

USPTO Roundtable on Genetic Diagnostic Testing

Written Commentary of MPEG LA

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Thank you to the USPTO for hosting this roundtable and to the efforts of the esteemed committee in facilitating it. I am Kristin Neuman, the Executive Director of the Librassay® patent licensing supermarket for molecular diagnostics. Librassay® is owned and operated by MPEG LA, the world's leading independent provider of alternative patent licensing solutions.

Librassay® is unique in these proceedings because we are the only entity offering a private sector solution to the issues concerning patent licensing in the context of independent second opinion diagnostic test availability, and indeed, all diagnostic testing. On one side, we have those who call for a ban on gene patents, or a legislative infringement exemption, or compulsory licensing – none of which exist in the law today and in all likelihood would unleash a raft of unintended consequences and produce more harm than good. On the other extreme, we have those who justifiably make the case that the patent system is working as it should to protect and reward innovation and investment, and that patents are not the culprit in the second opinion test problem, if there even is such a problem. Librassay® occupies the middle ground by recognizing the indispensability of patents to the development and commercialization of new healthcare innovations, while at the same time addressing inefficiencies in bilateral patent licensing transactions that hold back the supply of new products and tests in the field of molecular diagnostics.

The good news is that the Librassay® solution is a **reality** – it is up and running **right now** and is fully funded, leaving our government free to turn its attention to the

many other issues facing our country for which no private sector solution is at hand.

Here are the details:

- Librassay® is a one-stop shop for the nonexclusive licensing of molecular diagnostic patent rights to any and all test providers and product developers who desire a license on fair, reasonable and cost-effective terms.
- Librassay® balances the interests of test providers and product developers with the interests of patent holders and investors who rely heavily on patents as inducement for taking on the investment risk necessary to fund development efforts, regulatory approvals where required, and marketplace acceptance and adoption. In the absence of patent protection and its quid pro quo of public disclosure, at best innovations will become locked up in corporate vaults as trade secrets which will choke off the rapid dissemination of innovations in this important field. At worst, they will not be developed at all.
- The Librassay® patent licensing supermarket opened for business in September of 2012 with the support of eight anchoring institutions including preeminent research and health care institutions such as *the National Institutes of Health, the Ludwig Institute for Cancer Research, Memorial Sloan-Kettering Cancer Center, and Partners Healthcare of Boston*, and world class universities such as *Johns Hopkins, Stanford, the University of Pennsylvania and the University of California, San Francisco.*

- The Librassay® patent portfolio presently contains nearly 400 patents available for licensing on a nonexclusive basis to any and all medical practitioners, labs and companies wishing to use them. Currently, the portfolio contains more than 150 patents and pending applications with claims to isolated nucleic acid molecules; more than 250 patents and pending applications with claims to isolated peptides, proteins, and antibodies; more than 350 patents with claims to diagnostic methods and assays for a wide variety of diseases and other medical conditions, including cancer (our highest concentration), autoimmune, cardiovascular, central nervous system, gastrointestinal, infectious disease, metabolic disease, neuropsychiatric conditions, reproductive health, and many others. In addition, we have patents directed to the use of biomarkers as therapeutic indicators and companion diagnostics. And further, we have patents relating to diagnostic devices such as microfluidics and arrays, diagnostic imaging, and next generation sequencing. We expect to add many more institutions and patents to the program in the coming year.
- Answering the call for unencumbered research in this field, Librassay® provides a royalty-free license under all patents in the portfolio for basic research and educational purposes.
- The Librassay® website provides an online storefront for searching, downloading and viewing patents available for licensing through the store, plus a summary of the key terms and conditions for the license. I invite you all to visit the store at www.librassay.com.

- We believe that Librassay® will bring down the costs of molecular diagnostic tests by evening the playing field when it comes to patent licensing; providing transparent licensing information to licensors and licensees; removing barriers to entry for patent owners and patent users; and, because the patents will be licensed nonexclusively in volume and in combination with other patents to any and all entities desiring a license, patent holders stand to do better in Librassay® than they would had they chosen to license exclusively to a single Licensee.
- We have plans to advance Librassay® as fast as is humanly possible. In addition to growing the portfolio, we are hard at work cultivating from the portfolio patents that lend themselves to being licensed in bundles that will assist companies and labs in their effort to obtain freedom to operate with respect to new test services and product offerings. Further, we desire to work with other entities having the common mission of furthering knowledge and technology dissemination in this field, such as the NIH's Genetic Testing Registry and ClinVar resources.

The advantage of Librassay® over any of the other solutions proposed in the course of these proceedings is that it fits squarely with our country's established leadership role in healthcare innovation and with our legal system as it exists *right now*. Librassay® requires no legislative, regulatory or other measures of unintended consequence.

In Librassay®, patents retain their full stature and continue to perform the role envisioned by our founding fathers in the Constitution – as an indispensable vehicle for, as Abraham Lincoln put it best, “adding the fuel of interest to the fire of genius in the discovery and production of new and useful things” – and nowhere is this more necessary than in the high risk field of life sciences product development. As the administrator of the Librassay® patent portfolio and online licensing store, we bring efficiency to patent licensing by offering nonexclusive licenses to a multitude of patents held by many different entities in a single, express, cost-effective and transparent license agreement that is available to all.

We are confident that Librassay® will work to alleviate patent bottlenecks and speed up test and product development in molecular diagnostics because it is based on licensing models that MPEG LA has employed very successfully in other areas. The patent situation we face now with genetic diagnostics is similar in many ways to the patent situation present in consumer electronics in the mid-1990s. Then, the MPEG-2 standard for digital television and DVDs faced a patent thicket that threatened widespread adoption of the technology. The single biggest challenge to MPEG-2 adoption was access to essential patents. MPEG LA created the MPEG-2 patent pool as a solution to the market's need for greater transactional efficiency. The solution revolutionized patent rights management by enabling all MPEG-2 product developers to acquire access to essential patents in a single transaction as an alternative to negotiating a series of costly, bilateral licenses. As a result in part of the efficiencies created by the MPEG-2 patent pool, MPEG-2 became the most successful standard in consumer electronics history

giving rise to an industry characterized by 5 billion digital video devices and 50 billion video discs, amounting to some \$3.5 trillion in product sales.

I think it is fair to say that each of us in the room today wishes the same relative growth rate and success for the emerging field of genetic diagnostics and personalized medicine. Like the situation with MPEG-2, the simple enhancement of patent licensing efficiencies within the framework of our existing patent and tech transfer systems holds the greatest promise for the growth and success of genetic diagnostics. We believe that patent licensing efficiencies are best promoted through the private sector – and Librassay® is ready, willing and able to serve that purpose.