No. 12-398

IN THE

Supreme Court of the United States

THE 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* THE INSTITUTE OF PROFESSIONAL REPRESENTATIVES BEFORE THE EUROPEAN PATENT OFFICE (EPI) IN SUPPORT OF NEITHER PARTY

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INTEREST OF THE *AMICUS CURIAE*[1]

The Institute of Professional Representatives before the European Patent Office (**epi**) came into existence pursuant to the European Patent Convention (EPC) upon provisions adopted by the Administrative Council of the European Patent Organization. These provisions also pertain to the European qualifying examination successful passing of which is a prerequisite for obtaining entitlement to act as a representative before the European Patent Office (EPO), and to the disciplinary powers exercised by the Institute over these representatives. The Institute (**epi**) being an international non-governmental public law corporation has its own by-laws and code of professional conduct.

At present, the Institute representing the community of European patent practitioners admitted to represent before the EPO comprises about 10,000 members from 38 European countries, both from industry and free profession.

epi as an organization deals primarily with the development and implications of patent law. **epi** through its Biotech Committee is at the forefront of all patent law developments in the fields of biotech and genetic engineering and has a sound expertise in this very specialized area. It also serves to advise the **epi** members

1. No party or party's counsel authored this brief in whole or in part. No party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amicus curiae made a monetary contribution to its preparation or submission. Both parties in this case consented to the filing of this amicus brief in support of neither party.

and to forward the opinion of **epi** to other stakeholders and organizations. The **epi** Biotech Committee meets regularly and makes reports to the Council and Board of **epi** on all biotech related matters. The reports of the **epi** Biotech Committee are regularly published in the official journal of **epi** named "**epi** information" (copies of the reports can be seen on http://www.patentepi.com/patentepi/en/Information/epi-information.php). In addition, the **epi** Biotech Committee is frequently requested on an *ad-hoc* basis to produce reports for the **epi** President in support of biotech matters to be dealt with at the Standing Advisory Committee before the European Patent Office (SACEPO) or at other important meetings. The **epi** Biotech Committee also prepares the *amicus curiae* briefs on behalf of the **epi** President on biotech related inventions.

SUMMARY OF THE ARGUMENT

European Patent Convention countries have implemented the EU Directive of the European Parliament and the Council on the legal protection of biotechnological inventions (EU Directive 98/44/EC). According to the EU directive, assuming that a DNA sequence is novel, the isolated substance of the DNA itself is patentable. The claims concern a molecule which has a defined chemical structure and function. The approach adopted by the EU Directive is that a nucleic acid corresponding to a complete or part of a gene, even if its structure is identical to that of a natural element, may constitute a patentable invention, if isolated from the human body or otherwise technically produced. According to Article 5(2) of the Directive the natural pre-existence of biological material alone does not constitute a patentability obstacle. The EU Directive

established that no patent can cover a substance *in situ* in the human body; the patent must cover the isolated substance. Also, the industrial applicability of the isolated DNA, in other words its function, has to be disclosed in the patent application as filed. In Europe, especially before the EPO, genetic material is not seen as a special case requiring treatment different from chemical compounds and other products. Thus far, this view has been shared by the patent offices of the United States and Japan. In the opinion of **epi** there is no reason to change this view.

ARGUMENT

In accordance with the European Patent Convention (EPC) and with well-established case law of the Boards of Appeal of the European Patent Office, **epi** is of the opinion that isolated human DNA and other isolated nucleic acids represent patent-eligible subject matter. Although this issue has been in the public debate for years, the patent authorities in the OECD countries have been clear and consistent on this topic over the last couple of years. **epi** wishes to refer the Supreme Court to the Declaration dated 22 December 2009 of Professor Joseph Straus submitted in support of the Motion for Summary Judgment in the District Court by Myriad. The declarant Professor Joseph Straus is a renowned expert in IP law and has been a consultant and advisor to various European organizations including the European Patent Organization (EPO).

This Declaration of Professor Straus argues in detail a technical and legal basis in support of the patent-eligibility of isolated DNA claims under European patent law and practice. As a conclusion from a European patent

perspective Professor Straus takes the position that Myriad's product claims for isolated human DNA at issue are patent-eligible.

epi herewith declares that it fully shares and endorses the opinion of Prof. Straus.

CONCLUSION

epi does not see any technical or legal reason why the Supreme Court could or should deny patent-eligibility of isolated human DNA including isolated human genes. Therefore, **epi** thinks that the Supreme Court should answer Question 1 in the affirmative.

Respectfully submitted,

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