No. 15-1182

IN THE

Supreme Court of the United States

SEQUENOM, INC.,

Petitioner,

v.

ARIOSA DIAGNOSTICS, INC., NATERA, INC., AND DNA DIAGNOSTICS CENTER, INC.

Respondents.

On Petition for a 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 IN SUPPORT OF NEITHER PARTY

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.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 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. It is governed by a Council which is elected by members of respective national constituencies and by a Board elected by its Council which includes its President, Vice-Presidents and further members representing each of the 38 contracting states of the EPC. The Board Members have competence in all questions regarding the epi, the EPO and the EPC.

At present the Institute, representing the community of European patent practitioners admitted to represent before the EPO comprises about 10,000 members from each of the 38

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[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. All parties in this case gave blanket consent to the filing of amicus briefs.

contracting states, both from industry and from the free profession.

epi as an organization deals primarily with the development and implications of patent law. **epi** through its Committee on Biotechnological Inventions (Biotech Committee) is at the forefront of patent law developments in the field of biotech and genetic engineering and has sound expertise in this specialized area. It also serves to advise the **epi** members 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://patentepi.com/en/epi-information/epi-information.html. 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 *amicus curiae* briefs on behalf of the **epi** President on biotech related inventions.

SUMMARY OF THE ARGUMENT

The present petition should be granted because decisions of the lower courts have world-wide implications, repeatedly conflict with internationally accepted standards of patent-

eligibility which decisions of this Court do not, and jeopardize research investment in medicine and other life sciences.

Refusal to allow discovery of a new law of nature or natural product to count towards eligibility under the *Myriad/Mayo* framework applies that framework with undue breadth and breaches internationally accepted norms for patent eligibility. The framework is applied as a rigid rule rather than a general principle, and without the balance called for in earlier decisions of this Court.

ARGUMENT

I. The present petition should be granted because decisions of the lower courts have world-wide implications, repeatedly conflict with internationally accepted standards of patent-eligibility which decisions of this Court do not, and jeopardize research investment in medicine and other life sciences.

The international implications of recent eligibility decisions of the Federal Circuit are apparent both in the present case where the invention originated in the United Kingdom and in the recent and legally and factually similar decision in *Genetic Technologies v Merial* (Fed Cir., Apr 8 2016 at p. 12) where the applicant was Swiss. That decision is relevant to the present appeal because the Federal Circuit there explained in greater detail and applied the same reasoning as in this case,

identifying basis for its reasoning here in several of its earlier decisions.

The panel majority in this case purported to apply a framework derived from decisions of this Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) and *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). The rule of law derived by appropriate interpretation of those decisions raises no issues of international harmonization. In contrast, the framework repeatedly applied with extended scope by the Federal Circuit raises issues of compliance with the Art. 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO), the consequential Directive 98/44/EC of the European Parliament, and consistency with pertinent decisions of courts in Europe and of the Appeal Boards of the EPO.

The claim that came before this Court in *Mayo* was directed to measuring the level of a thiopurine metabolite in the red blood cells of a patient treated with a thiopurine compound. The only novelty in that claim was information firstly as to a lower level of the metabolite defining an effective dose and secondly as to a higher level of the metabolite corresponding to an undesirably high dose. The court's holding that the claimed method when considered as an ordered combination was ineligible because the only novel feature merely recited a law of nature while not extending to an eligible

application of that discovery raises no issue as to international harmony. Mere presentation of information is not regarded as inventive under Art.52 EPC, see the *CIPA Guide to the Patents Acts*, 8th Ed. Sweet & Maxwell, London, 2016 at 1.15.

Patent-eligibility of naturally occurring DNA segments and of synthetically created cDNA was considered by this Court in *Myriad*. The Court held that "a naturally occurring DNA segment is a product of nature and not patent-eligible *merely because* it has been isolated but that cDNA is patent-eligible because it is not naturally occurring." (emphasis added). As explained with reference to *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) and to the seminal decision in *Hartranft v Weigman* 121 U.S. 609 the key to eligibility is human ingenuity providing something new and useful. The claim to gBRCA1 fell short since nothing new had been produced, and mere separation of the gene was not an act of invention. Insofar as the Court also held that the claim was not directed to the specific chemical composition of a particular molecule but to the information contained in the genetic sequence, the decision harks back to *Mayo* and presentation of information. Blanket approval was given to the eligibility of cDNA with qualification that the blanket approval did not cover short sequences with no intervening introns which might be indistinguishable from natural DNA. As discussed below, the Federal Circuit has interpreted this passage as blanket disapproval of the eligibility of short sequences identical to natural DNA. However, when correctly understood the passage merely deals

with blanket eligibility as a new composition of matter and leaves the actual eligibility of such short sequences in future cases to be determined on the facts of each case and on the principles set out in *Hartranft* and *Chakrabarty*, mere isolation not sufficing, but isolation accompanied by new utility potentially sufficing.

