

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED: 12/17/2014

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

Costs are taxed against the appellant in favor of the appellee under Rule 39. The party entitled to costs is provided a bill of costs form and an instruction sheet with this notice.

The parties are encouraged to stipulate to the costs. A bill of costs will be presumed correct in the absence of a timely filed objection.

Costs are payable to the party awarded costs. If costs are awarded to the government, they should be paid to the Treasurer of the United States. Where costs are awarded against the government, payment should be made to the person(s) designated under the governing statutes, the court's orders, and the parties' written settlement agreements. In cases between private parties, payment should be made to counsel for the party awarded costs or, if the party is not represented by counsel, to the party pro se. Payment of costs should not be sent to the court. Costs should be paid promptly.

If the court also imposed monetary sanctions, they are payable to the opposing party unless the court's opinion provides otherwise. Sanctions should be paid in the same way as costs.

Regarding exhibits and visual aids: Your attention is directed Fed. R. App. P. 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.)

FOR THE COURT

/s/ Daniel E. O'Toole

Daniel E. O'Toole
Clerk of Court

cc: M. Miller Baker
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Jonathan Elliot Singer
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14-1361 - University of Utah Research v. Ambry Genetics Corporation
United States District Court for the District of Utah, Case No. 2:13-cv-00640-RJS, 2:14-md-02510-RJS

**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.

2014-1361, -1366

Appeals from the United States District Court for the
District of Utah in Nos. 2:13-cv-00640-RJS and 2:14-md-
02510-RJS, Judge Robert J. Shelby.

Decided: December 17, 2014

JONATHAN E. SINGER, Fish & Richardson P.C., of Minneapolis, Minnesota, argued for plaintiffs-appellants. With him on the brief were DEANNA J. REICHEL; and GEOFF D. BIEGLER, of San Diego, California. Of counsel on the brief were DAVID G. MANGUM, MICHAEL R. MCCARTHY, KRISTINE E. JOHNSON, and C. KEVIN SPEIRS, Parsons Behle & Latimer, of Salt Lake City, Utah.

WILLIAM G. GAEDE, McDermott Will & Emery LLP, of Menlo Park, California, argued for defendant-appellee. With him on the brief were ERIC W. HAGEN and JAMES W. HILL; M. MILLER BAKER and DANIEL K. GREENE, of Washington, DC, and JOHN C. LOW, of Houston, Texas.

SANDRA S. PARK, American Civil Liberties Union Foundation of New York, New York for amici curiae. With her on the brief was LENORA M. LAPIDUS. Of counsel on the brief was BARBARA JONES, AARP Foundation Litigation of Pasadena, California.

Before PROST, *Chief Judge*, CLEVINGER and DYK, *Circuit Judges*.

DYK, *Circuit Judge*.

Plaintiffs are the University of Utah Research Foundation, The Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc., and Myriad Genetics, Inc. (collectively “Myriad”). Myriad owns U.S. Patent No. 5,753,441 (“the ’441 patent”), U.S. Patent No. 5,747,282 (“the ’282 patent”), and U.S. Patent No. 5,837,492 (“the ’492 patent”), which cover compositions of matter and methods relating to the BRCA1 and BRCA2 genes. Defendant is Ambry Genetics Corporation (“Ambry”), a company that

sells medical kits designed to test for the presence of gene mutations linked to breast and ovarian cancer.

Myriad sought to, *inter alia*, enjoin alleged infringement of six claims of three patents: claims 7 and 8 of the '441 patent, claims 16 and 17 of the '282 patent, and claims 29 and 30 of the '492 patent. Myriad appeals from a decision of the District Court for the District of Utah denying Myriad's motion for preliminary injunction. Because we hold that these claims are directed to ineligible subject matter under 35 U.S.C. § 101, we affirm and remand.

BACKGROUND

The Supreme Court has addressed some of the patents at issue here in its June 13, 2013, opinion in *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013) ("*Myriad*"), as has our court in *Association for Molecular Pathology v. United States Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), and *Association for Molecular Pathology v. Myriad*, 689 F.3d 1303 (Fed. Cir. 2012), *aff'd in part, rev'd in part*, 133 S. Ct. 2107 (2013). This case involves claims of those patents not previously considered by the Supreme Court or by this court. A brief summary of the relevant factual background follows.

