
**United States Court of Appeals
for the Federal Circuit**

THE ASSOCIATION FOR MOLECULAR PATHOLOGY,
THE AMERICAN COLLEGE OF MEDICAL GENETICS,
THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY,
THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD,
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BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD,
PATRICE FORTUNE, VICKY THOMASON, and KATHLEEN RAKER,
Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant,

and

MYRIAD GENETICS, INC.,
Defendant-Appellant,

and

LORRIS BETZ, ROGER BOYER, JACK BRITAIN, ARNOLD B. COMBE,
RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS,
THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG,
in their official capacity as Directors of the University of Utah Research Foundation,
Defendants-Appellants.

*Appeal from the United States District Court for the Southern District
of New York in Case No. 09-CV-4515, Senior Judge Robert W. Sweet.*

**BRIEF FOR AMICI CURIAE MARK J. GATSCHET AND
RICHARD W. KNIGHT IN SUPPORT OF NEITHER PARTY**

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June 15, 2012

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Association for Molecular Pathology v. USPTO and Myriad Genetics

No. 2010-1406

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) amicus certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is: Mark John Gatschet and Richard Warren Knight

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: Mark John Gatschet and Richard Warren Knight

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

4. [X] 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: Mark J. Gatschet of MARK JOHN GATSCHET, P.L.L.C. and Richard W. Knight of R.W.KNIGHT, P.C.

June 15, 2012 Date

Mark J. Gatschet Signature of counsel MARK J. GATSCHET Printed name of counsel

Please Note: All questions must be answered cc:

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INTERESTS OF AMICI CURIAE

Amici Curiae are practicing patent attorneys having professional interests in the reasonable and sensible development of the U.S. patent system but having no personal interest or stake in the outcome of this case.¹

On April 30, 2012, this Court entered an Order inviting *Amicus Curiae* briefs in accordance with Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29 to address a question posed in the Order. The Order further indicated *Amicus Curiae* briefs could be filed without leave of the Court.

QUESTION PRESENTED AND BRIEF ANSWER

The Court identified the following question in its April 30, 2012 Order setting this matter for consideration:

What is the applicability of the Supreme Court's decision in *Mayo v. Prometheus* to Myriad's isolated DNA claims and to method claim 20 of the '282 patent?

Amici Curiae briefly answer as follows. For Myriad's isolated DNA claims, the Supreme Court's decision in *Mayo v. Prometheus* (i.e., the *Prometheus* decision) has only limited applicability. "Isolated" DNA

¹ Pursuant to Federal Circuit Rule 29(c)(5), no party's counsel authored the brief in whole or in part, no party or party's counsel contributed money that was intended to fund preparing or submitting the brief, and no person other than the *amici* or their counsel contributed money that was intended to fund preparing or submitting the brief. This brief is filed pursuant to the Order dated April 30, 2012, which also granted leave for *amici curiae* to file briefs without consent.

molecules claimed by Myriad are not naturally produced without the intervention of man and therefore cannot properly be excluded in view of the *Prometheus* decision from patentable subject matter as “products of nature” (*i.e.*, as patent ineligible “laws of nature”). For compound screening claims like claim 20 of the ‘282 patent, the *Prometheus* decision is not effective for assessing patentable subject matter eligibility. However, the patentable subject matter eligibility of claim 20 is not clearly contradicted by “abstract idea” commentary of the Supreme Court in its *Prometheus* decision. In addition, 35 U.S.C. 103(b) provides statutory support for the subject matter eligibility of claim 20. For compound screening claims like claim 20 (wherein the claim includes as an element a potentially novel gene), the Supreme Court likely intended that its *Prometheus* decision be applied in a way that preserves patent eligibility.

SUMMARY OF THE ARGUMENT

The *Prometheus* decision adopts an expansive “law of nature” exclusion to patentable subject matter eligibility for certain diagnostic method claims. But the DNA molecules claimed by Myriad are “isolated” DNA molecules, which are not found in nature (*i.e.*, these DNA molecules are not naturally produced without the intervention of man). In this light, Myriad’s “composition of matter” claims to “isolated” DNA cannot properly be

excluded from patentable subject matter in view of the *Prometheus* decision as being to “products of nature” (*i.e.*, patent ineligible “laws of nature”). As a result, the *Prometheus* decision has only limited applicability to Myriad’s isolated DNA claims.

