Roche, Ariosa Defeat Illumina on Prenatal DNA Test Patents
By Dana A. Elfin

Illumina Inc.'s patent infringement suit against Roche subsidiary Ariosa Diagnostics Inc. over fetal genetic trait detection patents hit a dead end.

Illumina's patents were directed toward naturally occurring phenomena that can't be patented in the first place, Judge Susan Illston of the U.S. District Court for the Northern District of California said in a Dec. 24 ruling. Because the patents were invalid, Illston granted Roche's request to toss the suit.

The question of what's an abstract idea or law of nature that can't be patented is a major topic in life sciences, and the invalidation of a patent has huge financial consequences for litigants.

"This case illustrates the fundamental problem of patentable subject matter, that where you draw the line of naturally occurring dictates the outcome," Michael Risch, associate dean of faculty research and development and professor of law at Villanova University School of Law, told Bloomberg Law Dec. 26.

"Here, courts have drawn that line at a high level, and it means that diagnostic patents that leverage observations of the real world, no matter how genius, are unpatentable." Risch said.

"The implication for the biotech industry remains that patenting diagnostic methods and methods of analyzing genetic material using conventional techniques—albeit based on allegedly new discoveries (e.g., the size of fetal DNA relative to the size of maternal DNA, underlying the claims at issue in Illumina)—will continue to be very difficult," Andrew M. Alul, an intellectual property attorney with Taft Stettinius & Hollister LLP in Chicago, told Bloomberg Law Dec. 26. Alul's practice focuses on pharmaceutical drug patent litigation and regulatory litigation.

Life Sciences Industry Impact

Patent eligibility questions have been roiling the life sciences community since 2012, when the U.S. Supreme Court found a diagnostic method claim patent ineligible in *Mayo Collaborative Servs. v. Prometheus Labs., Inc*. The *Mayo* ruling and its progeny have made it more difficult for life sciences companies to protect their intellectual property, a federal court said.

Illumina sued Ariosa Diagnostics Inc. in May claiming the company's non-invasive Harmony Prenatal Test, which involves sequencing maternal and fetal DNA in blood drawn from expectant mothers, infringed Illumina's patents. Those patents, U.S. Patent Nos. 9,580,751 and 9,738,931, are directed to an improved technique for preparing and analyzing extracellular circulatory DNA in blood samples.

But Illston agreed with Roche that the asserted patent claims were directed to natural phenomena and weren't eligible to be patented.

"Both patents claim results from a test of naturally occurring fetal DNA and do not transform the naturally occurring product into something new," she said.

The claims also failed to cover an inventive concept, she said. "[T]he claims extend only to isolation and analysis of a naturally occurring phenomenon and employ routine, well-known laboratory techniques," she wrote.

Illumina and Roche declined to comment on the litigation.

Roche Molecular Systems Inc. bought Ariosa in 2014.

Weil Gotshal & Manges LLP represented Illumina Inc. and co-plaintiff Sequenom Inc. Wilmer Cutler Pickering Hale & Dorr LLP represented Roche Molecular Systems, Inc. and Roche Sequencing Solutions, Inc.

Durie Tangri LLP represented Ariosa Diagnostics, Inc.

The case is *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 2018 BL 477018, N.D. Cal., 18-CV-02847-SI, 12/24/18.
