AIPLA
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

March 26, 2010

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314 Via email: genetest@uspto.gov

Dear Under Secretary Kappos:

Re: Leahy-Smith America Invents Act Section 27, Genetic Testing Study
77 Fed. Reg. 3748 (January 25, 2012)

The American Intellectual Property Law Association ("AIPLA") is pleased to have the opportunity to present its views with respect to the Notice entitled "Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing"[1] published in the January 25, 2012, issue of the *Federal Register*, 77 Fed. Reg. 3748 (the "Notice").

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. Our members practice or are otherwise involved in patent law and other intellectual property law 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 impacted 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.

[1] AIPLA notes the recent Supreme Court decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, No. 10-1150, U.S., Mar. 20, 2012), 566 U.S. ___ (2012), which dealt with patent eligibility of aspects of medical diagnostic tests. However, there has not been sufficient time since the issuance of the opinion in that case to analyze what, if any, relevance it has to the present request for comments.

The legislative history of Section 27 of the Leahy-Smith America Invents Act (Public Law No. 112-20, "AIA"), suggests that the patent system should be evaluated to see if problems surrounding second opinion genetic testing can be resolved with amendments to the Patent Act. However, the evidence discussed herein does not reveal that the general access problem with second opinion testing that motivated this investigation is caused by patents.

Accordingly, AIPLA opposes modifying patent eligibility or enforcement provisions with respect to confirmatory diagnostic testing. The primary reasons for this position are:

- It has not been established that there is a need for patent legislation to remedy a systematic lack of access to confirmatory genetic diagnostic testing, and in all likelihood this could not be established, because other factors are generally more relevant, including the tremendous complexity, vast diversity, and rapidly evolving technologies and issues relating to training, reimbursement and regulation.

- The existing patent system is in itself adequate to resolve infringement disputes and licensing issues.

- Any attempt to make patents on genetic testing statutorily ineligible, non-enforceable, or to otherwise devalue valid patent rights may make investments in innovation and commercialization less likely, causing less patient access to optimal health care, not more access.

- Efforts to carve out genetic testing from patentability or enforcement thereof could place the United States at odds with treaty commitments, such as TRIPS, NAFTA, and ACTA, potentially raising constitutional questions under the takings clause.

Non-patent factors are important to consider.

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. Moreover, any role that patents might play in limiting access to confirmatory testing in such a complex and changing system as genetic diagnostic testing cannot be readily determined. AIPLA cautions that any changes to U.S. patent laws should occur only after full consideration of all factors, patent and non-patent. Reform of existing patent laws and categorical treatment of genetic testing could have a potentially wide-sweeping impact on investment in the biotechnology and diagnostic industries without fully addressing the goal of providing patients with access to safe and effective genetic testing.

Three primary areas of United States governmental responsibility may be identified for potential impact on the current state of genetic diagnostic testing: (1) the regulatory practices of the U.S. Food and Drug Administration ("FDA"), (2) the reimbursement practices of U.S. Center for Medicaid and Medicare ("CMS"), and (3) the patent statute.

Launch of the National Institutes of Health ("NIH") Genetic Testing Registry on March 1, 2012, illustrates the complexity of the genetic testing environment. The registry contains an estimated 2,500 genetic tests, most of which are not required to have premarket review by the FDA under the present system.[2]

FDA Regulatory Practices: Safe and Effective Diagnostic Products

While U.S. patent laws are useful in fostering innovation, they are not directed toward, nor should they be confused with, the governance of safe and effective diagnostic products. AIPLA respectfully submits that the issue of reliable diagnostic products and an associated need for confirmatory testing falls under the authority of the FDA. Any policy considerations of reform associated with patient access to safe and effective diagnostic tests should begin with the authority conferred to the FDA under the existing laws.

Specifically, in 1976, Congress amended the Federal Food, Drug, and Cosmetic Act to include oversight of medical devices which encompasses *in vitro* diagnostics.[3] As a consequence, the regulatory pathway for a commercially distributed diagnostic test entails pre-market FDA evaluation of clinical data to assure that the test is safe and effective.[4] The impact of FDA oversight is illustrated by the widespread availability of HIV testing. To the tremendous benefit of public health, tests to diagnose and screen for infectious diseases such as HIV underwent FDA clinical data scrutiny during an approval process prior to obtaining pre-market clearance.[5] Although the HIV test was protected by patent rights, access to confirmatory tests in multiple laboratories was available, if desired, because the tests were FDA approved and commercially distributed.[6]

Current genetic tests are not well distributed commercially, largely because they do not typically undergo clinical data evaluation by the FDA.[7] In contrast to FDA approved tests, most genetic tests are marketed under the designation "laboratory developed tests ('LDT')" and are generally subject to regulation by the CMS under the Clinical Laboratories Amendments of 1988 ("CLIA"). CMS regulation of LDTs focuses on reviewing the quality of the laboratory performing the test rather than review of the LDT.[8]

---

[2] *See* http://www.ncbi.nlm.nih.gov/sites/GeneTests/?db=GeneTests.
[3] *See* Title 21 Code of Federal Regulations Part 800-1200 (21 CFR Parts 800 - 1299).
[4] *See* 21 CFR 807; 21 CFR 814.
[5] *See*http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/UCM080466.
[6] *See, e.g.*, Gill, Jas, et al., Corporate Vision and Rapid Technological Change, the Evolution of Market Change, 1993, Routledge, London, New York, ISBN 0415091357, 182-205.
[7] *See, e.g.*, Pendergast, Mary K., *Experimental Biology and Medicine* (2008), 233:1498-1503.
[8] *See Transcript from Public Meeting on Oversight of Laboratory Developed Tests*, U.S. Department of Health and Human Services, Food and Drug Administration, July 19-20, 2010, Testimony of Dr. Courtney Harper, Division Director for the Division of Chemistry and Toxicology, 11-55.

