No. 10-1150

IN THE

Supreme Court of the United States

MAYO COLLABORATIVE SERVICES (D/B/A/ MAYO MEDICAL LABORATORIES) AND MAYO CLINIC ROCHESTER,

Petitioners,

v.

PROMETHEUS LABORATORIES, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICI CURIAE ASSOCIATION INTERNATIONALE POUR LA PROTECTION DE LA PROPRIÉTÉ INTELLECTUELLE AND INTERNATIONAL ASSOCIATION FOR THE PROTECTION OF INTELLECTUAL PROPERTY (U.S.) IN SUPPORT OF NEITHER PARTY

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I. INTEREST OF AMICI CURIAE[1]

This brief is submitted on behalf of *amici curiae* Association Internationale Pour La Protection De La Propriété Intellectuelle ("AIPPI") and International Association For The Protection Of Intellectual Property (U.S.) ("AIPPI-US") (hereinafter referred to collectively as "AIPPI").

AIPPI is an international organization, founded in 1897, dedicated to the development, improvement, and legal protection of intellectual property. AIPPI is a politically neutral, non-profit organization headquartered in Switzerland having over 9000 members representing over 100 countries and operating mainly through National and Regional Groups, such as the AIPPI-US.

The members of AIPPI include intellectual property lawyers, patent and trademark attorneys, and patent agents in corporate and private practice throughout the world, as well as academics and other persons interested in intellectual property, and including members from North America, South America, Europe, Asia, Australia, and Africa.

The primary goals of AIPPI, in accord with its implementing statutes and regulations, are to promote the protection of intellectual property on a national and international basis and to study and compare existing law and proposed laws to propose improvements thereto. AIPPI pursues these objectives, in part, by working for the development, expansion and improvement of international and regional treaties and agreements and also of national laws relating to

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[1] The parties have consented to the filing of this brief. No counsel for a 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 the Amici has made a monetary contribution to the preparation or submission of this brief.

intellectual property. In its long history, AIPPI has adopted more than 700 Resolutions and Reports. An AIPPI "Resolution" is a Statement of Policy regarding a specific Intellectual Property issue, approved by the collective National and Regional Group members of AIPPI. Such a Resolution is issued only after lengthy study and discussion and subsequent vote by a majority of delegates present at an Annual Meeting of the Executive Committee of AIPPI. The presentation of these Resolutions and Reports to international Governmental Organizations, in particular the World Intellectual Property Organization ("WIPO"), has contributed considerably to the development, improvement and harmonization of the international protection of intellectual property. AIPPI has adopted a Resolution on an issue touching that before this Court: Resolution Q202 ("The impact of public health issues on exclusive patent rights"), discussed below and attached hereto (Appendix at A1-A3).

For at least the above-noted reasons, and on behalf of both resident and non-resident AIPPI members who seek, on behalf of the clients they represent, clarity in the applicability of patent rights in the United States to methods of medical treatment of patients, AIPPI submits this brief to this Court.

II. INTRODUCTION

The framers of the United States Constitution recognized the need to encourage innovation, and dissemination of the same, by rewarding inventors and granted the United States Congress the authority "[t]o promote the Progress of … useful Arts, by securing for limited Times to … Inventors the exclusive Right to their … Discoveries." U.S. Const. art. I, § 8, cl. 8. Congress enacted the first United States Patent Act in 1790 requiring, *inter alia*, the applicant to "have invented or discovered any useful art, manufacture, engine, machine, or device, or any

improvement therein." Patent Act of 1790, ch. 7, § 1, 1 Stat. 109 (April 10, 1790). Congress amended this Act in 1793 to require that the applicant "have invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement." Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (February 21, 1793). In the revisions to the Patent Act of 1952, Congress amended the language of 35 U.S.C. § 101 to use the term "process" in lieu of "art," stating: "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." The Patent Act of 1952 further required the subject matter of the invention to be novel (*see* 35 U.S.C. § 102), to be non-obvious (*see* 35 U.S.C. § 103), and to satisfy certain disclosure requirements (*see* 35 U.S.C. § 112).

The United States has been historically, and remains currently, a leader in innovation. Manufacturing, chemistry, electronics, biotechnology, and computer software are just a few of the technological fields that have seen tremendous commercial development within the United States. The Patent Laws of the United States have accommodated and fostered innovation in and development of all of these technologies, and have helped the United States to achieve and maintain its position in the global economy.

