No. 12-398

IN THE

Supreme Court of the United States

ASSOCIATION FOR MOLECULAR PATHOLOGY, *et al.*,

Petitioners,

v.

MYRIAD GENETICS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE IN SUPPORT OF NEITHER PARTY

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TABLE OF CONTENTS

Table of Contents

TABLE OF CITED AUTHORITIES

Cited Authorities

Page

RULES

OTHER AUTHORITIES

INTEREST OF THE *AMICUS CURIAE*.[1]

Pursuant to Supreme Court Rule 37.2(a) Fédération Internationale Des Conseils En Propriété Intellectuelle ("FICPI") submits this brief as *amicus curiae* in support of neither party.

Established in 1906, FICPI is a Switzerland-based international and non-political association of approximately 5,000 intellectual property attorneys from over eighty countries, including the United States. *See* About FICPI, http://www.ficpi.org/aboutframe.html (follow "History-Future" hyperlink) FICPI's members are in private practice and their clients include individual inventors as well as large, medium and small companies. Both applicants for IP rights and entities concerned about potential infringement of the claimed subject matter are represented. One of the members' major roles is to advise inventors in intellectual property matters and secure protection for industrial innovation. FICPI supports predictable, balanced global protection of patents, the global harmonization of substantive patent law, and the interests of inventors and the U.S. Patent and Trademark Office (the "PTO") in recognizing a fair scope of patent protection consistent with the claimed invention.

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1. Pursuant to this Court's Rule 37.2(a), all parties have consented to the filing of this brief. Letters evidencing such consent have been filed with the Clerk of the Court. Pursuant to Rule 37.6, *Amicus Curiae* affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *Amicus Curiae*, its members, or its counsel made a monetary contribution to its preparation or submission.

FICPI recognizes that the instant case has significant potential to impact the patentability of a potentially broad class of subject matter.

Specifically, FICPI is concerned that research and valuable university and private company work in the areas of gene expression and genetic engineering applied science to solving major, catastrophic illnesses must be protected.

Furthermore, FICPI is concerned that the application of the principles announced in the Court's *Mayo* decision in this case, will negatively affect the so far very clear distinction between composition of matter claims and method claims in case law.

Because FICPI is largely comprised of patent practitioners representing both foreign and domestic inventors and corporate entities, FICPI is poised to give the court the perspective of the international patent community. In this vein, FICPI desires to ensure that its members' clients are afforded fair opportunities with respect to patenting their inventions in the United States and, therefore, respectfully submits this brief in support of neither party.

INTRODUCTION

On November 30, 2012, this court granted the petition for a writ of certiorari limited to the question 1 presented by the petition:

"Are human genes patentable?"

The challenged composition claims cover two isolated human man made genes BRCA1 and BRCA2 and certain

alterations, or mutations in these genes associated with a predisposition to breast and ovarian cancers.

SUMMARY OF ARGUMENT

The issue presented is the patentability of human gene expression.

The Genes BRCA1/2 are patentable. The claims are related to isolated DNA molecules which are obtained in a laboratory and not found in nature. The isolated DNA has a markedly different chemical structure compared to native DNA. Isolating the genes from human DNA is not a natural phenomenon. It is a human accomplishment for which a protection has to be rewarded.

Mayo v. Prometheus has no bearing on Myriad. Mayo addresses patent method claims and not compositions of matter. The patent eligibility in Mayo has no application to the composition claims in Myriad and the criteria for patent eligibility of compositions was not reviewed or reserved in Mayo by this Court.

This Court's prior judgment also remains unaffected under *Mayo v. Prometheus* and has no impact on the Federal Circuit's prior judgment. The Federal Circuit concluded properly that in Myriad the composition claims cover molecules that are "markedly different" from molecules that exist in nature. Its decision was also made in accordance with the longstanding practice of the PTO.

ARGUMENT

I. THE GENES BRCA1/2 ARE PATENTABLE

Concerning the Patent-eligibility under the patent Act 35 U.S.C. 101, the Court's precedents provide three judicially created exceptions to 101 principles: "Laws of nature, natural phenomena and abstract ideas". Considering the isolated genes BRCA 1/2 it appears that the Court is dealing with a natural product but it has been isolated by the work of man.