In addition, testing services that utilize an LDT are restricted to the single laboratory where the test was designed and developed.[9] Patient samples must be sent to this single laboratory because the LDT designation does not permit any testing, let alone alternative or confirmatory testing, outside of the approved originating laboratory.[10]

Unless the developer of a genetic test obtains FDA approval through a traditional regulatory pathway where evaluation of clinical data occurs, the genetic test cannot be commercially distributed.[11] Thus, for genetic tests, the lack of alternative, secondary confirmatory testing is not necessarily associated with restrictive patent rights as much as being marketed under the LDT designation and within the CLIA business model. By definition, an LDT cannot be transferred to or employed by an alternative laboratory for confirmatory re-testing. Reform in how the LDT segment of diagnostic testing is currently regulated is under consideration by the FDA and far from resolved.[12]

CMS Reimbursement Practices

Another principal non-patent factor in determining patient access to confirmatory genetic testing is whether the cost of a confirmatory test will be compensated under relevant Medicaid, Medicare, and private payer policies.[13] Medicare is the largest single payer in the United States and plays a significant role in setting reimbursement for *in vitro* diagnostics tests.[14] Diagnostic pricing is frequently benchmarked by commercial payers to the Medicare Clinical Lab Fee Schedule.[15] Health technology assessment criteria and diagnostic pricing standards are recognized as an area of possible change as health care reform policy evolves.[16]

Other Non-Patent Considerations

Additional factors include contractual limitations, institutional policies, malpractice and other tort concerns, practice patterns, professional talent distribution, financial and time restraints, and more. In some situations, anti-kickback, health care fraud statutes, and government reimbursement policies may also serve as barriers to diagnostic companies who would otherwise elect to offer tests at little or no cost based on financial need.[17]

---

[9] *See Id.*
[10] *See, e.g.*, Gold, E. Richard, et al. *Myriad Genetics: In the eye of the policy storm, Genet Med.* 2010 April 12 (4 Suppl.) S39-S70.
[11] *See supra* note 5, at 11-55.
[12] *See Transcript from Public Meeting on Oversight of Laboratory Developed Tests*, U.S. Department of Health and Human Services, Food and Drug Administration, July 19-20, 2010; *See also*, Katsanis, SH, Javitt G., Hudson K: *A case study of personalized medicine, Science*, 2008:320:53-54.
[13] *See* The Study Priorities of the Secretary's Advisory Committee on Genetics, Health, and Society, *A Roadmap for the Integration of Genetics and Genomics into Health and Society* (June 2004), http://oba.od.nih.gov/oba/sacghs/reports/SACGHSPriorities.pdf.
[14] *See* Medical Device Pricing and Coverage – USA, *International Society for Pharmacoeconomics and Outcomes Research (ISPOR)*, http://www.ispor.org/htaroadmaps/usmd.asp, Updated/posted February 2012 (Accessed March 3, 2012).
[15] *Id.*
[16] *Id.*
[17] *Id.*

Patents and Licensing

To the extent that patient concerns suggest that multi-source tests should be mandated, AIPLA believes that patent protection can assist in ensuring that those offering a test are properly qualified to do so, that databases are properly maintained, that important testing information relating to reliability will be made available to FDA, that physicians, patients, payers, and the public are educated about genetic testing, that timely genetic counseling is made available to patients, that reimbursement agreements with private and public payers are secured, and that genetic insights from testing are appropriately shared with researchers and with the medical community.

More importantly, criticisms of how a given diagnostic patentee may have chosen to commercialize its test are more than outweighed by other factors. Most diagnostic tests would never have been developed or commercialized in the first place were it not for the incentives and protections offered by our patent system. The United States patent system, with its high standards for patentability, high predictability, robust enforcement provisions, and strong licensing tradition, has been and will continue to be essential to the creation and commercialization of diagnostic tests that benefit patients. It is still the best system for promoting "progress of the useful Arts" and for bringing a steady stream of innovative products and services into our economy. Without commercially available tests, patients have no access even to primary tests.

Multiple studies have failed to find a negative impact of "gene patents" on access to healthcare or to innovation.

The essential role that patents and licensing play in bringing diagnostic testing to market is not widely understood. Insufficient knowledge about patenting and licensing of such tests, about the relationship between genetic patents and product commercialization, and about the complexity of the genetic diagnostic business, can lead to misunderstandings and misconceptions, provoking misplaced efforts to weaken or eliminate patents.

Fortunately, these concerns on such matters have been demonstrated to be unfounded in repeated studies of the issue. These studies have instead determined that current laws permitting patenting and licensing of genetic tests do not restrict availability of genetic tests.