Nearly all developed and developing nations worldwide have patent laws that likewise seek to foster innovation in and development of important technologies and advancements for their own societies and for the global society at large. In one important respect, however, the patent laws of the United States differ from those of virtually all other nations (the sole exception being Australia): only in the United States (and Australia) are methods of medical treatment of patients considered patent-eligible subject matter. Because this important distinction sets U.S. patent law

apart from the patent laws of nearly every other country around the globe, the applicability of exclusive patent rights to methods of medical treatment of patients raises unique concerns for all people who seek medical treatment in the United States.

In 1996, Congress addressed these concerns at least partially by enacting 35 U.S.C. § 287(c), which eliminates a patentee's remedy by civil action, and the right to injunction, damages, and attorney fees against medical practitioners and related health care entities for the performance of certain patented medical procedures.

This brief attempts to serve the Court by providing both a global perspective on the issue of patent eligibility for methods of medical treatment of patients, and a commentary on the effectiveness and impact of the current U.S. statutory scheme affecting this issue. Finally, AIPPI urges that federal subject matter jurisdiction is lacking here, in light of that U.S. statutory scheme.

III. SUMMARY OF THE ARGUMENT

AIPPI's mandate is to study the way patent systems around the world protect intellectual property and make recommendations for improvement. To this end, AIPPI has studied the particular limitations of exclusive patent rights in a wide variety of countries to determine the extent such limitations may play a role in providing access to patented medicines, other medical or biological products, and methods of medical treatment of patients, so as to facilitate health care, notably in the context of public health crises. AIPPI, through its Resolution Q202 (*see* Appendix at A2, Resolution Para. 5), encourages all member countries to allow medical personnel the freedom to provide medical treatment of patients without the authorization of any patentee, at least under certain circumstances discussed further below.

In the overwhelming super-majority of countries (indeed, in all 33 countries studied by AIPPI other than the United States and Australia), the societal objective of allowing medical treatment of patients to be unfettered by exclusive patent rights is achieved by excluding methods of medical treatment of patients from patent eligibility altogether. In the United States, this objective is supposed to be achieved by a statutory scheme eliminating, more or less, the availability of certain provisions of the Patent Laws with respect to certain types of potential actions against certain defined sets of individuals and entities. *See generally* 35 U.S.C. § 287(c). For reasons that are not clear, Congress' legislative effort to achieve a globally-desired limitation of exclusive patent rights, at least under certain circumstances, appears to have been unapplied, misapplied, or simply overlooked by the district court and the Court of Appeals for the Federal Circuit in this case. AIPPI urges this Court to apply the statutory scheme eliminating entirely this patent dispute (and the attendant costs to society, the medical profession, and patients themselves) involving medical treatment of patients.

IV. ARGUMENT

AIPPI's Resolution Q202 ("The impact of public health issues on exclusive patent rights"), adopted at the Boston Congress, September 6-11, 2008, states (Appendix at A2, Resolution Paragraph 5):

> To the extent that the patent law permits patentability of methods of medical treatment, the law should provide for an exception to the rights of a patentee, allowing medical personnel to use patented methods of medical treatment, without the authorisation of the patentee, in circumstances where it is not practicable to negotiate a licence before treatment.

AIPPI did not study the issue of patent eligibility of methods of medical treatment of patients, *per se*. However, such study was not necessary, as only two of the countries' laws studied

allowed for such patent eligibility at all (those two countries being Australia and the United States).[2] In the realm of public health issues, notably in the context of public health crises, it was resolved that a nation's patent laws should not impede or impair access to medical treatment, at least under certain circumstances. Given the state of the laws around the world, it should be understood that Resolution Q202 confirms the current situation in most countries, even including the United States, at least in theory.[3]

In *Laboratory Corp. of America Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006), a prior case presenting essentially the same question as is presented in this case, and in which certiorari had been granted but then dismissed as having been improvidently granted, Justices Breyer, Stevens, and Souter wrote that "special public interest considerations" are implicated by the question of patent eligibility for methods of medical treatment of patients because allowing such patents would "inhibit doctors from using their best medical judgment," would "force doctors to spend unnecessary time and energy to enter into license agreements," and would "divert resources" from healthcare tasks to "the legal task of searching patent files," among other deleterious effects. *Id.* at 135. These are the very same concerns addressed in AIPPI Resolution

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[2] *See* AIPPI Summary Report, Question Q202 attached hereto (Appendix at A4-A17), Sec. (I)(5), at A7.

