Groups Sweat Scope Of High Court Gene Patent Ruling

By Ryan Davis

_Law360, New York (April 12, 2013, 8:51 PM ET) --_ The U.S. Supreme Court case set for argument Monday over whether isolated human genes can be patented has spurred heated debate in dozens of amicus briefs over how the court's ruling will impact the biotechnology industry, patient care and the patent system.

Medical groups and others supporting the challenge to Myriad Genetics Inc.'s patents on isolated breast cancer genes claim that genes are natural products and patents on them impede health care and research. Intellectual property and biotechnology groups supporting Myriad claim that isolated DNA is a man-made composition and that striking down the patents could cripple the biotech industry.

"This case is really asking the question of what is the dividing line between a patentable invention and an unpatentable product of nature," said Barbara Rudolph of Finnegan Henderson Farabow Garrett & Dunner LLP, who filed a brief on behalf of the American Intellectual Property Law Association. "How the court approaches that issue will really impact the result."

Here, Law360 examines some of the key arguments made in the amicus briefs.

**Arguments against Myriad's patents**

The crux of the position taken by the plaintiffs, a group of doctors represented by the American Civil Liberties Union, is that isolated DNA is DNA that is "simply removed from its natural environment," making it a product of nature that cannot be patented.

The plaintiffs also claim that Myriad's patents "create barriers to scientific progress and medical care" and "have had a proven chilling effect on research, as laboratories are dissuaded from pursuing scientific work that requires using the patented genes."

That theme is echoed in many of the amicus briefs supporting the plaintiffs, including one by the American Medical Association and other medical groups, which calls patents on human genes "legally inappropriate and morally indefensible."

Myriad's patents give it exclusive control over a test that can detect a heightened risk of breast and ovarian cancer, leading to the misdiagnosis of patients and preventing improved tests from being developed, the medical groups claim.
"Patents on human genes impede the provision of health care, thwart public health objectives, shackle innovation and violate ethical tenets," their brief said.

According to a brief filed by the National Women’s Health Network and related groups, Myriad’s exclusive rights to the test means that if the test is inconclusive, a patient cannot get a second opinion, impairing the decision making of patients and doctors.

"These exclusionary patents privatize and monopolize the use of this knowledge, which necessarily produces grave harms for the health of women and their families," the groups said.

The plaintiffs also have the support of James Watson, who in 1953 co-discovered the double helix structure of DNA and said in his brief that human genes should not be patented because "life's instructions ought not to be controlled by legal monopolies created at the whim of Congress or the courts."

Patent protection is not necessary to encourage scientists discover human genes and "a human genome cluttered with no trespassing signs granted by the patent office inhibits scientific progress, particularly the development of useful tests and medicines in areas requiring multiple human genes," he said.

**Arguments for Myriad's patents**

In its merits brief, Myriad argues that its isolated genes are eligible for a patent in part because they can be used to detect the risk of nature, something the genes cannot do in their natural state.

"These new attributes are the result of human ingenuity — the quintessential mark of patent-eligible subject matter," the company said.

Many of the briefs supporting Myriad focus on the potential harm to the biotechnology industry, which relies on stable patent protection, should the patents be struck down.

"The industry has a lot of patents and new inventions that often depend in some way on the use of isolated portions of DNA," said Erik Belt of McCarter & English LLP. "The fear is that if the Supreme Court does not accord these types of inventions patentability, it would severely disrupt the biotech industry."

The American Bar Association said in its brief supporting Myriad that isolated DNA, which is different from compounds that occur in nature, should remain patent eligible.

"A per se or categorical disqualification of such claims would be a material change in this court's traditional approach to determining patent-eligibility and would unjustifiably undercut significant investment-backed expectations and needs of the biotechnology industry," the group said.

The Boston Patent Law Association, in a brief filed by Belt, told the court that its analysis should focus on the specific chemical structures claimed by Myriad, not on whether genes can be patented, and cautioned that invalidating the patent could have wide-ranging effects.

The term "gene" is ambiguous, so "a decision that simply refers to patent eligibility of 'genes' would be unintentionally broad sweeping and might effectively disqualify many worthy patentable inventions," the group said.

The AIPLA's brief did not formally support Myriad, but said the validity of its patents should be affirmed and challenged the assertions of the plaintiffs and their amici that the patents inhibit research.
Patent law has long distinguished between experimenting on a patented invention and using the invention for its stated purpose, thereby infringing it, the group said.

"Thus, there is substantial room for scientific inquiry into DNA sequencing, even as patent protection rewards the inventors by excluding others from exploiting commercial use of the inventions," it said.

MPEG LA LLC, a company that packages patent pools, including one called Librassay that includes hundreds of DNA molecules and other technologies, argued that licensing programs are an effective way to allow for patents on biotechnology without hindering important research.

"Petitioners and others have posited a false dichotomy between providing incentives to innovate through patents, on the one hand, and permitting researchers and health care professionals to make use of others’ patented inventions, on the other," the group said.

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