Evaluating its patent-eligibility it is necessary to consider each individual case. The claims of the patents before us relate to isolated DNA molecules[2]. Those are not found in nature. Rather, they are obtained in laboratory and are man-made. To consider this case in a proper light it is essential to examine the idea why products of nature and laws of nature shouldn't be patent-eligible.

Through a patent, useful inventions are encouraged since the inventor's right to exclude others from making, using, offering for sale or selling his invention is protected.

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2. The term "isolated", which is used in the claims of the patents, does not mean "purified". The claimed genes are in fact not present in the human body in admixture with other substances; they cannot be purified from any naturally existing mixture. To the contrary, they are a portion of a larger molecule, i.e. the DNA of human chromosomes, to which they are chemically bound. Consequently, in order to be obtained in the claimed "isolated" form, either they must be cleaved from chromosomal DNA or they must be synthesized; but human intervention is necessary in both cases; and such an intervention creates a new molecule which did not and does exist in nature as such.

Therefore, a natural product or a law of nature is not patent-eligible because no one invented it or should be privileged by having a patent issued.

The isolated DNA molecules before us are made from natural materials like mostly all other inventions. Nevertheless, it has a markedly different chemical structure compared to native DNAs. The isolation of the genes from the native DNA for use in the fight against breast and ovarian cancer is a significant human achievement and accomplishment. It's a scientific advance in the fight against breast and ovarian cancer. Indeed, it is necessary to differentiate between achievements produced out of natural material by using a great scientific effort and natural products or laws of nature which have just been found out by coincidence and are just described or existed before in the exact same way.

Isolating the before mentioned genes from human DNA is not a natural phenomenon. There will never be an isolated gene like the disputed ones found in nature. It is an achievement in molecular biological science. Hence, a protection of this accomplishment for the process in finding and isolating the molecules has to be rewarded. The alternative will be less activity in science.

II. *MAYO v. PROMETHEUS* HAS NO BEARING ON *MYRIAD*

Moreover, the Federal Circuit was right in its finding that *Mayo vs. Prometheus* has no bearing on the present case. The decisions are not comparable:

A. *Mayo* Addresses Patent Method Claims, Not Compositions of Matter.

In *Mayo*, this Court concluded that a three-step process to help doctors who treat patients with autoimmune diseases to determine the correct dosage of thiopurine drugs according to the patient's metabolite level is not patent eligible. This Court held that such a method simply sets forth laws of nature and does not fulfill the requirements of a transformation of unpatentable natural laws into an application that rewards inventions.

This three-step process, however, is clearly not what this Court has defined as a "composition of matter," which is one of the broad categories of patent eligible subject matter. According to this Court, a "composition of matter" includes "all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." *Diamond v. Chakrabarty*, 447 U.S. at 308 (1980). This Court identifies *Mayo* to be a case concerning "patent claims covering processes". *Mayo* at 1293.

B. Mayo has no Application to *Myriad*, other than to Restate General Principles of Patent Eligibility.

As different tests have been applied by the courts over the years for compositions as compared to method claims when examining the claims' patent eligibility, a different line of case law has been developed for each of the claim types. There is a continuous line of cases by the courts and the PTO concerning composition claims, which all follow this Court's patent eligibility test for compositions.

According to the test, only those compositions that human intervention has given "markedly different" or "distinctive" characteristics are patent eligible, whereas other compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, are not patentable. *Hartranft v. Weigmann*, 121 U.S. at 615 (1887); *American Fruit Growers v. Brodgdex Co.*, 283 U.S. 1, 11 (1931). The claimed compositions in *Myriad* more than adequately meet this test for patent eligibility for a composition. The patent eligibility analysis in Mayo has no application to the composition claims in *Myriad*.

C. The Criteria for Patent Eligibility of Compositions Was Not Reviewed, Much Less Reversed, in *Mayo*.

This Court in *Mayo* cites prior composition claim cases such as *Chakrabarty* only as a reference for the very general principle that "laws of nature, natural phenomena, and abstract ideas" are not patentable under 35 U.S.C. 101, which is applicable regardless of whether the patent claims a method or a composition of matter. *Mayo* at 1293.