In the 1990s, Myriad and its partners discovered the precise locations and sequences of the BRCA1 and BRCA2 genes, mutations of which are linked to hereditary breast and ovarian cancers. By discovering the particular locations and sequences of the genes, Myriad was able to determine the typical sequences of the genes most often found in humans (i.e., the "wild-type" sequence for each), as well as mutations, which depart from the two wild-type sequences. Some mutations are harmless, but other mutations are correlated with an increased likelihood of

developing particular cancers. By testing for the presence of these mutations, doctors can determine whether the patient is particularly prone to developing breast or ovarian cancer. Myriad's efforts to commercialize its discovery through the sale of medical test kits have been successful; to date, Myriad has earned roughly \$2 billion in revenue from the sale of the tests.

The Supreme Court, in its *Myriad* decision, held that claims of the '282 patent directed to isolated DNA were drawn to patent-ineligible subject matter because the isolated DNA strands, which are naturally occurring and separated from the rest of the human genome, were natural phenomena. *See Myriad*, 133 S. Ct. at 2117–19. Thereafter, generic competitors, including Ambry, entered the market for medical kits designed to test for susceptibility to particular kinds of cancer.

On July 9, 2013, Myriad sued Ambry in the United States District Court for the District of Utah and, on that same day, requested a preliminary injunction. Myriad's amended complaint alleges infringement of sixty-six claims across fifteen different patents. The preliminary injunction motion asserted, *inter alia*, the six claims listed above.¹

On March 10, 2014, the district court denied Myriad's motion for preliminary injunction. In a detailed, 106-page opinion, the court found that Myriad was unlikely to

¹ Myriad originally sought to enjoin infringement of four additional claims: claims 2 and 4 of U.S. Patent No. 5,654,155 ("the '155 patent"), claim 5 of U.S. Patent No. 6,951,721 ("the '721 patent"), and claim 4 of U.S. Patent No. 6,033,857 ("the '857 patent"). Myriad no longer pursues those claims as grounds for the preliminary injunction.

succeed on the merits because the claims were likely drawn to ineligible subject matter, although it found that Myriad would likely suffer irreparable harm from the denial of the injunction and the public interest was in equipoise. The court found that the balance of hardships slightly favored Ambry.

The four composition of matter claims now on appeal are directed to primers, which are “short, synthetic, single-stranded DNA molecule[s] that bind[] specifically to . . . intended target nucleotide sequence[s].” J.A. 13. The court held these were likely patent ineligible because they claim so-called products of nature—that is, they claim the same nucleotide sequence as naturally occurring DNA.

The two method claims now on appeal involve comparisons between the wild-type BRCA sequences with the patient’s BRCA sequences. The court reasoned that these method claims were likely ineligible because “the only ‘inventive concepts’ in the[] [m]ethod [c]laims are the patent ineligible naturally occurring BRCA1 and BRCA2 sequences themselves.” J.A. 93. As found by the district court, “the other steps set forth in the method claims are conventional activities that were well-understood and uniformly employed by those working with DNA at the time Myriad applied for its patents” J.A. 94.

We have jurisdiction pursuant to 28 U.S.C. §§ 1292 and 1295. We review the district court’s denial of a motion for preliminary injunction for abuse of discretion, but we review legal issues relating to that denial de novo. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375 (Fed. Cir. 2009); *Globetrotter Software, Inc. v. Elan Computer Grp., Inc.*, 236 F.3d 1363, 1367 (Fed. Cir. 2001). The ultimate question of patent eligibility under

§ 101 is an issue of law, reviewed de novo. *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1333 (Fed. Cir. 2012).

DISCUSSION

I

We consider separately the asserted composition of matter claims and the asserted method claims. We address first the composition of matter claims (the “primer” claims). Claim 16 of the ’282 patent is representative. It is directed to:

A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene.

’282 patent col. 155 ll. 23–29. Claim 17 of the ’282 patent and claims 29 and 30 of the ’492 patent are similar to claim 16 of the ’282 patent.

