Appeal No. 2017-2508

United States Court of Appeals

for the

Federal Circuit

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD., MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.,

Plaintiffs-Appellants,

v.

MAYO COLLABORATIVE SERVICES, LLC,
dba Mayo Medical Laboratories, MAYO CLINIC,

Defendants-Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS IN CASE NO: 1:15-CV-40075-IT
INDIRA TALWANI, UNITED STATES DISTRICT JUDGE

BRIEF OF *AMICUS CURIAE* THE CHARTERED INSTITUTE OF PATENT ATTONEYS IN SUPPORT OF APPELLANTS

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November 13, 2017

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel for *Amicus Curiae* The Chartered Institute of Patent Attorneys certifies the following:

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

The Chartered Institute of Patent Attorneys.

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* 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 (and who have not or will not enter an appearance in this case) are:

Aaron F. Barkoff, MCANDREWS, HELD & MALLOY, LTD.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal:

None.

Dated: November 13, 2017

/s/ Aaron F. Barkoff
Aaron F. Barkoff

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INTEREST OF *AMICUS CURIAE*

The Chartered Institute of Patent Attorneys (CIPA) is the professional and examining body for patent attorneys in the United Kingdom. The Institute was founded in 1882 and was incorporated by Royal Charter in 1891. It represents over 2000 chartered patent attorneys, whether they practice in industry or in private practice. Total membership is over 3500 and includes trainee patent attorneys and other professionals with an interest in intellectual property matters.

The scope of patent-eligible subject matter in the United States and its consistency with international treaties and practice is of fundamental concern to CIPA members and their clients.

All parties have consented to the filing of this *amicus* brief. *See* D.I. 31-1. No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting the brief. No person—other than the *amicus curiae*, its members, or its counsel—contributed money that was intended to fund preparing or submitting the brief.

ARGUMENT

I. The district court decision conflicts with international treaties to which the United States is a party, as well as international practice

The district court decision disqualifies as ineligible under § 101 patent claims "directed to" or "focused on" a laboratory procedure that (a) is based on a newly selected starting material, and (b) involves two newly created chemical entities. In its focus on the newly discovered physiological facts of which the claimed diagnostic method represents an application, the reasoning underlying the district court decision, if approved by this Court, would render ineligible many diagnostic method inventions considered eligible under the Patent Cooperation Treaty (PCT) and the European Patent Convention (EPC). Hence, the scope of patent-eligible subject matter would be inconsistent with the obligations of the United States under Article 27 and Note 5 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO).

Article 27.1 of TRIPS, entitled "Patentable Subject Matter," provides a complete code for patent-eligibility that WTO member countries, including the United States, have agreed to respect. It requires patents to be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application. It further provides that patent rights should be enjoyed without discrimination as to

the field of technology. In negotiating TRIPS, care was taken to ensure consistency with United States domestic law. Thus, Article 27 is to be read with note 5, which provides that the term "capable of industrial application" may be deemed to be synonymous with the term "useful".

Exclusions from patentability are covered by Articles 27.2 and 27.3. They include the protection of *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. Other exclusions also exist, but there is no provision for the exclusion of natural products or processes involving natural products.

PCT-eligible treatment and diagnostic methods are discussed in the PCT International Search and Preliminary Examination Guidelines published by the World Intellectual Property Organization and last revised in June 2017. The Guidelines, Chapter 9, paragraph 9.10, cites PCT Rules 39.1(iv) and 67.1(iv), which provide that international search and international preliminary examination are excluded for diagnostic methods but only when practiced on the human or animal body. The Guidelines explain that the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded. The patent at issue in the present case resulted from an application whose eligibility for international search and examination was never disputed, published as WO

01/96601, subsequently granted in Europe as EP-B-1327147, and granted in Canada as Patent No. 2455271.

The Case Law of the Boards of Appeal of the European Patent Office, 7th Ed. 2013, explains at page 15 that discoveries, scientific theories and mathematical methods excluded under Article 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:

> [i]f 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.