[3] At the time AIPPI Resolution Q202 was adopted, Australia was the only studied country in which methods of medical treatment were eligible for patenting and in which there was no defense, exclusion or exemption of any kind from liability for patent infringement resulting from the practice of such methods. *See* AIPPI Summary Report, Question Q202, Sec. (I)(5), Appendix at A7, and discussion of "Medical treatment defence," Appendix at A14.

Q202. At minimum, there is a recognized danger, or at least special undesirability, of requiring doctors to negotiate and obtain patent licenses in order to treat patients, at least when "not practicable" to do so before treatment.

It is difficult to imagine many circumstances in which it would be "practicable" for a physician to identify the need for, seek and then successfully obtain a patent license before ordering optimization of a course of drug administration to a patient. In this case, a method of dosage optimization for a specific patient, by that patient's physician, is precisely what is claimed in the patent-in-suit. Respondent has previously argued that the "entire purpose of these inventions is to improve a process of patient treatment. *There are, in fact, no uses of the claimed processes other than in connection with patient treatment*." (*See Prometheus Labs., Inc. v. Mayo Collaborative Servs. (dba Mayo Medical Labs),* Appeal No. 2008-1403, Appellant's Reply Brief dated April 24, 2009, at 14 (Fed. Cir.) (emphasis added). Thus, the "special public interest considerations" previously recognized by this Court are precisely implicated here.

Under current U.S. law, the provisions of 35 U.S.C. § 287(c)(1) of the Patent Act eliminate the availability of 35 U.S.C. § 281 (remedy by civil action), § 283 (injunction), § 284 (damages), and § 285 (attorney fees) against both the "medical practitioner" and "related health care entity" (defined as including but not limited to nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic), at least as to a "medical activity," defined as "the performance of a medical or surgical procedure on a body." Thus, when Section 287(c)(1) applies, the courts lack subject matter jurisdiction to hear a specified class of claims of patent infringement against specified classes of potential infringers.

By enacting Section 287(c)(1), Congress has pronounced that at least some medical activities should be outside of, and free from interference by, the patent system. AIPPI respectfully

suggests that both the infringement claims at issue and the named defendants in this case fall within those specified classes.

The definition of "medical activity" to which the exemption of § 287(c)(1) applies contains three exceptions codified in Section 287(c)(2)(A), but none of them applies here. It is indisputable that neither Section 287(c)(2)(A)(i) ("use of a patented machine, manufacture, or composition of matter") nor Section 287(c)(2)(A)(iii) (practice of process in violation of a biotechnology patent) applies. Similarly, while Section 287(c)(2)(A)(ii) removes "the practice of a patented use of a composition of matter" from the exemption, the claims at issue in this case do not fall within this exemption.

U.S. Patent No. 6,355,623, "Method of treating IBD/Crohn's disease and related conditions wherein drug metabolite levels in host blood cells determine subsequent dosage" (hereinafter "the '623 patent"), describes a method of improving the treatment of autoimmune diseases by providing physicians a way to "individually calibrate a patient's dosage [of a particular medication] without having to take a wait-and-see approach." Brief for the Respondent in Opposition (to the petition for writ of certiorari), at 4. First, at least one asserted claim, i.e., claim 46, of the '623 patent recites only "determining" a patient's metabolite levels. (It is apparent that such "determining" requires withdrawal of a certain amount of the patient's blood, without question a "medical activity.") Second, as Respondent argues, the asserted patent claims are not drawn to the use of a composition of matter but instead are "processes to generate useful treatment information for physicians." Brief for the Respondent in Opposition (to the petition for writ of certiorari), at 12. Instead of requiring that the drug dosage be increased or decreased based on metabolite levels found in the patient's blood, the claims simply "indicate a need" to

adjust the dosage. *See* Petition for a Writ of Certiorari, at 6-7 ("Importantly, Prometheus's claims do *not* recite what is to be done once the physician mentally recognizes the correlation.").

