

Public Hearing on Genetic Diagnostic Testing
February 16, 2012

- (1) Testimony delivered by: Kristin H. Neuman
Executive Director, Librassay®
MPEG LA, LLC
- Also present:
Lawrence A. Horn
CEO
MPEG LA, LLC
- (2) Contact information: kneuman@mpegla.com
lhorn@mpegla.com
(301) 986-6660
- (3) Organization: MPEG LA, LLC
5425 Wisconsin Avenue, Suite 801
Chevy Chase, MD 20815

*Testimony of MPEG LA, LLC
Patent Licensing Practices in the Field of Genetic Diagnostics*

Good morning ladies and gentlemen. Thank you Congresswoman Schultz, Deputy Under Secretary Rea, and distinguished members of the panel for the opportunity to contribute to the public discourse on the topic of how to effectively provide easily accessible, widespread genetic diagnostic testing while also providing a reasonable return on investment to patent owners. I am Kristin Neuman, the incoming Executive Director of Librassay® – a new patent licensing facility offered by MPEG LA, LLC. I am joined by Mr. Larry Horn, the CEO of MPEG LA.

I will begin by introducing MPEG LA and the trailblazing role it has played in providing mass market patent licensing solutions to unlock and accelerate technological advances. Then, I will introduce MPEG LA’s Librassay® – a patent licensing “supermarket” designed to accelerate the adoption and availability of personalized medicine technologies, including genetic diagnostic testing.

MPEG LA is the world’s leading alternative intellectual property solutions source, enabling users to acquire patent rights for technology standards and platforms from multiple patent owners in a single licensing transaction.

MPEG LA was formed in the 1990s, when the MPEG-2 digital data compression standard (which is required for digital television applications including DVD) faced a patent thicket that threatened widespread adoption of the technology. The single biggest challenge to MPEG-2 adoption was access to essential patents. *Many* MPEG-2 patents owned by *many* parties made it virtually impossible for most users to negotiate the number of licenses necessary to practice the standard. MPEG LA offered an alternative –

the first modern-day patent pool – as a solution to the market's need for transactional efficiency. The solution revolutionized intellectual property rights management by enabling *multiple* MPEG-2 users to acquire essential patent rights from *multiple* patent holders in a single, nondiscriminatory transaction as an alternative to negotiating separate, bilateral licenses. MPEG-2 became the most successful standard in consumer electronics history, and the MPEG LA® Licensing Model has become the template for addressing other patent thickets. Today, MPEG LA operates several licensing programs consisting of more than 6,000 patents in 74 countries with over 130 licensors and 5,000 licensees.

The MPEG LA® “many-to-many” licensing model entails *many* patent owners licensing patent rights in a given field to MPEG LA, as licensing administrator. MPEG LA, in turn, uses its well-honed and fine-tuned mass market licensing techniques to sublicense the patent rights out to *many* users on a non-exclusive basis, in a single transaction.

Let’s turn now to the subject of today’s hearing – genetic diagnostic testing, particularly second opinion testing, patent rights and patent licensing. Based on substantial input over a three-year period of time from stakeholders across the spectrum of the genetic diagnostics industry, MPEG LA has invested in the creation of a new “many-to-many” market-based solution to address patent licensing inefficiencies and potential patent thickets in the field of molecular diagnostics and personalized medicine. The solution is called Librassay® and it is an easy-to-use, web-based catalog or store of patent rights available for licensing on a non-exclusive basis to any and all users on reasonable, transparent and nondiscriminatory terms. Librassay® licensees will be able

to shop the Librassay® website store for the patent rights they need to clear, develop and offer genetic diagnostic tests, bundle the patents into a customized package, and license the package on a non-exclusive basis in a single, efficient and cost-effective transaction. The Librassay® many-to-many licensing model will be particularly useful and valuable in connection with multiplex genetic testing, where patents rights belonging to many different owners may be needed to support a single multiplexed genetic test.

Librassay® is expected to launch in the second quarter of this year. We are in the process now of concluding agreements with the world's leading universities and research institutions to include their patents upon launch, and the Librassay® website store is in beta test, as I speak. The licensor institutions see Librassay® as a welcome marketplace alternative, giving them the opportunity to meet their Bayh-Dole obligation to license to a wide market in service to patients and the public; and to monetize their IP for diagnostics while still preserving the right to enter into drug development collaborations where exclusivity may still be necessary.

MPEG LA acknowledges that there are different views surrounding the patentability of genes and diagnostic methods. MPEG LA is not appearing today to take a position in this debate. We do, however, note that exclusive licensing practices, market behavior and related legal cases cry out for the need to provide nonexclusive access to essential patents in the diagnostics field of use, and MPEG LA, through Librassay®, intends to answer that call. Our role is to take the market as we find it, and to help patent owners and users come together in an efficient fashion to hasten transactions that incentivize technology innovation and adoption by balancing reasonable access to IP rights with a reasonable return on investment.

The non-exclusive licensing platform provided by Librassay® will promote the availability of independent, second opinion genetic diagnostic testing by providing a wide variety of patent rights to any and all users in a single, easy, and cost-effective transaction. As more and more patents become available through Librassay®, the medical community will experience greater levels of genetic test availability because no entity will be able to license patents from Librassay® on an exclusive basis – the Librassay® patent rights will be available to all. Further, we expect the widespread, non-exclusive licensing opportunities available through Librassay® to drive down the cost of genetic diagnostic testing, as fewer patent owners continue to hold exclusive patent positions. And all of this can be attained while still providing a reasonable financial return to patent owners for their innovation in this very important field.

Thank you for your time and attention. Additional information may be obtained by visiting MPEG LA's website at www.mpegla.com or by contacting me at kneuman@mpegla.com.