

genetest

From: Sundby, Suzannah <ssundby@sgrlaw.com>
Sent: Monday, March 26, 2012 7:41 PM
To: genetest
Subject: Genetic Diagnostic Testing Comments
Attachments: image467394.JPG

ATTN: Saurabh Vishnubhakat
Attorney Advisor
Office of Chief Economist

Dear Mr. Vishnubhakat,

With regard to consideration of (4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests as required by the AIA, I refer you to a news story by CBS entitled "Should Firms Be Able to Own Your Genes". See <http://www.cbsnews.com/stories/2010/04/01/60minutes/main6354069.shtml> dated April 5, 2010.

In the CBS news story, the patient Ceriani stated that her medical insurance company would cover and pay for the Myriad breast cancer gene genetic test, but the lab would not accept her insurance. CBS also states that most insurance companies pay for the Myriad genetic test, but Myriad will not accept Ceriani's insurance plan because it pay the full amount.

This seems to be the crux of the matter -- access to genetic diagnostic testing is a health care reform and medical insurance issue rather than a patent issue.

With regard to question (9) What effects, if any, do patents and exclusive licenses have on genetic diagnostic testing, the public fails to understand the quid pro quo part of patents, i.e. the disclosure of the invention, adds to the wealth of knowledge and science and the patent coverage spurs others to design around and find improvements. Hence, we, the public, get new and improved diagnostics and medicines.

Without adequate patent protection, one would not likely spend billions on research and development as one would not likely be able to recoup the cost of R&D in addition to the millions required to bring the genetic diagnostic test to market. The CBS news story points to the fact that genetic diagnostic tests are often less expensive in foreign countries than in the United States. Because, however, other countries such as Europe and Canada have nationalized health care and different patent systems and often less stringent regulatory approval processes (as compared to the US FDA approval process), I believe it is impossible to fairly point to why such foreign countries are able to offer genetic diagnostic tests at lower costs.

Instead, I argue that it is more fair and accurate to draw correlations to the reasons we have patent term extensions for patents listed in the FDA Orange Book, a lack of treatments for orphan diseases, and a recent and ever increasing lack of new drug innovation. In particular, one should refer to Section VI of H.G. Grabowski (2007) "Competition Between Generic and Branded Drugs" In F. A. Sloan and C. T. Hsieh (Eds.), *Pharmaceutical Innovation: Incentives, Competition, and Cost-Benefit Analysis in International Perspective*, (pp. 153-173) Cambridge University Press. Grabowski et al.

also states in a recent article that "Various studies have found that research and development pipelines and new drug introductions have been insufficient to replace the loss of sales revenues to generic competition over the past decade, and this is likely to continue." See Grabowski et al. (November, 2011) Evolving Brand-Name and Generic Competition May Warrant a Revision of the Hatch-Waxman Act. *Health Affairs*, 30(11):2157-2166. With regard to the lessons that can be learned from orphan diseases, see, for example, the following article by Grabowski (2005) Increasing R&D Incentives for Neglected Diseases: Lessons from the Orphan Drug Act. In Keith E. Maskus and Jerome H. Reichman (Eds.), *International Public Goods, and Transfer of Technology Under a Globalized Intellectual Property Regime*, (pp. 457-480). Cambridge University Press. (Published by Cambridge University Press (Conference volume)). These articles by Grabowski can be obtained from

<http://econ.duke.edu/people?subpage=publications&Gurl=%2Faas%2FEconomics&Uil=grabow>. See also http://en.wikipedia.org/wiki/Orphan_drugs. A recent article by D'vorah Graeser entitled "Encouraging Real Drug Innovation" published in a BNA news article explains the new drug pipeline is rapidly drying up and that the pharmaceutical industry has a wall financially and creatively. This means less new drugs and treatments in the future.

These articles are represent just some of the economic analyses and evidence that strong and adequate patent protection is necessary for incentivizing the biotech and pharmaceutical industry to spend the billions of dollars necessary for developing the genetic diagnostic tests the public seeks. Without strong and adequate patent protection that was in existence when the Myriad genetic test was developed, it is likely that one would not even have access to the Myriad genetic test today. What company is willing to spend millions to billions of dollars on R&D to develop a genetic diagnostic test only to give it away for free? Such a company would be a bankrupt company without any money to spend on R&D for developing other needed diagnostics and treatments.

Thank you for this opportunity to comment on genetic diagnostic testing.

Best regards,
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