Our analysis of the primer claims under § 101 is guided by the Supreme Court’s *Myriad* decision. In its 2013 *Myriad* decision, the Supreme Court reviewed claims 1, 2, 5, 6, and 7 of the ’282 patent, claim 1 of U.S. Patent No. 5,693,473, and claims 1, 6, and 7 of the ’492 patent. *Myriad*, 133 S. Ct. at 2113 n.2. Six of the nine claims covered isolated DNA molecules, which are DNA strands that have been separated from the rest of the human genome. The remaining claims, claims 2 and 7 of the ’282 patent and claim 7 of the ’492 patent, covered isolated cDNA molecules, which are synthetically created DNA molecules consisting only of exons—DNA nucleotides that

code for amino acids. *Myriad*, 133 S. Ct. at 2111; *Myriad*, 689 F.3d at 1329 n.12.

The Court held ineligible the isolated DNA claims, explaining: “Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them.” *Myriad*, 133 S. Ct. at 2116. Rather, “Myriad’s principal contribution was uncovering the precise location and genetic sequence of the BRCA[genes].” *Id.* Even if Myriad made a “[g]roundbreaking, innovative, or even brilliant discovery,” *id.* at 2117, that is not enough. With respect to the isolated DNA, “Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.” *Id.* The Court held that “[g]enes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.” *Id.* at 2120.

The cDNA claims, however, were held to be patent eligible under § 101. cDNA is an exon-only sequence, with no introns, that does not occur in nature, “except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA.” *Id.* at 2119. To the extent that the exon-only sequence does not exist in nature, the lab technician “unquestionably creates something new when cDNA is made.” *Id.*

The primers before us are not distinguishable from the isolated DNA found patent-ineligible in *Myriad* and are not similar to the cDNA found to be patent-eligible. Primers necessarily contain the identical sequence of the BRCA sequence directly opposite to the strand to which they are designed to bind. They are structurally identical to the ends of DNA strands found in nature.

Contrary to Myriad’s argument, it makes no difference that the identified gene sequences are synthetically replicated. As the Supreme Court made clear, neither naturally occurring compositions of matter, nor synthetically created compositions that are structurally identical to the naturally occurring compositions, are patent eligible. *Id.* at 2117. After all, as the district court in the earlier *Myriad* case and our opinion in *Myriad* made clear, isolated DNA is routinely synthetically created. See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F. Supp. 2d 181, 217 (S.D.N.Y. 2010) (construing “isolated DNA” to “include both DNA originating from the cell as well as DNA synthesized through chemical or heterologous biological means”); *Myriad*, 689 F.3d at 1313 (explaining that “[i]solated DNA has been cleaved . . . or synthesized to consist of just a fraction of a naturally occurring DNA molecule” and that “isolated DNA results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA”).

Myriad argues that primers are in fact not naturally occurring because single-stranded DNA cannot be found in the human body. But, as the Supreme Court made clear, “separating [DNA] from its surrounding genetic material is not an act of invention.” *Myriad*, 133 S. Ct. at 2117. The Supreme Court held ineligible claims directed to segments as short as 15 nucleotides, the same length as the primer claims at issue here, suggesting that even short strands identical to those found in nature are not patent eligible. Compare ’492 patent col. 170 ll. 32–38, with ’282 patent col. 153 ll. 66–67. This situation is similar to *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1337 (Fed. Cir. 2014). There, we held unpatentable a genetic copy of a naturally occurring organism—Dolly, a cloned sheep—because she “is an exact genetic replica of another sheep and does not possess ‘markedly different

characteristics from any farm animals found in nature.” *Id.* (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)) (punctuation omitted).

Myriad also argues that the sequences, when extracted as primers, have a fundamentally different function than when they are part of the DNA strand. When part of the naturally occurring genetic sequence, DNA “stores the biological information used in the development and functioning of all known living organisms,” but when isolated as a primer, the DNA fragment “prime[s], i.e., . . . serve[s] as a starting material for a DNA polymerization process.” Appellants’ Br. 50–51. In fact, the naturally occurring genetic sequences at issue here do not perform a significantly new function. Rather, the naturally occurring material is used to form the first step in a chain reaction—a function that is performed because the primer maintains the exact same nucleotide sequence as the relevant portion of the naturally occurring sequence. One of the primary functions of DNA’s structure in nature is that complementary nucleotide sequences bind to each other. It is this same function that is exploited here—the primer binds to its complementary nucleotide sequence. Thus, just as in nature, primers utilize the innate ability of DNA to bind to itself.