In addition to immunizing the allegedly infringing activity from suit, Section 287(c) also frees certain classes of defendants in an infringement suit, Petitioners here, from liability. The evidence of infringement presented by Respondent Prometheus centered on the patient treatment activities of Dr. Rokea A. el-Azhary, M.D., Ph.D., a clinical dermatologist working in the Dermatology Department at Mayo Clinic Rochester, who is unquestionably a "medical practitioner" entitled to the protection of 35 U.S.C. § 287(c)(1). That evidence concerned blood tests ordered by Dr. el-Azhary from the Biochemical Genetics Laboratory of Mayo Clinic Rochester.[4] Mayo Clinic Rochester is unquestionably a "related health care entity" with respect to Dr. el-Azhary, and is also entitled to the immunity from suit provided by 35 U.S.C. § 287(c)(1). Prometheus argues in passing that while "individual doctors generally are immune from suit, ... the commercial entities that enable and induce the infringement (such as Mayo's for-profit laboratory) are not." *See* Brief for the Respondent in Opposition (to the petition for writ of certiorari), at 34. However, 35 U.S.C. § 287(c) makes no distinction between "for-profit," "not-for-profit," and any other types of the defined "related health care entities" based upon financial motivation or any other criteria, for that matter; all are immune from suit unless one of the three § 287(c)(2)(A) exceptions applies. Prometheus fails completely to explain why Mayo Clinic Rochester and its related Mayo Collaborative Services are not "related health care

[4] It is understood that the Biochemical Genetics Laboratory at Mayo Clinic Rochester is actually part of Petitioner Mayo Collaborative Services, strictly as a matter of corporate organization.

entities" within the meaning of 35 U.S.C. § 287(c)(2)(C) and (D), both entitled to be free from patent infringement suits of the instant type. In fact, AIPPI respectfully suggests that both named defendants are plainly "related health care entities" and that, accordingly, Congress has eliminated availability of a federal civil action for patent infringement of Prometheus' patent against them. The immunity from suit provided by Congress in 35 U.S.C. § 287(c)(1) should be given effect, and the case dismissed for lack of federal subject matter jurisdiction. That this issue apparently was not raised before either the District Court or the Federal Circuit is of no import, as it is hornbook law that "[o]bjections to subject-matter jurisdiction … may be raised at any time." *Henderson v. Shinseki*, 562 U.S. __, __, 131 S. Ct. 1197, 1202 (2011).

Dismissal of this action for lack of federal subject matter jurisdiction comports with the letter and spirit of AIPPI Resolution Q202, which states that medical personnel should not be constrained by patent rights in circumstances where it "not practicable to negotiate a licence before treatment." Given the nature of the patent claims in this case and the types of defendants against whom the assertions of infringement have been made, allowance of the infringement action would either: (a) require a hospital laboratory such as the Biochemical Genetics Laboratory at Mayo Clinic Rochester to identify, obtain, and maintain a complete library of patent licenses covering every test that any doctor at Mayo Clinic Rochester might ever order, or (b) require the hospital laboratory to itself order a patent infringement search and study each time a Mayo Clinic doctor orders a diagnostic blood test, and then obtain a license when deemed necessary or advisable in the opinion of Mayo Clinic Rochester's qualified patent counsel. Because neither of these options is "practicable," application of Congress' legislative solution in 35 U.S.C. § 287(c)(1) is appropriate and would achieve the purpose of AIPPI Resolution Q202.

V. CONCLUSION

The U.S. Congress has chosen to implement a public policy nearly deemed universally desirable, namely, freedom of doctors and their related facilities from patent infringement concerns, by eliminating availability of federal civil actions in certain defined circumstances. AIPPI, through its Resolution Q202, supports this public policy for at least the "special public interest considerations" previously recognized by Justices Breyer, Stevens, and Souter. This case appears to fall squarely within the statutory immunity from patent suit under 35 U.S.C. Sec. 287(c)(1), yet this seemingly critical issue does not appear to have been briefed, or even seriously raised, at any stage of the proceedings below. AIPPI respectfully submits that in view of Congress' withdrawal of the remedy by civil action in cases such as this one, federal subject matter jurisdiction is lacking, and that the case should be dismissed on this basis.

Respectfully submitted,

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