

Nutter Attorneys Represent Seven Major International Biotech Industry Associations at the U.S. Supreme Court

Amici Urge the Court to Reconsider Patent Eligibility Standard That is Hindering Development of Diagnostics and Life-Saving Medicines

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News

A broad coalition of the biotechnology industry associations filed an amici brief in a seminal patent case *Sequenom v. Ariosa*, currently pending petition for review by the U.S. Supreme Court. Nutter attorneys filed the brief on behalf of the UK BioIndustry Association (BIA), EuropaBio, AusBiotech, Swiss Biotech Association, HollandBio, BioteCanada, and the Japan BioIndustry Association. The amici expressed a broad worldwide support urging the U.S. Supreme Court to reconsider the interpretation of patentable subject matter under 35 USC 101 and arguing that the current approach hinders investment in the development of new diagnostics and life-saving medicines.

The brief as filed can be accessed [here](#).

“The current U.S. jurisprudence puts the U.S. out of synch with the rest of the industrialized world,” said Konstantin M. Linnik, Ph.D., partner in Nutter’s Intellectual Property Department and one of the authors of the brief. “It effectively deprives the emerging field of personalized medicine of any intellectual property protection in the U.S., while most other countries are taking a different approach.”

The coalition of the biotech associations, collectively representing thousands of member companies across the world, expressed concerns over the disparity of patent-eligibility standards in the U.S. and equivalent issues by courts and patent offices in Europe, Australia, Canada, and Japan. The recent legal developments in the U.S. frustrate the long-standing international efforts to harmonize intellectual property laws. Such harmonization is essential to support the development of new diagnostics and personalized medicines in an increasingly interconnected, global market.

Sequenom’s new procedure, which is already available to patients, eliminates the need for risky amniocentesis which was previously used to assess genetic abnormalities during pregnancy.

In 2015, the Federal Circuit ruled that Sequenom’s fetal DNA test was not eligible for patenting. It found that under the Supreme Court precedent, the patented technology was not an invention, but merely the application of a well-understood, routine technique applied to the natural phenomenon of paternally-inherited fetal DNA present at low levels in the mother’s blood. However, Sequenom claims that the idea of applying the detection method to their ground-breaking discovery was new and therefore patentable. In addition to the U.S. patent, Sequenom was awarded similar patents in Europe, Canada, Japan, and Australia.

The brief submitted by Nutter argues that the ruling of the lower court in *Sequenom* is the result of an over-broad interpretation and application of the U.S. Supreme Court’s 2012 decision in *Mayo v. Prometheus*. If left unchanged, the prior ruling could prevent patents on any method that involves something naturally occurring—a fragment of a gene, a biomolecule, a correlation of biomarkers, or new disease treatments relying on the same. As currently stands, U.S. patent case law on patent eligibility is inconsistent with laws in Europe, Canada, Australia, and Japan, among others.

The Nutter attorneys who co-authored the brief with Linnik include Lana A. Gladstein and Isaac A. Hubner, Ph.D. The U.S. Supreme Court is expected to rule in June whether to take the case up for review.

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About Nutter

Nutter is a top-tier, Boston-based law firm providing high-level legal counsel to clients who range from well-established companies and institutions to early stage entrepreneurs to foundations and families. The firm's lawyers are well-known for their extensive experience in business and finance, intellectual property, litigation, real estate and land use, labor and employment, tax, and trusts and estates. Nutter represents an international roster of innovative clients involved in a range of sophisticated technologies in the medical device, biotechnology and pharmaceutical industries, as well as renowned medical institutions and research universities, emerging growth companies and angel and venture capital firms. With an understanding of science and technology and a business savvy approach, our interdisciplinary team provides life science clients with a comprehensive service solution – from intellectual property and transactional advice to government enforcement, products liability and regulatory matters. Nutter was co-founded by Louis D. Brandeis, who later became a renowned justice of the U.S. Supreme Court, and has been in continuous practice for 136 years. For more information, please visit www.nutter.com.

Practice Areas

Intellectual Property

- IP Litigation

- Patent Portfolio Development and Counseling

Industries

Life Sciences: Biotechnology, Pharmaceuticals & Medical Devices

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