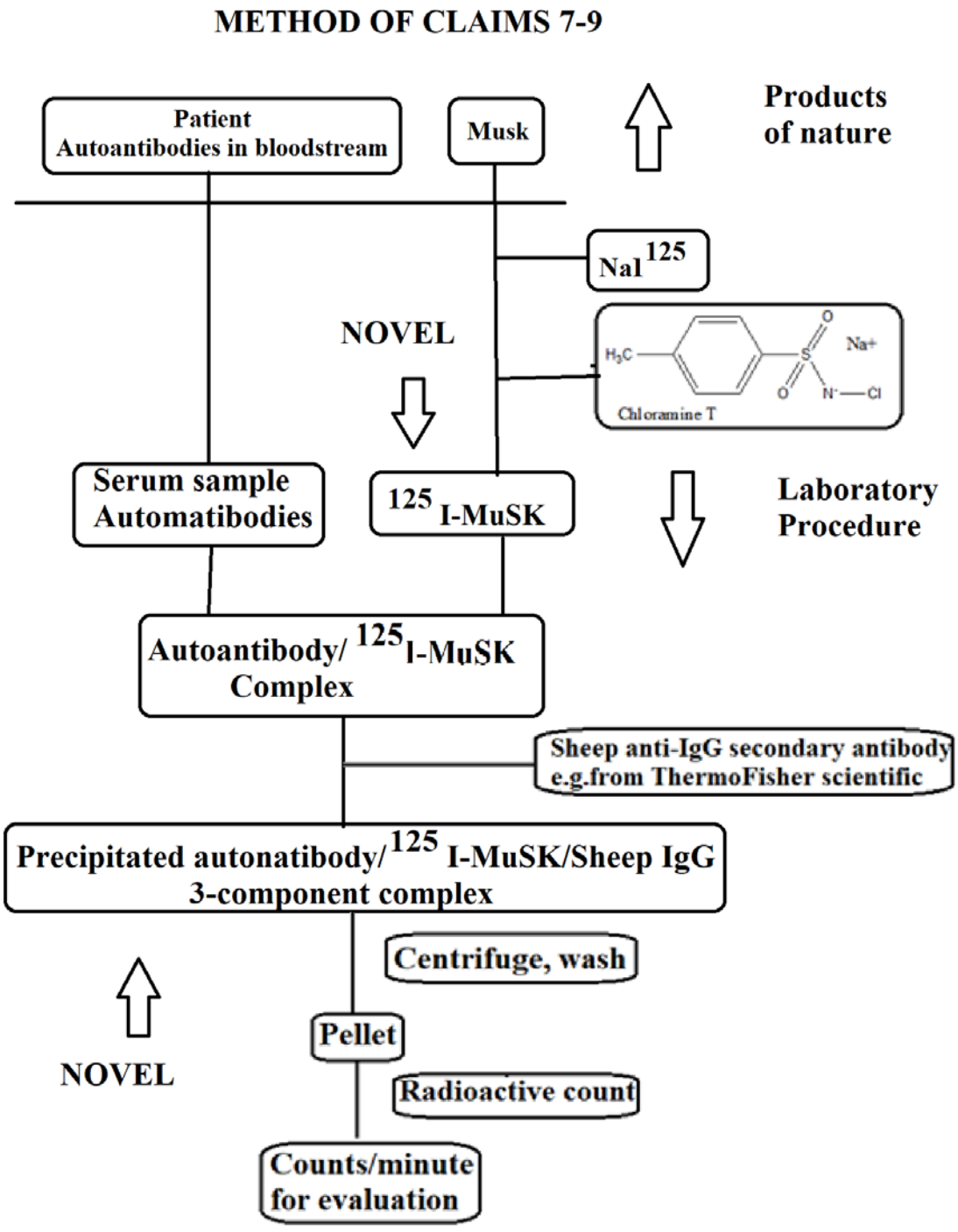
This statement encapsulates the proper bounds of the exclusion under TRIPS Article 27 and any difference in United States law arises from over-expansive interpretation of *Mayo*, *Myriad*, and *Alice*. Outcomes in cases which have reached the EPO Appeal Board are illustrated by T 385/86 B*RUKER/Non-invasive measurement*, where it was observed that the exclusion of Article 52(4) EPC should be narrowly construed, and T 310/99 *MACRI/Down Syndrome*.

II. The district court decision misinterprets the "focus" of the claims and the subject matter that the claims are "directed to"

The method of claim 9, which depends from and thereby incorporates the limitations of claims 1, 7, and 8, is reproduced below with functional elements emphasized in bold type:

> A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal
>
> comprising the step of **detecting** in a **bodily fluid** of said mammal **autoantibodies** to an epitope of muscle specific tyrosine kinase (MuSK), comprising
>
> **contacting MuSK** or an epitope or antigenic determinant thereof **having a suitable label thereon**, with said bodily fluid, wherein said label is a **radioactive label** and is ^{125}**I**,
>
> **immunoprecipitating** any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and
>
> **monitoring** for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex, wherein
>
> the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to muscle specific tyrosine kinase (MuSK).

The method of claim 9 is depicted in the following diagram, with products of nature shown above the horizontal line and products created by human intervention shown below the horizontal line:



The district court decision fails to evaluate the claims in accordance with established canons of patent claim construction, wrongly confusing non-structural language that merely explains purpose or result with the operative combination of structural steps. For example, the preamble reciting diagnosis of disorders gives structure and life to the claim but does not recite any technical step limiting the claim. *See Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995); MPEP, 2111.02 (Effect of Preamble). Similarly, the final "whereby" clause should not be given weight because it simply expresses the intended result of the process steps without importing any technical feature, and is simply explanatory or laudatory. *See Minton v. Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003).

The district court's attention was misdirected to these statements of purpose or result and away from the recited combination of structural steps on which the method is truly directed or focused. Thus, at page 7 of its decision, the district court misapplied *Electric Power Group., LLC v. Alstom S.A.*, 830 F.3d. 1350 (Fed. Cir. 2016) and *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016). The true focus of claims 7-9 is not on any natural occurrence but rather on the recited non-naturally occurring materials and the recited sequence of process steps.

