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Via Electronic Mail
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The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Comments - Patents
P.O. Box 1450
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Attn: Saurabh Vishnubhakat, Attorney Advisor
Re: Comments on Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing, 77 Fed. Reg. 3748 (Jan. 25, 2012)

Dear Under Secretary Kappos:

The ABA Sections of Science & Technology Law and Intellectual Property Law appreciate this opportunity to respond to the United States Patent and Trademark Office's Request for Comments, dated January 25, 2012, on issues relating to the patenting and exclusive licensing of genetic diagnostic tests and, more particularly, the effect of such patents and exclusive licenses on the availability to patients of independent second opinion genetic diagnostic testing.

The views expressed in this letter are presented on behalf of the Sections of Science & Technology Law and Intellectual Property Law (the "Sections") of the American Bar Association ("ABA"). These comments have not been approved by the House of Delegates or the Board of Governors of the ABA and, accordingly, should not be construed as representing the position of the ABA.

The mission of the Section of Science & Technology Law, which was formed in 1974, is to provide leadership on emerging issues at the intersection of law, science, and technology; to promote sound policy and public understanding on such issues; and to enhance the professional development of its members. The purpose of the Section of Intellectual Property Law, which was founded in 1894, is to further the sound development and improvement of intellectual property laws and their fair and just administration; to promote the public interest in, and understanding of, intellectual property rights as socially beneficial incentives to foster progress, human knowledge, economic development and competition; to apply the knowledge and

experience of the profession to the examination of the impact of these laws on developments in science and technology; to examine changes to be made in these laws by reason of such developments; to develop and disseminate information in these fields; and to cooperate in the foregoing with all appropriate interested groups.

The Section of Science & Technology Law's Committee on Biotechnology Law has had a longstanding interest in public policy issues that affect both proprietary rights in biotechnology developments in the United States, as well as patient access to such medical breakthroughs. This Committee comprises legal experts on biotechnology issues from industry, government, private law practice, and academia. The Section of Intellectual Property Law's Patent Division has had a similar longstanding interest in such issues as they relate to patent rights specifically and is comprised of patent experts with a similar breadth of backgrounds and legal practice. This letter largely reflects the work product of these two groups.

Background – A Perspective on Gene-Based Diagnostic Testing

There is little doubt of the important role genetic diagnostic testing plays today, as well as the increasingly significant role that such testing will play over the decades that lie ahead. For an individual patient, access to testing of this type can be transformative, both in understanding susceptibility to disease and in selecting the most appropriate treatment options.

This was not always the case. Indeed, just a few decades ago, this type of gene-level diagnostic testing was all but non-existent. The available "genetic" testing was typically limited to detection of gross, chromosome-level abnormalities, such as those associated with Down's syndrome.

In contrast to decades past, in the contemporary practice of medicine, detecting nucleotide-specific abnormalities within a single gene on a particular chromosome stands in some respects as a crowning achievement of modern biotechnology. Today, the ability to do diagnosis at the gene-level – even the single nucleotide level – is taken as much for granted in modern medicine as sending a text or video messaging is today in mobile telecommunication. Remarkably, both of these revolutionary technological advances have come into flower over the span of a single human generation.

To a similar extent, both of these remarkable innovations are almost certainly just in their infancy. In its own way, each new technology holds the promise of enormous future innovation. Like any infant technology, however, how these new technological capabilities are nurtured in legal and policy arenas will likely determine the extent and speed with which these promising fields will thrive in the decades ahead.

Given the future promise of gene-level innovations in the practice of medicine, the issues that the Office seeks to address should be viewed as vitally important to the

future health and well-being of all U.S. citizens. Pursuit of enlightened policies could yield highly desirable public health consequences. Making the wise policy choices is facilitated by some background and perspective, which the Sections offer below.

Looking back just 60 years, the chemical structure of the genetic material forming the basis for all living organisms was yet to be discovered. In April 1953 that all changed. Watson and Crick published their seminal work that identified the structure for DNA. In the decades following this achievement, powerful new recombinant DNA technologies were invented. These advances in biochemistry were matched by equally profound inventions in computing, with the advent of microprocessors and other types of micro-circuitry. These twin revolutions, in these seemingly diverse and unrelated technologies, operated with unparalleled synergy to make possible a profoundly more complete understanding of the basis for life at a molecular level than anyone might have readily imagined in 1953.

The most remarkable accomplishment to date from this historic technological synergy is worthy of particular reflection. *Within the last decade, it became possible to sequence the entire genome of an individual human being*.

