No. 2010-1406

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, ARUPA GANGULY, PHD, WENDY CHUNG, MD, PHD, HARRY OSTRER, MD, DAVID LEDBETTER, PHD, STEPHEN WARREN, PHD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH 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 BRITTAIN, 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.

ON 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

PLAINTIFFS-APPELLEES' PETITION FOR PANEL REHEARING

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August 25, 2011

CERTIFICATE OF INTEREST

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

Association for Molecular Pathology; American College of Medical Genetics; American Society for Clinical Pathology; College of American Pathologists; Haig Kazazian, MD; Arupa Ganguly, PhD; Wendy Chung, MD, PhD; Harry Ostrer, MD; David Ledbetter, PhD; Stephen Warren, PhD; Ellen Matloff, M.S.; Elsa Reich M.S.; Breast Cancer Action; Boston Women's Health Book Collective; Lisbeth Ceriani; Runi Limary; Genae Girard; Patrice Fortune; Vicky Thomason; and Kathleen Raker.

2. The name of the real party in interest represented by me is:

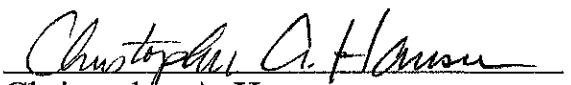
Same as above.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus 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:

American Civil Liberties Union Foundation (Christopher A. Hansen; Sandra S. Park; Lenora M. Lapidus; Aden Fine); Public Patent Foundation (PUBPAT), Benjamin N. Cardozo School of Law (Daniel B. Ravicher; Sabrina Y. Hassan).



Christopher A. Hansen
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POINTS OF LAW AND FACT OVERLOOKED OR MISAPPREHENDED BY THE COURT

Pursuant to Fed. R. App. P. 40, plaintiffs/appellees respectfully move for rehearing by the panel on the grounds that the panel majority erred as a matter of fact and law. More specifically, the majority erred in analyzing the chemical structure of the patented genes and gene fragments without considering (1) that the language of the patents defines the function, not the structure of the patented genes and gene fragments; (2) that gene fragments with the altered chemical structure identified by the Court exist in nature. The panel also erred in denying standing to two other plaintiffs, both of whom have standing under the panel's own standard and that of the Supreme Court.

ARGUMENT

I. THE COURT ERRED IN FAILING TO CONSIDER WHETHER THE DNA FRAGMENTS CLAIMED IN THESE PATENTS ARE PRODUCTS OF NATURE.

The opinion of the Court (authored by Judge Lourie) and the concurrence (by Judge Moore) both carefully analyzed the chemical structure of DNA and concluded that fragments of a chromosome are different chemicals from whole chromosomes and therefore patentable. However, the dispositive legal question in this case is not whether a fragment of DNA is a different chemical from a full chromosome of DNA

but whether the fragments claimed in the patents by Myriad are products of nature. In concluding that the fragments are not products of nature because they are "markedly different" from what exists in nature, Ct. Op. at 41, the majority (Judges Lourie and Moore) relied on facts not in the evidentiary record and failed to consider other, relevant facts clearly establishing that the claimed fragments are products of nature as a matter of both fact and law.

The opinion for the Court upheld the patenting of human genes on the ground that the process of isolation of a gene inevitably requires the breaking of a covalent bond which creates a "portion of a native DNA molecule" that is chemically different from a "naturally occurring DNA molecule." Ct. Op. at 42. Thus, the Court concluded, isolation has created a chemically different (and therefore "markedly different") chemical from "native DNA" as a result of human intervention and the new chemical is therefore patentable subject matter. *Id.* The concurrence relied heavily on the same analysis of the chemistry. Conc. at 9-10 (emphasizing that when DNA is fragmented in the isolation process, the fragments will have different chemical terminations).

The majority's emphasis on the chemical nature of DNA fragments led it into two errors. The majority erroneously ignored the language of the

claims and erroneously ignored the scientific fact that DNA fragments with identical chemical structure are found in nature.

