

Prometheus Dooms DNA Analysis Patent, Merial Claims

By **Ryan Davis**

Law360, New York (May 02, 2012, 6:24 PM ET) -- A patent held by Genetic Technologies Ltd. on a method of using DNA in genetic analysis should be invalidated in light of the U.S. Supreme Court's recent Prometheus ruling, Sanofi-Aventis SA's animal health unit Merial Ltd. said in a re-examination request filed Monday.

Merial, one of several companies Australia-based Genetic Technologies has sued over the patent, told the U.S. Patent and Trademark Office that the patent contains claims akin to those the high court found to be unpatentable laws of nature under Section 101 of the Patent Act in a March decision.

Genetic Technologies' claims "are not patent-eligible subject matter under Section 101 because ... they fail to provide 'significantly more than a law of nature, a natural phenomenon or an abstract idea with conventional steps specified at a high level of generality appended thereto,'" the request stated, quoting a memo the USPTO sent to its examiners about how to apply the Prometheus ruling.

The re-examination request also alleges that Genetic Technologies patent is rendered anticipated and obvious by several pieces of prior art that the USPTO has not previously considered.

The claims in the patent do not meet the requirements of Section 101 because they do not cover a patentable invention, so they also necessarily fail to meet the requirement under Section 112 to provide a written description of the invention, the request states.

Because the patent does not meet the Section 112 requirement, it is entitled to a filing date in 1992, not the earliest possible filing date of 1989 that it claims, which renders the patent obvious in view of the newly presented prior art, the request claims.

Genetic Technologies sued Merial and several pharmaceutical giants over the patent in Colorado federal court in May 2011. According to the complaint, the patent covers applications for "noncoding" DNA for use in genetic analysis and gene mapping across all genes in all species.

Genetic Technologies alleges that Merial infringed its patent with its Igenity line of genetic tests for DNA markers found in cattle. The suit claims that the patent was also infringed by blockbuster drugs made by the other defendants, including Bristol-Myers Squibb Co.'s Plavix and Pfizer Inc.'s Zolofit.

At the time the suit was filed, Genetic Technologies said in a statement that it had filed several suits over the patent since February 2010 and had to date secured \$14.5 million in licensing fees through settlements.

In a landmark decision, the Supreme Court unanimously ruled in March that Prometheus Laboratories Inc.'s blood testing method patents were unpatentable because they disclose only a natural phenomenon and steps consisting of "well-understood, routine, conventional activity already engaged in by the scientific community."

In the re-examination request, Merial claims that Genetic Technologies' patent is similarly unpatentable. The patent describes detecting a coding region allele and analyzing it to determine the presence of a genetic variation.

The patent does not include "any recitation of what steps or claim elements one performs to make such a determination," the request states.

Merial alleges that the claims "do little more than recite a law of nature and add the instruction 'apply the law,'" a construction the Supreme Court expressly identified as unpatentable in Prometheus.

Genetic Technologies' patent was previously re-examined by the USPTO in 2010, and the claims were upheld. Merial's re-examination request cites prior art that it says was not considered in the previous re-examination.

In March, a Colorado federal judge ruled that the defendants in the Genetic Technologies case were improperly joined and transferred the claims against several defendants to different courts. The case against Merial is now pending in the Delaware federal court.

An attorney for Merial declined to comment further on the the re-examination request, and a representative of Genetic Technologies could not immediately be reached for comment Wednesday.

The patent-in-suit is U.S. Patent Number 5,612,179.

The re-examination request was filed by Merial in-house attorneys Judy Jarecki-Black and Chad M. Kitchen, and Thomas J. Kowalski and Smitha B. Uthaman of Vedder Price PC.

Merial is represented in the underlying litigation by Judy Jarecki-Black, J. Patrick Elsevier and Olivia E. Marbutt of Jones Day and Frederick L. Cottrell III, Kelly E. Farnan and Jason J. Rawnsley of Richards Layton & Finger PA.

Genetic Technologies is represented in the underlying litigation by Raymond H. Lemisch of Benesch Friedlander Coplan & Aronoff LLP and Benjamin B. Lieb of Sheridan Ross PC.

The case is Genetic Technologies Ltd. v. Merial LLC, case number 1:12-cv-00396, in the U.S. District Court for the District of Delaware.

--Editing by Lindsay Naylor.