No. 15-1182

In the Supreme Court of the United States

SEQUENOM, INC.,

Petitioner,

v.

ARIOSA DIAGNOSTICS, INC., *et al*.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR MURGITROYD & COMPANY AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Many modern diagnostic tests and treatment methods utilize knowledge of the levels or presence of biological molecules determined in test samples.

The non-statutory exception to patent-eligibility to judicially assure that patents cannot be granted for laws of nature, natural phenomena or abstract ideas is provided to operate in conjunction with explicit statutory provisions in the Patent Act, for example 35 U.S.C. §§ 102, 103 and 112.

As set out in the petition for writ of certiorari filed by Sequenom, Inc., the Question presented is:

> Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without pre-empting other uses of the discovery?

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35 U.S.C. § 102 . . . . . 4, 8

35 U.S.C. § 103 . . . . . 4, 8

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Other Authorities

DTTL Life Sciences and Health Care Industry Group analysis of World industry outlook: Healthcare and pharmaceuticals, The Economist Intelligence Unit, May 2014 2

INTEREST OF *AMICUS CURIAE*[1]

Murgitroyd & Company is a company of European Patent Attorneys that represents a number of clients ranging from small and medium size enterprises ("SMEs"), universities and large corporations who are active in research, development and commercialization of technologies in the life sciences. Typically, the SMEs are involved in raising investment from angel investors, venture capital funds or are seeking collaborations with larger companies. Universities also typically seek to enter into collaborative partnerships with companies or license technology they have developed to commercial companies.

Murgitroyd & Company's renewals department has taken on responsibility for paying renewal fees for one patent family that is related to U.S. Patent 6,258,540 for Sequenom, Inc. Murgitroyd & Company does no other work for Sequenom, Inc. Murgitroyd & Company also represents Illumina, Inc. in patent prosecution matters. It is Murgitroyd & Company's understanding that Sequenom, Inc. and Illumina, Inc. have entered an agreement whereby the parties pooled certain intellectual property relating to noninvasive prenatal testing and will share revenue from such patent pool.

Intellectual property is typically the bedrock that allows such companies and universities to obtain

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[1] This brief was not authored, in whole or in part, by counsel for any party. No person or entity other than amicus curiae, and their counsel, made a monetary contribution to the preparation or submission of this brief. Counsel of record for each of the parties received timely notice of the intent to file this brief. Each party filed a blanket consent for all amicus briefs.

funding or to attract collaboration to further the research and development of new technologies, including diagnostic assays or treatments and the clinical development and validation of the same.

Lack of patent protection or uncertainty over the way in which patent protection in relation to diagnostic methods, markers and kits will be considered in the United States – typically the most significant market for the SMEs[2] – limits the ability of companies to develop such technology, attract investment, and commercialize the technology, in turn limiting the potential of these companies to develop economic scale, employment opportunities (both in Europe and in the United States), and provide new diagnostic assays or treatments for patients.

The research into the ways in which the human body works in healthy or diseased/infected states, and the development of new products and methods for the diagnosis of specific diseases typically involves the identification of a link between a bio-marker and a disease; a process itself that requires ingenuity and rigorous technical investigation. From this point researchers must then develop a methodology that allows them to accurately and predictably characterize the presence or correct quantity of the bio-marker that enables them to understand more regarding the disease

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[2] The North America region accounted for the largest share of the estimated 2014 global pharma market at 41.9 percent, followed by Asia/Australia at 26.8 percent, Western Europe at 19.8 percent, and Latin America at 6.8%. DTTL Life Sciences and Health Care Industry Group analysis of World industry outlook: Healthcare and pharmaceuticals, The Economist Intelligence Unit, May 2014.

state. The provision of such diagnostics not only enables the public to know whether or not they have a disease, but can also guide the use of therapeutics to only those patients that can be helped by the therapeutic, track the progression of a therapeutic treatment, or assist in the identification of new therapeutics. None of the processes or products that permit such determinations would have been known or obvious prior to the work carried out by such researchers.

