

Remarks to USPTO meeting (organized by Duke) 27 March 2012

- I am a practicing physician (General Internal Medicine and Medical Genetics)
- The issue of gene patenting and licensing is not arcane; it has tangible impact on patients and medical practice
- I would like to point out that I am not an anti-patent zealot. Patents can and do serve an incredibly important role in this country and the world. But in the case of genetic diagnostics patent-enabled exclusivity is demonstrably unneeded and demonstrably harmful.
- Where exclusivity does not exist b/o a lack of patents or broad licensing we see a thriving market in which numerous labs offer testing and compete on the basis of quality, service and innovation (e.g. CF, Huntington Disease, Lynch syndrome for colorectal cancer risk, etc.)
- Where patent-enabled exclusivity has reigned we see:
 - limitation of access to testing by groups of patients, especially the most vulnerable, for example, patients on Medicaid in which a state does not have a contract with the sole provider of a test
 - no choice of laboratories to which a test is sent
 - inherent and unavoidable limitations on the ability to ensure quality through proficiency testing
 - inability to obtain second opinion testing – which will not be solved by the proposed simple exclusion since the most significant need is for 2nd opinion testing *in the event of a negative test* – something that can't and won't be offered unless labs are able to perform whole gene analysis and thus create the infrastructure in their labs that will support making and keeping the test available
 - The proposed exclusion for infringement for second opinions is thus a fig leaf that does little to address the actual problem
- The interpretation of sequence data is highly complex and represents the single greatest challenge to our ability to harness emerging genomic technologies for improved patient care
 - Therefore, the hoarding of variant data hurts the entire field and most of all, patients. In Myriad's case, their failure to contribute variant data to publically accessible databases since 2004 is an attempt to "evergreen" their soon-to-expire patents and should be discouraged - as it will undermine the entire field and is not in keeping with the constitutionally stated *raison d'être* of patents: to "advance progress in the sciences and useful arts"
- The patent on individual BRCA2 mutations issued in August of 2011 is equally vacuous in its legitimacy, harmful to patients and frankly Orwellian. If enforced it will impede my ability to report life-threatening information to my patients which they could act upon. Moreover, I would submit that in light of last week's Prometheus decision these simple methods claims are dead. They claim nothing more than the simple step of correlative reasoning in which physicians engage every day and I'm delighted that the SCOTUS recognized that in a 9-0 ruling.
- Recently we have seen the emergence of next generation technology which vastly improves the sensitivity of genetic testing and offers tremendous promise for improving patient care. However, in commercial offerings of such testing, the most important genes,

BRCA1 and BRCA2 are currently left off these panels purely b/o fear of infringement. This turns a game-changing test into a second tier add-on test and creates a situation where I now have to get two tests at double the price to my patient and their insurer if I want them to have access to full information about their own genome, their own disease and to the kinds of modalities that should be employed to prevent cancer in them in the future. The exclusion of BRCA1/2 from such panels makes real precisely the fear that we articulated in the SACGHS report - that the current patent landscape will severely restrict our ability to harness emergent technologies for improved patient care.

- And while it may seem I've been picking on Myriad, I would actually submit to you that –except for their harmful and highly unfortunate patent and licensing practices, they are a company with excellent service, fast turn-around times and high quality, informative reports. The same cannot be said of some other companies which have used the patent system to exploit a business model that simply rests upon buying patents and exclusive licenses, clearing the market of competition and then providing poor service. In my own personal clinical experience with, for example, Athena laboratories, I find their reports opaque, their service slow and I have serious concerns about their quality. But in the current situation I am forced to send my patient's tests to a lab that I fear does not provide them with what they need. The question becomes: who should set the standard for testing protocols? Patients and doctors or a random company that has snapped up exclusive licenses for the promise of short term economic gain?
- In another example of harm resulting from this unfortunate situation, for a two-year period when DNA Sciences had cleared the market of Long-QT testing competitors, but did not get a test on the market itself, no commercial test was available for this set of life-threatening conditions.
- It is also important to recognize that in the realm of diagnostic testing, the patent incentive is demonstrably unnecessary (and, as above, results in harms). This is manifestly demonstrated by the fact that where no patent protection exists many labs – indeed, mostly small university labs with limited resources for development, develop and offer these tests on a routine basis (as in the case of CF or Lynch syndrome).
 - I am consciously not remarking on whether the patent incentive is necessary in the therapeutic realm. This is a completely different issue with a very different landscape due to the demonstrably prohibitive costs of drug development.

I will end by simply reminding all of us, as these issues are debated, that patents exist for one overarching reason – as articulated in the US Constitution - to promote progress in the sciences and useful arts. Their primary purpose is for social benefit. And nowhere is that point more important than in the application of patent practices in healthcare. There is a fine line between insufficient patent protection and too much patent protection. If we get that wrong in the realm of consumer electronics I may be inconvenienced. But if we get it wrong in the realm of healthcare, as we have for the last two decades, real people will continue to suffer.

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