First, the composition claims in the patents are not defined by chemical structure. They are defined by function. Patent '282, claim 1, for example, reaches any chemical that "codes for a BRCA1 polypeptide" (or any fragment of that polypeptide). A-597-98, 19:41-48; 21:1-5 ("The term polypeptide … does not refer to a specific length"). Multiple chemicals with different structures and covalent bonds broken in different places are included in the claims. A-597, 19:37-40 (includes "all allelic variations"), *id.* 53-55 ("polynucleotide compositions…may be chemically or biochemically modified"); A-599, 24:19-21 (nucleic acid sequence need only be 60% similar to claimed sequence); *id.* 24:60 (polypeptide need only be 30% similar "with a naturally occurring protein"). Indeed, the many different chemicals described in each claim of the patent have nothing in common (and nothing to distinguish them from most of the rest of the genome) except that they serve a particular function, *i.e.* they encode a particular protein or a fragment of the protein. And that function (and the chemical differences) are created by nature, not by Myriad. For the majority to therefore find that function is irrelevant or of peripheral relevance, *see* Ct.

Op. at 44; Conc. at 18, to the claims in this case is an error in claim construction.

Second, DNA fragments identical to those claimed in the patents appear in the body. Nature breaks the covalent bonds that hold together the full chromosome, creating two or more fragments. This occurs every time gametes are produced during the normal process of meiotic recombination as well as during the cellular process by which cells make copies of themselves. It also occurs naturally when DNA experiences a double strand break (which then is often repaired). Wolf-Dietrich Heyer *et al*., *Holliday Junctions in the Eukaryotic Nucleus: Resolution in Sight*, 28 Trends in Biochemical Sciences 548 (2003); *see also* Robyn L. Maher *et al*., *Coordination of DNA Replication and Recombination Activities in the Maintenance of Genomic Stability*, J. of Cellular Biochemistry (forthcoming), *available at* http://onlinelibrary.wiley.com/doi/10.1002/jcb.23211/abstract.

The entire fetal and maternal genome can also be found in short fragments in maternal plasma. Y.M. Dennis Lo *et al*., *Maternal Plasma DNA Sequencing Reveals the Genome-Wide Genetic and Mutational Profile of the Fetus*, 2 Science Translational Medicine 61ra91 (2010). Thus, all of the fragments that make up the BRCA1/2 genes can be found in natural

maternal blood with the covalent bonds having been broken and the same chemical terminations as in Myriad's claimed isolated BRCA1/2 DNA. *Id.*

And, DNA fragments, including fragments of the BRCA1/2 genes, can be found in the blood of those suffering from cancer. Maurice Stroun, *et al., Isolation and Characterization of DNA from the Plasma of Cancer Patients*, 23 Eur. J. Cancer Clin. Oncol. 707 (1987). Again, covalent bonds have been broken and terminations altered in nature, creating fragments similar to or identical to the BRCA1/2 genes. Under the analysis of the majority, the fragments in all of these circumstances are different chemicals from the full chromosome. Even if true, that fact is irrelevant. The relevant fact is that multiple fragments of the chromosomes/genes exist in nature - *i.e.* they are products of nature.

To the extent the Court was suggesting that Myriad has patented only two of the fragments, those represented as the BRCA1 and BRCA2 genes, it erred. The patents themselves claim all fragments (and variations) of those genes/chemicals. *E.g.*, A-597, 19:1-19, 41-48; A-600, 25:36-37; A-664, claim 1. The patents use open transitional phrases and thus claim any fragment of DNA that can code for any fragment of a BRCA1/2 polypeptide. *Id*. In addition, certain claims specifically reach smaller fragments of DNA. Conc. at 15.

To the extent the majority considered the existence of the multiple DNA fragments that exist in the body and concluded they were different from those patented by Myriad or are patentable because the scientist determined the length or composition of the isolated fragment, it also erred. *See, e.g.*, Ct. Op. at 45-46; Conc. at 22-23 (rejecting the magic microscope argument because it, unlike the scientist, cannot choose where to make a break). Either view misapprehends the isolation process.

In isolating a gene, DNA is removed from the cell and then fragmented. In the terms of the majority, covalent bonds are broken and terminations altered, creating new chemical structures. The scientist, however, does not decide or control the size or composition of the fragments/chemicals. She does not decide where the covalent bonds should be broken or what the terminations should look like at the 3' and 5' ends. Indeed, if a scientist were to isolate the DNA of a person on Monday, and then do so again on Tuesday, it is likely the fragments would have a different size and composition. Many fragments are likely to include a portion of the BRCA1/2 gene and a portion of the adjacent DNA. These fragments are of random length and composition. Bruce Alberts *et al., Molecular Biology of the Cell* Ch. 8 (4th ed. 2002); Robert L. Nussbaum *et al., Thompson and Thompson Genetics in Medicine* Ch. 4 (7th ed. 2007);

Harvey Lodish *et al.*, *Molecular Cell Biology* Ch. 7-8 (4th ed. 2000); Joseph Sambrook *et al.*, *Molecular Cloning: A Laboratory Manual* (3rd ed. 2000).