The impact of patenting on the availability of healthcare and diagnostic testing has been studied and reported many times. Data and conclusions cited in a number of government-sponsored reports, including 2004 Australia[18], 2011 Australia[19], 2006 National Academies of Science

[18] AUSTRALIAN LAW REFORM COMMISSION (ALRC) REPORT, GENES AND INGENUITY: GENE PATENTING AND HUMAN HEALTH (ALRC 99, 2004).

[19] Australian Senate, Legal and Constitutional Affairs Legislation Committee, Patent Amendment (Human Genes and Biological Materials) Bill 2010 (September 2011).

("NAS")[20] and 2010 SACGHS[21] Reports, as well as in other reliable scientific literature, support the conclusion that no convincing evidence supports weakening patent enforcement mechanisms in order to provide access to confirmatory genetic diagnostic testing.

The "Anticommons"

In 1998, a theory commonly referred to as "the tragedy of the anticommons," posited that intellectual property rights would restrict or otherwise adversely impact biomedical research.[22] Ten years later, one of the authors of this theory, Professor Rebecca Eisenberg, reported on the results of empirical testing of the theory.[23] Professor Eisenberg found that "the results suggest, overall, intellectual property has presented fewer impediments to research than policymakers may have projected on the basis of early salient controversies. Most scientists report no difficulties in attempting to acquire IP-protected technologies, and only a small percentage report significant delays in research or having to abandon a project because of IP issues."[24]

2006 National Academy of Sciences

Likewise, in an extensive study of the impact of patents on genetic research, NAS could not find evidence of an "IP anticommons" ("it appears that access to patented inventions or information inputs into biomedical research rarely imposes a significant burden for biomedical researchers").[25] While the focus of the NAS study was on impact of patents on biomedical research, the pertinence to the present study is that concern about hypothetical impacts of patents are almost never borne out by careful study.

2010 SACGHS

The Department of Health and Human Services "Secretary's Advisory Committee on Genetics, Health, and Society" ("SACGHS") conducted a study on the impact of gene patenting and licensing practices on patient access to genetic tests. The study arose from suggestions that patents may be limiting the availability, cost, and/or quality of genetic tests.

---

[20] NAT'L RESEARCH COUNCIL COMM. ON INTELLECTUAL PROP. RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (Stephen A. Merrill and Anne-Marie Mazza eds., National Academies Press 2006).

[21] 2010 Secretary's Advisory Committee on Genetics, Health, and Society available at: http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pd

[22] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

[23] R. S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059 (2008).

[24] *Id.* at 1061.

[25] NAT'L RESEARCH COUNCIL COMM. ON INTELLECTUAL PROP. RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (Stephen A. Merrill and Anne-Marie Mazza eds., National Academies Press 2006), at p. 2.

It was also suggested that patents could potentially be responsible for quality control issues, for example, where an exclusive license to a single test lab might prevent verification of test results by unlicensed labs.

The Report acknowledges a tradeoff between potential social costs incurred from patents relating to genetic testing and the incentives provided by patents to develop new genetic tests. AIPLA believes, however, that the Report overstates the potential costs and fails to adequately value the incentives derived from patents. Notwithstanding the Report's conclusion of a lack of evidence that patents pose a problem with access to genetic testing, the Report concludes that there are, or will be, problems. [26]

Like many others,[27] SACGHS assumed the existence of a "gene patent thicket,"[28] which has been refuted with respect to an impact on research[29] and which recently has been refuted with respect to gene patents preventing development of certain genetic tests.[30]

Three members of the SACGHS Committee dissented from the Report. The dissenting opinion from the Report is worth quoting:[31]

> …it is our position that statutorily modifying the gene patent system, including the creation of exemptions from liability for infringement upon such patents as defined in this report and proposed in the recommendations, would be more harmful than helpful to patient access and to the quality of innovative genetic diagnostics.
>
> …The basis of our position is recognition that there are a variety of financial and scientific decisions made by both government and private stakeholders throughout our health care system that impact patient access to genetic tests. We recognize the importance of supporting and encouraging discovery and, most importantly, translating those genetic discoveries into new tools to improve patient treatment and outcomes.

---

[26] 2010 Report Secretary's Advisory Committee on Genetics, Health, and Society; http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pdf.

[27] *See, e.g.*, Letter from ACLU to Chairman David Dreier, Comm. on Rules, U.S. House of Representatives et al. *ACLU Opposes Inclusion of Flawed Second Opinion Testing Language in Manager's Amendment to H.R. 1249, the America Invents Act* (June 15, 2011), at 2, *available at* http://www.aclu.org/files/assets/final_ltr_re_opposing_wasserman_schultz_amendment_with_coalition_letter.pdf; Eric Hoffman, *Why Gene Patent are Bad for Patients and Science*, THE AMERICAN INTEREST, Aug. 9, 2011, http://www.the-american-interest.com/article.cfm?piece=1154; and John Sulston, *How Science is Shackled by Intellectual Property*, THE GUARDIAN, Nov. 25, 2009, http://www.guardian.co.uk/commentisfree/2009/nov/26/science-shackles-intellectual-property.

[28] *Id.*, at 49-62.

[29] *See supra*.

[30] Christopher Holman, "Debunking the myth that whole-genome sequencing infringes thousands of gene patents," 30 Biotechnology 240-44 (2012).