On the other hand, to answer the core issue of whether or not the process in question is patent eligible, this Court takes under consideration two prior cases, *Diamond v. Diehr*, 450 U.S. 175 (1981) and *Parker v. Flook*, 437 U.S. 584 (1978), that are described as "controlling precedents." Both *Diehr* and *Flook* concern method claims and not composition claims. *Mayo* at 1298. In *Diehr*, the patent claim concerned a process for molding rubber. In *Flook* it concerned a process for adjusting alarm limits in catalytic conversion of hydrocarbons.

The Mayo decision makes clear the composition-mattered distinction that exists between composition case law and method case law. This Court unequivocally decided the case according to prior method claim case law. Accordingly, there is no reason for the method claim case law in *Mayo* to be applied on the composition claims in *Myriad*, as the dichotomy was recognized by this Court in *Mayo* itself. There is simply no common ground between the two (except for the very general principles mentioned above) which would allow the application of the method claim rules reaffirmed in *Mayo* to the examination of the composition claims in *Myriad*.

For the above reasons, *Mayo* does not shed any light on *Myriad*. There is no reason for this Court to consider *Mayo* in *Myriad* as far as the question of patent eligibility of isolated DNA is concerned.

III. THIS COURT'S PRIOR JUDGMENT ABOUT PATENT ELIGIBILITY REMAINS UNAFFECTED UNDER *MAYO v. PROMETHEUS*

As shown above, *Mayo* does not have an impact on the Federal Circuit's prior judgment that the isolated DNA composition claims of the '282 patent are patent-eligible.

Under the framework set out by this Court's decision in *Chakrabarty* for deciding patent eligibility, the Federal Circuit decided that isolated DNAs have surpassed the line of being mere compositions having similar characteristics as in nature. Isolated DNA has been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body. The Federal Circuit correctly concluded that in

Myriad the composition claims cover molecules that "have a distinctive chemical identity and nature" and therefore are "markedly different" from molecules that exist in nature. *Myriad* at 1351.

The Federal Circuit's decision was also made in accordance with the longstanding practice of the PTO (see PTO's 2001 Revised Utility Examination Guidelines for Gene Patent Application). The PTO has issued thousands of patents directed to DNA molecules for almost thirty years. *Myriad* at 1355. This Court stated in *Mayo* that changes in this longstanding practice of protecting DNA inventions under the broad scope of 35 U.S.C. § 101 should come from Congress, not the Courts. *Mayo* at 1304.

According to this Court, the drug-dosage calibration method used in *Mayo* merely and simply describes unpatentable natural laws, namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. This Court found that the several steps in the process involve well-understood, routine, conventional activity previously engaged in by researchers in the field. The Court further stated that while it takes human action (the administration of a thiopurine drug) to trigger a manifestation of this relationship in a particular person, the relationship itself exists in principle apart from any human action. This Court concludes that the relation is a consequence of the way in which thiopurine compounds are metabolized by the body in an entirely natural process and that, therefore, a patent that simply describes that relation sets forth a natural law.

Regardless of whether one agrees with these findings of this Court or not, and even if this Court finds *Mayo* to be applicable to *Myriad*, these findings do not render Myriad's composition claim patent ineligible.

When an advance in science occurs and it relates to creating a new product that product is intended to be protected by our patent laws. And Courts should not concern themselves with the nuances of the chosen language under the admirably broad 35 U.S.C. § 101 to deny that protection. That is the evil of all these new § 101 arguments that this Court must put to rest. The filter of § 101 arguments was designed to be very large and not intended to be cluttered by semi-ingenuous lawyer created (and judicial) confusions. This broad filter created intentionally by Congress must not be narrowed by those more directed by monied interests than the inventions that move our country in the forefront of medical discoveries.

CONCLUSION

For the foregoing reasons, FICPI submits that in the present case human genes, isolated and created for the purpose of fighting cancer, should be found patent-eligible. Moreover, FICPI submits that this Court's *Mayo* decision has no bearing on this case.

Dated: January 24, 2013

Respectfully Submitted,

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