USPTO to Hold Hearing on Genetic Diagnostic Testing

By Donald Zuhn – February 15, 2012



On Thursday, the U.S. Patent and Trademark Office will hold the first of two hearings on independent second opinion genetic diagnostic testing where patents and exclusive licenses exist that cover primary genetic diagnostic tests. The Office is holding the hearings to collect information for the preparation of a report to Congress pursuant to § 27 of the Leahy-Smith America Invents Act (see "<u>USPTO News Briefs</u>," January 26, 2012). Thursday's hearing will take place in the USPTO's Madison Auditorium located at 600 Dulany Street in Alexandria, Virginia, with a second hearing scheduled for March 9, 2012 in San Diego.

Agendas for both public hearings can be found <u>here</u> (February 16) and <u>here</u> (March 9). WebEx and teleconference numbers and passwords or access codes for each hearing can be found on the agendas. On Thursday, a USPTO panel consisting of Deputy Director Teresa Stanek Rea; Dana Robert Colarulli, Director, Office of Governmental Affairs; Janet Gongola, Patent Reform Coordinator; Stuart Graham, Chief Economist; and George Elliott, Director, Technology Center 1600 will hear testimony between 9:35 am and 12:05 pm from the following individuals:

- Thomas Kowalski, Shareholder, Vedder Price, P.C.
- Mercedes Meyer, Member, Board of Directors, American Intellectual Property Law Association
- Mary Williams, Executive Director, Association for Molecular Pathology
- · Lori Pressman, Independent Consultant on Technology Transfer
- Hans Sauer, Associate General Counsel for Intellectual Property, Biotechnology Industry Organization
- Ellen Jorgensen, President, Genspace
- Lawrence Horn, CEO, MPEG LA, LLC and Kristin Neuman, Executive Director, Librassay, MPEG LA, LLC
- Lisa Schlager, Vice President, Community Affairs & Public Policy, FORCE
- Kevin Noonan, Patents Docs author and Partner, McDonnell Boehnen Hulbert & Berghoff LLP



Prior to this testimony, the panel will hear (via video) from Rep. Debbie Wasserman Schultz (D-FL) (at left) who introduced an amendment to H.R. 1249 that would have exempted from infringement a "genetic diagnostic tester's performance of a confirming generic diagnostic test activity" that would otherwise constitute infringement under §§ 271(a) or (b). H.R. 1249 was eventually passed by both the House and Senate -- without Rep. Wasserman Schultz's amendment (*see* "<u>House Judiciary Committee Approves H.R. 1249</u>") -- and signed into law as the Leahy-Smith America Invents Act. USPTO Chief Economist Stuart Graham will also give an overview of the genetic diagnostic testing study. Unscheduled testimony will be taken beginning at 1:30 pm.

In addition to the public hearings, the Office is also seeking written comments, which must be submitted by March 26, 2012. Additional information regarding the submission of written comments can be found <u>here</u> and in the Office's Federal Register notice (<u>77 Fed. Reg. 3748</u>).



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