utah Research Foundation, et al., v. Ambry Genetics Corporation
No. 14-1361, -1366

CERTIFICATE OF INTEREST

Counsel for Amicus Curiae, AARP, certifies:

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

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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:

Same as above

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the amici curiae represented by me are:

None

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

Barbara Jones, AARP Foundation Litigation

[Please note: Sandra S. Park, Lenora M. Lapidus, American Civil Liberties Union Foundation and Daniel B. Ravicher, Public Patent Foundation (PUBPAT) represented other amici on the same brief]

September 29, 2014
Date

/s/ Barbara Jones
Signature of counsel
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STATEMENT OF INTEREST OF AMICI

Amici were counsel, plaintiffs, or amici in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) [hereinafter, “AMP”] and thus are well-positioned to inform the Court about the issues raised in this case. They previously filed a brief containing detailed descriptions of each *amicus*' interest, which is adopted here. Br. of Amici Curiae ACLU, et al., 1-2, ECF No. 51. *Amici* file this supplemental brief pursuant to the invitation of this Court in its September 11, 2014 order, ECF No. 73, and with the consent of the parties.

Amici confirm, pursuant to Rule 29(c)(5), that (a) no counsel to any party authored this brief, in whole or in part; (b) no party or party's counsel contributed money intended to fund preparing or submitting the brief; and (c) no person other than *amici* and their counsel contributed money intended to fund preparing or submitting this brief.

ARGUMENT

The Supreme Court's decision in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), soundly rejects the legal arguments presented by Myriad to this Court and is additional compelling precedent that supports the district court's finding of a substantial Section 101 patent-eligibility question. First, *Alice* confirmed that the inventive concept requirement is not satisfied by shorthand approaches to Section 101. While Myriad urged this Court to accept its claims

based on the incorporation of physical steps, generic physical embodiment, or because the “inventive” element is a previously undisclosed law of nature, *Alice* dismissed these criteria as thresholds for patent-eligibility. Second, contrary to Myriad’s assertions that pre-emption is not a test for patent-eligibility, Myriad Opening Br. 37, ECF No. 33; Myriad Reply Br. 8, ECF No. 61, the Supreme Court declared that pre-emption animates its Section 101 analysis. *Alice Corp.*, 134 S. Ct. at 2354, 2358. *Alice* further highlighted how the pre-emption standard focuses on whether the patent claim disproportionately ties up uses of the product of nature, law of nature, or abstract idea, as Myriad’s claims do. Under *Alice* and prior Supreme Court decisions, the method and primer claims do not survive Section 101 scrutiny and the district court correctly denied Myriad’s preliminary injunction motion.

I. MYRIAD’S PATENT CLAIMS DO NOT SATISFY *ALICE*’S INVENTIVE CONCEPT REQUIREMENT.

Alice elaborated on the inventive concept that is required to cross the Section 101 threshold. The Supreme Court instructed that the elements of a claim must be examined to determine whether it contains an inventive concept sufficient to transform the underlying product of nature, law of nature, or abstract idea into a patent-eligible application. *Id.* at 2357. Citing *Mayo*, *Alice* explained that transformation into a patent-eligible invention requires more than reciting the law of nature and adding the words “apply it,” or limiting the use of the abstract idea or

law of nature to a particular technological environment. *Id.* The incorporation of the element of computer implementation, without more, could not transform the abstract idea contained in the claims because of the widespread use of computers. “Given the ubiquity of computers, wholly generic computer implementation is not generally the sort of ‘additional feature[e]’ that provides any practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself.” *Id.* at 2358 (citations omitted).