In contrast, the *Prometheus* decision may be applicable to compound screening claim 20 of the ‘282 patent. In relevant part, the *Prometheus* decision suggests that “well-understood, routine, conventional [WRC] activity” inquiries be used for assessing the subject matter eligibility of diagnostic method claims that contain a “law of nature.” After applying these WRC activity inquiries, the Supreme Court concluded that the diagnostic method claims of *Prometheus* are patent ineligible. However, WRC activity inquiries are not effective for assessing subject matter eligibility of compound screening claims like claim 20 of the ‘282 patent. The “law of nature”-based WRC activity inquiries of the *Prometheus* decision do not clearly distinguish compound screening claim 20 as being patent ineligible or patent eligible.

Furthermore, statements regarding “abstract ideas,” “algorithms,” “mathematical formulas,” and the like by the Supreme Court in its *Prometheus* decision do not clearly contradict the subject matter eligibility of claim 20 as the claim does not claim a scientific principle, but instead is “tied to specific host cells transformed with specific genes and grown in the

presence or absence of a specific type of therapeutic” wherein the claim is further “tied to measuring a therapeutic effect on the cells solely by changes in the cells’ growth rate.” (*Myriad I*, 653 F.3d at 1358). Hence, “abstract idea” considerations from the *Prometheus* decision do not clearly contradict the patentable subject matter eligibility of compound screening claim 20.

In addition, 35 U.S.C. §103(b) remains largely unaffected by the *Prometheus* decision, and, if the “altered BRCA1 gene causing cancer” element of claim 20 is novel and nonobvious, the statute supports the subject matter eligibility of claim 20. (Note: 35 U.S.C. §103(b) remains in effect until Mar. 16, 2013, when simplified prior art provisions of the America Invents Act, which do not include the text of 35 U.S.C. §103(b), are to take effect.) Congressional intent in adding §103(b) to Title 35 in the “1995 Biotechnology Process Act” seemingly includes an implicit recognition of the subject matter eligibility of compound screening claims like claim 20, which include transformed (or genetically altered) cells as claim elements (at least where the transforming gene sequences of such claims are novel and nonobvious).

For these reasons, the *Prometheus* decision has only limited applicability to Myriad’s isolated DNA claims, and, while WRC activity inquiries under a *Prometheus*-based “law of nature” method of claim analysis do not clearly distinguish claim 20 as being patent ineligible or patent eligible,

other considerations in view of 35 U.S.C. §103(b) and “abstract idea” commentary in the *Prometheus* decision support the subject matter eligibility of claim 20. Accordingly, for compound screening claims like claim 20 (wherein the claim includes as an element a potentially novel gene), the Supreme Court likely intended that the WRC activity inquiries of its *Prometheus* decision be applied in a way that preserves patent eligibility.

ARGUMENT

I. THE *PROMETHEUS* DECISION HAS ONLY LIMITED APPLICABILITY TO MYRIAD’S ISOLATED DNA CLAIMS

The Supreme Court’s *Prometheus* decision adopts an expansive “law of nature” exclusion to patent subject matter eligibility for diagnostic method claims (as demonstrated in section II below). However, the “isolated” DNA molecules claimed by Myriad are not naturally produced without the intervention of man, and therefore these DNA molecules cannot properly be excluded from patentable subject matter as “products of nature” (*i.e.*, as patent ineligible “laws of nature”). As a result, the *Prometheus* decision has only limited applicability to Myriad’s isolated DNA claims. Method claim 20, however, requires a more in-depth inquiry, which is presented herein.

As an aside, it should be noted that *Amici Curiae* recognize that the Supreme Court’s expansive “law of nature” exclusion to patent eligibility for

diagnostic method claims might indicate an openness to a correspondingly expansive “products of nature” exclusion for claims to isolated DNA; however, to be succinct, *Amici Curiae* do not herein develop that conjecture but instead focus on the current state of the law.

