**Can diagnostics companies afford to provide Ebola testing?**

**(A Reality Check on the Effect of Supreme Court Activism)**

Brian R. Stanton[[1]](#footnote-1)

Most patent practitioners continue to reel from recent Supreme Court decisions that limit the scope of patent subject matter eligibility. *Myriad*, *[[2]](#footnote-2)* *Mayo*,[[3]](#footnote-3) and *Alice[[4]](#footnote-4)* are just the most recent entries into the debate on what limits should be placed on patents. Outside the judiciary, we have also seen executive branch initiatives[[5]](#footnote-5) aimed at limiting patenting of, e.g., genomic sequences and some types of computer code. Not to be left out, Congress, who has so far, refused to engage in modification of 35 U.S.C.§101, continues its patent reform efforts in, e.g., seeking to address patent enforcement practices.[[6]](#footnote-6)

Whether one favors expansive patent eligibility or limited claims to clearly tangible, non-naturally occurring products, the question still remains regarding the role of patenting in incentivizing innovation and providing economic reward for bringing new products and services to the marketplace. We could debate this question as a mere academic exercise. Unfortunately, when issues of public health are impacted, the answer takes on new importance and its resolution greater urgency. This is no place better highlighted than by looking at the convergence of intellectual property and biotechnology that addresses the Ebola[[7]](#footnote-7) crisis.

Ebola is a virus-based hemorrhagic disease that causes mortality in as many as 70% of its victims.[[8]](#footnote-8) The recent outbreak in west Africa has already taken over five thousand lives[[9]](#footnote-9) and affected the foundation of at least three countries. In addition, open travel and globalism has allowed the virus to spread to at least Spain, Germany, the UK, and the US. While the number of patients outside of Africa is small, the presence of this devastating disease in first-world countries has helped bring enormous public health resources to bear on this pandemic. Nonetheless, it will take private sector resources to bring large-scale diagnostics and (hopefully) treatments and cures to the public.

Public efforts like those supported by the NIH have put the sequence of 99 Ebola virus genomes into the public domain.[[10]](#footnote-10) The wide scale dissemination of this information will be critical to understanding this disease and finding a cure. However, what are the practical implications of this information dissemination when coupled with the *Myriad* and *Mayo* decisions?

In a least one instance, a major laboratory test provider has indicated (in confidence) that it would not be entering the Ebola testing market for three principle reasons: (1) the lack of availability of exclusivity for genetic testing; (2) the liability attendant in disease diagnostics; and (3), the limited reimbursements available due to emerging cost control measures under Affordable Care Act reforms.

The *Mayo* decision and its predecessors such as *Labcorp v. Metabolite*,[[11]](#footnote-11) have raised significant questions regarding the availability of patent rights in diagnostic medicine. Businesses are wary of either not being able to obtain exclusivity or that any patent rights will be extremely narrow. Even if public policy would dictate that wide scale testing by multiple companies is desirable, in the absence of economic returns, at least one company has decided to stand on the sidelines.

Liability has always been an issue in diagnostics. Inaccurate tests, false test results (positives and negatives), and reagent quality control (among other issues) makes providing tests a risky endeavor. In situations where reasonable profits may be garnered, risk tolerance increases; however, in emergent health crises, the ability to validate testing modalities is limited. Time critical delivery of products and services must therefore be made in the absence of scientific surety thereby imputing greater private sector risk.

Making a perfect storm, the ongoing implementation of the ACA, while of great potential public health benefit, carries with it significant cost-control measures. Without seeking to debate rising health care costs, a problem remains as to what prices are “reasonable” for health care products. It is certain that rising costs carry with them decreasing availability of products and services. However, limiting payments minimizes both private sector financial returns as well as risk mitigation.

The convergence of recent Supreme Court decisions *in combination* with a failure to establish much needed tort reform and the extant changes to health care concordant with the ACA has resulted in at least one company deciding to stand aside and avoid entry into the Ebola testing market. Whether or not other service providers will follow suit is unknown. It is also remains to be seen if the *Ebola* exemplar discussed here will generalize to other emergent diseases. However, unless public sector actors step into what has traditionally been a private sector role, provision of needed healthcare products and services will be negatively impacted by lack of availability of exclusivity until concerted public policies are established to bridge humanitarian and for-profit business models.

1. Brian R. Stanton, Ph.D. is a principle in Stanton Consulting Services, LLC. The view reflected in this commentary are his own. [↑](#footnote-ref-1)
2. *Association for Molecular Pathology* v. *Myriad Genetics* (*Myriad)*, 569 [U.S.](http://en.wikipedia.org/wiki/United_States_Reports) \_\_\_ (2013). [↑](#footnote-ref-2)
3. *Mayo Collaborative Services* v. *Promethius Laboratories*, 566 U.S. \_\_\_ (2012). [↑](#footnote-ref-3)
4. *Alice Corporation* v. *CLS Bank*, 573 U.S. \_\_\_(2014). [↑](#footnote-ref-4)
5. Preliminary Examination Instructions in view of the Supreme Court Decision in *Alice Corporation Ply. Ltd. v. CLS Bank International, et af.* June 25, 2014, available at http://www.uspto.gov/patents/law/exam/memoranda.jsp, last visited Nov. 24, 2014. Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature, Natural Principles, Natural Phenomena, And/Or Natural Products, Mar. 4, 2014, available at http://www.uspto.gov/patents/law/exam/myriad-mayo\_guidance.pdf, last visited Nov. 24, 2014. [↑](#footnote-ref-5)
6. As of Nov. 25, 2014, Congress has more than 21 substantive patent law related bills pending. [↑](#footnote-ref-6)
7. At the time of initial drafting, the world was at the peak of the Ebola virus epidemic in West Africa. As global resources have been brought to bear, viral spread has slowed and mortality rate dropped. However, more than 5000 people have died from the disease. See Ebola Virus Disease, World Health Organization, http://www.who.int/mediacentre/factsheets/fs103/en/, last visited Nov. 25, 2014. [↑](#footnote-ref-7)
8. Ebola (Ebola Virus Disease), Centers for Disease Control and Prevention, www.cdc.gov/vhf/ebola/, October 29, 2014. (Last visited Oct. 29, 2014.) [↑](#footnote-ref-8)
9. The World Health Organization reported 5,459 deaths in the 2014 West African pandemic. There are 15,351 confirmed cases of Ebola infection. (Data current as of Nov. 21, 2014.) See http://www.who.int/csr/disease/ebola/situation-reports/en/?m=20141121, last visited Nov. 25, 2014. [↑](#footnote-ref-9)
10. Francis Collins, Using Genomics to Follow the Path of Ebola, National Institutes of Health, U.S. Dept. of Health and Human Services, September 2, 2014. (Last visited October 29, 2014.) [↑](#footnote-ref-10)
11. *Labcorp.* v. *Metabolite*, 548 U.S. 124 (2006(. [↑](#footnote-ref-11)