Alice specifically rebuffed the notion that physical steps or physical embodiment of the unpatentable subject matter would satisfy Section 101. The Court flatly stated that “[t]he fact that a computer ‘necessarily exist[s] in the physical, rather than purely conceptual, realm’ is beside the point” when analyzing the method claims involving generic computer implementation. *Id.* at 2358-59 (citations omitted). Thus, contrary to Myriad’s arguments, the addition of routine physical steps such as amplifying part of a gene and sequencing it cannot alone comply with Section 101. Myriad Opening Br. 31-32, ECF No. 33. *Alice* makes clear that Myriad’s method claims fall far short of patent-eligibility, because they merely combine widely known physical steps with what this Court concluded in *AMP* were abstract mental processes contained in Patent ‘441, cl. 1. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1334-35 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom. Ass’n for Molecular*

Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013). Similarly, the primer claims suffer from the same problems that plagued Alice's system claims. Just as the system claims "recite a handful of generic computer components configured to implement" the abstract idea of intermediated settlement, the primer claims recite generic primers derived from naturally-occurring DNA that can be used to ascertain a person's BRCA genetic code. *Alice Corp.*, 134 S. Ct. at 2360. There is no "meaningful limitation" to Myriad's claims on primers beyond generically linking the primers to sequencing the BRCA genes, as they cover any use of BRCA primers for PCR.

Alice also rejects Myriad's view that the law of nature, product of nature, or abstract idea itself can serve as the inventive concept. In considering the method claims and their computer implementation, the Supreme Court found that Alice's formulation of a type of intermediated settlement did not rescue its claims even when it was a "method of organizing human activity, not a 'truth' about the natural world 'that has always existed.'" *Id.* at 2356. Here, Myriad has conceded that it did not first develop the general processes of hybridizing, amplifying, or sequencing or making probes or primers. A7528-29, 7531-32. What it added was knowledge of the BRCA1 genetic sequence, a truth about the natural world that has long existed and is indisputably a product and law of nature. It would defy *Alice* to adopt Myriad's argument that Section 101 permits the discovery of a law

of nature – such as the BRCA1 genetic sequence – to qualify as the element that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.” *Alice Corp.*, 134 S. Ct. at 2355 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012)).

Combining the discovery of the sequence with generic biotechnological steps such as hybridizing using probes does not alter this conclusion. In *Alice*, the Court zeroed in on the fact that Prometheus’ claims involved methods well known in the art and an instruction to apply the applicable laws. *Id.* at 2357. The Court did not give any weight to the metabolite levels indicating therapeutic response that Prometheus identified and recited as elements that could, in combination with the other physical steps, merit a finding of patent-eligibility. Likewise, Alice’s claims did not survive scrutiny by adding the idea of a type of intermediated settlement to physical steps of computer implementation. *Id.* at 2357-58. There is no meaningful distinction between the routine, scientifically conventional implementation of its genetic discovery recited by Myriad and the routine computer implementation of intermediated settlement recited by Alice.

II. MYRIAD’S PATENT CLAIMS PRE-EMPT USES OF LAWS AND PRODUCTS OF NATURE, IN VIOLATION OF SECTION 101 AS DESCRIBED IN *ALICE*.

In direct conflict with Myriad’s arguments to this Court, *Alice* places pre-emption at the center of the Supreme Court’s Section 101 analysis. The Supreme Court stated that it has “described the concern that drives this exclusionary [patent-eligibility] principle as one of pre-emption.” *Id.* at 2354. The pre-emption concern “undergirds our § 101 jurisprudence.” *Id.* at 2358. While permitting patents on “building blocks” of human ingenuity such as products of nature, laws of nature, and abstract ideas “would risk disproportionately tying up the use of the underlying’ ideas,” there is “no comparable risk of pre-emption” where the patentee has integrated the building block and transformed it into something more. *Id.* at 2354-55.

Pre-emption under Section 101 does not mean that a patent claim must foreclose every practical application of the underlying abstract idea, product of nature, or law of nature, as Myriad contends. Myriad Reply Br. at 10-11, ECF No. 61. *Alice* did not involve claims that pre-empted *all* uses of the abstract idea of intermediated settlement. The claims incorporated characteristics that could arguably distinguish them from other forms of intermediated settlement, such as computer implementation (rather than recording by hand), the creation of shadow credit and debit records (rather than recording all transactions in a single record),

and adjusting the shadow records after each transaction (rather than at certain time periods). *Alice Corp.*, 134 S. Ct. at 2352 n.2, 2359. Yet, the Supreme Court concluded that Alice’s claims impermissibly tied up the abstract idea of intermediated settlement because “the claims at issue amount to ‘nothing significantly more’ than an instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer.” *Id.* at 2360 (quoting *Mayo*, 132 S. Ct. at 1297).

