USPTO Holds First Hearing on "Second Opinion" Genetic Testing

By Kevin E. Noonan -- February 16, 2012

The U.S. Patent and Trademark Office held the first of two planned hearings aimed at fulfilling one of the reporting provisions of the Leahy-Smith America Invents Act (*see* "USPTO to Hold Hearing on Genetic Diagnostic Testing"). Section 27 of the Act requires the Office to conduct a study regarding the advisability of permitting "second opinions" for patented genetic diagnostic tests without patent infringement liability:

SEC. 27. STUDY ON GENETIC TESTING.

(a) IN GENERAL.—The Director shall conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist.

(b) ITEMS INCLUDED IN STUDY.—The study shall include an examination of at least the following:

(1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses.

(2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test.

(3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to: the interpretation of testing results and performance of testing procedures.

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

(c) CONFIRMING GENETIC DIAGNOSTIC TEST ACTIVITY DEFINED.—For purposes of this section, the term "confirming genetic diagnostic test activity" means the performance of a genetic diagnostic test, by a genetic diagnostic test provider, on an individual solely for the purpose of providing the individual with an independent confirmation of results obtained from another test provider's prior performance of the test on the individual.

(d) REPORT.—Not later than 9 months after the date of enact- ment of this Act, the Director shall report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on the findings of the study and provide recommendations for establishing the availability of such independent confirming genetic diagnostic test activity.

In acting to satisfy this Congressional mandate, the Office invited public testimony and published in the Federal Register a list of questions to be addressed by such testimony (77 Fed. Reg. 3748).

At the hearing, the Patent Office was represented by Deputy Director Teresa Stanek Rea; Janet Gongola, Patent Reform coordinator; Stuart Graham, Chief Economist (who has taken responsibility for preparing the Report) and George Elliot, Group 1600 (Biotechnology) Director. Deputy Director Rea opened the proceedings, setting forth the overarching goal of the undertaking: trying to find a balance between protecting innovation through the patent system and providing the "best" patient care possible. Janet Gongola next explained the structure of the meeting, and introduced a video welcome from Congresswoman Debbie Wasserman Schultz (D-FL), the author of the AIA provision introduced in lieu of a more extensive draft provision introduced and then withdrawn after furious opposition by the ACLU and others (*see* "House Judiciary Committee Approves H.R. 1249"). Rep. Wasserman Schultz explained her personal involvement with this issue, being both a cancer survivor who bears one of the BRCA2 mutations. Although for her the test was definitive, in doing her research Rep. Wasserman Schultz became aware that not all instances of the Myriad test were as unambiguous as her mutation, and because of its patent position, Myriad could (and generally did) prevent any other testing lab from performing its patented test. The significance of BRCA gene mutation detection (and the extensive surgical prophylaxis recommended for BRCA mutation bearers) convinced Rep. Wasserman Schultz that women should have the opportunity to obtain a "second opinion." (While generally not an unreasonable position, it is unclear whether the basis for any diagnostic ambiguity is how Myriad performs the test or that certain mutations/variants found in the BRCA gene sequence are "polymorphisms of uncertain significance," *i.e.*, nucleotide sequence polymorphisms not yet unambiguously associated with disease -- in the latter case, of course, no number of "second," "third," or "*n*th" opinions would provide any greater degree of diagnostic certainty.)

After Rep. Wasserman Schultz's video, the first witness offering testimony was Thomas Kowalski of Vedder Price LLP. Mr. Kowalski provided the most extensive testimony, referencing the *AMP v. USPTO* (*Myriad*) case and the deficiencies in the plaintiffs' arguments (and the wisdom of the Federal Circuit's opinion), saying that the study mandated by § 27 of the AIA was in the nature of a "do-over," a legislative attempt to avoid patent infringement for BRCA testing that the plaintiffs had not been able to obtain in the lawsuit. He also contended that any legislative action to provide a patent infringement exemption for "second opinion" genetic diagnostic testing would be an "unconstitutional, unrecompensed taking" of the patentee's property right. It perhaps goes without saying that Mr. Kowalski urged the Office to provide Congress with a report that did not recommend such an exemption.

The panel next heard from Mercedes Meyer, a member of the Board of Directors of the American Intellectual Property Law Association. Like Mr. Kowalski, Dr. Meyer urged the Office to carefully consider the risks to innovation that could arise from passage of an patent infringement exemption for "second opinion" testing.

