

## Gene Patents: Getting Beyond Witch Trials January 16, 2013

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A good old fashioned witch trial can be jolly fun for most participants (save one). They are briefly cathartic, providing accusers a platform to be sanctimonious, while misleading a trusting public. Such efforts are best conducted behind closed doors as they lose credibility in the light of day. Thus, it was a relief to see the Patent and Trademark Office resist this approach in its January 10th Roundtable on Genetic Testing. This openness exposed claims that have driven the debate so far to a rare scrutiny. Perhaps the bonfires being prepared for the accused are premature.

The PTO is charged under section 27 of the America Invents Act with conducting a study on the influence of patents and exclusive licensing on the availability of confirmatory genetic testing – that is, the ability to obtain an independent confirmation of a genetic test by a second laboratory for patented tests only available from an exclusive provider. The sponsor, Congresswoman Debbie Wasserman-Schultz, is a breast cancer survivor who had to make serious medical decisions based on her own genetic test. Understandably, anyone in that situation wants to ensure they received the most accurate testing possible.

The Roundtable attracted the usual “gene patent” critics condemning patenting and exclusive licensing; offering remedies from expanded use of march in procedures under the Bayh-Dole Act, to compulsory licensing. However, after listening all day it seems we’re trying the wrong witch.

For example, it was not clear how many patients want confirmatory tests. Even the advocates admitted that the demand for such services is insufficient to create a private market. The only witness addressing the source of testing errors showed that 80% of so-called laboratory errors actually happen elsewhere. Mislabeling and mismatching samples at the hospital or in transit are more frequent than analytic mistakes in the lab. These aren’t patent or licensing problems, and aren’t fixed by confirmatory testing of the same samples.

One critic condemned universities issuing exclusive licenses as culprits responsible for preventing physician-run laboratories “that are begging to do the test” from offering competing testing services. The underlying notion appears that exclusive licensees who spend millions on test development and clinical validation actually provide shoddy lab work in practice, and that physician-run laboratories could do a better job. If so, no supporting evidence was given.

Mark Rohrbaugh, Director of NIH’s Office of Technology Transfer, spoke of the importance of scaling licenses to market and development risks, adding that in a few cases where they would only offer nonexclusive licenses the tests remain undeveloped. Can anyone think this outcome benefited patients? Obviously, sometimes exclusive licensing is a necessary incentive. The best judge is the inventing organization, not critics without licensing experience.

One witness with knowledge of both the science and technology transfer, Lori Pressman, objectively looked at the problem.  She pointed out that it is not possible to classify a “gene patent” when it is first invented, that even when licensed such inventions do not block research into alternative approaches, and that one reason why universities are so successful commercializing genetic tests is because they have the flexibility to grant exclusive field of use licenses when warranted.

 Remarkably it became clear during the Roundtable how little the opponents of “gene patents” seemed to care about second opinion testing. After years of hyping the purported unavailability of such tests into a major argument against patents and exclusive licensing, critics now claim that only targeting this issue in legislative recommendations is insufficient. Instead, they want blanket infringement exemptions for general diagnostic uses, or misuse of the Bayh Dole Act to bully licensees aiming at eliminating exclusive patent rights in diagnostic testing altogether. Fortunately, Rep. Wasserman-Schultz takes a more responsible approach, focusing on enhancing patient opportunities for confirmatory testing when necessary, without undermining incentives for developing first opinion tests.

Linda Bruzzone, a Lynch syndrome patient and Executive Director for Lynch Syndrome International made a telling point. Lynch syndrome is an inherited condition predisposing victims to aggressive cancers, often at a young age. It is a forgotten disease that’s vastly underdiagnosed even though genetic tests are available. Doctors have little awareness of the tests, which insurance companies inconsistently reimburse. Thus: “Our family members are dying.”

Patients with familial breast cancer are referred twice as often for genetic testing than Lynch Syndrome patients, even though the two conditions are equally common. When Lynch patients are lucky enough to be referred, tests vary between laboratories as each works in different ways with different parameters. Ms. Bruzzone said it’s critical to educate physicians on the availability and importance of testing, and for producing clinical data needed for insurance coverage. Because the companies offer slightly different tests, no individual company will invest to solve these issues.

She concluded *if Lynch syndrome testing were like BRCA testing with a patent and a company committing the required resources promoting the test, our families could be as fortunate having access to early diagnosis as families affected by hereditary breast cancer.* (<http://www.bloomberg.com/news/2012-10-24/life-saving-dna-test-overlooked-in-rise-of-colon-cancer.html>)).

Ironically, the candidate usually proposed for condemnation is Myriad Genetics-- the company that developed the BRCA test-- and the universities which issued its exclusive licenses. Critics claim exclusivity was not needed as any number of physician-operated laboratories could have done what Myriad did. Let’s look back.

When Myriad took the license there was no widespread demand for personalized genetic tests. Myriad not only had to figure out how to develop the test and accurately characterize a patient’s risk, they had to educate doctors and patients how the tests help them make better informed medical decisions. *Perhaps most importantly as pointed out at the Roundtable, they had to persuade insurance companies to pay for the tests through expensive data generation and validation.* Myriad and other pioneering companies succeeded in all three endeavors, and the US now enjoys the greatest public access to increasingly accurate genetic testing. Interestingly, insurance companies do not normally pay for confirmatory tests—a core problem that neither government march in’s or compulsory licensing alleviates.

Myriad says that without exclusive licenses they could not have succeeded. Perhaps this is less a case of the evils of patents and exclusive licenses than second guessing an entrepreneurial company that took a huge risk, and helped create a new industry protecting public health. Maybe a thank you is more in order than a bonfire.