As in *Alice*, Myriad’s claims violate Section 101 because they tie up use of products and laws of nature, without adding significantly more or transforming them. On its method claims, Myriad has acknowledged that it did not first invent the processes of hybridizing, amplifying, or sequencing using probes or primers. Myriad Opening Br. 34. Yet, it seeks to control all of these basic scientific activities with respect to the BRCA genes because it was the first to identify their complete sequence. The future innovation excluded by the method claims is far greater than the threat posed by Alice’s claims, which at least were confined to a form of intermediated settlement.

Myriad’s primer claims also disproportionately tie up use of a product of nature, BRCA genomic DNA.¹ The primer claims here are defined by the identity

¹ While *Alice* dealt primarily with method claims, there is no doubt that the pre-emption concern articulated by the Supreme Court applies with equal force to all types of patent claims. See *Alice Corp.*, 134 S. Ct. at 2354-55 (citing *Bilski*, *AMP*,

of the primers' sequence with naturally-occurring genomic DNA. Given that the practice and utility of making primers was well-established at the time, Myriad's disclosure of primers derived from the BRCA genes contributed little – beyond the product and law of nature itself – relative to the future innovation foreclosed by the claims. *See Alice Corp.*, 134 S. Ct. at 2354; *Mayo*, 132 S. Ct. at 1303. Unlike a patent on a drug, the primer claims do not confine their reach to particular applications of the law of nature but instead embrace a basic tool of scientific work. *Mayo*, 132 S. Ct. at 1302. This is particularly evident when considering that others already had made primers specific for portions of the BRCA genes prior to Myriad's discovery of the complete BRCA coding region and published papers based on their work. A7528-29.

Alice reinforces the Supreme Court's prohibition on patents that pre-empt use of underlying products of nature, laws of nature, and abstract ideas when the patentee does not transform them into significantly more. The fact that Myriad can assert its claims against other laboratories seeking to examine patients' BRCA genetic information using different methods of genetic analysis, often in conjunction with examining the many other genes associated with hereditary cancer risk, underlines the pre-emptive effect of its patents. At least fifteen

and *Mayo* in its discussion). In considering the system claims at issue in *Alice*, the Supreme Court relied on the same analytical framework it had for the method claims. *Id.* at 2360.

laboratories other than Myriad now provide testing of the BRCA1 and BRCA2 genes. Robert Cook-Deegan & Annie Niehaus, *After Myriad: Genetic Testing in the Wake of Recent Supreme Court Decisions about Gene Patents*, *Current Genetic Med. Rep.*, tbl. 1 (Sept. 11, 2014), *available at* <http://link.springer.com/article/10.1007/s40142-014-0055-5>. Several of these laboratories have not yet been sued by Myriad, but their ability to provide options to physicians, patients, and researchers will surely be harmed if a preliminary injunction issues in this case.

CONCLUSION

For the reasons stated above and in *amici*'s initial brief, the ruling of the district court should be affirmed.

Respectfully submitted,

Dated: September 29, 2014

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**Certificate of Compliance with Type-Volume Limitation,
Typeface Requirements and Type Style Requirements**

1. This brief complies with length requirements of the court order dated September 11, 2014, ECF No. 73, because:

This brief does not exceed 10 pages.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because:

This brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point Times New Roman.

Dated: September 29, 2014

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the Supplemental Brief of the American Civil Liberties Union, Association for Molecular Pathology, Breast Cancer Action, Public Patent Foundation, and AARP as Amici Curiae In Support of Appellee with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the appellate CM/ECF system on September 29, 2014.

Dated: September 29, 2014

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