It is worthwhile to reflect on this achievement, both in its technological and scientific dimensions – together these dimensions suggest just how much more promise may lie ahead in mankind's continued focus of biotechnology tools on gene-related science.

At the beginning of the last decade, the reported cost for original sequencing of the first complete human genome was $2.3 billion. While this was a great scientific achievement, its cost alone meant that it could not form the basis for revolutionizing therapies through "personalized medicine."

That reality, however, was short lived. By the end of the last decade commercial entities were reportedly offering sequencing of an individual human genome at a cost of a few thousand dollars. See Lauerman, John (2009-02-05) "*Complete Genomics Drives Down Cost of Genome Sequence to $5,000*" http://www.bloomberg.com/apps/news?pid=20601124&sid=aEUlnq6ltPpQ. Almost everyone familiar with this sequencing technology now foresees that its highest and best uses are yet to come.

The full public health implications of understanding human life at the molecular level do not, however, arise simply out of the naked coupling of chemistry and computational power. Those chemical/computing tools, although impressive in their own right, merely yield raw genetic data that, by itself, does nothing more than pinpoint minute differences in the DNA sequences from one human being to another.

The potential for greatly improving human health and well-being has instead come from the *application* of these modern tools to an understanding of *specific* human diseases and conditions. One seminal discovery that illustrates this point – of applying data to disease – was the discovery that certain variations of particular human genes signaled an increased susceptibility to developing breast and other reproductive cancers in women.

The discovery of so-called "BReast CAncer" or "BRCA" gene sequences has done no less than open a new chapter in the ability to individualize recommendations for a patient's care and treatment based upon the patient's individual genetic fingerprint. In this case, women at high genetic risk for developing breast and ovarian cancers can now be diagnosed by a simple, painless, non-invasive, readily available diagnostic test.

It is useful to reflect for a moment on what can best be characterized as a true inflection point in human history – the change in the practice of medicine made possible by BRCA gene diagnostic testing. For as long as medicine had been practiced over the long course of human history, the type of individualized treatment opportunities, now readily available through BRCA genetic testing, were simply unavailable – indeed, *unavailable at any price*. Simply put, the practice of medicine has now been forever changed by this achievement. *For as long as human medicine is practiced into the future, women will take for granted that their medical treatment recommendations will be made with an informed understanding of their individual genetic susceptibility to developing breast cancer*.

In terms of the intellectual property protection for the seminal inventions relating to the discovery of the BRCA gene, a similarly historic inflection point is upon us. We are now in the last years of the patent-protection period for inventions specifically related to the BRCA gene discovery and its use in genetic testing.

Patent life spans roughly a single human generation, typically ending 20 years from the time the initial patent filing occurs. As this two-decade period draws to a close, patent expiration will open the prospect of BRCA genetic testing being readily available from a potentially large number of competing providers.

As with any competitive market of this type, we can expect further patented (and unpatented) improvements in BRCA gene testing to emerge – further benefiting patients and the physicians called upon to advise and treat them. We can expect shortly to experience an era in which a competitive "BRCA-gene diagnostic product" market will emerge, with each competitor vying to provide patients advantages with the use of its product over the competing products marketed by others.

Intellectual Property as an Incentive to Invest in New Diagnostic Tools

As noted above, we live today among the first generation of women in all of human history with access to genetic testing that is able to quantify an individual's genetic susceptibility to breast and ovarian cancer. The benefits to this first-generation population have been significant. They can access improved and tailored treatments based upon each individual's unique genetic structure. *Pharmacogenomics: The Rediscovery of the Concept of Tailored Drug Therapy and Personalized Medicine*, The Health Lawyer, Vol. 19 Issue 3, 1-10 (2007) (discussing the movement of researchers and corporations focusing their efforts towards utilizing recent genetic advances to usher in a new genomic-based era of personalized medicine); Rong Stephanie Huang and Mark J. Ratain, Pharmacogenetics and Pharmacogenomics of Anticancer Agents. 59 CA Cancer J Clin. 42 (2009) (explaining that the goal of the emerging disciplines of genetic testing is to personalize treatment based on an individual's genotype).

This particular revolution in genetic diagnostic testing capabilities, which is part of a larger revolution in understanding of the human genome, has not come cheaply or easily. These advances in medicine are tied to huge investments, both public and private. This progress has been particularly dependent on the willingness of the private sector to invest, quite literally, hundreds of billions of dollars in biomedical research. Much of that investment was made on a sound expectation that the risks being taken to commercialize new technology hold the promise of producing financial returns commensurate with the magnitude of the inherent risks.

