

Reproduced with permission from Patent, Trademark & Copyright Law Daily, 161 [ptd-bul], 08/20/2014. Copyright © 2014 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

Patents

Defense to Myriad Patent Infringement Claim Now Moved to Patent Trial and Appeal Board

The Supreme Court's *Myriad* decision rattled the biotech patent community somewhat, but it did not stop Myriad Genetics Inc. from asserting patent infringement. One defendant in federal court has initiated a second line of attack, at the Patent Trial and Appeal Board.

GeneDx Inc., a wholly owned subsidiary of BioReference Laboratories, Inc., filed 11 petitions for inter partes review on Aug. 18, challenging claims of 11 different patents Myriad is asserting against GeneDx and five other genetic testing service competitors (*GeneDx Inc. v. Myriad Genetics Inc.*, P.T.A.B., IPR2014-01296 et al., petitions filed 8/18/14).

The court defendants have the ability to continue the charge that Myriad's claims are not statutory subject matter, under 35 U.S.C. § 101, the issue in the high court's decision.

The IPR challenges have the additional benefit, compared to district court litigation, of removing the presumption of validity and a broader claim construction standard that can make patent claims more susceptible to anticipation and obviousness charges as well.

Myriad's Infringement Complaints Consolidated. Myriad's patents covering the BRCA1 and BRCA2 genes associated with occurrences of breast and ovarian cancer were the subject of a Supreme Court decision on Section 101 patent eligibility for claims on isolated DNA and cDNA. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2013 BL 155804, 106 U.S.P.Q.2d 1972 (2013) (115 PTD, 6/14/13).

The court's controversial decision that isolated DNA is generally not patent eligible and cDNA generally is obscured the fact that Myriad had many other claims on their testing methods that were not challenged before the high court. Nevertheless, competitors seized on the

Supreme Court's ruling and announced plans to offer genetic testing for the BRCA1 and BRCA2 genes, relevant to breast and ovarian cancer, that were at issue in the case.

Myriad asserted some of the same patents, but mostly later issued ones, and other patents on detecting the human MUTYH gene, linked to colon cancer, against GeneDx on Oct. 28, 2013, in *Univ. of Utah Research Found. v. GeneDx, Inc.*, No. 2:13-CV-00954-RJS (D. Utah). It filed additional complaints against Ambry Genetics Corp., Counsyl Inc., Gene By Gene Ltd., Invitae Corp., Pathway Genomics Corp. and Quest Diagnostics Inc. (134 PTD, 7/12/13). Counsyl, Invitae and Quest filed declaratory judgment actions in California courts.

Gene By Gene settled, and the remaining cases were consolidated in the District of Utah *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, No. 2:14-md-02510, 2014 BL 59830 (D. Utah March 3, 2014). Myriad's motion for a preliminary injunction was denied on March 10, 2014 BL 64538(49 PTD, 3/13/14).

Anticipation, Obviousness Challenges at PTAB. Attorneys at Sterne, Kessler, Goldstein & Fox PLLC, Washington, filed the IPR claims on behalf of GeneDx, based in Gaithersburg, Md.

IPR does not offer an attack based on a Section 101 argument. The new post-grant review challenge does, but the patent claims asserted here were applied for well before the relevant availability date.

Consequently, the 11 IPR petitions cite prior art, that the Patent and Trademark Office did not consider in the original examination of Myriad's applications, in support of anticipation and obviousness arguments under Sections 102 and 103, respectively.

Eldora L. Ellison is lead attorney on the six petitions directed to asserted BRCA1/2 patents:

- IPR2014-01310, challenging claims 2 and 4 of U.S. Patent No. 5,654,155, Consensus sequence of the human BRCA1 gene;

- IPR2014-01316, seeking cancellation of claims 7, 8, 12, and 23 of U.S. Patent No. 5,753,441, 170-linked breast and ovarian cancer susceptibility gene;

■ IPR2014-01311, against claim 4 of U.S. Patent No. 6,033,857, Chromosome 13-linked breast cancer susceptibility gene;

■ IPR2014-01313, looking to cancel claims 7, 8, 13, 14, 16, 17, 19, 20, 32 and 33 of U.S. Patent No. 6,051,379, Cancer susceptibility mutations of BRCA2;

■ IPR2014-01312, attacking claims 8, 9, 14, 15, 20, 21, 38, 39, 41, 42, 44, 45, and 73 of U.S. Patent No. 6,083,698, Cancer susceptibility mutations of BRCA1; and

■ IPR2014-01314, against claim 5 of U.S. Patent No. 6,951,721, Method for determining the haplotype of a human BRCA1 gene.

Five petitions, filed by Sterne Kessler's Deborah A. Sterling, attack the more recently granted MUTYH-related patents:

■ IPR2014-01315, to cancel claims 10-12 and 14-18 of U.S. Patent No. 7,470,510, Methods for diagnosing cancer and determining a susceptibility for developing cancer

■ IPR2014-01299, challenging claims 2 and 7 of U.S. Patent No. 7,563,571; and IPR2014-01298, seeking can-

cellation of claims 2, 3, 5, 9, 10 and 12 of U.S. Patent No. 7,670,776, both titled, MYH gene variants and use thereof; and

■ IPR2014-01301, against claims 10, 11, 15-17 and 19 of U.S. Patent No. 7,622,258; and IPR2014-01296, seeking cancellation of claims 2, 8, and 16 of U.S. Patent No. 7,838,237, both titled, Screening methods and sequences relating thereto.

Litigation Differences. The consolidated litigation going forward against the multiple testing firms also includes allegations of infringement of additional patents not challenged by GeneDx.

For example, seven other patents are asserted against Quest. But Quest, as well as GeneDx, also continue to assert a Section 101 defense in district court.

GeneDx's IPR petitions thus create a two-venue attack with potentially different challenges at issue in each—and an increased chance of success on the Sections 102 and 103 fronts.

By TONY DUTRA