We do not read the Supreme Court’s opinion in *Myriad* as conferring patent eligibility on composition of matter claims directed to naturally occurring DNA strands under such circumstances. A DNA structure with a function similar to that found in nature can only be patent eligible as a composition of matter if it has a unique structure, different from anything found in nature. *Myriad*, 133 S. Ct. at 2116–17 (citing *Chakrabarty*, 447 U.S. at 309–10). Primers do not have such a different structure and are patent ineligible.

II

We next address the two asserted method claims, claims 7 and 8 of the '441 patent. While we addressed some of the method claims of the '441 patent in our *Myriad* decision, the Supreme Court did not address any method claims. *See* 133 S. Ct. at 2119.

Claim 7, revised to include the language of claim 1, from which it depends, provides:

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 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[,]

wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and detecting the presence of a hybridization product wherein a presence of said product indicates the presence of said allele in the subject.

'441 patent col. 155 ll. 16–25, 57–63.

Claim 8, revised to include the language of claim 1, from which it depends, provides:

A method for screening germline of a human subject for an alteration of a BRCA1 gene which com-

prises 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 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[,]

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.

Id. col. 155 ll. 16–25, 64–67.

Ambry argues that the method claims are ineligible under “a straightforward application” of the Supreme Court decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). Appellee’s Br. 44.

In *Mayo*, the patentee had discovered the relationship between the level of a particular metabolite in a patient’s blood and whether a patient could and should safely be administered additional medication. Specifically, 6–TG metabolite in concentrations in excess of about 400 picomoles per 8×10^8 red blood cells risked toxicity, whereas concentrations of less than about 230 picomoles per 8×10^8 red blood cells risked ineffectiveness. *Mayo*, 132 S. Ct. at 1295. The asserted claims taught that doctors should test the metabolite levels of the patient and, if the patient’s metabolite concentration was less than the 230 picomoles floor, the doctor should increase the dosage; if the concentration was greater than the 400 picomoles cap,

the doctor should decrease the dosage.² The court reiterated that a bare recitation of the natural law was patent ineligible, *id.* at 1296–97, and then went on to consider “whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?” *Id.* at 1297 (emphases in original).

The Court found that the additional elements amounted to little more than a broad command to “apply

² The patent claimed:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6–thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6–thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6–thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6–thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

U.S. Patent No. 6,355,623 col. 20 ll. 10–20.

the law [of nature].” *Id.* Focusing on the “determining” step, the Court explained that “methods for determining metabolite levels were well known in the art” and that “scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of [the drug].” *Id.* at 1297–98. Because the additional steps did little more than instruct the practitioners to apply the natural law in routine and conventional ways, the claim was patent ineligible. *Id.* at 1298.

Ambry argues that *Mayo* is directly on point because the method claims here, as there, simply identify a law of nature (the precise sequence of the BRCA genes, and comparisons of the wild-type BRCA sequences with certain mutations of those gene sequences found in the test subject) and apply conventional techniques. We need not decide if *Mayo* is directly on point here because the method claims before us suffer from a separate infirmity: they recite abstract ideas.

Laws of nature are not the only implicit exception to patentable subject matter identified by 35 U.S.C. § 101. Natural phenomena and abstract ideas are also not patentable. *See Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014).

Recently in *Alice* the Supreme Court reiterated its two-step test to determine patent eligibility for any claims that allegedly encompass abstract ideas. First, “we determine whether the claims at issue are directed to [a] patent-ineligible concept[]. If so, we then ask, ‘what else is there in the claims before us?’” *Id.* at 2355 (quoting *Mayo*, 132 S. Ct. at 1296–97) (citations and punctuation omitted). That is, we next ask whether the remaining elements, either in isolation or combination with the other non-patent-ineligible elements, are sufficient to “trans-

form the nature of the claim’ into a patent-eligible application.” *Id.* at 2355 (quoting *Mayo*, 132 S. Ct. at 1297). Put another way, there must be a further “inventive concept” to take the claim into the realm of patent-eligibility. *Id.* at 2355.