[31] *Id.*, Statement of Dissent from Ms. Aspinall, Dr. Billings, and Ms. Walcoff.

> …The suspension of patent protections such as exemptions from liability for patent infringement for a restricted class of innovation (gene patents)…is unwarranted and a risky intrusion into a process that has delivered many key innovations to needy Americans.

The dissent emphasized the role of public health plans such as Medicaid and Medicare, as well as private payers that "continue to be free to refuse coverage and payment, even if every laboratory in the country offers a test," as well as other factors such as practice patterns and professional talent distribution, in determining which genetic tests are conducted in what regions of the country. Their assessment of the SACGHS data suggested that "clinicians are often significantly limited by contractual and financial barriers placed on them by their institution or cost containment restrictions imposed by public and private payers." In view of these other factors, they state: "…we do not support the assertion that in most cases gene patents have had a direct and overarching negative impact on the ability of a patient to obtain a test."[32]

The dissenters also suggest a need to "evaluate relevant laws, regulations and policies, such as anti-kickback, health care fraud statutes, and government reimbursement policies, that are overly burdensome or result in practical barriers on diagnostic companies who would otherwise elect to offer tests at little or no cost based on financial need."[33]

Dr. Robert Cook-Deegan of the Center for Genome Ethics, Law & Policy at Duke University conducted the original case studies on the relationship between patents and access for eight inherited (Mendelian) genetic disorders that informed the SACGHS Report and provided assistance to the SACGHS Committee throughout its work.[34] He and his colleagues subsequently published a series of research papers based on these case studies examining empirical evidence for the impact of gene patents on the availability of genetic testing.[35] In summary, the studies concluded that there was no firm evidence that patents negatively or permanently limited research or access.

---

[32] *Id.*
[33] *Id.*
[34] *Id.*, Appendix A: Compendium of Case Studies Prepared for SACGHS by the Duke University Center for Genome Ethics, Law & Policy. These studies are referenced extensively throughout the SACGHS Report and summarized on pp. 9-10.
[35] Duke Studies:

S. Chandrasekharan, *et al.*,, Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Cystic Fibrosis, 12 *Genetic Medicine* S171 (2010) ["Cystic Fibrosis Study"];

K. Skeehan, *et al.,* Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Alzheimer's Disease 12 GENETIC MEDICINE S71 (2010) ["Alzheimer's Study"];

S. Chandrasekharan and M. Fiffer, Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Hearing Loss, 12 *Genetic Medicine* S171 (2010) ["Hearing Loss Study"];

S. Chandrasekharan, *et al.*,, Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Hereditary Hemochromatosis, 12 *Genetic Medicine* S155 (2010) ["Hemochomatosis Study"];

A. Colaianni, *et al.,* Impact of Gene Patents and Licensing Practices on Access to Genetic Testing and Carrier Screening for Tay-Sachs and Canavan Disease, 12 *Genetic Medicine* S5 (2010) ["Tay Sachs/Canavan Study"].

In one article, Dr. Cook-Deegan concluded that licensing practices have more of an effect on the availability of a genetic test than whether the test is patented: "By acknowledging and engaging with the distinctive problems that patenting and licensing practices raise for DNA diagnostics, both the universities licensing out technology and the companies licensing it in can bring about real improvement without the need for legislation."[36] Similarly in another: "If managed sensibly, and with involvement of stakeholders, patented technologies can generate revenues for research institutions without hindering research or clinical use and at least in this case ultimately with few discernible impacts on prices of or access to genetic testing."[37]

Comparing pricing and access to Myriad's patented BRCA1/BRCA2 whole gene sequencing service with several non-patented or non-exclusively licensed services for determining genetic predisposition to colon cancers, Cook-Deegan *et al*. found:

> Prices for BRCA1 and 2 testing do not reflect an obvious price premium attributable to exclusive patent rights compared to colorectal cancer testing, and indeed Myriad's per unit costs are somewhat lower for BRCA1/2 testing than testing for colorectal cancer susceptibility. Myriad has not enforced patents against basic research, and negotiated a memorandum of Understanding with the National Cancer Institute in 1999 for institutional BRCA testing in clinical research.[38]

Australian Government Studies

The Australian Law Reform Commission ("ALRC") conducted a multi-year study of the impact of gene patenting on the availability of medical services in Australia, and produced a lengthy report titled "Genes and Ingenuity Report, Gene Patenting and Human Health."[39] The Commission concluded that it had found no firm evidence of increased costs, limited access to genetic testing, lower quality of healthcare services, or lower levels of clinical research and development. However, it did note the existence of excessive worry about *hypothetical* exploitative activity, but an absence of evidence that patent holders were aggressively enforcing their patents against genetic testing laboratories. The ALRC reported "...there is limited evidence to date that gene patents or licensing practices have had any significant adverse impact on the conduct of genetic research or on healthcare provision in Australia,"[40] and urged a cautious approach to radical changes in patent law "in view of the equivocal nature of the evidence" to date.[41]

---

[36] J. Carbone, *et al.*, "DNA patents and diagnostics: not a pretty picture" *Nature Biotechnology* (2010) 28: 784-791, at p. 791.
[37] A. Colaianni, *et al., Genetic Medicine* (2010) 12:S5-S14, *Supra*.
[38] R. Cook-Deegan, *et al.*, "Impact of Gene Patents and Licensing Practice on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers: Patents and Licensing for Breast, Ovarian and Colon Cancer Testing." *Genetic Medicine* (2010) 12:S15-S38, at p. S15.
[39] Australian Law Reform Commission, *Genes and Ingenuity Report* 99, Gene Patenting and Human Health (June 2004).
[40] *Id.*, at Para. 3.73, p. 79.
[41] *Id.*, at Para. 3.74, p. 79.