From basic research, to investments in preclinical development of potential new therapies or diagnostics, to the clinical trials needed to validate their effectiveness, to the development of a market for an innovative product, the journey from bench to bedside is long and arduous, fraught with opportunities for failure, and ultimately gratifying only to those willing to persist long enough to realize success.

Such long-term, high-risk, capital-intensive efforts to create a new therapeutic or diagnostic product are often dependent upon the expectation of strong, enforceable, and long-lived patent protection. Without such protection, many such endeavors would have no realistic prospect of being seen through to commercial reality. The simple reason: what may take a massive and sustained effort to create, once realized in its final commercial form, can often be copied. More to the point, a copied version can be developed for marketing with an investment of a few pennies by the copier for each dollar of the original investment by the innovator.

Common sense dictates that protection from this type of low-cost copying is essential to produce a viable investment thesis for attracting the capital needed to bring a new biomedical discovery to patients. That reality, however, has not prevented public health concerns from being posited over the impact of patent protection, both in the context of the protection it affords the innovator and the implications of the innovator's

option to select who and how many individual licensees, if any, might be authorized to practice a particular patented invention.

The most commonly cited – and readily understandable – of these posited concerns relates to the relatively high cost of a new biomedical therapy or diagnostic relative to the much lower cost at which copied versions are – or could be – made available were patent protection no longer to apply. The creator of a new medicine or a new diagnostic is positioned not much differently from the creator of a new motion picture or software product when it comes to the relationship between the originator and a copier – bringing such a new creation to market means a massive, high-risk investment, while the later cost to vend a copied version is typically *multiple orders of magnitude less*.

Myriad Genetics, which developed a diagnostic test under exclusive license from the University of Utah to identify mutations of two BRCA genes (specifically, the "BRCA1" and "BRCA2" genes) is a prototypical example of a test that, once copied versions of the test come to market in the years ahead, may well be available relatively inexpensively compared to the price today for Myriad's product.

The dilemma for many policy makers is a simple one. Even at the current market price for the Myriad test, patients can realize significant value relative to that price. On the other hand, the potential impact of price competition, once patent protection expires, for a product of this type (*i.e.*, one that will cost copiers relatively little to manufacture and market) means patients can realize that same value at a much reduced cost.

These policy makers accept that women with certain mutations of the BRCA1 and BRCA2 genes are approximately 80 percent more likely to develop breast and ovarian cancer and the Myriad test is extremely accurate at identifying in many women whether such genetic susceptibility exists. Unlike past generations of women who had no such testing option, a woman today – at a cost of approximately $3000 per test – can gain a much more precise understanding of her relative risk of developing breast or ovarian cancer. In the post-patent era, copied versions of the Myriad test may well be available at the same "pennies on the dollar" ratio that applies to the cost of copying discoveries of this type.

Viewed in this light, the BRCA gene diagnostic test underscores the change that takes place over the course of a single generation of innovation – first, a new and innovative capability is created that theretofore was unavailable at any price; thereafter the innovation becomes available at a price that typically reflects both its value to human medicine at the costs and risks undertaken to create it; and, ultimately, a competitive marketplace emerges based upon that innovation in which copied versions can be vended at little more than the cost to copy and manufacture them.

The Issues Limiting Access to Genetic Testing Are Many and Varied

If a new type of therapeutic or diagnostic testing becomes available on the market, and could greatly benefit those who take advantage of such a test, then there are potential public health issues if such a testing is not being done when indicated. Indeed, as with any new therapeutic or diagnostic product, absent actual access by patients to the innovation, its prospective public health benefits are merely theoretical.

If real barriers in fact do exist to making the highest and best use of a new opportunity for diagnosis or treatment, then it is important to identify what those access barriers are – and, of course, what measures might best be taken to address them. The Myriad BRCA gene diagnostic test is again an illustrative example from which to explore such public health issues.

Many barriers do in fact stand in the way of assuring that the Myriad test is used by the women whose health and well-being would be benefited from access to the testing. One such barrier is the apparent reluctance of as many as one-half of the patients for whom the testing is recommended to actually agree to undergo testing. *It appears from at least some credible research on the subject that insurance coverage (or the lack thereof) appears to have little or no impact on whether patients referred for BRCA gene testing actually receive the test*:

> There were no statistically significant differences in tested versus untested groups by age, race, language, family history, parity, marital status, religion, socioeconomic status, or *insurance status*. Of patients whose insurance plans offered coverage for genetic testing, 51.4% underwent testing and 48.6% did not (P = not significant [NS]). Of those who had no insurance coverage for testing, 41.2% underwent testing and 58.9% did not (P = NS)."