Here, we treat separately the first paragraphs of claims 7 and 8, which describe the comparison of wild-type genetic sequences with the subject’s genetic sequence and correspond to the first step of *Alice*, and the second paragraphs, which describe the techniques to be used in making the comparisons and correspond to the second step of *Alice*.

We have already addressed the first paragraphs—the comparison step—in our own 2012 *Myriad* decision. Claims 7 and 8 at issue here depend from claim 1. Claim 1, which is the first paragraph of claims 7 and 8, is the comparison step.³ In our 2012 decision, we held that claim 1 was patent ineligible because it claimed an ab-

³ Claim 1 reads as follows:

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 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.

⁴441 patent, col. 155 ll. 15–25.

stract mental process of ‘comparing’ and ‘analyzing’ two gene sequences. *Myriad*, 689 F.3d at 1334. We found:

[The] claim thus recites nothing more than the abstract mental steps necessary to compare two different nucleotide sequences: one looks at the first position in a first sequence; determines the nucleotide sequence at that first position; looks at the first position in a second sequence; determines the nucleotide sequence at that first position; determines if the nucleotide at the first position in the first sequence and the first position in the second sequence are the same or different, wherein the latter indicates an alteration; and repeats the process for the next position.

Id.

Here, under our earlier decision, the comparisons described in the first paragraphs of claims 7 and 8 are directed to the patent-ineligible abstract idea of comparing BRCA sequences and determining the existence of alterations. The methods, directed to identification of alterations of the gene, require merely comparing the patient’s gene with the wild-type and identifying any differences that arise. ’441 patent col. 155 ll. 16–25. The number of covered comparisons is unlimited. The covered comparisons are not restricted by the purpose of the comparison or the alteration being detected. Because of its breadth, the comparison step covers detection of yet-undiscovered alterations, as well as comparisons for purposes other than detection of cancer. Even with respect to cancer, the comparisons are not limited to the detection of risk of breast or ovarian cancer. Similar concerns to the ones the Supreme Court expressed in *Myriad* with respect to isolated DNA exist here: allowing a patent on the comparison step could impede a great

swath of research relating to the BRCA genes, and it is antithetical to the patent laws to allow these basic building blocks of scientific research to be monopolized. See *Myriad*, 133 S. Ct. at 2116; see also *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972) (holding that a claim on an algorithm for converting binary-coded decimal numbers into pure binary numbers was not patent eligible because “[t]he claims were not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use”).⁴ The first paragraphs in claims 7 and 8 are therefore unpatentable abstract ideas, as we held in *Myriad*.

Having determined that the comparison steps of claims 7 and 8 are abstract ideas, we move to the second step of *Alice* and ask whether the particular mechanism for the comparisons added by claims 7 or 8 renders the claims patent-eligible. For this step, *Alice* dictates that we ask whether the remaining elements, either in isolation or combination with the other non-patent-ineligible elements, are sufficient to “transform the nature of the claim’ into a patent-eligible application.” *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1297). There must be a further inventive concept to take the claim into the realm of patent-eligibility. *Id.* at 2355. The second paragraph of claim 7 describes the way in which the sequences are compared: they are compared by 1) hybridizing a BRCA gene probe and 2) detecting the presence of a hybridization product. Similarly, claim 8 requires 1)

⁴ The preemptive nature of the claims is not ameliorated even if we accept *Myriad*’s argument that other methods of comparison exist. If the combination of certain routine steps were patent eligible, so too would different combinations of other routine steps.

amplification of the BRCA1 gene and 2) sequencing of the amplified nucleic acids.

The non-patent-ineligible elements of claims 7 and 8 do not add “enough” to make the claims as a whole patent-eligible. The district court found, and Myriad does not challenge, that the elements of the second paragraphs of claims 7 and 8 “set forth well-understood, routine and conventional activity engaged in by scientists at the time of Myriad’s patent applications.” J.A. 93 (internal capitalization removed). Moreover, “[a]ny scientist engaged in obtaining the sequence of a gene in a patient sample would rely on these techniques.” J.A. 95. Myriad does not challenge the district court’s finding that “the claims contain no otherwise new process for designing or using probes, primers, or arrays beyond the use of BRCA1 and BRCA2 sequences in those processes.” Appellants’ Rep. Br. 5 (quoting J.A. 93–94) (alterations omitted). The second paragraphs of claims 7 and 8 do nothing more than spell out what practitioners already knew—how to compare gene sequences using routine, ordinary techniques. Nothing is added by identifying the techniques to be used in making the comparison because those comparison techniques were the well-understood, routine, and conventional techniques that a scientist would have thought of when instructed to compare two gene sequences.

