

genetest

From: Siu K. Lo <slo@genesisbiotechgroup.com>
Sent: Monday, March 26, 2012 4:09 PM
To: genetest
Subject: Re: "Genetic Testing Study" - Written Comments

Dear Saurabh Vishnubhakat,

I am a patent counsel in a medical diagnostic company in the United States. I am concerned about the availability of second independent opinion in genetic diagnostic testing. I write to express my personal view concerning the subject matter as follow.

I believe that the current lack of independent second opinion in some genetic diagnostic testing would not adversely affect the medical care to patients. Many of genetic diagnostic tests are either not patented or under license to other independent laboratories, thus permitting an independent second opinion. Regarding to the minority of patented diagnostic testing, many are not analogous to Congresswoman Wasserman Schultz's situation where an independent second opinion regarding the *BRCA2* gene mutation may be used by patients in deciding drastic surgical operation. It remains to be seen whether there exists a real demand for a second opinion regarding a confirming genetic diagnostic test. Equally unclear is whether such confirming genetic diagnostic test would clarify the primary test result instead of complicating it.

The proposed safe harbor provision is anticipated to stifle the innovation of genetic testing. It deprives medical diagnostic companies the very incentive to invest money and effort in developing new diagnostic testing without the guarantee of recuperating the investments. Without the guarantee, less diagnostic laboratories would make breakthrough necessary in the personalized medicine field. The implementation of safe harbor may at best bring second opinion to a limited genetic diagnostic testing, but would severally tramp patent rights and brings the innovation to a halt.

Section 27 of the H.R. 1249 intends to provide a safe harbor for an independent second opinion in genetic diagnostic testing. Under this provision, a confirming genetic diagnostic test activity would not constitute infringement of a patent under section 271(a) or (b) of the title 35. At its present form, the provision provides no compensation to patent holders for the loss in patent rights to exclude others to make, sell or use of the patented invention. If passed, the provision in effect constitutes an uncompensated "taking" of property rights from the patent holders. If there is any lesson we should have learned, government should not trim patent rights by exercising its "taking" power without careful consideration. Instead, Congress should consider a more balance framework to respect patent rights. One option is to implement a patent term extension to compensate patent holders of genetic testing. An analogous model comes from Hatch-Waxman Act, where Congress provided patent term extension for brand pharma in exchange for generic company's early generic drug entry. Another option is to permit patent holders to demand a higher royalty fee (e.g., 30-40%) and limit to a few independent laboratories that provide a second opinion.

The provision is completely silent when it comes to regulation of the diagnostic laboratories that perform the second opinion diagnostic testing. Without a sound regulatory framework, it is difficult to envision how the quality of the second diagnostic test be supervised and maintained.

One central issue in genetic diagnostic testing may simply relate to patent monopoly through gene patenting. A patent claim directed to an isolated gene or an isolated gene segment encompassing many SNPs may has a broad preempt effect to all diagnostic tests developed from the particular gene. It is essential to regulate the

issuance of any patents that dominantly patenting isolated genes and SNP contained therein. Leahy-Smith America Invents Act (AIA) directs that “no patent may issue on a claim directed to or encompassing a human organism.” AIA 33(a), 125 Stat. at 340. But AIA fails to go beyond that to preclude gene patenting. Rather, Congress recognizes the eligibility for patent protection of diagnostic method claims, often involving detecting the absence or presence of a mutated gene. On March 20, 2012, the Supreme Court delivered a unanimous opinion in *Mayo v. Prometheus*. The Court noted that “to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words “apply it.”” On March 26, 2012, the Supreme Court has vacated the Myriad’s judgment and the case is remanded to the United States Court of Appeals for the Federal Circuit for further consideration in light of *Mayo v. Prometheus*. Given the Court’s concern that broad preemptive effects of gene patenting that may inhibit future discovery by tying up the use of laws of nature, and that human genes represent “the basic tools of scientific and technological work”, Myriad’s patents claiming isolated *BRAC1* and *BRAC2* likely would not withstand the invalidity challenge.

The responsibility also lies squarely on USPTO. Examiners at the patent office should utilize 35 U.S.C. §§102 and 103 (in combination with §101) to preclude patent eligibility for broadly-claimed isolated genes in view of the fact that many of these gene sequences have been publically disclosed by the human genome project. It would be obvious for one skilled in the art to isolate a known gene. Without the barrier of gene patenting, independent second opinion is accessible via design around a patented diagnostic method.

The current exclusive licensing system is insufficient to provide adequate remedy to a patent holder of a diagnostic testing. Government’s mandatory licensing has not been working. Genetic diagnostic testing varies significantly among different companies. Care must be taken to ensure uniformity and regular monitoring. Another option includes ensuring that the second opinion must be performed after the first opinion performed by the patent holder. The first diagnostic company must be given authority to ensure the same procedures as well as reimbursing some portion of the costs.

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