II. FOR COMPOUND SCREENING CLAIMS LIKE CLAIM 20, INQUIRIES OF THE *PROMETHEUS* DECISION ARE NOT EFFECTIVE FOR ASSESSING SUBJECT MATTER ELIGIBILITY

The method of claim analysis for determining subject matter eligibility that the Supreme Court uses in its *Prometheus* decision is one that the Court appears to have adopted in modified form from its decision in *Parker v. Flook* (1978). This *Flook*-inspired method makes the *Prometheus* decision potentially much more applicable to claim 20 of the ‘282 patent than to Myriad’s isolated DNA claims. But this method of claim analysis, if applied without qualification, is not effective for assessing patentable subject matter eligibility of compound screening claims like claim 20.

The *Prometheus* method of claim analysis may be described as follows: *if a claimed process uses a “law of nature,” dissect away other steps in the claimed process and ensure that those other steps contain an “inventive concept”* (slip op. at pp. 3 & 13); *but if those other steps consist of only “well-understood, routine, conventional activity” [WRC activity]* (slip op. at pp. 4, 10, 11 & 13), *the claim does not contain an “inventive concept” and,*

consequently, it is patent ineligible (slip op. at p. 3 citing *Flook*). In citing *Flook*, the Court further states:

“[A] process that focuses upon the use of a natural law [must] also contain other elements or a combination of elements, sometimes referred to an ‘inventive concept’ sufficient to ensure that the patent in practice amounts to significantly more than a patent on the natural law itself.”

Id. Because the Supreme Court found, after setting aside the component “law of nature,” that the diagnostic method claims of Prometheus involve (or consist of) only WRC activity, it held these diagnostic method claims to be patent ineligible (slip op. at pp. 3, 4, 8, 11, 18 & 24).

In view of elements in claim 20 of the ‘282 patent that relate to “growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer,” the WRC activity inquiries of the *Prometheus* decision are not effective for assessing patentable subject matter eligibility of claim 20.

The “growing” steps of claim 20 (in *bold italics* font) are as follows:

20. A method for screening potential cancer therapeutics which comprises: *growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer* in the presence of a compound suspected of being a cancer therapeutic, *growing said transformed eukaryotic host cell* in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.

Because a “law of nature” may potentially be tied to these “growing” steps of claim 20, the claim arguably may be patent ineligible under WRC activity inquiries of the *Prometheus* decision. On the other hand, these “growing” steps of claim 20 may be viewed as using cells transformed with a novel gene (*i.e.*, “an altered BRCA1 gene”), and claim 20 arguably may be patent eligible despite the WRC activity inquiries of the *Prometheus* decision.

Therefore, in view of these conflicting outcomes of *Prometheus*-based analyses (as detailed further below), the WRC activity inquiries of the *Prometheus* decision do not clearly distinguish claim 20 as being patent ineligible or patent eligible. Consequently, the method of claim analysis that the Supreme Court adopts in its *Prometheus* decision for patentable subject matter determinations – at least if its WRC activity inquiries are applied without qualification – is not effective for assessing the patent eligibility of compound screening claims like claim 20.

In following the Supreme Court’s teaching in its *Prometheus* decision on an expansive “law of nature” exclusion to patent eligibility for diagnostic method claims, “law of nature” element(s) are easily found in the steps of compound screening claim 20. For example, a key “law of nature” may be found in using the slower growth rate for transformed eukaryotic host cells “containing an altered BRCA1 gene causing cancer” that are grown “in the

presence of a compound suspected of being a cancer therapeutic” to identify that compound as being a cancer therapeutic. In other words, claim 20 may include the following component “law of nature”: a compound that is therapeutic for BRCA1-related cancer slows the rate of growth of transformed eukaryotic host cells containing an altered BRCA1 gene causing cancer.

Importantly, even though such a component “law of nature” in claim 20 may be considered to be a narrow “law of nature,” that status may not remove it from being a “law of nature.” The Supreme Court in its *Prometheus* decision cites with approval its *Flook* decision in noting that “our cases [on patent eligibility] have not distinguished among different laws of nature [for patent eligibility assessments] according to whether or not the principles they embody are sufficiently narrow” (slip op. at p. 20).