Myriad argues that these claims should be patent eligible because they are similar to claim 21 of the ’441 patent, which Judge Bryson suggested was patent eligible in his separate opinion in our 2012 *Myriad* decision. *Myriad*, 689 F.3d at 1349. There, Judge Bryson indicated that, “[a]s the first party with knowledge of the sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.” *Myriad*, 689 F.3d at

1349 (Bryson, J., concurring in part and dissenting in part) (citing claims found in the '441 patent, the '492 patent, and the '282 patent). The Supreme Court approved of Judge Bryson's general suggestion, directly quoting him for the propositions that "[a]s the first party with knowledge of the BRCA1 and BRCA2 sequences, Myriad was in an excellent position to claim applications of that knowledge," and that "[m]any of its unchallenged claims are limited to such applications." *Myriad*, 133 S. Ct. at 2120. But, nowhere in the opinion did the Court express approval of the individual claims identified by Judge Bryson, much less of claim 21 in particular. Indeed, no method claim was even before the Supreme Court. *Id.* at 2119.

Even if claim 21 of the '441 patent were patent eligible—a question about which we express no view—claim 21 is qualitatively different from the method claims at issue here. Claim 21 claims a method of detecting alterations in which the alterations being detected are expressly identified in the specification by tables 11 and 12.⁵ These

⁵ Claim 21 (revised to include the language of claim 20, from which it depends) provides:

A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 11 and 12 which comprises analyzing a sequence of the BRCA1 gene or BRCA1 RNA from a human sample or analyzing the sequence of BRCA1 CDNA made from mRNA from said sample[,]

wherein a germline alteration is detected by hybridizing a BRCA1 gene probe which specifically hybridizes to an allele of one of said alterations to

tables expressly identify ten predisposing mutations of the BRCA1 gene sequence discovered by the patentees. '441 patent col. 157 ll. 11–17, col. 56 ll. 50–59, col. 60 ll. 7–18. Thus, the detection in claim 21 is limited to the particular mutations the inventors discovered: detecting ten specific mutations from the wild-type, identified as “[p]redisposing [m]utations,” for the specific purpose of identifying increased susceptibility to specific cancers. '441 patent col. 60 ll. 8–19. Claims 7 and 8 are significantly broader and more abstract, as they claim all comparisons between the patient’s BRCA genes and the wild-type BRCA genes. '441 patent col. 155 ll. 16–63. The first paragraphs of claims 7 and 8, as we held in our 2012 *Myriad* opinion, claim abstract comparisons. We hold today that the second paragraphs recite only routine and conventional steps. The claims, therefore, are directed to patent-ineligible subject matter.

CONCLUSION

The claims on appeal are directed to ineligible subject matter in violation of 35 U.S.C. § 101. Therefore, the district court properly denied Myriad’s motion for preliminary injunction. We remand to the district court for an entry of an order consistent with this opinion.

AFFIRMED AND REMANDED

COSTS

Costs to appellee.

RNA isolated from said human sample and detecting the presence of a hybridization product, wherein the presence of said product indicates the presence of said allele in the sample.

'441 patent col. 157 ll. 11–24.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

INFORMATION SHEET

FILING A PETITION FOR A WRIT OF CERTIORARI

There is no automatic right of appeal to the Supreme Court of the United States from judgments of the Federal Circuit. You must file a petition for a writ of certiorari which the Supreme Court will grant only when there are compelling reasons. (See Rule 10 of the Rules of the Supreme Court of the United States, hereinafter called Rules.)

Time. The petition must be filed in the Supreme Court of the United States within 90 days of the entry of judgment in this Court or within 90 days of the denial of a timely petition for rehearing. The judgment is entered on the day the Federal Circuit issues a final decision in your case. [The time does not run from the issuance of the mandate, which has no effect on the right to petition.] (See Rule 13 of the Rules.)