In addition, scientists performing isolation generally do not chemically stitch the fragments back together to form longer segments, such as an entire gene. Sequencing generally relies on computers to recreate the gene sequence without creating a molecule or chemical that is an entire gene. *Id.* Thus, the process of determining a gene's sequence does not rely on reassembling the gene in the laboratory.

In short, the chromosomal fragments/chemicals in the bottom of Myriad's test tubes are no more the result of human decision-making than the fragments/chemicals created when there is a naturally-occurring double strand break or in the blood of pregnant women or cancer patients. And, the fragments in all of those situations will be identical to the sequences claimed by Myriad's patents at least some of the time. Even more, the undisputed evidence in this case is that fragments of the BRCA1/2 genes as short as 15 nucleotides can be found throughout the human genome. A-7017-21; 7228-30. Thus a scientist isolating an entirely different chromosome, in order to sequence an entirely different gene, is likely to create a 15-nucleotide fragment identical in chemical composition to a 15-nucleotide fragment from BRCA1/2. Perhaps most importantly, the scientist could not avoid this

result. If the majority's analysis is correct, the scientist isolating any human gene cannot take steps to ensure that she will not infringe Myriad's patents because some of the fragments/chemicals that occur may be identical to those that are fragments of the BRCA1/2 genes. [1]

To the extent the Court held that the full genes and the fragments are all patentable because they have a different chemical structure from anything found in nature, it was simply incorrect. To the extent the concurrence was relying on the fragments having a different structure from anything found in nature, its reliance was misplaced. And, if the claims cover, even in part, any product of nature, they must be found invalid.

The majority overlooked these facts because it relied on scientific facts and/or arguments that were not supported by the record. *See, e.g., Boone v. Chiles*, 35 U.S. 177, 178 (1836) ("By the rules of an appellate court, it can act on no evidence which was not before the court below, or receive any paper that was not used at the hearing."); *Regents of University of Michigan v. Genesearch, L.L.C.*, 81 Fed. Appx. 335, 338 (Fed. Cir. 2003) (the Federal Circuit Court of Appeals "does not review evidence or arguments that were not presented to the trial court in the first instance. The

[1] This is not a § 112 issue. Ct. Op. at 47. Instead it is relevant because if any of the compositions claimed are products of nature, then the entire claim is invalid.

scope of appellate review in this court is limited to the record established in the proceedings before the trial court.")

Myriad did not refer to covalent bonds in the district court. The patents do not use the term to describe the backbone of the chromosome or gene or chromosome fragment. The claims have no express limitations to gene fragments that have had their covalent bonds broken by man, and such an inherent limitation is not supported by the specification, the file history, or any argument Myriad made at any time in this matter. The term does not appear in any of Myriad's briefs or declarations presented to the district court.[2] Myriad did not refer to the relevance or importance of breaking a covalent bond.

Similarly, the patents do not refer to "hydroxyl" termination points (Conc. at 9) existing after isolation. Myriad did not use the word hydroxyl in any brief or declaration presented to the district court. The patents do not refer to "phosphate" or "phosphodiester" in describing termination points existing after isolation. Myriad did not argue that after isolation, BRCA1/2 or any of the fragments contained different termination points. Myriad did

[2] Appellants did refer to covalent bonds in their appellate briefs as part of a descriptive string of terms. Brief for Appellants at 36; Reply Brief at 17. None of the citations to the record in these briefs referred to covalent bonds. For example, the first citation at p. 36 was to the definition of "isolation" in one of the patents. That definition makes no reference to covalent bonds.

not argue that it determines the length or composition of fragments created during isolation or that it chemically stitches together an entire gene. Myriad did not argue that fragments of the BRCA1/2 genes, either covalently bonded to adjoining DNA or not, do not exist in the body. Myriad's argument has been that removing the full genes from all bodily material and removing them from the body makes them patentable because they have been removed from all adjacent chemicals, whether those to which they were bonded covalently or otherwise, *and* that because they have been entirely removed from the body, they can be used.

