AIPLA
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

February 8, 2013

The Honorable Theresa Stanek Rea
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Re: Written Comments in Relation to Leahy-Smith America Invents Act Section 27 Genetic Testing Study and Public Roundtable, 77 Fed. Reg. 71170 (November 29, 2012)

Dear Acting Director Rea:

The American Intellectual Property Law Association (AIPLA) is grateful for the opportunity to present its views with respect to the Notice entitled "Notice of Public Roundtable on Genetic Diagnostic Testing" published in the November 29, 2012, issue of the *Federal Register*, 77 Fed. Reg. 71170 (the "Notice") to support the United States Patent and Trademark Office (USPTO) study on genetic testing. The comments presented here are intended to supplement the related comments submitted by AIPLA on March 26, 2012.

AIPLA is a U.S.-based national bar association whose approximately 15,000 members are primarily lawyers in private and corporate practice, government service, and the academic community. AIPLA represents a diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, unfair

competition, and trade secret law, as well as other fields of law affecting intellectual property in the United States and in jurisdictions throughout the world.

AIPLA is fully supportive of the principle that providing patients with access to the finest possible medical care and diagnostic tests is a top policy priority. This principle is affected by many factors, including availability of confirmatory testing for patients facing very important medical decisions. AIPLA supports efforts to study all of the many factors that affect access to such medical care, and its membership shares the underlying concern for the need to facilitate the development and availability of confirmatory genetic tests.

AIPLA acknowledges that, while the goal of ensuring patient access to genetic tests is shared by virtually all members of the public, opinions differ widely on how best to achieve this goal. AIPLA stands behind its March 2012 Comments, in which we explain why we oppose modifying patent eligibility or enforcement provisions with respect to confirmatory diagnostic testing, and in which we caution that non-patent factors are generally more important than patents and exclusive licensing in determining whether a confirmatory diagnostic test will be available to a patient in the U.S. While AIPLA considers this position to be further supported by the substantial amount of study data and anecdotal evidence that has already been presented in both oral testimony and written comments in connection with this Study, we also recognize that many organizations and individuals strongly favor legislative action to prevent patents from hindering patient access to second opinion genetic tests.

AIPLA does not find sufficient evidence that patents pose a problem with patient access to tests. However, we would be happy to work together with the USPTO in arriving at an effective solution that addresses any need for increased access to confirmatory tests without interfering

with the incentives for innovation and commercialization in genetic diagnostic medicine. In the March 2012 Comments, AIPLA laid out eight points related to a patent owner's exclusive rights on this subject. We continue to urge that any consideration of revising the patent statute in this area should at least consider whether:

1) The patent owner or a licensee (exclusive or not) has performed a diagnostic test on a sample of an individual's tissue, or the patent owner's or a licensee's product has been used in performing such a test.
2) The patent owner or licensee has declined to perform a confirmatory test on a sample of the individual's tissue for reasons not related to payment.
3) The patent in question is specific to the genetic question at issue and is not a more general technology patent (e.g., method or machine useable for carrying out genetic diagnostic tests regardless of the nature of the genetic makeup of a sample).
4) The provider of the confirmatory test has not licensed the patent.
5) A single confirmatory test is performed by a single provider.
6) The provider gives notice to the patent owner or exclusive licensee that a confirmatory test was performed for the individual.
7) The provider of the confirmatory test pays commercially reasonable compensation to the patent owner or exclusive licensee for infringement of the patent rights.
8) Finally, a sunset period and a reporting system should be included to monitor the impact of the legislation on innovation and on investments in new products and services.

In addition to addressing concerns that patents potentially may hinder the development of future genetic tests, AIPLA could support a statutory experimental use exemption. Such a use exemption for bona fide scientific research should be technology-neutral, and limited to non-

commercial acts done to study or experiment on the subject matter of a patented invention, *e.g.*, to investigate its properties or to improve it. In addition, the research exemption should be available only if study or experimentation (as opposed to a commercial use) is the dominant use, and the existence of a commercial purpose should not pre-empt or preclude exemption.

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AIPLA appreciates the opportunity to present comments on this important issue, and we look forward to working closely with the USPTO as these discussions go forward.

Sincerely,

Jeffrey I.D. Lewis
President
American Intellectual Property Law Association