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The news media kicked up quite a fuss this spring when a U.S. district court invalidated the patents on two isolated genes that are strong indicators of a risk of breast cancer. Association for Molecular Patenting v. United States Patent and Trademark Association, 1:09-cv-04515-RWS (S.D.N.Y. Mar. 29, 2010); see Blog Post of Kevin E. Noonan, Myriad Appeals AMP v. USPTO Decision (June 16, 2010) (collecting news articles and blog posts). The genes in question, BRCA1 and BRCA2, were researched, located, isolated, and patented by Myriad Genetics, one of the older genetics start-up companies (founded in 1991). They are among over 2,000 existing gene patents, which grant market exclusivity to inventors who have put in the work to identify and isolate specific human genes. Friday, the U.S. government unexpectedly reversed its previously held position supporting such patents, and issued a friend-of-the-court brief in the appeal of that case condemning the patenting of isolated human genes. Association for Molecular Patenting v. United States Patent and Trademark Association, No. 2010-1406, Amicus Curiae Brief for the United States in Support of No One (Fed. Cir.) (filed Oct. 29, 2010).

The government is wrong. Because it will fuel scientific progress, give a reasonable financial incentive to companies interested in genomics, and lead to further research in this rapidly expanding field, not to mention the fact that it is consistent with prevailing Federal Circuit precedent, the court should overturn this dangerous ruling. The government should not support the ruling, which in effect would invalidate over 2,000 genomic patents. Instead, Congress should selectively enact compulsory licenses on genetics patents when the test and gene in question are so significant that leaving the testing in the hands of one company puts potentially life-saving testing out of the reach of the average consumer. A sliding scale is more appropriate than the current all-or-nothing approach.

First, background is important. Myriad is a pioneer in a financially uncertain but potentially revolutionary field. In his recent book Dr. Francis Collins, the lead scientist in charge of the initial mapping of the human genome and the current head of the National Institute of Health, predicts that the most significant change in health care will come from advancements in genetic testing. Francis S. Collins, The Language of Life (2010). Three companies already offer personalized human genome mapping, and Dr. Collins predicts this will soon become a mandatory test required at birth and included in all individuals' health records, as scientists isolate and characterize more and more genes and their hereditary effects. Id. at 44. ("Newborn screening [which already occurs for very specific and treatable genetic conditions, such as cystic fibrosis] seems almost certain to evolve into an even broader and more comprehensive survey. . . . A softer version of *GATTACA* may be coming soon.")

Genes BRCA1 and 2 are well known in the genomics field as some of the first genes whose common genetic mutations show a significant increase in the risk of a specific, treatable, and even sometimes preventable condition, breast cancer. Id. at 27 ("women who carry a BRCA1 mutation have about an 80 percent lifetime risk of developing breast cancer and a 50 percent risk of developing ovarian cancer."). Myriad was the first to identify a method of testing for the genes and has moved to protect its interest as the sole holder of a suite of patents for those isolation and testing methods. Myriad, attempting to remain profitable while conducting further research and recouping the investment it has already put in through its initial research, is charging roughly $3,000 for the test. AMP v. USPTO 1:09-cv-04515-RWS. at 52-78.

The ACLU, breast cancer interest groups, and now the U.S. government oppose these patents as profiting from what is essentially our own human body, which they argue violates the statutory grant to the USPTO under 35 U.S.C. § 101, violates our individual First Amendment rights, and prevents lifesaving testing from being widely used. Their opposition is too

extreme, misunderstands the important place of industry in genetic research, and makes it harder for technology and research in genomics to grow at the current rapid pace. Furthermore, it is consistent with all of the known precedent concerning gene isolation patents, as well as with the over 2,000 patents the USPTO has granted consistent with their policies.

To be sure, no one wants important and potentially life-saving tests for breast cancer to be out of reach of the American public. That is why a congressionally mandated compulsory license is more appropriate for genetic tests of strong indicators of treatable serious conditions, particularly in the case of public hospitals and research institutions. Such a license would allow other companies and researchers to use the tests for a set licensing fee, and in certain limited cases, for free, which would reward and compensate Myriad for their research while striking the balance with public access to the tests.

However, simply invalidating the patents would give Myriad and other genetic start-up companies absolutely no incentive to research in this volatile and uncertain field, and will actually stifle genomic innovation in the end at a key time in the industry's adolescence. In a perfect world, well-funded government researchers in highly regarded public universities and research centers would exclusively carry out this important work, they would excel in the endeavor, and that would be sufficient. But absent some windfall grant of funding to the NIH or some newly instituted and very well-funded prize program, Congress needs to act to limit the reach of such intellectual property while ignoring a more sweeping and dangerous open grant, which offers no incentives whatsoever for companies to invest in key lifesaving research. To invalidate these patents would be far more dangerous to our health in the long run, and would put our industry and nation at a disadvantage worldwide in one of the only scientific fields in which we are still a leader, the genomics revolution.