The Commission found there were no grounds to justify changing Australia's patent laws, and any reforms should be technology neutral and not based solely on extremely difficult or hypothetical cases (such as *Myriad*) and should conform with Australia's international IP treaty obligations, particularly TRIPs.[42] Most pertinently, the Commission recommended against a medical or diagnostic treatment exemption in the absence of demonstrable harm for fear of hampering healthcare innovation, recognizing that framing the scope of such an exemption would be difficult.[43]

In 2009-2011, a committee of the Australian Senate, while considering a bill to ban patents on biological materials substantially the same as found in nature, reviewed the prior studies of the impact of gene patenting and took additional testimony. The committee's Report concluded, in part:[44]

- No evidence was received by the committee that patents on human genes or biological materials are systematically leading to adverse impacts on the provision of healthcare in Australia.

- The bill would not resolve the issue concerning BRCA1 and BRCA2 genetic testing.

- The bill could lead to significant adverse consequences for healthcare, including delays for access to new diagnostic tests, medicines and treatments, reduced access to clinical trials, and reduced investment in medical research and development in Australia.

While the 2010 Report included recommendations to consider government use, compulsory licensing, and a defined, limited, experimental research exemption to preclude potential problems that might arise, the Report's Dissent pointed out that compulsory licensing and government use are restricted by TRIPS and AUSFTA,[45] and that compulsory licensing can only occur in exceptional circumstances, such as a pandemic or military hostilities.[46]

The Government did embrace the research exemption recommendation, and introduced an Amendment into the then pending Intellectual Property Laws Amendment (Raising the Bar) Bill 2011[47] that would define a limited technology-neutral research exemption as well as expand the pharmaceutical regulatory research exemption to non-pharmaceutical technologies.

---

[42] *Id.*, at Para. 13.71, p. 335.
[43] *Id.*, at Para. 13.47, p. 329.
[44] Australian Senate, Legal and Constitutional Affairs Legislation Committee, Patent Amendment (Human Genes and Biological Materials) Bill 2010 (September 2011), at Para. 5.13, p. 61.
[45] Australia-United States Free Trade Agreement.
[46] *Id.*, Dissent at Para. 3.77, p. 98.
[47] Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (www.austlii.edu.au/cgi-bin).

Part of the reason for introducing this research exemption was the Government's recognition that research scientists largely assumed a research exemption or ignored patent rights.[48] The legislation passed the Senate in February 2012 and is awaiting passage in the House.[49]

In summary, the studies discussed herein, as well as additional studies examining the impact of patenting on continuing research and on patient access to medical diagnostics, have failed to demonstrate a net negative impact of intellectual property. The potential for other, non-patent factors to negatively impact patient access to confirmatory diagnostic testing may be more relevant than patenting.

It may be that patients who undergo genetic testing have reason to doubt the accuracy of a specific genetic test or the performance of the test by the particular test laboratory. However, addressing the perceived problem by limiting intellectual property rights does not appear to be an effective solution. Instead, confirmatory testing should be addressed on a global scale by working with test providers and technology licensors to establish best practices for licensing. We point to such approaches recommended by the Association of University Technology Managers,[50] OECD,[51] and the NIH,[52] which have been adopted by many licensors and test providers.

Limiting patent enforcement must comply with the Constitution and with treaty commitments.

It has been suggested that limiting patent enforcement may be an approach to address concerns in this area. However, allowing an infringing act to occur while eliminating the patent owner's rightful remedies effectively imposes a compulsory license on owners of genetic test patents. Unlike in the case of compulsory licenses, however, the patent owner's rights would be undermined without compensation for the compulsory use of his or her intellectual property.

Any government may allow a third party to make, use, offer to sell, or sell a patented product or method through the use of statutory safe harbor or compulsory license provisions, provided they are consistent with treaty obligations. A safe harbor typically removes a potential infringer's

---

[48] AUSTRALIAN LAW REFORM COMMISSION, REPORT GENES AND INGENUITY, GENE PATENTING AND HUMAN HEALTH, AT PARA. 12.55 – 12.57, PP. 307-308.

[49] See, Mallesons Stephen Jaques Alert, *Raising the bar on patents and trademarks – Bill passes Senate*, www.mallesons.com (February 27, 2012).

[50] Association of University Technology Managers (www.autm.net). *See* "In the Public Interest: Nine Points to Consider in Licensing University Technology" available at http://www.autm.net/Nine_Points_to_Consider.htm (last visited March 17, 2012).

[51] Organisation for Economic Co-operation and Development (http://www.oecd.org/home/0,2987,en_2649_201185_1_1_1_1_1,00.html). See "Guidelines for the Licensing of Genetic Inventions" available at http://www.oecd.org/dataoecd/39/38/36198812.pdf (last visited March 17, 2012).

