DNA IP Ruling Creates 'Serious Ethical' Issues, Justices Told

By Dorothy Atkins

Law360 (January 6, 2021, 9:54 PM EST) -- Ariosa Diagnostics Inc. and Roche Sequencing Solutions have asked the U.S. Supreme Court to take up the Federal Circuit's decision to revive Illumina DNA-test patents that were invalidated for claiming a natural phenomenon, arguing that the decision conflicts with precedent, raises "serious ethical concerns" and will create confusion "at all levels of the patent system."

In a 33-page Dec. 30 petition for writ of certiorari, prenatal test product makers Ariosa Diagnostics Inc. and Roche Sequencing Solutions Inc. said the justices should clarify whether patents that describe a method for separating smaller DNA fragments from larger ones, and analyzing the separated DNA for diagnostic purposes using well-known techniques, can be patented.

The companies argued that such patents should not be patentable, particularly in light of precedent set by the high court in its 2013 decision in Molecular Pathology v. Myriad Genetics Inc 🔴, which held that human genes are patent-ineligible products of nature.

The petition says the Federal Circuit's split ruling, which favored Illumina and upheld the patents, "creates a back door to the effective patenting of human DNA, presenting serious ethical and scientific issues," and further frustrates the lack of clarity about what type of DNA technology is patent eligible under Section 101.

"The Federal Circuit's treatment of Myriad creates an end run around this court's decision, threatening to revive the effective patenting of human DNA without any inquiry into whether the techniques used to separate the DNA were inventive," the petition says.

The patents, which Illumina licensed from Sequenom Inc., cover technology for determining whether a fetus has Down syndrome, based on a discovery that fetal DNA can be detected in a mother's blood and is shorter than maternal DNA.

A trial judge initially invalidated the patents, but in March, a split [2-1 appellate court panel](#) revived the two patents, finding that unlike other fetal DNA testing patents previously challenged by Ariosa, the patents-in-suit are not directed to natural phenomena.

The following month, Ariosa and Roche [asked the full Federal Circuit](#) to review the decision. They argued that the patents are "indistinguishable" from other patents the court previously invalidated as natural phenomena, so the decision "will unnecessarily sow confusion."

But the full appellate court [refused](#) to review the decision, while the original panel revised its opinion to more fully explain its reasoning. The majority held that the patent describes a patent-eligible method of preparing DNA for testing, and the revised opinion repeatedly stressed that the patents cover techniques of increasing the amount of fetal DNA in a given sample that are "human-engineered," a phrase that didn't appear in the original opinion.

But in their petition, the appellants argued that the majority's decision creates a "roadmap for patent drafters" to evade Supreme Court precedent and exacerbates the confusion regarding the scope and proper application of the Patent Act to DNA-based diagnostic patents. The diagnostics companies urged the high court to take up the case and clarify that such DNA techniques are ineligible for patent protection.

Counsel and representatives for the parties did not immediately respond Wednesday to requests for comment.

The patents-in-suit are U.S. Patent Nos. [9,580,751](#) and [9,738,931](#).

Illumina is represented by Edward Reines, Christopher Lavin, Derek Walter and Zachary Tripp of [Weil Gotshal & Manges LLP](#).

Ariosa is represented by Daralyn Durie and Kira A. Davis of [Durie Tangri LLP](#).

Roche is represented by Robert Gunther Jr., Omar Khan, Christopher Noyes and Thomas Saunders of WilmerHale.

The case is Ariosa Diagnostics Inc. et al. v. Illumina Inc. et al., case number 20-892, in the U.S. Supreme Court.

--Additional reporting by Ryan Davis and Dani Kass. Editing by Peter Rozovsky.