Olaya, et al, "*Disparities in BRCA testing: when insurance coverage is not a barrier*," American Journal of Surgery - Volume 198, Issue 4, pp. 562-565 (October 2009), available at http://www.sciencedirect.com/science/article/pii/S0002961009003754.

Nevertheless, for many women, the availability of all forms of medical treatment, including essential diagnostic testing, is compromised because of the lack of health care insurance. Even when health insurance is obtained, its coverage is limited or restricted. This includes limitations on the availability of genetic testing such as the Myriad test.

However, in the case of the Myriad BRCA genetic test, it is instructive to look at how that test is used and how reimbursement for the test is handled by insurers. The

available data indicates that, when a patient is insured, it appears the insurance coverage is particularly generous. Myriad reports that more than 90% of BRCA tests are covered by insurance plans and the average reimbursement for an individual patient is more than 90% of the cost of the test. http://www.bracnow.com/faqs/#75.

Another area of anxiety for patients – inherent in all diagnostic testing – is the potential for either false positives or false negatives. In the case of BRCA gene testing, these types of "false" results refer, respectively, to errantly reporting a high susceptibility to developing breast/ovarian cancer or to affording a false sense of assurance that no increased susceptibility exists.

The data available from Myriad on the reliability of its BRCA gene diagnostic test appears on its website. It reports, in the technical specifications for its BRCA genetic test (see http://www.myriad.com/lib/technical-specifications/BRACAnalysis-Technical-Specifications.pdf). an accuracy of at least 99%, with "false" reporting of less than 1%. Thus, if these data are accurate, it would appear that patients are not being denied access to accurate and reliable test results because of inadequacies or insufficiencies in the Myriad test itself.

The topic of "confirmatory testing," however, is not devoid of controversy. Notwithstanding Myriad's own reports the high level of accuracy of its test results, anxiety over false positives/negatives for the Myriad BRCA test has been fueled by contentions of a "high error rate" in its testing A commentary on these contentions can be found in the Journal of the National Cancer Institute, http://jnci.oxfordjournals.org/content/94/2/80.full, which identifies a group of French scientists, who are flatly opposed to the awarding of gene-related patents, as the apparent source of these contentions.

Patents, of course, do play a role in access to biomedical innovation. *As an incentive to commercially develop new biomedical innovations,* patents are often at the core of what makes access *possible* in the first place. Once access to a new diagnostic or therapeutic treatment is possible – because the product has successfully made it to the market – a full analysis of the post-marketing access issues will typically reveal that there are many and varied factors that determine whether access in fact to the innovation is being realized by the patients the product was intended to benefit.

Congress Has Acted to Tightly Circumscribe the Biomedical Innovation That Can Be Protected through Patents

Patent protection, of course, is not available *carte blanche*, to any innovator seeking to develop a new product and, even if patents can be secured, they afford no guarantee that they will protect the market from copied versions of the innovation coming to market. Why so?

While the patent laws serve to provide protection for many innovative biomedical therapies and diagnostics, patent protection is tightly circumscribed by a rigorous set of requirements that must be met before a claimed invention in a patent can be found valid and enforceable. One primary purpose of our patent laws is to promote the progress of science and useful arts by incentivizing the disclosure of these novel and useful inventions with a guarantee of time-limited rights to the inventors for inventions meeting the statutory standard.

The individual sections of the Patent Act work together to prevent overly broad, excessively vague, unduly conceptual, or inadequately inventive patents from issuing or, if issued, from being successfully enforced. Importantly, the Supreme Court has consistently denied patents that are not sufficiently concrete applications in the useful arts – eschewing a patent law that would protect inventions that are excessively conceptual or otherwise abstract. The Court has repeatedly held that laws of nature, physical phenomena, and abstract ideas are all beyond patenting.

While all inventions must operate consistent with laws (and principles) of nature, the patent law specifically prevents the patenting of inventions that fail to represent a concrete application of a principle of nature. Such conceptual inventions are barred from patenting under 35 U.S.C. § 101 and, thus, assure that ideas and concepts themselves will remain in the public domain.