[52] National Institutes of Health. See "Best Practices for the Licensing of Genomic Inventions" available at http://www.ott.nih.gov/policy/lic_gen.html#best (last visited March 17, 2012).

liability by declaring certain non-commercial acts carried out for regulatory purposes to be non-infringing.[53] However, a compulsory license typically imposes a requirement upon the patentee to allow a third party to make, use, or sell the patented product or process for commercial purposes in return for compensation from the third party.

Any limitation on the enforcement of a patent right, however, should not run afoul of the treaty obligations of the United States. For example, the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement") permits compulsory licensing by its member States as long as the license adheres to certain requirements.[54] Article 30 of the TRIPS Agreement allows a Member State to "provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not reasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[55] This provision allows a member state to deem certain uses of patented inventions as non-infringing.

Compulsory licenses that are generally considered to be consistent with Article 31 of the TRIPS Agreement are those that are: (1) imposed to rectify violations of antitrust law; (2) imposed to rectify abuse of the patentee's exclusive rights; (3) issued in the public interest to address environmental, public health, national security or economic development concerns by promoting third-party production of the patented products; (4) issued on behalf of owners of dependent patents; (5) imposed by governments to permit them and their contractors to make non-commercial public use of the patents without the consent of the rights holders; or (6) instituted to permit the exportation of pharmaceutical products to poor countries.[56] Certain statutory compulsory license provisions discussed below are already in place in the U.S. and each falls in one of these categories. Each also requires compensation to be paid to the rights holder.

Under the TRIPS Agreement, a compulsory license is permissible if the proposed user has made reasonable efforts to obtain a license from the patent holder.[57] Most importantly, under normal circumstances, the TRIPS Agreement requires that a patent holder shall receive compensation.[58] Accordingly, a limitation that amounts to a compulsory license without compensation may actually run afoul of the TRIPS Agreement.

The long-standing policy of the U.S. reflects recognition that compulsory patent licensing can adversely affect the economy. Compulsory licensing must be used sparingly, only for urgent issues of national public interest. Permitting compulsory licensing, generally speaking, will negatively affect the interests of businesses, investors and ultimately patients.

---

[53] *See*, for example, Section 271(e)(1) of the Patent Act where "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1) (1984).

[54] TRIPS Article 31.

[55] TRIPS Article 30.

[56] Jerome H. Reichman, *Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement*, Presented to the AALS Mid-Year Workshop on Intellectual Property, Vancouver, Canada (2006).

[57] TRIPS Article 31(b).

[58] TRIPS Article 31(h).

Strong intellectual property rights play an important role in the U.S. economy, and weakening IP protection could cause businesses to avoid investments. These considerations must be balanced against providing private parties or courts with broader abilities to force, essentially, compulsory licensing for diagnostics.

Compulsory licensing runs contrary to basic patent theory.[59] In the general case, the possibility of an involuntary compromise of a patentee's intellectual property will erode incentives to invent and to invest in the development of new products and services. Inventors and investors would be unable to depend on exclusivity as a means to recoup investment costs. This remains true in the particular circumstance at issue, when presumably the patentee or exclusive licensee has already performed a first genetic diagnostic test for a patient and has received compensation for the first test.

Compulsory licensing of U.S. patents has been previously granted by statute or by courts. However, the non-compensatory aspects of some proposed solutions are contrary to most, if not all, examples of compulsory licensing in the U.S. and most other countries. For example, the Atomic Energy Act allows for compulsory licensing when the patented innovation is "[u]seful in the production or utilization of special nuclear material or atomic energy."[60] The Atomic Energy Commission determines whether a compulsory patent license should be granted[61] and the reasonable royalty owed by the licensee.[62]

Likewise, the Clean Air Act provides for compulsory patent licenses when the patented innovation is necessary to comply with emission requirements, no reasonable alternative is available, or where nonuse of the patented innovation would lead to a "lessening of competition or a tendency to create a monopoly."[63] Here, the federal district court, with the assistance of the Attorney General, determines if a compulsory patent license should be granted and what terms are reasonable.[64]

Even the Bayh-Dole Act[65] permits compulsory patent licensing when a recipient of federal grants and contracts "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention."[66] Here, the federal government can exercise "march-in rights" by showing a compulsory patent license is necessary "to alleviate health or safety needs,"[67] or "to meet requirements for public use specified by Federal regulations."[68] The license is required to have "terms that are reasonable under the circumstances."[69]

---

[59] Colleen Chien, *Cheap Drugs at What Price to Innovation: Does Compulsory Licensing of Pharmaceuticals Hurt Innovation*?, 18 BERKELEY TECH. L.J. 853, 872-73 (2003).
[60] 42 U.S.C. § 2183(c) (1994).
[61] 42 U.S.C. § 2183(d)-(e).
[62] 42 U.S.C. §§ 2183(g), 2187(c).
[63] 42 U.S.C. § 7608 (1994).
[64] *Id*.
[65] 35 U.S.C. §§ 200–212 (1994).
[66] *Id.* § 203(a)(1).
[67] *Id.* § 203(a)(2).
[68] *Id.* § 203(a)(3).
[69] 35 U.S.C. § 203(a).