With claim 20 including such a “law of nature,” other elements or steps of claim 20 would need to contain an “inventive concept” (*i.e.*, consist of more than only WRC activity). But the other elements of claim 20 (*i.e.*, those elements beyond the “law of nature” that “a compound that is therapeutic for BRCA1-related cancer slows the rate of growth of transformed eukaryotic host cells containing an altered BRCA1 gene causing cancer”) may be viewed as being for only WRC activity. If so, claim 20 may be patent ineligible.

On the other hand, the Supreme Court’s *Prometheus* decision also indicates that the novelty of a “law of nature” component of a claim might contribute to the overall novelty of the claim, and *that this novelty might contribute to the patent eligibility of the claim* (see slip op. at p. 20 from “Third, the Government argues ...” to slip op. at p. 22 stating: “These considerations lead us to decline the Government’s invitation to substitute §§102, 103, and 112 inquiries for the better established inquiry under §101”). In particular, the Supreme Court acknowledges that “the §101 patent-eligibility inquiry and, say, the §102 novelty inquiry might sometimes overlap” (slip op. at p. 21). Under this analysis and with respect to claim 20 of the ‘282 patent, if the claim’s “altered BRCA1 gene causing cancer” element were found to be novel, this novelty might then contribute to the patent eligibility of claim 20.

The novelty of the “altered BRCA1 gene causing cancer” element in claim 20 depends on the novelty of the DNA sequences that this element embraces. Although the “altered BRCA1 gene causing cancer” element in claim 20 is not limited by specific SEQ ID NOS (through which the novelty of the DNA sequences that this element embraces could be more easily assessed), if this “altered BRCA1 gene causing cancer” element were found to embrace novel DNA sequences, claim 20 may be patent eligible.

Therefore, depending on the sections of the *Prometheus* decision that are applied, compound screening claims like claim 20 of the ‘282 patent are potentially either patent ineligible (*e.g.*, as having a “law of nature” focus and as otherwise, under WRC activity inquiries, being without inventive concept), or patent eligible (*e.g.*, as using cells transformed with a novel gene). In view of these contradictory results, the *Prometheus* decision, if its WRC activity inquiries are applied without qualification, would not be effective for assessing the patent eligibility of compound screening claims like claim 20.

III. SUBJECT MATTER ELIGIBILITY OF CLAIM 20 IS NOT CLEARLY CONTRADICTED BY “ABSTRACT IDEA” COMMENTARY IN THE *PROMETHEUS* DECISION

The patent eligibility of claim 20 of the ‘282 patent also warrants scrutiny under the Supreme Court’s discussion in its *Prometheus* decision of “abstract idea” exclusions. Although the Supreme Court frequently makes note of “abstract idea” exclusions in its *Prometheus* decision, the Supreme Court had as a focus the issue of whether the claims of *Prometheus* fall within a “law of nature” exclusion. Understandably, the Supreme Court’s holding (*i.e.*, that the diagnostic method claims of *Prometheus* lack subject matter eligibility for essentially claiming patent ineligible “laws of nature”) does not directly follow from its discussion of “abstract idea” exclusions. Nonetheless,

this discussion is informative, and the subject matter eligibility of claim 20 is not clearly contradicted by the content of this discussion.

On this theme, the Supreme Court in its *Prometheus* decision twice quotes a rule from its decisions in *Diamond v. Diehr* (1981) and *Bilski v. Kappos* (2010) that the “prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of the formula to a particular technological environment’” (slip op. at pp. 4 and 9). Furthermore, the Court also quotes *Diehr* for a related rule that “the prohibition against patenting abstract ideas ‘cannot be circumvented by’ ... adding ‘insignificant post-solution activity’” (slip op. at p. 10). After noting that in *Bilski* “[t]he Court held that the described ‘concept of hedging’ was ‘an unpatentable abstract idea,’” the Court reiterates that “*Flook* established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable” (slip op. at p. 10).

For these reasons, claim 20 of the ‘282 patent does not appear to be in danger of running afoul of any of these rules concerning “abstract idea” exclusions from patent eligibility. Claim 20 is not clearly claiming an “abstract idea” that is limited to a particular technological environment, nor is claim 20 clearly reciting an “abstract idea” to which an insignificant post-solution activity is added (or token post-solution components are added).