The patent system was developed precisely to encourage such scientific advancements. *See* U.S. Const. Art. I, § 8, Cl. 8. Without such encouragement, many of those working in the field will be less willing to advance or fund work in the diagnostic area. Attached are three declarations, namely from representatives of a European university, the diagnostic industry, and the National Health Service in Northern Ireland, that demonstrate the negative ramifications if the Federal Circuit ruling regarding the claims of U.S. Patent 6,258,540 is upheld by the Supreme Court.

SUMMARY OF ARGUMENT

The non-statutory exceptions to patent-eligibility[3] to judicially assure that patents cannot be granted for laws of nature, natural phenomena or abstract ideas is provided to operate in conjunction with explicit statutory provisions in the Patent Act, for example 35 U.S.C. §§ 102, 103 and 112. The Court has established an analysis consisting of two steps to determine if a claimed invention is to be rendered unpatentable for being directed to a law of nature, natural phenomenon, or abstract idea.[4]

The two part test for patent eligibility under 35 U.S.C. § 101, as set forth in *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1296-97 (2012), is being applied in a manner which expands the reach of the non-statutory exceptions beyond what was set forth in *Mayo* and other precedent such that it is overriding the explicit patentability requirements set forth in the Patent Act.

As the effect of a therapeutic on a patient or an assessment of a condition of a patient is generally governed by the presence or absence of a naturally

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[3] The Court has long held that 35 U.S.C. §101 contains an important exception. "'[L]aws of nature, natural phenomena and abstract ideas' are not patentable." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,* 132 S. Ct. 1289, 1293 (2012).

[4] "In [*Mayo*] we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of these concepts." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 134 S. Ct. 2347, 2355 (2014).

occurring substance in the body, many inventions in this area are likely to be subject to the two part test as set forth in *Mayo*.

This expansive application of 35 U.S.C. § 101 will discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, and further guidance on the analysis to be used when considering the judicial exceptions provided in relation to 35 U.S.C. § 101 should be provided, taking into account the explicit statutory provisions in the Patent Act and preventing the improper or unintended expansion of these exceptions.

ARGUMENT

In addition to the statutory patentability requirements provided by the Patent Act, the Court has set a further non-statutory hurdle to assure that patents cannot be granted for laws of nature, natural phenomena or abstract ideas. Taking into account the Court's decisions in relation to patent eligibility, it is understood that while laws of nature, natural phenomena or abstract ideas are not eligible for patenting, methods and products employing such natural laws, natural phenomena and abstract ideas may well be patentable.

Where a claim is considered to be directed to a judicial exception, it is further analyzed to determine if the claim as a whole amounts to more than the exception itself.

The Supreme Court has described a two-step test to analyze and determine patent eligibility of a claimed invention. In the two-step test, the claimed subject matter is first reviewed to determine if it falls within

one or more of the three categories of patent-ineligible subject matter: laws of nature, natural phenomena, and abstract ideas. *Alice Corp. Pty. v. CLS Bank Int'l,* 134 S. Ct. 2347, 2355 (2014)*; Mayo,* 132 S. Ct. 1289, 1296-97 (2012), and, if so, the claimed subject matter is then further reviewed to determine whether it contains an additional, inventive concept sufficient to transform it into a patent-eligible application of the ineligible subject matter. *Id.*

In applying the two part test in the present analysis, the Federal Circuit considered the method claims at issue (independent claims 1, 24 and 25 of the '540 patent as set forth below) to be directed to a natural phenomenon.

> 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.
>
> 24. A method for detecting a paternally inherited nucleic acid on a maternal blood sample, which method comprises: removing all or substantially all nucleated and anucleated cell populations from the blood sample, amplifying a paternally inherited nucleic acid from the remaining fluid and subjecting the amplified nucleic acid to a test for the Paternally [sic] inherited fetal nucleic acid.

> 25. A method for performing a prenatal diagnosis on a maternal blood sample, which method comprises obtaining a non-cellular fraction of the blood sample amplifying a paternally inherited nucleic acid from the non-cellular fraction and performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal nucleic acid.

Thus, the second step of the test set out in *Mayo* was applied – whether the claim is more than a drafting effort designed to monopolize the abstract idea, law of nature or natural phenomenon.