However, the U.S. government rarely exercises its march-in rights when petitioned to do so. For example, in 2004, Essential Innovations, Inc. submitted a petition for the government to exercise march-in rights in respect to the AIDS drug Norvir, manufactured by Abbot Laboratories.[70] The NIH denied this petition.[71] As another example, CellPro sought license rights through the march-in provision after failing to secure a license from a prospective licensor. CellPro submitted a petition to the Department of Health and Human Services ("HHS"), which funded the research that led to the subject invention. The NIH denied march-in petitions for Norvir, Xalatan, and CellPro because it determined that exercise of march-in rights would stifle commercial development.[72]

On the other hand, the federal government does not have to seek a license or negotiate for use of a patent. Here again, a patentee is entitled to compensation, but cannot enjoin the government or a third party authorized by the government, to prevent the use. Any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights is construed as use by the federal government, and cannot be sued for infringement.[73]

Further, under the Plant Protection Act, the Secretary of Agriculture is permitted to grant a compulsory patent license when it is "necessary in order to ensure an adequate supply of fiber, food, or feed in this country and its owner is unwilling or unable to supply the public needs."[74] Also, concerning mine safety and health, HHS may fund the development of clinical facilities for examination and treatment of lung ailments in coal miners and make available such information, including patents, to the general public.[75] But in each case, reasonable compensation is provided. Even U.S. district courts have granted compulsory patent licenses when a patentee engaged in anticompetitive activity, but not without compensation to the patent owner.[76]

In each the aforementioned statutory provisions, compulsory licensing of patents is permitted in order to further the public interest, which, more often than not, is public health. However, with respect to genetic diagnostics, there does not appear to be a sufficient public need to provide individual patients with confirmatory testing to justify compulsory licensing with all of its attending harm to innovation. Such a scheme would be very complicated to monitor and enforce.

---

[70] Essential Innovations, Inc. *Petition to Use Authority Under Bayh-Dole Act to Promote Access to Ritonavir, Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220* (Jan. 29, 2004).

[71] National Institute of Health, *In the Case of Norvir, Manufactured by Abbot Laboratories, Inc.* (July 29, 2004).

[72] Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L.J. 1095 (1999).

[73] 28 U.S.C. § 1498; *see* Crater Corp. v. Lucent Technologies, 255 F.3d 1361 (Fed. Cir. 2001) (The Court upheld the District Court's dismissal of plaintiff's infringement claim because defendant was entitled to an affirmative defense under 28 U.S.C. § 1498).

[74] 7 U.S.C. § 2404 (1994).

[75] 30 U.S.C. § 937.

[76] *See* United States v. Glaxo Group Ltd., 410 U.S. 52 (1973) (granting a compulsory license where the patentees were a group of pharmaceutical companies that had a patent pooling arrangement); Image Technical Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195 (9th Cir. 1997) (examining accusations that Kodak was monopolizing the photocopy machine equipment service market).

Most importantly, such grounds for making patents unenforceable are unlike any grounds upon which governments around the globe have agreed justify the granting of compulsory licenses. It is certainly worth noting again that in the debates leading to TRIPS, the United States took a public stand against compulsory licensing and against expanding the circumstances in which it could be invoked.

There have been several failed attempts to implement compulsory licensing for medical technologies. The proposed Affordable Prescription Drugs and Medical Inventions Act would have established compulsory licensing for "any invention relating to health care" where HHS determined that health or safety needs were not adequately satisfied by the patent holder's use of the invention, among other factors.[77]

The proposed Public Health Emergency Medicines Act would have given the Secretary of HHS authority to grant compulsory licensing to "address a public health emergency," determine reasonable compensation to the patent holder, authorize exportation of medicines and other health care products to address global public health emergencies, and adopt any regulation pursuant to this section consistent with TRIPS.[78]

In the mid-1990s, the proposed Health Care Research and Development and Consumer Protection Act would have given the Secretary of HHS the authority to issue a compulsory license for biological substances or other materials for research.[79] Finally, the proposed Essential Pharmaceuticals Act of 1994 would have given the Secretary of HHS authority to issue a compulsory license of a patent, where "the availability of the product to the public is of vital importance to the public health or welfare."[80]

Compulsory licensing of patented U.S. inventions has been reserved for situations where extreme public need mandates commandeering a patent owner's enforcement rights. Where circumstances have required authorization of compulsory licenses, the patent owner is compensated for the loss of such rights.

Weakening patent enforcement is likely to harm innovation and reduce quality without solving the problem of patient access to diagnostic testing.

AIPLA believes that it would be a mistake to weaken the patent system to resolve issues not demonstrated to have been caused by the patent system. Current laws permitting the patenting of genetic tests have not been demonstrated to restrict the availability of genetic tests. Other factors overshadow the effects of patent policy in dictating accessibility. Objective consideration of data from several well-respected studies requires a conclusion that patenting, on balance, promotes rather than hinders patient access to health care.

---

[77] H.R. 1708, 107th Cong. (2001).
[78] H.R. 3235, 107th Cong. (2001).
[79] H.R. 4270, 104th Cong. (1996).
[80] H.R. 4151, 103rd Cong. (1994).