The first witness to speak in favor of such an exemption was Mary Williams, Executive Director of the Association of Molecular Pathologists. Ms. Williams repeated most of the arguments advanced by the ACLU in the *Myriad* case, reminding the Office that her Association was the lead plaintiff in the case; these arguments included AMP's position that neither genes nor genetic diagnostic tests should be patented. She also noted that the Secretary's Advisory Committee on Genetics, Health and Society

(SACGHS) of the Department of Health and Human Services had produced an extensive (~400 page) Report in April 2010 (*see* "BIO Comes out Swinging against SACGHS Report"). She urged the Office to consider that Report in preparing its own, citing the four years the Committee spent in producing the Report and the limited time Congress provided the Office to do its work. She also urged the Office to adopt the SACGHS Report's recommendation, failing to mention that the recommendations of the SACGHS Report were in many instances either unsupported or contradictory of the evidence set forth in the body of the Report.

Lori Pressman, an independent technology transfer consultant testified next. She referenced her own studies on the effects of patents on technology transfer and providing diagnostic testing to patients, and suggested that patent protection would be more important for future testing that it had been in the past. Like other witnesses, she did not recommend legislation providing an infringement liability exemption for "second opinion" genetic diagnostic testing.

Hans Sauer, Associate General Counsel for IP for the Biotechnology Industry Organization (BIO) spoke next. Dr. Sauer provided the Office with some demographic information about BIO (including the fact that Myriad is not a member) and explained the frustration of BIO's members who see a threat to their intellectual property (in agricultural genetics, for example) in the ACLU's lawsuit that many feel was prompted (and has been somewhat successful if only in the court of public opinion) due to Myriad's aggressive assertion of its patent rights. Interestingly, Dr. Sauer told the Office panel that anecdotal reports from physicians was that patients don't want a "second opinion" on the test as much as they want a second opinion on their medical options (which of course is not impacted by the Myriad patents).

Lisa Schlager, Vice President for Community Affairs and Public Policy of FORCE, a cancer patient advocacy group, testified regarding the need for patient access to their genetic information and opposing patents on human genes, genetic information (which is not patented), and genetic diagnostic testing.

The next witness, Kristin Neuman, Executive Director of Librassay™, a division of MPEG LA, testified that MPEG LA (which began in response to establishment of the MPEG2 video program/playback standard) has established a "clearinghouse" for licensing rights to patented genetic sequences. This clearinghouse, named Librassay™, will provide a "one stop shop" for obtaining rights to include patented sequences, for example, on a gene chip. She said the Internet interface was undergoing beta testing and that the company was working to obtain sublicensing rights for university-owned gene sequence IP.

Ellen Jorgensen then testified regarding her organization, Genspace. She advocated "at-home" or "do-it-yourself" DNA testing, asserting that individuals could perform their own testing much more inexpensively. Genspace provides the technology and the lab space for performing such tests, and she suggested that soon performing whole genome sequencing would be as common in high school laboratories as dissecting a frog had been in earlier, simpler times. She did not discuss any dangers in errors that might arise from such "at-home" genetic diagnostic testing, nor precautions in interpreting results (especially concerning the emotional consequences of finding a genetic mutation in an individual's BRCA genes).

[*Patent Docs* author Kevin Noonan of McDonnell Boehnen Hulbert & Berghoff LLP concluded the scheduled testimony portion of the hearing. Dr. Noonan's testimony can be found here. *Ed.*]

After taking one comment from the audience (from another patient advocacy group opposed to gene patenting and patented genetic diagnostic assays), Ms. Gongola thanked the witnesses and informed the audience that a transcript of the hearing would be available on the USPTO AIA microsite. The second hearing on genetic diagnostic testing will be held in San Diego on March 9, 2012. The Office will accept written comments until March 26, 2012, and the Report is due on June 16, 2012.

Although this was just the first hearing, the panel of Office officials and their questions provided a few indications of the direction of their inquiry. First, Stuart Graham is in charge of the exercise, and asked many of the witnesses for further information, statistics and other evidence supporting their testimony. His questions seemed directed to garnering hard evidence (which may not exist in some instances) on the effects of patents on innovation and patient access to testing. Several witnesses mentioned the interaction with the healthcare system and the role of public and private insurance in promoting or hindering access to genetic diagnostic testing (and the likelihood that second opinion testing would not be reimbursed in many cases because it would be deemed to be duplicative). But it may be safe to presume that Dr. Graham will bring an economist's objectivity to his work, and thus that the testimony and written comments should include as much evidence as possible in support of the advocated position. It would be prudent that those who advocate the position that patenting supports innovation in genetic diagnostic testing make the Office aware not only of their views but the factual grounds for them.

It is also reasonable to presume that the Office will be sensitive to Rep. Wasserman Schultz's passion for this issue and will be certain that whatever its recommendations they include the possibility for some accommodation to "second opinion" genetic diagnostic test providers. The form and extent of this accommodation will depend on the strength of the evidence pro and con regarding the need and wisdom of "second opinion" genetic diagnostic testing.