In *Mayo* this Court reiterated the approach promulgated in *Diamond v. Diehr:* a claim must be considered in its entirety, not piecemeal. *Mayo,* 134 S. Ct. at 1298. The *Mayo* Court discussed the prior *Diehr* decision and agreed that the application of a known formula to a process does not make that process ineligible by virtue of the fact that the formula is law of nature, rather, when considering a claim's eligibility, one must consider the claim as a whole and not as isolated elements. *Id.* at 1298-1300.[5]

It appears the interpretation of *Mayo* used by the Federal Circuit in the present analysis did not take into account the combination of the method steps together with the natural law, but separated the teaching of the natural law from the additional claimed elements.

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[5] "A claim that recites an abstract idea must include 'additional features' to ensure that the [claim] is more than a drafting effort designed to monopolize the [abstract idea]." *Alice,* 134 S. Ct. at 2357 (alterations in the original)(quoting *Mayo,* 132 S. Ct. at 1297).

In 1996, there was a discovery of cell-free fetal DNA (cffDNA) circulating in maternal plasma. This natural law or natural phenomenon – the existence of cffDNA in maternal blood – can be distinguished from the practical use of the same to solve a specific technical problem – the use of the discovery *for detecting fetal genetic conditions in pregnancy* that avoids dangerous, invasive techniques.

As indicated by Judge Linn's concurrence, "no one was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 788 F.3d 1371, 1381 (Fed. Cir. 2015) (Linn, J., concurring).

It is clear that the method steps of claims 1, 24 and 25 when performed in isolation of the knowledge of the natural law or phenomenon – fractionating blood, amplifying DNA, looking for genetic sequences, would not lead to the new result (detecting fetal genetic conditions in pregnancy that avoids dangerous, invasive techniques) provided by the whole claim.

Thus, by considering the technical problem overcome by the claimed steps used in conjunction with the discovery of the natural law, such consideration finds the claim to be clearly directed to an application of the natural law or phenomenon (the existence of paternally derived cell free DNA in material blood) and not the natural law itself.

This claimed subject matter can then be correctly assessed in relation to inventive concept, taking into account Sections 102 and 103 of the Patent Act as they are intended to be applied.

It is considered that these statutory patentability requirements are the correct provisions to determine whether the specific technical problem of the invention is overcome, for example as set out by Judge Linn's concurrence regarding whether an alternative solution to the prenatal diagnosis requiring invasive methods, which presented a degree of risk to the mother and to the pregnancy, is provided. The combination of the steps of amplifying a paternally inherited nucleic acid of fetal origin from the serum or plasma sample from a pregnant female and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample was a practical result of the knowledge of the presence of the natural phenomenon (cff DNA in a maternal serum or plasma sample).

Thus, the Court should use this opportunity to clarify its interpretation of the non-statutory exception to provide that where: (1) a researcher is the first to discover a natural phenomenon; (2) and that unique knowledge motivates him or her to apply a new combination of known techniques to that discovery; and (3) he or she thereby achieves a previously impossible (or at least previously unobtainable) result without pre-empting other uses of the discovery, the claim should be considered to relate to more than the exception itself and the subject matter thus claimed should be considered patent eligible and subject to the further statutory framework of the Patent Act.

CONCLUSION

For the above reasons, Murgitroyd & Company respectively urges the Court to review the decision set forth by the Federal Circuit and consider the way in which the present non-statutory exception is considered in relation to laws of nature, natural phenomena or abstract ideas.

Respectfully submitted,

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APPENDIX

DECLARATION

I, Tas Gohir, am an IP Manager at The University of Leicester, University Road, Leicester, LE1 7RH, UK, and hereby declare and state as follows:

1. I am a member of a board responsible for deciding whether or not to fund the commercialisation and IP protection of developments coming from the research of the University Of Leicester, UK.

2. We have more potential developments to fund than we have funds; consequently there are many developments that we must decide not to provide funding for. Currently, about 70 % of our funded developments are in the life science field. A significant proportion of these developments relate to diagnostic methods.

3. We are currently experiencing difficulties in obtaining patent protection in the US for our developments relating to diagnostic methods; difficulties that we are not experiencing in other jurisdictions. This has noticeably increased the cost and uncertainty of seeking patent protection for such technologies in the US compared to other jurisdictions.