We cannot lose sight of the fact that our patent system is based on a dual benefit. The Constitutional mandate of a limited reward for invention and discovery is balanced against the duty of the patentee to disclose the invention. By encouraging invention, new technology is given to the public in perpetuity. In exchange for the grant of potential exclusive rights for a finite period of time, the inventor must disclose to the public complete information such that a person of "ordinary skill in the art" of the invention can make and use the invention without "undue experimentation."[81] This level of teaching and sharing about the invention enables further innovation and improvement of the invention, particularly valuable in the area of genetic testing.

While some argue the cost is high, it is a short-term cost whose long-term return in patient care, technology access, and future innovation has proven, over and over again, to give a vastly net positive benefit to the public. This system for advancing innovation has served the U.S. economy well. This is demonstrated by the rapid public dissemination of human genomic data and concomitant rapid growth of the biotechnology industry in the United States, while countries with weaker patent systems lagged behind.

Today, we are beginning to see the promise of personalized medicine that is increasingly visible in approved genetic diagnostic products and services. These new genetic diagnostic tools do not simply identify if a person is at risk for disease, but offer particular answers to a patient's expected prognosis, response to a particular drug, the correct dose for a patient, and much more. This new era of personalized medicine requires even greater innovation to meet the needs of the different groups of people that need and respond to different treatments. Said another way, application of bioinformatics is expanding the need for innovators and adaptation of new observations to practical solutions. We need more, not less innovation, and the patent system's *quid pro quo* relating to invention disclosure is more important than ever. We need to continue to encourage the use of open disclosure rather than reliance on limited licensing and trade secrets that hold new discoveries as closely guarded corporate property.

Rapid advancement of these tools and the recent lawsuit against Myriad Genetics challenging gene and genetic medical diagnostic patent claims has caused the patent system to fall under intense scrutiny once again. Even though the practices of a few actors have been questioned, the few cases where technology has been sequestered or priced beyond the reach of the general public are relatively small in number, and even these actors are beginning to change their behavior in light of public scrutiny.

The purpose of the patent clause in Article I, Section 8 of the Constitution was to give Congress the power to advance the progress of technology by offering inventors limited periods of exclusivity to ply their inventions.[82] Significant investments have been made, and will continue to be made, in all technological areas, but the degree of investment in the fields most relevant to diagnostic testing are among the highest and riskiest. Without a guarantee that a patent would be available and enforceable, the investment required to commercialize cutting edge diagnostic inventions for the good of patients likely would not occur.

---

[81] 35 U.S.C. §112.
[82] *See* U.S. Const. art. I, § 8.

One only needs to consider the veritable explosion of investment in biotechnology that has occurred since 1980 when the Supreme Court ruled that organisms could be patented.[83] Those investments led directly to today's dynamic diagnostics industry. Without the protections that enforceable patents provide, investments go elsewhere, or become highly protected trade secrets given the lack of FDA regulation. It can be reasonably expected that the complexity of development and clinical testing for diagnostic testing will increase with time, that higher evidentiary standards will be expected, and that the FDA will increase regulation in the interests of safeguarding patient safety and confidence. The direction is one in which robust patent protection will increasingly be expected to protect investments in research and development and commercialization.

Conclusions

AIPLA does not believe that the U.S. patent system is an obstacle to patients obtaining second opinion medical testing, nor that the patent laws must be amended to cure the referenced problem. There seems little likelihood that alternate test providers would provide confirmatory testing for markedly lower costs than primary test providers, that alternate tests would likely be less prone to error than primary tests, or that payers would pay for confirmatory testing. Moreover, the non-patent considerations on how the U.S. government approaches the safety and efficacy of genetic tests as well as reimbursement of genetic tests are unresolved and the subject of active discussions. Changes to the U.S. patent system would be premature until these non-patent considerations are fully addressed.

Thus, AIPLA would oppose efforts to limit patent rights in genetic diagnostics absent clear evidence that such legislation is necessary. AIPLA submits that no credible and substantial evidence exists that changes to the patent statute will improve access. Innovation and economic growth in the growing genetic diagnostics industry should not be constrained absent a definitive and overriding need, which has not been demonstrated.

Out of a concern for the risks posed to innovation and investment and the damage to the patent holder's rights, AIPLA believes that any revision of the patent statute in this area should at least consider whether:

- 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;

- 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;

[83] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

- the patent in question is specific to the genetic question at issue and not a more general technology patent (*e.g.*, a specific gene mutation or panel of specific SNPs vs. method or machine useable for carrying out genetic diagnostic tests regardless of the nature of the genetic makeup of a sample);

- the provider of the confirmatory test has not licensed the patent;

- a single confirmatory test is performed by a single provider;

- the provider gives notice to the patent owner or exclusive licensee that a confirmatory test was performed for the individual;

- the provider of the confirmatory test pays commercially reasonable compensation to the patent owner or exclusive licensee for infringement of the patent rights; and

- a sunset period and a reporting system are needed to monitor the impact of the legislation on innovation and on investments in new products and services.

To stem any remaining concern that the law recognizes a research use exemption for bona fide scientific research, AIPLA would support a statutory research exemption provided that the exemption is technology neutral, is 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, and is available only if study or experimentation (as opposed to a commercial use) is the dominant use, and that existence of a commercial purpose does not pre-empt or preclude exemption.

AIPLA appreciates the opportunity to present comments on this important issue.

Sincerely,

William G. Barber
AIPLA President