No. 2010-1406

IN THE 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, ARUP A GANGULY, Ph.D, WENDY CHUNG, MD, Ph.D, HARRY OSTRER, MD, DAVID L EDBETTER, Ph.D, STEPHEN WARREN, Ph.D, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION,

Defendant,

MYRIAD GENETICS, INC.; LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND G ESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMPARKS, 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

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

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Hayden, Nanopore genome sequencer makes its debut, Nature News, February

nucleotide sequences that do not exist in nature — are patent-eligible subject matter under 35 U.S.C. § 101, isolated but otherwise unaltered genomic DNA molecules are unpatentable products of nature.

With respect to the challenged composition claims, a panel of this Court unanimously held that cDNA molecules are patent-eligible, but divided regarding the patent eligibility of isolated but otherwise unmodified DNA. See 653 F.3d 1329 (Fed. Cir. 2011).

2. After this Court denied cross-petitions for panel rehearing, appellees filed a petition for a writ of certiorari. While the petition was pending, the Supreme Court issued its decision in Mayo. There the Court addressed the validity of a process patent that "purport[ed] to apply" what the Court concluded were "natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects." Mayo, 132 S. Ct. at 1294. The Court concluded that the patented claims were invalid because they effectively claimed the natural law that they described.

The Court began its analysis by reiterating the longstanding "implicit exception" to patent eligibility under § 101 for "[l]aws of

nature , natura l phenomena, and abstract ideas." Id. at 1293 (int ernal quot at ion m arks omit ted) (cit ing, e.g., Diam ond v. Chakra bart y, 447 U.S. 303, 309 (1980)). "ap natura

1296-97. The Court emphasized that a process utilizing a natural law is not patent-eligible "unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." Id. at 1297.

After issuing its decision in Mayo, the Supreme Court granted the petition in this case, vacated this Court's judgment, and remanded for further proceedings in light of Mayo. See 132 S. Ct. 1794.

ARGUMENT

Mayo Supports The View That Isolated Genomic DNA Is Not Patent-Eligible Under 35 U.S.C. § 101.

As the United States explained in its original and original

(discussing this "important implicit exception" to § 101). As discussed below, the Court's guidance on policing this limitation reinforces the conclusion that Myriad cannot patent DNA it discovered in and isolated from nature.

I. Mayo Implies That A Composition Claim Is Not Patent-Eligible If It Effectively Precludes The Public From Using A Product Of Nature.

The principal issue in this appeal is whether composition claims for isolated genomic DNA are directed to patent-eligible subject matter or, instead, whether such claims are impermissible attempts to patent products of nature.[1] The answer to that question turns on the relationship between the claimed compositions and naturally occurring DNA.

To be eligible for a patent, a claimed composition must be "human-made" and "markedly different" from a naturally occurring substance. Chakrabarty, 447 U.S. at 310, 313. The members of this panel agreed on that basic proposition. See 653 F.3d at 1350-51 (Lourie, J.); id. at 1359-60 (Moore, J., concurring in part); id. at 1379 (Bryson, J., concurring in part and dissenting in part). But the panel

[1] Plaintiffs also challenge Myriad's method claims. See Appellees' Br. at 52-60. The United States takes no position on this issue.

members parted company in applying that general principle to the composition claims at issue here. More specifically, the panel members disagreed about whether distinctions between isolated and genomic DNA are significant enough to render isolated DNA "markedly different" for § 101 purposes.

The Supreme Court's decision in Mayo provides guidance regarding that question. To be sure, that guidance is indirect. Mayo involves process, not composition, claims, and the Court's analysis focuses on the standards for determining whether a claimed process effectively claims a law of nature. Thus, Mayo does not directly address the criteria to be used in deciding the parameters of the product-of-nature exception, and every nuance of the Court's analysis may not mechanically extend to products of nature. Nevertheless, in at least one respect, Mayo provides an important point of reference for deciding whether a claimed composition and a naturally occurring substance are "markedly different" for purposes of § 101. cu rring substb 0D@ …` !0rpane

laws. See, e.g., 132 S. Ct. at 1294 (warning "against upholding patents that claim processes that too broadly preempt the use of a natural law"); id. at 1301 ("The Court has repeatedly emphasized . . . that patent law not inhibit further discovery by improperly tying up the future use of laws of nature."); ibid. (warning against the "danger that the grant of patents that tie up [natural laws'] use will inhibit future innovation premised upon them"). To avoid that outcome, the Court held that a "process reciting a law of nature" is not patent-eligible "unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." Id. at 1297. With respect to the method claims in Mayo, the Court concluded that "the steps add nothing of significance to the natural laws themselves" and "amount[] to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients." Id. at 1298, 1302. For that reason, upholding such claims "would risk disproportionat

(discussing "basic underlying concern that these patents tie up too much future use of laws of nature").[2]

The concerns implicated by patent claims that "t[ie] up the use of the underlying natural laws," and thereby "inhibit [] their use in the making of further discoveries," may also be present when a patent contains a composition claim that relates to a product of nature. Products of nature, like laws of nature, are "manifestations of * * * nature" that are "free to all men and reserved exclusively to none." Chakrabarty, 447 U.S. at 309 (internal quotation marks omitted). A composition claim that effectively prevents the public from studying and making use of a product of nature is just as objectionable, and for the same underlying reason, as a method claim that effectively prevents the public from studying and exploiting a law of nature.