4. As the US is the largest market for such inventions, barriers such as the decision from Ariosa v Sequenom will cause us to rethink our willingness to file diagnostic patents entirely. It is likely now that when faced with competing developments to

fund, we will be more likely to fund a development that is not related to a diagnostic method than one that is related to such a method.

5. Furthermore, and more importantly, the main losers in having fewer and less innovative diagnostics will likely be patients, where early diagnosis of a condition can be crucial to clinical outcomes. We would highly recommend that this case law be re-considered.

6. It is also my view that the US case law relating to diagnostic methods as it currently stands is baffling in its logic and that it is likely to be very damaging to the US diagnostics industry.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further these statements are made with the knowledge that wilful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Signed /s/ Tas Gohir Dated 19/4/2016

Printed Tas Gohir

DECLARATION

I, Dr Steven McMaster, am a Patent Scientist at Randox Laboratories Limited, Diamond Road, Crumlin, County Antrim, BT29 4QY, UK, and hereby declare and state as follows:

1. Randox Laboratories Limited is an International company that develops and manufactures diagnostic solutions for hospitals, clinical, research and molecular laboratories, food testing, forensic toxicology and veterinary laboratories.

2. I am responsible for reviewing technological developments arising from research within Randox Laboratories, with a view to ensuring that they are adequately protected by Intellectual property in a way that supports their commercialisation by the company.

3. In my position, I have experience of patent prosecution for patent applications in the field of diagnostic methods in the US, and in other countries. Since the decision of Ariosa V Sequenom we have found that the cost and difficulty of obtaining patent protection for our technologies in the US has dramatically increased.

4. As a result, in my opinion, we are likely as a company to now decide not to seek patent protection for many of our diagnostic developments in the US.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further these statements are made with the knowledge that wilful false statements and the

like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Signed /s/ Steven McMaster Dated 19th APR 2016

Printed Steven McMaster

DECLARATION

I, Dr David Brownlee, am an Innovation Advisor at Health and Social Care Innovations, The Royal Group of Hospitals, Grosvenor Road, Belfast, BT12 6BA, UK, and hereby declare and state as follows:

1. The department in which I work provides an intellectual property and innovation management (also known as technology transfer) service for all Northern Ireland health and social care staff. Our aim is to ensure that ideas that have the potential to improve patient care or offer benefits to healthcare providers are developed, with a focus on ideas that can be protected by a patent and that are commercially viable.

2. As such, I am responsible for assisting with early stage funding and development of technologies in the diagnostic field coming out of research from the National Health Service in Northern Ireland. I am also responsible for identifying routes for commercialisation of these projects, which mostly involves encouraging an appropriate member of the diagnostic industry to invest in the technology. As we are not manufacturers of healthcare products, it is only in this way that we can ensure novel diagnostics are developed from our own technology, and ultimately can be provided to patients in our care.

3. I am aware that more and more prognostics and diagnostics will be required for the early identification, prediction, prevention and precise treatment of disease. A significant amount of the

success in this area will be directly linked to individuals' genetic constitution.

4. This will be particularly evidenced in the expanding and more significant area which is now called precision medicine (stratified or personalised). Not one/every drug/treatment will be able to resolve, slow down or prevent the same disease in all people with that same disease. These new prognostics and diagnostics will be vital for healthcare (people, patients, and providers) – impacting people lives globally – both now and for generations to come.

5. In my experience, it is unlikely that companies will invest in translating and developing research and development (R&D) results coupled to clinical information into commercially available prognostic and diagnostic kits unless that investment can be protected by patents globally.

6. Thus, individuals and populations will suffer for longer whilst progress in the development of new kits is slowed.

7. Given my recent experiences with the difficulty of obtaining patent protection for diagnostic methods in the US, I am also aware that projects in my care relating to diagnostics may be more difficult and more costly to develop internally to the point that they are attractive to investment. Consequently, I am now more likely to progress non-diagnostic technologies than diagnostic technologies, given their relative chances of successfully developing into a product that our patients can utilise.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements

made on information and belief are believed to be true; and further these statements are made with the knowledge that wilful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Signed /s/ D. Brownlee Dated 19 April 2016

Printed Dr David Brownlee