The district court's contrary view does not focus on the claim but instead inadmissibly blurs it. It confuses natural occurrence with laboratory procedure. The

only elements recited in the pertinent claims that occur naturally are bodily fluid *in vivo* in the patient's bloodstream, MuSK *in vivo* in the patient's bloodstream, and IgG autoantibodies circulating undetected *in vivo* in the patient's bloodstream. Every other element recited in the claims is brought to a laboratory by the hand of man and used transformatively in that laboratory in a reaction tube or other laboratory equipment.

Further, the district court misinterprets column 4, lines 9-12 of the patent-in-suit in relation to iodination of MuSK with ^{125}I. ^{125}I is a non-naturally occurring material made by irradiation of xenon in a nuclear reactor. *See* '820 patent, col. 10, l. 55. The passage correctly explains that standard techniques existed for iodination of proteins in general. It does not imply that iodination of MuSK or deletion fragments thereof was well-understood, routine, conventional activity already engaged in by the scientific community. Indeed, there was no identified motivation to do so before the present invention. References 4 and 6 mentioned at page 10 of the district court decision refer not to anti-MuSK antibodies but to antibodies against the acetylcholine receptor (AChR), which has an entirely different molecular structure. There is no evidence that ^{125}I-MuSK had previously been produced. For that reason, the dictum in *Rapid Litig. Mgmt., Ltd. v. CellzDirect, Inc.*, has no relevance to the claimed method. *See* 827 F.3d 1042, 1047 (Fed. Cir. 2016).

The district court decision correctly acknowledges that the claimed method starts with a sample of bodily fluid, implicitly in a laboratory reaction tube. The ^{125}I-MuSK is added to the sample in the reaction tube. The reaction forming a labelled complex is not a natural event occurring *in vivo* (district court decision, page 9) but is brought about by the hand of man within the reaction tube.

Although immunoprecipitation was known, for example, in relation to AChR, it had not been reported in relation to MuSK. The resulting material consisting of IgG autoantibody/ ^{125}I-MuSK/sheep IgG secondary antibody, which is recovered as a pellet by centrifugation and washing, is *prima facie* a novel and non-naturally occurring material because its three chemically linked constituents had not been reported as having been brought together prior to the invention. Further, it is useful by virtue of its labelled state and is a matter of substance (and not merely a product of skilled claim drafting) within the eligible "composition of matter" category of § 101.

Any contrary holding would conflict with Supreme Court authority. *See Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887) (quoted in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303 (2013)). If ^{125}I-MuSK and the triple antibody are qualifying chemical entities, a method that employs them as part of an ordered combination of steps cannot logically be treated as ineligible subject

matter. Moreover, radioactive counting of the pellet is a laboratory procedure involving sophisticated electronic apparatus.

Athena's method differs fundamentally from that in *Mayo* because in that case the claim was directed to analyzed levels of a metabolite formed *in vivo* and defining upper and lower levels of a therapeutic window for thiopurine drugs, whereas the present case concerns new materials formed *in vitro* as part of a multi-step laboratory test procedure providing new benefits for an identifiable group of Myasthenia Gravis patients. The claimed method in *Mayo* could be alleged to be novel neither in its starting material nor in the chemical entities involved, but only in ineligible information about upper and lower limits of the therapeutic window.

Athena's method also differs fundamentally from that in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1372 (Fed. Cir. 2015), because the representative claims do not seek to monopolize all methods of detecting relevant IgG autoantibodies but only those embodiments which are easier to standardize as a result of radio-labelling, and not, for example, alternative ELISA assay embodiments. It also differs fundamentally from *Ariosa* in that the starting material there was paternally inherited nucleic acid, which was a product of nature, and the representative claims identified no novel chemical entity in either the amplification step or the subsequent detecting or testing steps. In contrast, the laboratory procedures recited here are transformative in the sense that the starting materials

^{125}I-MuSK and autoantibodies are "transformed and reduced to a different state or thing," and not so sweeping as to cover all possible uses of the newly discovered MuSK autoantibodies. *See Gottschalk v. Benson*, 409 U.S. 63, 70 (1972) (quoting *Cochrane v. Deener*, 94 U.S. 780, 788 (1876)).

Reversal of the district court decision is therefore necessary both for international harmonization of patent law and under United States domestic law.

Dated: November 13, 2017

Respectfully Submitted,

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Athena Diagnostics, Inc., et al. v.
Mayo Collaborative Services, LLC, et al., 2017-2508

CERTIFICATE OF SERVICE

On November 13, 2017, a copy of the **Brief of *Amicus Curiae* The Chartered Institute of Patent Attorneys in Support of Appellants** was filed and served using the CM/ECF System.

Dated: November 13, 2017

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Circuit Rule 32(a) because:

this brief contains 2,124 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because:

this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point Times New Roman font.

Dated: November 13, 2017

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