The ruling in *Myriad* is therefore in part consistent with Art.52 EPC which requires a claimed invention to be both novel and industrially applicable, note 5 to TRIPS Art. 27 equating industrial applicability and utility under §101. Rule 26 of the EPC Implementing Regulations now specifies that the EPC shall be interpreted in accordance with Directive 98/44/EC, Art. 5(2) of which provides than an element isolated from the human body or otherwise produced by means of a technical process may constitute a patentable invention subject to Art. 5(3) which requires the industrial application or utility to be disclosed in the patent application, the requirement for this additional information going beyond mere isolation and being consistent with the "merely because" holding in *Myriad*.

The ruling in *Alice* raises no international harmonization or TRIPS compliance issues. In Europe, applications corresponding to the patents in issue were refused at first instance and appeals, though filed, were not pursued. The following passages from a communication accompanying a summons to oral proceedings in one of the European

applications[2] encapsulate the objections of the EPO examining division which closely follow the decision of this Court:

> 3.2 The claims of the present application are considered to relate to subject matter excluded from patentability under Art. 52(2) and (3) EPC and, although not completely devoid of technical character, are formulated to merely specify commonplace features relating to a technological implementation of such matter without inventive step (Art. 56 EPC). The examiner could not, and still cannot, determine any technical solution defined in response to a problem within the content of the application as originally filed. Any problems which are addressed do not appear to require a technical, but rather an administrative, i.e. business solution. Whilst the implementation of such a solution may include the use of generic technical features these merely serve their well-known functions as would be recognised by the skilled person in the technical field under consideration.

In contrast, the present case provides an example of a continuing sequence of decisions of the Federal Circuit that have disrupted the harmonious development of patent law internationally and raise

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[2] https://register.epo.org/espacenet/application?documentId=EKSSP5XV3748FI4&number=EP96921823&lng=en&npl=false

issues of compliance with Art. 27 of the TRIPS Treaty.

The decision in *In re BRCA1- & BRCA2-Based Hereditary Cancer Test*, 774 F.3d 755 (Fed. Cir. 2014) which followed on from *Myriad* concerned a pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the use of said primers in a polymerase chain reaction resulting in the synthesis of DNA having all or part of the sequence of the BRCA1 gene. The primers were held to be not distinguishable from the isolated DNA found patent-ineligible in Myriad and are not similar to the cDNA found to be patent-eligible. The holding (slip opinion, p. 8) was that:

> "The Supreme Court held ineligible claims directed to segments as short as 15 nucleotides, the same length as the primer claims at issue here, suggesting that even short strands identical to those found in nature are not patent eligible"

and further at p.9:

> "A DNA structure with a function similar to that found in nature can only be patent eligible as a composition of matter if it has a unique structure, different from anything found in nature."

No such prohibition is derivable from the opinion in *Myriad*, which as explained above left

open the eligibility of claims to isolated DNA elements of new utility. Furthermore, the holding is directly contrary to European Directive 98/44/EC and to Appeal Board decision T 1213/05 *Breast and ovarian cancer/UNIVERSITY OF UTAH* where probes were held patent-eligible (EP-B2-0705902), see also T 666/05 *Mutation/UNIVERSITY OF UTAH* where claims to a probe were upheld (EP-B2-0705903, claim 7). It should be added for completeness that the Federal Circuit failed to realize that even if, contrary to the belief of this *amicus*, the individual primers are patent-ineligible natural materials, the claim was to a pair of them, being a combination or mixture selected and made by human intervention and therefore plainly qualified under the "composition of matter" category of §101.

Method claims were also considered by the Federal Circuit and held to be ineligible through over-broad application of the *Myriad/Mayo* framework. Such holdings are discordant with the holdings by the EPO Appeal Board in T 666/05 *Mutation/ UNIVERSITY OF UTAH* where novelty, inventive step, sufficiency of disclosure and patent-eligibility were all considered and acknowledged, see EP-B2-0705903 claims 1-4 and see also T 80/05 *Method of Diagnosis/UNIVERSITY OF UTAH* and EP-B2-0699754 claims 1-7.

The Federal Circuit decision in the present case, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373–74, 1376 (Fed. Cir. 2015) follows the established pattern of inattention to the statutory patent-eligible categories of §101 combined with

over-broad application of the *Myriad/Mayo* framework. The decision of the Federal Circuit here is in discord with EPO Appeal Board decision T 146/07 *Prenatal diagnosis/ISIS*. The issue of patent-eligibility was never disputed before the EPO, but if such dispute had been raised it would have been decided in favour of eligibility following decisions T 1213/05, T 666/05 and T 80/05.