Thus, “abstract idea” content from the *Prometheus* decision simply does not clearly contradict the patent eligibility of compound screening claim 20.

IV. 35 U.S.C. §103(b) SUPPORTS PATENT ELIGIBILITY FOR CLAIM 20

Statute 35 U.S.C. 103(b) is largely unaffected by the *Prometheus* decision, and, as noted previously, this statute seemingly supports the patentable subject matter eligibility of claim 20 of the ‘282 patent (particularly if the “altered BRCA1 gene causing cancer” element of claim 20 is novel and nonobvious, as explained below). This statute remains in effect until Mar. 16, 2013, when simplified prior art provisions of the America Invents Act (which do not include the text of 35 U.S.C. 103(b)) are to take effect. Congressional intent in adding §103(b) to Title 35 in the “1995 Biotechnology Process Act” arguably includes an implicit recognition of patentable subject matter eligibility for compound screening claims like claim 20, which include transformed (or genetically altered) cells as elements (again particularly where a gene used for cell genetic alteration is novel and nonobvious; in particular, §103(b)(1) concerns: “a biotechnological process *using* or resulting in *a composition of matter* that is *novel* under section 102 and *nonobvious* under subsection (a) of this section ...”)(emphasis added).

The compound screening method of claim 20 would appear to be a biotechnological process within the meaning of 35 U.S.C. 103(b) in that it is a

method of “using a transformed [*i.e.*, a genetically altered] eukaryotic host cell containing an altered BRCA1 gene causing cancer” in which that altered BRCA1 gene causing cancer is expressed for compound screening purposes. In particular, if the “altered BRCA1 gene causing cancer” element of claim 20 is novel and nonobvious, the compound screening method of claim 20 would appear to fall squarely within the provisions of 35 U.S.C. 103(b). In this light, the patentable subject matter eligibility of compound screening claims like claim 20 is supported statutorily under 35 U.S.C. 103(b).

V. THE *PROMETHEUS* DECISION SHOULD BE APPLIED IN A WAY THAT PRESERVES SUBJECT MATTER ELIGIBILITY FOR CLAIM 20

Review under “abstract idea” commentary in the *Prometheus* decision (and under the intent of Congress in adding §103(b) to Title 35) also provides indications of the subject matter eligibility of compound screening claims like claim 20 (particularly where the claim includes as an element a potentially novel gene). For method claim 20, the Supreme Court likely intended that its *Prometheus* decision be applied in a way that preserves the claim’s patent eligibility even though the claim has a “law of nature” focus and ostensibly falls short under WRC activity inquiries of *Prometheus*.

Thus one initial solution is to exempt compound screening claims like claim 20 (*i.e.*, process claims that contain, as part of a “law of nature” step, a

potentially novel gene) from *Flook*-inspired WRC activity inquiries under *Prometheus*.

CONCLUSION

Amici Curiae respectfully conclude that the *Prometheus* decision has only limited applicability to Myriad's isolated DNA claims, and that the *Prometheus* decision is not effective for assessing the patent eligibility of method claim 20. But in view of other indications of patent eligibility for method claim 20, the Supreme Court likely intended that its *Prometheus* decision be applied to claim 20 in a way that preserves its patent eligibility.

If questions should arise about this conclusion or our analysis, please do not hesitate to contact us.

Respectfully submitted,



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June 15, 2012

No. 2010-1406

**United States Court of Appeals
for the Federal Circuit**

ASSOCIATION FOR MOLECULAR V PTO, 2010-1406

CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr. being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Mark J. Gatschet, *Amicus Curiae*, to print this document. I am an employee of Counsel Press.

On the **15th Day of June 2012**, I served the within **Brief of Amici Curiae Mark J. Gatschet and Richard W. Knight** upon:

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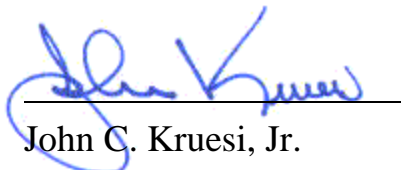
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Additionally, counsel for Amici known to be appearing at the time of filing will be emailed a copy of this brief.

Unless otherwise noted, 12 copies have been filed with the Court on the same date via hand delivery.

June 15, 2012


John C. Kruesi, Jr.