



March 26, 2012

Hon. David J. Kappos
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent and Trademark Office
600 Dulany Street
P.O. Box 1450
Alexandria, VA 22313-1450

Submitted via: genetest@uspto.gov

**Re: Comments on: “Request for Comments and Notice of Public Hearings
on Genetic Diagnostic Testing”
77 Fed. Reg. 3748 (January 25, 2012)**

Dear Under Secretary Kappos:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments to the U.S. Patent and Trademark Office in response to the Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing published in the *Federal Register* on January 25, 2012 (the “Notice”).

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO’s membership includes more than 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members.

IPO’s comments are addressed primarily to the issues raised in Questions 8 and 9 of the Notice. Regarding Question Eight, IPO believes that compelling patent owners to grant licenses for the purpose of permitting third parties to provide second opinion genetic diagnostic tests would have a detrimental effect on the U.S. patent system. Doing so would undermine the incentive created by the patent system to create new tests, as well as to design around existing patents to provide tests that are comparable to existing tests. Regarding Question Nine, IPO believes that exclusive licenses do not materially reduce the availability of second opinion genetic diagnostic tests, as these tests are usually available from the patent owner or another licensed provider.

The Notice indicates that the Leahy-Smith America Invents Act (“AIA”) defined “confirming genetic diagnostic testing activity” to mean 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. This is a very narrow category, as most patients who are seeking second opinions are asking for second medical opinions, not for second diagnostic tests performed by a

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different testing facility. The existence of patents and exclusive licenses does not impair in any way patients' access to second medical opinions.

To understand IPO's positions on these questions, it is helpful to provide a framework illustrating typical genetic diagnostic testing. There are several ways that genetic diagnostic testing is generally provided. The actual testing can be conducted by a hospital or institutionally based laboratory, by a reference laboratory to which practitioners (and hospitals) may send samples for testing or to specialized laboratories that have a narrow range of diagnostics that are usually related to those they invent or develop themselves. Reference labs and specialized labs may use diagnostic products they produce themselves ("home brews") but hospitals typically do not. Except for home brew types of tests, diagnostic companies generally supply diagnostic test kits and/or instrumentation for conducting the tests. Thus, while labs can be affected by the enforcement of patents, it is diagnostic companies that are most directly affected. If a diagnostic company is excluded from offering a genetic diagnostic test, in most cases, hospitals and reference labs can obtain the desired test from another genetic diagnostic company that is not excluded (either the patentee or the licensee).

It is rare that a single type of test for a single gene provides independent diagnostic capability. Usually, the presence or absence of a gene, the level of expression of a gene, the methylation status of a gene, or the mutation of a gene, together with other diagnostic indicators, have diagnostic power. In many cases, components for these diagnostics are substitutable—different portions of a gene, different genes, or different combinations of genes could be used. These types of diagnostics do not fit squarely into what would be considered an "independent second opinion genetic diagnostic test." Moreover, due to evolving case law in the area of biotechnology, patents for these types of diagnostics are increasingly difficult to obtain and are even more difficult to obtain with a broad claim scope.

Additionally, there is also a whole new class of diagnostics on the horizon, the so-called "companion diagnostics," which stratify patient populations into groups of responders, non-responders, or those who can and cannot safely tolerate a particular therapeutic. Typically, one or more analytes in these diagnostics are genetic. These tests are developed both by diagnostic companies and pharmaceutical companies that market the related therapeutic.

A diagnostic company has many options when confronted with patents to a single independent gene. It can look for alternative markers (which is typically done), license a number of patents needed to make the complete diagnostic, or choose to license and sell a diagnostic that comprises part of the diagnostic solution sought. These are all consistent with the objectives of the patent system. Designing work-arounds advances science and the useful arts by fostering further development and invention of genetic markers and additional diagnostic tests. Forcing those who have not invented to license provides an economic incentive to invent in the first place and rewards the inventor for doing so.

If broad classes of patents are unavailable in the future or required to be licensed on a compulsory basis, there will be little incentive for diagnostic companies to conduct or sponsor research in these areas. Additionally, compulsory licenses raise issues of unconstitutionality under

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the Fifth Amendment's "Takings Clause," and would need to comply with the provisions of TRIPS and NAFTA. Since compulsory licensing is virtually non-existent in the United States, allowing compulsory licensing for genetic diagnostic tests could open up the same questions in other technology areas.

For these reasons, IPO believes it is a mistake to weaken the patent system in the area of genetic diagnostic testing. IPO thanks the USPTO for considering these comments and would welcome any further dialogue or opportunity to assist the USPTO in gathering information for its report on genetic diagnostic testing.

Sincerely,

A handwritten signature in black ink, appearing to read "R. F. Phillips". The signature is stylized and somewhat cursive.

Richard F. Phillips
President