The latest instance of rejection of a claim to a technical process by reason of recurrent inattention to the statutory patent-eligible categories of §101 combined with recurrent over-broad application of the *Myriad-Mayo* framework is found in *Genetic Technologies v Merial*. In this instance a parallel patent application has been granted by the EPO without objection as to eligibility, but there was no opposition or appeal to the EPO Appeal Board.

It follows that the Court of Appeal for the Federal Circuit is following a pattern of interpretation of the §101 eligibility requirement that is not only at variance with the relevant decisions of this Court but also at variance with the corresponding legal position under the EPC and at variance with the requirements of Art.27 of TRIPS. The damage to investment in medical research is shown by the explanation in the Petition that Sequenom made an essential investment of some $70 million in bringing this invention to market as a viable medical test, clinically validating it and obtaining regulatory approvals, and that by reason of Ariosa's infringement and the continuing refusal to enforce the patent in issue that investment has not

yet been recovered. The need to "tread carefully" in construing exclusionary principles which is set out in the preamble to *Alice* and in other decisions of this Court is not being observed. Continuing investment in life sciences research and a more positive attitude to patent enforcement is needed if investor confidence is to be maintained and the flow of new medical, diagnostic and other life sciences products to the public is to continue unabated.

II. Refusal to allow discovery of a new law of nature or natural product to count towards eligibility under the *Myriad/Mayo* framework applies that framework with undue breadth and breaches internationally accepted norms for patent eligibility.

Under the *Myriad/Mayo* framework two steps are involved:

(i) to determine whether the claims at issue are *directed to* a patent-ineligible concept itself; and

(ii) If the answer is yes, to consider the elements of each claim both individually and as an ordered combination to determine whether additional elements transform the nature of the claim into a patent-eligible application.

The panel opinion here over-reaches the proper scope of the first stage of the test by inappropriately broad interpretation of the works "directed to". It held that the claimed method begins and ends with a naturally occurring phenomenon and is therefore directed to naturally occurring

phenomena. That this is a non-sequitur is apparent by applying the same analysis to a method of making an omelette. On the panel's reasoning the method begins with eggs, ends with an egg product and is therefore directed to eggs. The transformative intermediate stages of the cooking process are overlooked. In the panel opinion here the transformative nature of the amplification step, the resulting multitude of amplified sequences produced by nucleotide polymerization, and the utility of the amplification product for subsequent analysis are also overlooked.

The panel's reasoning here, set out even more explicitly in *Genetic Technologies v Merial*, is that "…under the Mayo/Alice framework, a claim directed to a newly discovered law of nature (or natural phenomenon or abstract idea) cannot rely on the novelty of that discovery for the inventive concept necessary for patent eligibility". That reasoning has been transformed by the Federal Circuit from a general principle to a rigid rule, contrary the need to adopt a balanced approach and to tread carefully as set out in *Alice* and other cases and contrary to the warning against inappropriate development of rigid rules in the decision of this Court *in KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

No such proposition forms part of European law or is accepted internationally. The proper bounds of the exclusion are set out in the *Case Law of the Boards of Appeal of the European Patent Office*, 7th Ed. 2013 which explains at page 15 that discoveries, scientific theories and mathematical methods

excluded under Art. 52(2)(a)-(d) EPC share the common feature that they do not aim at any direct technical result but are rather of an abstract and intellectual character and that:

> If a new property of a known material or article is found out, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1) EPC. If, however, that property is put to practical use, then this constitutes an invention which may be patentable. To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable…."

In the Enlarged Appeal Board decision in *Friction-reducing additive III/MOBIL OIL* (G 2/88) it was held that the fact that the idea or concept underlying the claimed subject-matter is a discovery does not necessarily mean that the claimed subject matter is a discovery "as such". In relation to a claim whose wording defined a new use of a known compound, the proper interpretation of the claim will normally be that attaining the technical effect which underlies the new use is a technical feature of the claimed invention. In the present case obtaining the effect that paternal sequences derived from maternal serum or plasma are amplified and useful for subsequent analysis would be regarded as an eligible

feature of the claim contributing strongly to novelty and inventive step.

The second step of the test is also applied in an unduly onerous manner that has no counterpart in European practice. Where a claim is to an ordered combination, eligibility, novelty and nonobviousness are considered in relation to the claim as a whole considered as an ordered combination of features, and a single novel feature normally suffices. There is no reason under European law why selection of a novel starting material, in this case maternal serum or plasma which was previously discarded, should not suffice to provide that feature and more should be demanded from the patentee.

CONCLUSION

For the reasons stated above, the judgment of the Federal Circuit should be reconsidered and reversed.

Respectfully submitted.

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