Fees. Either the \$300 docketing fee or a motion for leave to proceed in forma pauperis with an affidavit in support thereof must accompany the petition. (See Rules 38 and 39.)

Authorized Filer. The petition must be filed by a member of the bar of the Supreme Court of the United States or by the petitioner representing himself or herself.

Format of a Petition. The Rules are very specific about the order of the required information and should be consulted before you start drafting your petition. (See Rule 14.) Rules 33 and 34 should be consulted regarding type size and font, paper size, paper weight, margins, page limits, cover, etc.

Number of Copies. Forty copies of a petition must be filed unless the petitioner is proceeding in forma pauperis, in which case an original and ten copies of the petition for writ of certiorari and of the motion for leave to proceed in forma pauperis. (See Rule 12.)

Where to File. You must file your documents at the Supreme Court.

Clerk
Supreme Court of the United States
1 First Street, NE
Washington, DC 20543
(202) 479-3000

No documents are filed at the Federal Circuit and the Federal Circuit provides no information to the Supreme Court unless the Supreme Court asks for the information.

Access to the Rules. The current rules can be found in Title 28 of the United States Code Annotated and other legal publications available in many public libraries.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Questions and Answers

**Petitions for Panel Rehearing (Fed. Cir. R. 40)
and
Petitions for Hearing or Rehearing En Banc (Fed. Cir. R. 35)**

Q. When is a petition for panel rehearing appropriate?

A. Petitions for panel rehearing are rarely considered meritorious. Consequently, it is easiest to first answer when a petition for panel rehearing is not appropriate. A petition for panel rehearing should not be used to reargue issues already briefed and orally argued. If a party failed to persuade the court on an issue in the first instance, they do not get a second chance. This is especially so when the court has entered a judgment of affirmance without opinion under Fed. Cir. R. 36, as a disposition of this nature is used only when the appellant/petitioner has utterly failed to raise any issues in the appeal that require an opinion to be written in support of the court's judgment of affirmance.

Thus, as a usual prerequisite, the court must have filed an opinion in support of its judgment for a petition for panel rehearing to be appropriate. Counsel seeking panel rehearing must be able to identify in the court's opinion a material error of fact or law, the correction of which would require a different judgment on appeal.

Q. When is a petition for rehearing en banc appropriate?

A. En banc decisions are extraordinary occurrences. To properly answer the question, one must first understand the responsibility of a three-judge merits panel of the court. The panel is charged with deciding individual appeals according to the law of the circuit as established in the court's precedential opinions. While each merits panel is empowered to enter precedential opinions, the ultimate duty of the court en banc is to set forth the law of the Federal Circuit, which merits panels are obliged to follow.

Thus, as a usual prerequisite, a merits panel of the court must have entered a precedential opinion in support of its judgment for a petition for rehearing en banc to be appropriate. In addition, the party seeking rehearing en banc must show that either the merits panel has failed to follow decisions of the Supreme Court of the United States or Federal Circuit precedential opinions, or that the

merits panel has followed circuit precedent, which the party seeks to have overruled by the court en banc.

Q. How frequently are petitions for panel rehearing granted by merits panels or petitions for rehearing en banc granted by the court?

A. The data regarding petitions for panel rehearing since 1982 shows that merits panels granted some relief in only three percent of the petitions filed. The relief granted usually involved only minor corrections of factual misstatements, rarely resulting in a change of outcome in the decision.

En banc petitions have been granted less frequently. Historically, the court has initiated en banc review in a few of the appeals decided en banc since 1982.

Q. Is it necessary to have filed either of these petitions before filing a petition for certiorari in the U.S. Supreme Court?

A. No. All that is needed is a final judgment of the Court of Appeals.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2014-1361, -1366

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.

Appeals from the United States District Court for the District of Utah in Nos. 2:13-cv-00640-RJS and 2:14-md-02510-RJS, Judge Robert J. Shelby.

MANDATE

In accordance with the judgment of this Court, entered December 17, 2014, and pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure, the formal mandate is hereby issued.

FOR THE COURT

/s/ Daniel E. O'Toole

Daniel E. O'Toole
Clerk of Court