Mayo thus suggests one way (though by no means the exclusive way) for determining whether proffered differences between a claimed

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[2] The Court also pointed to the conventional nature of the steps added to the underlying nature law in the challenged claims. See, e.g., 132 S. Ct. at 1294. The Court did not suggest, however, that a patent is invalid simply because it incorporates a known processor other invention. Such a rule would be at odds with 35 U.S.C. § 100(b), which defines "process" to include "a new use of a known process, machine, manufacture, composition of matter, or material."

composition and a product of nature suffice to render the composition "markedly different" under Chakrabarty and related precedents. Mayo suggests that a court should ask whether a patent on the claimed composition has the practical effect of preempting the public's ability to use the product of nature itself. Issuance of a patent should leave others free to study and exploit the natural substance and to devise other alterations to it. If it does not, that is a strong indication that the differences between the claimed composition and the product of nature are insufficient to render the composition patent-eligible.

In Chakrabarty, for example, the patent the Supreme Court upheld on a genetically altered bacterium would not have interfered with the public's ability to investigate or further modify the original bacterium or to experiment on the DNA plasmids that the patentee inserted into it to create the "new bacterium." Chakrabarty

native DNA and pose little risk of preempting study of naturally occurring DNA. See U.S. Amicus Br. at 15-16; A134.

In contrast, patents on isolated but otherwise unmodified DNA would significantly impair the public's ability to study and make use

process of removing the product from its natural environment necessarily results in creation of the patented composition (and thus in infringement of the patent) — as is the case here[4] — the patent on the composition is in practical effect a patent on the product of nature itself. The "markedly different" standard is a flexible one, but Mayo suggests that it should interpreted and administered in a way that avoids this result.[5] Thus, Mayo provides guidance to courts attempting

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could require creation of gene-length segments, thus potentially infringing even Myriad's gene-length isolated DNA claims. See Hayden, Nanopore genome sequencer makes its debut, Nature News, February 17, 2012 (available at http://www.nature.com/news/nanopore-genome-sequencer-makes-its-debut-1.10051, last visited June [illegible]

to determine when a change to a product of nature is "significant" or "marked" enough "in terms of patent law's objectives" to qualify for patent protection. Mayo, 132 S. Ct. at 1299.

The members of this panel all relied on Chakrabarty's "markedly different" rubric but disagreed about how to apply that standard to DNA isolated from nature. See 653 F.3d at 1351-53 (Lourie, J.); id. at 1364-68 (Moore, J.); id. at 1374-75 (Bryson, J.). In light of Mayo, this Court should not rest patent-eligibility on the bare fact that isolating genes or gene segments involves the breaking of chemical bonds, or on the fact that scientists can use small gene segments to exploit the inherent chemical properties of DNA in ways that cannot be done with complete genes.[6] Instead, the Court should also ask whether the

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matter[.]"); id. at 34 (noting that isolated DNA "may have more potential applications than human genes in their natural context," but that "the same is equally true of mined coal, separated cotton fibers, pure metallic lithium, ductile uranium, and other products of nature whose industrial value to mankind likewise arises when they are extracted from their naturally occurring environments").

[6] The patent claims themselves do not refer to the chemical characteristics of isolated DNA invoked by the members of the panel majority. See 653 F.3d at 1351-53, 1361-65. Thus, assuming that the majority's chemical descriptions are accurate, it is clear that those characteristics are simply a consequence of separating DNA from its native environment.

differences identified in the original panel decision are sufficient to leave the public free to study and expl

argument. See id. at 1304-05. Noting that the two sides and their respective amici disagreed over the practical impact of according patent protection to the challenged methods, the Court stated that it did "not find this kind of difference of opinion surprising," since "[p]atent protection is, after all, a two-edged sword" that forecloses some forms of innovation while protecting others. Id. at 1305. The Court expressed reluctance about "departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another." Ibid. The Court thus refused to determine whether it was "desirable" to "increase[] protection for discoveries" concerning "diagnostic laws of nature" specifically. Ibid.

In this case, Myriad has argued that the extension of patent protection to isolated DNA is necessary in order to preserve financial incentives for making DNA discoveries. See, e.g., Myriad Opening Br. at 3-4. Mayo strongly suggests that the judicial inquiry should not focus on industry-specific incentive arguments of this sort, pro or con, and instead that the inquiry should be [illegible]

unpatentable products of nature). The potential incentive effects of allowing private parties to monetize discoveries about a particular naturally occurring product do not alter the boundaries the Supreme Court has set — and in Mayo reinforced — between unpatentable products of nature and patentable creations of man.

CONCLUSION

For the reasons stated above and in the United States' original amicus brief, the Court should reverse the district court's invalidation of the composition claims that are limited to cDNAs and similar man-made constructs, but affirm the district court's conclusion that the claims encompassing isolated human genomic DNA are invalid.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH PAGE LIMITS AND FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

I hereby certify that this amicus brief is 15 pages long and thus complies with the page limit specified in this Court's order of April 30, 2012. I further certify that this brief complies with the type-face requirements set forth in Federal Rule of Appellate Procedure 32(a) because the type face is Century Schoolbook, proportionally spaced, fourteen-point font.

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