

genetest

From: Christine Gritzmacher <cagritzmacher@gmail.com>
Sent: Monday, March 26, 2012 1:48 PM
To: genetest
Subject: Genetic Testing Study

Dear Sir:

My comments respond to some issues presented in the Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing published in the Federal Register (Vol. 77, No. 16, Jan. 25, 2012). Examples in my comments relate to the use of genetic diagnostic testing in cancer diagnoses because those were the primary focus at a public hearing on Genetic Diagnostic Testing that I attended on March 9, 2012 in San Diego, California.

With regard to an "effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test," I believe an existing patentee and/or license holder would be significantly harmed if the patentee and/or exclusive licensee were required grant a license to an independent entity to provide a second opinion genetic diagnostic test. As discussed in the March 9th public hearing, "providing independent second opinion genetic diagnostic testing" is presumed to involve some type of compulsory license to an independent entity that would develop another genetic diagnostic test to compare results with those of the patent and/or exclusive license holder's genetic diagnostic test for the purpose of providing a second medical opinion. My comments presume that a primary genetic diagnostic test provided by the patentee and/or its exclusive licensee (hereafter "patentee/exclusive licensee") would be an FDA-approved test because most physicians and patients would not rely on an unapproved test as a basis for making a serious medical decision. An existing patentee/exclusive licensee has taken a financial risk in attempting to develop a test that reliably detects a genetic marker of clinical significance for diagnoses. Most privately-funded and government-funded research that identifies a genetic marker associated with a clinical condition or disease relies on a limited set of data to suggest a positive correlation between a genetic sequence and the condition or disease. Such research may have been conducted by using cells that have been "immortalized" and maintained under laboratory conditions for decades, or by using human biopsy samples obtained from a single patient or a few people. Although the research, in fact, may correctly conclude that a genetic marker correlates with a clinical condition or disease, the sample sizes used in many research studies are insufficient to show a statistically significant correlation that would support FDA approval of a diagnostic test. Therefore, the patentee/exclusive licensee must not only develop a test that is reliable and robust enough to accurately detect the genetic marker in diverse biological samples (e.g., biopsy samples collected or preserved under different conditions), but must also conduct clinical studies using the test to demonstrate a statistically significant correlation between detection of the genetic marker and the condition or disease. Such clinical studies are expensive endeavors because they include the costs of enrolling large numbers of patients and normal controls in the study, obtaining and testing the human samples with the new diagnostic test and a conventional method (e.g., pathology analysis) for comparison, follow-up testing as needed, statistical analysis of the data, and preparation of a detailed written report of the study to present as part of an FDA review. An existing patentee/exclusive licensee has taken all the risk of development of a commercial genetic diagnostic test. A compulsory license would be given a "free ride" to rely on the clinical significance of the genetic marker shown in the clinical trial of the primary genetic diagnostic test, without sharing the patentee/exclusive licensee's risk associated with development of the primary genetic diagnostic test.

In addition, the existing patentee/exclusive licensee may be harmed if the entity that provides the independent second opinion genetic diagnostic test fails to develop or provide a reliable test. If the primary genetic diagnostic test results are not confirmed by the independent second opinion genetic diagnostic test, the patentee/exclusive licensee's reputation may be damaged significantly in the medical community even though the patentee/exclusive licensee had no role (other than providing the compulsory license) in the development or practice of the second opinion genetic diagnostic test. The existing patentee/exclusive licensee should not be expected to provide resources or know-how to ensure that the compulsory

licensee's efforts provide a reliable second opinion genetic diagnostic test. Yet, the existing patentee/exclusive licensee bears the risk of loss of reputation and if the independent second opinion genetic diagnostic test is unreliable.

In my opinion, requiring a patentee/exclusive licensee to grant license to another entity to provide an independent second opinion genetic diagnostic test would greatly diminish or negate the patentee/exclusive licensee's incentive to develop an approved genetic diagnostic test. Most commercial entities would not accept the great financial risk associated with development of an approved genetic diagnostic test unless there was a compensating potential market for the resulting commercial products. A compulsory license to another entity to provide an independent second opinion genetic diagnostic test must include payment to the patentee/exclusive licensee for a fair share of its development costs for the primary genetic diagnostic test.

The above comments about the significant risks associated with development of a primary genetic diagnostic test are also relevant to the questions on the effects that patents and exclusive licenses for genetic diagnostic tests have on the development of new testing procedures, how new testing procedures are performed, and on further improvements to testing procedures. Few entities will accept the financial risk of development of a new testing procedure unless the entity believes that it can recover its development costs when the approved genetic diagnostic test becomes commercially available. Without a commercial test to improve upon, further development of an existing genetic diagnostic test is unlikely to occur because there will be no standard procedure for comparison. Without sufficient protection provided by patenting, entities that develop new testing procedures will likely hold them as trade secrets, thus precluding disclosure of the procedure to others who could use the information to improve the existing procedure or developing new procedures. Without patent protection to encourage development of approved commercial genetic diagnostic tests, a variety of genetic diagnostic tests may be independently devised and practiced by some hospitals, clinical laboratories and research facilities. The impact on medical care of those various procedures, however, may be limited and variable. An approved commercial genetic diagnostic test may be purchased for any patient whose doctor orders it, whether the patient lives in a small community distant from a major medical center or within an easy commute to the National Institutes of Health. In contrast, patient access to any of the test procedures devised by hospitals, clinical laboratories or research facilities may be limited to those patients whose physicians practice at a particular hospital or clinic, or to only people who are selected for participation in a research study. Costs to patients and their families for procedures that are only available at locations distant from the patient's home can be significant and a barrier to medical diagnosis and treatment for many. Development of new testing procedures does not necessarily equate with increased access by patients to the procedures.

With regard to "the impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients ...", it is my opinion that medical care of a patient rarely relies on a single diagnostic procedure and diagnostic tests typically are not repeated when a patient seeks a second medical opinion. A variety of tests are used to detect cancer, including those that use imaging technologies (X-ray, MRI, CAT scans), analysis of biopsy samples by a pathologist, and tests to detect protein and genetic markers. If initial test results are considered insufficient or unreliable, a primary physician may order a follow-up test. All of the test results are analyzed by the primary physician, often in consultation with a team of medical specialists. When a patient seeks a second medical opinion, all of the test results are sent for analysis to a second physician selected by the patient. When a patient has been diagnosed with cancer, a physician typically recommends that the patient begin treatment as soon as possible. Delays resulting from unnecessary retesting are inadvisable. These comments are based on personal knowledge of the experiences of multiple family members diagnosed with cancer. Although this is a limited sample size, no independent second testing was required for a physician to provide a second medical opinion.

Finally, I question why genetic diagnostic testing has been singled out for, particularly on non-patent subject matter, i.e., costs and insurance coverage. Almost all new and technologically complex diagnostic tools are expensive. Insurance coverage and costs can be highly variable depending on the insurer, coverage plan, and who purchases it (e.g., employer-paid group plans vs. personally purchased insurance). This is unrelated to patent protection which is based on finding a claimed invention to be novel, nonobvious, and useful. If genetic diagnostic testing is singled out for limiting patent protection, will patenting of other technologies follow? Will improvements in patented imaging procedures require a compulsory license so that patients can choose a particular machine to be used for a mammogram, CAT or MRI scan? Will patented improvements in food processing methods or agricultural machinery require a compulsory license so that improved

food production can be universally available because certain medical conditions have been linked to poor nutrition (e.g., Type 2 diabetes)? These examples are noted to demonstrate the slippery slope that may result if patent rules and regulations are changed to carve out exceptions based on a particular technology.

Respectfully submitted,

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