Had Myriad made the factual assertions and legal arguments on which the majority relies, plaintiffs would have put responses in the record. Those responses would have agreed that covalent bonds are broken as part of the isolation process but placed that concession in the context of the covalent bonds that are broken in the body (and the composition of the resultant fragments) and the covalent bonds that are broken in the isolation process (and the identical composition of the resultant fragments). That submission would have established that the patented items are still products of nature. Given that Myriad did not do so, plaintiffs did not have that opportunity. If the panel believes this case would benefit from declarations as to these

responsive facts, plaintiffs would be happy to provide those declarations. Fed. R. App. P. 10(e)(3).[3]

Because the majority premised its conclusions on the chemical alterations caused during the isolation process and either did not consider (or simply got wrong) the question of whether the altered chemicals are "markedly different" from chemicals found in nature, the majority erred. Even if the chemical alterations deemed significant by the majority are significant, they result in chemicals that are not markedly different from and are at times identical to those found in nature. They are thus not patentable subject matter.

II. THE COURT FAILED TO ACKNOWLEDGE UNDISPUTED FACTS THAT GIVE TWO OTHER PLAINTIFFS STANDING.

The panel found that plaintiff Dr. Ostrer has standing. Ct. Op. at 35. The undisputed record reflects that Dr. Ostrer is a member of the organizational plaintiff American College of Medical Genetics (ACMG). A-

[3] Some of the articles or books cited in this motion were referenced in the trial court; others were not. To the extent they were not previously discussed, they are included in the motion to respond to the new facts and/or arguments raised by the majority. Plaintiffs have cited only well-established scientific evidence in learned treatises. However, if this Court views these citations as expanding the record, it has authority to do so. *Dakota Indus., Inc. v. Dakota Sportswear, Inc.*, 988 F.2d 61, 63 (8th Cir. 1993) (appellate court can supplement a record) (citing *Turk v. United States,* 429 F.2d 1327, 1329 (8th Cir. 1970)); *United States v. Aulet,* 618 F.2d 182, 187 (2d Cir. 1980) (same); *Castle v. Cohen,* 840 F.2d 173, 180 n. 12 (3d Cir. 1988) (same).

1463. The undisputed record reflects that gene patenting is germane to ACMG's purpose. A-1300. Pursuant to well-established Supreme Court law, ACMG therefore has organizational standing. *Warth v. Selden*, 422 U.S. 490, 511 (1975).

In addition, the panel asserted that "[n]one of the plaintiffs besides Drs. Kazazian, Ganguly, and Ostrer, allege that Myriad directed any letters or other communications regarding its patents at them." Ct. Op. at 20. That is simply incorrect. Plaintiff Ellen Matloff's declaration makes clear that she personally had conversations with Myriad in which she was told by Myriad that she and geneticists at Yale would violate Myriad's patents if they performed the tests that she wanted to perform. A-34-5, 1553. The Court held that a plaintiff had standing if Myriad directed "any … communications regarding its patents at them." Under that standard, Ms. Matloff has standing.[4]

[4] Plaintiffs/appellees believe that the majority made other errors with respect to standing and the patentability of the composition claims. Plaintiffs do not waive those contentions. However, in this petition, plaintiffs argue issues raised by the majority opinion for the first time.

CONCLUSION

For these reasons, plaintiffs respectfully ask the panel to rehear the case and find (1) the composition claims are invalid; and (2) the American College of Medical Genetics and Ms. Ellen Matloff have standing.

Dated: August 25, 2011

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ADDENDUM

CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of August, 2011, I caused the original and eleven true and correct copies of the foregoing Plaintiffs-Appellees' Petition for Panel Rehearing to be mailed to the Court via FedEx overnight; two copies to be served upon counsel for Defendants-Appellants via FedEx overnight; and one true and correct copy of the Petition to be served upon the counsel of record listed below via first-class United States mail.

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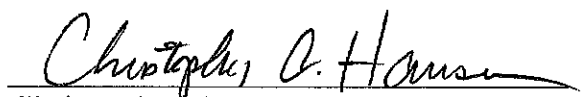

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