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Saurabh Vishnubhakat
Attorney Advisor
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United States Patent and Trademark Office
PO Box 1450
Alexandria, VA 22313-1450

Re: Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing
[Docket No.: PTO-P-2012-0003]

Dear Mr. Vishnubhakat:

The American Medical Association (AMA) is pleased to offer its comments to the United States Patent and Trademark Office (USPTO) on genetic diagnostic testing, and the impact of gene patents on access to both primary and secondary genetic diagnostic testing. Our comments are rooted in the AMA's dedication to the advancement of patient care and public health by supporting the nation's physicians and physicians-in-training.

The AMA is firmly opposed to the patenting of genes. It has filed amicus briefs in support of the plaintiffs in the *Association for Molecular Pathology et al. v. Myriad Genetics* case, arguing that gene patents interfere with diagnosis and treatment, quality assurance, access to appropriate care, and innovation. In turn, physicians are not able to utilize tools critical for patient care, and patients are unable to derive health benefit from such tools. It is under this overarching view that we provide comments in response to the USPTO's questions. **We identify two main themes that we will address in turn: availability of primary and secondary genetic diagnostic testing to physicians, and access for patients.**

Availability of primary and secondary tests to physicians

Clinical genetic testing is available for more than 2500 diseases and disorders.¹ However, availability of these tests for physician use is dependent on a number of factors, one of which is patent status. **Restrictive patents and licenses inhibit availability to physicians.** For example, in the case of genetic testing for Long-QT syndrome, for a period of 18 months between 2002-2004, exclusive license holders did not offer a commercial test, and also did not allow any other clinical laboratories

¹ GeneTests. Growth of Laboratory Directory. Available at <http://www.ncbi.nlm.nih.gov/projects/GeneTests/static/whatsnew/labdirgrowth.shtml>. Accessed 03-16-12.

to offer the test.² This practice effectively prevented physicians from being able to utilize the test to diagnose a form of familial Long-QT during that time period.

Clinical laboratories have reported that patenting has limited their ability to offer certain genetic tests. Clinical laboratories are a vital resource for physicians, with many offering laboratory- developed tests that are lower-cost than those developed by commercial manufacturers, and that meet the needs of physicians and patients specific to the clinical setting (specialty practice, hospital, academic medical center, etc.). However, more than half of clinical laboratories have reported that they have decided not to develop a new genetic test because of a patent or license, and a quarter reported that they have stopped performing a test altogether because of a patent or license.³ Public comments submitted in response to the draft version of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) report on Gene Patenting indicated that after the exclusive licensee of a patent covering a leukemia-associated gene stopped several clinical laboratories from performing the test, physicians experienced slow turn-around time in receiving test results from the exclusive licensee.⁴ **These accounts indicate that gene patents severely restrict a physician's ability to practice effectively, and patients will suffer as a result.**

The AMA's Code of Medical Ethics holds that physicians should recommend a second opinion whenever they believe it is necessary for medical decision-making.⁵ **Thus, the AMA believes that secondary genetic testing should be available to physicians as they carry out quality patient care.** Secondary testing for genetic tests offered by an exclusive licensee is not possible, denying physicians and patients additional information by which important medical and life decisions are made. Though we are not aware of formal studies assessing the availability of secondary testing, we are aware that there is no option for secondary testing for the *BRCA1* and *BRCA2* mutations associated with hereditary breast and ovarian cancer, and that the potential for this gap in clinical care to persist with other genetic tests exists as long as there are gene patents and exclusive licenses.

Access for patients

Patents and exclusive license practices negatively affect patient access to genetic tests, both in the context of cost and insurance coverage. The most common access problems occur when an exclusive licensee does not accept certain insurance carriers. Patients covered by these carriers are faced with the decision to cover costs out-of-pocket, or forego testing altogether. For example, the sole provider of genetic testing for spinocerebellar ataxia is not a participant in any Medicaid programs, and even with discounts offered by the company, Medicaid patients are charged up to \$10,000 for testing. This situation is similar for the genetic test for hearing loss, the exclusive provider of which does not accept MediCal, and for Myriad's *BRCA* test, which is not covered by MassHealth. The trend of exclusive licensees not accepting Medicaid is especially troubling given that the patient populations covered by such programs are the least likely to be able to pay for the cost

² M Angrist, S Chandrasekharan, C Heaney, and R Cook-Deegan. (2009). Impact of patents and licensing practices on access to genetic testing for long QT syndrome. Appendix F. Available at http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf. Accessed 03-19-2012.

³ Cho MK, Illangasekare S, Weaver MA, Leonard DG, Merz JF. (2003) Effects of patents and licenses on the provision of clinical genetic testing services. *J Mol Diagn* 5(1):3-8.

⁴ Secretary's Advisory Committee on Genetics, Health, and Society. (2010) Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. Available at http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf. Accessed 03-19-2012.

⁵ American Medical Association Code of Medical Ethics. Opinion E-8.041: Second Opinions.

of testing out-of-pocket. **With regard to secondary genetic testing, AMA policy supports coverage for such tests when physicians believe that they are medically necessary.**⁶

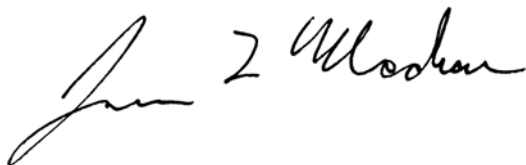
Our own data indicate that cost and insurance coverage influence physician behavior in ordering genetic tests. Physicians report that when genetic testing is affordable, they are more likely to order it.⁷ Also, more than half of physicians have reported that they have chosen not to order a genetic test when insurance will not cover it. These findings are alarming, given that both primary and secondary genetic tests are often critical tools in diagnosing genetic conditions and developing treatment plans. **To the extent that patents and exclusive license practices affect cost and insurance coverage of genetic tests, the reluctance of physicians to order such tests contributes to the problem of patient access. The same cost and coverage challenges exist for secondary genetic testing.**

The availability and access issues resulting from gene patents deny physicians the use of essential tools needed to ensure that their patients receive high value, quality care, directly impacting patient outcomes. Gene patents inhibit further innovation, including the development of more accurate and cost-effective diagnostics (as detailed in the SACGHS report on Gene Patenting). At this time, there is no way to independently validate or confirm the results of a patented test without fear of infringement. **When delivering care, physicians should not have to ponder the legality of obtaining something as simple, yet as critically important, as a second opinion.** In addition, gene patents could stand in the way of emerging technologies. The clinical use of next-generation technologies, such as whole-genome and whole-exome sequencing may infringe on single-gene patents. The fees for licensing each of the single patents would be cost-prohibitive, effectively squashing these promising new technologies for clinical care.

Our observations within the physician and patient community indicate that many are not aware of the restrictions placed on access by patents and exclusive license practices until they (physicians) try to order a test that is not covered by insurance and/or is very expensive, and until they (patients) must decide whether they can afford to pay out-of-pocket or forego testing. **This obstruction to clinical care is unacceptable, and must change.**

We thank the USPTO for this opportunity to comment, and reiterate our commitment to work to ensure that physicians are able to utilize tools critical for patient care, and that patients are able to access and derive health benefit from such tools.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD

⁶ American Medical Association Policy Database. Policy H-320.984: Mandated Second Opinions

⁷ Data available from the AMA upon request.