Even those claimed inventions that make it beyond the §101 limitations on the reach of patenting must still pass scrutiny under the written description, utility, enablement, definiteness, novelty, non-obviousness filters of non-patentability. When these filtering limitations are properly applied, this constellation of statutory requirements not only limits the reach and breadth of patents across all technologies, but such requirements have historically been applied with a special rigor to biotechnology inventions. See *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) and *Ariad Pharm., Inc. v. Eli Lilly & Co*., 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*).

Indeed, the most recent example of patent claims lacking in the required rigor to meet the §101 test for subject-matter eligibility for patenting was a claimed invention in the biomedical field. The Supreme Court, by a margin of 9-0, struck down a patent directed to adjusting the dosage of a medicine to be given to an individual patient based on a determination of the serum levels of the medicine's active metabolite. The Supreme Court held that the asserted claims in the patent before the court lacked sufficient specificity in limiting the claimed invention to a specific and concrete application of the correlation between effective dose to be administered and serum level for the active metabolite. *Mayo Collaborative Services v. Prometheus Laboratories*, 566 U.S. ___, ___ (2012).

Fortunately, however, nothing in the *Prometheus* decision will necessarily exclude specific implementations or applications of such biomedical correlations from

patenting, including those that might serve as the basis for genetic diagnostic tests. Where claims to such tests are properly limited to specific, concrete applications, that is, they are not excessively conceptual in character (whether expressed as a natural phenomenon , a law of nature or otherwise insufficiently concrete subject matter), they can readily pass the threshold eligibility standard of §101 of the Patent Act.

As noted by the Federal Circuit in *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, biotechnological advances are wholly different from mere scientific discoveries or merely uncovering what lies beneath a rock, "[N]o one could contemplate that snapping a leaf from a tree would be worthy of a patent, whereas isolating genes to provide useful diagnostic tools and medicines is surely what the patent laws are intended to encourage and protect. Snapping a leaf from a tree is a physical separation, not one creating a new chemical entity." *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1354 (Fed. Cir. 2011). As stated by Judge Moore in *Ass'n for Molecular Pathology, supra*, the biotechnology industry is among our most innovative, and isolated gene patents, including the patents in suit, have existed for decades with no evidence of ill effects on innovation.

While patenting is subject to a rigorous set of limitations found in the patent statute itself, the protection available under such a robust Patent Act has nonetheless had a positive impact in assuring that the research performed in university laboratories was both disclosed to the public (consistent with the mission of the university) and made the subject of commercial investments to develop new products. Indeed, the inventions developed within university laboratories that subsequently became the subject of technology transfers to development-oriented, private-sector entities include the gene-splicing technology that served as the foundation for much of the biotechnology industry, as well as diagnostic tests for breast cancer and osteoporosis, to name just a few successful efforts at university technology transfer.

Additionally, a report from the Association of University Technology Managers showed that in 2008 alone, 648 new commercial products were introduced and 5,039 licenses and options were executed. This data highlights the important role that patent protection has played in disclosure – and subsequent commercialization – of new and useful inventions benefiting the public.

A strong and effective patent system is, thus, one crafted with a careful balance between affording adequate and effective protection for meritorious innovation, but with rigorous limits on patenting assuring that patents cannot be enforced unless properly limited in their reach. As the courts continue to refine the application of the statutory standards for patentability, it would appear that both the Congress and the courts are today carefully – and successfully – balancing strong protection for innovation with rigor in the applications of the principles of patentability.

Biotechnology Has Only Just Begun – IP Incentives Must Remain a Positive Force for Attracting Investment

The biotechnology field is a new and emerging one. Having been in meaningful existence only 30 years, almost every commentator would agree that it is still in its infancy. The promise of the next decades, in just the genetic diagnostic field alone, is that the early successes at discovering single mutations will shortly give way to an onslaught of vastly more sophisticated genetic markers for disease that require identifying multiple genetic variants and far more nuanced correlations.

To develop such next-generation tests requires continuing (and massive) private-sector investments and secure IP regimes. Patents must afford assured and extended protection periods before patented innovations can be freely copied. It is unlikely any investor would willingly shoulder the burden of massive investments in new technology development without the promise of recouping that investment through IP protections that prevent immediate copying. Limiting the availability of patent protection in the biotechnology arena, beyond the rigorous limitations already in place, would needlessly put an entire industry at risk.

As with any IP regime, as noted extensively above, a balance is necessary between strong protection for innovation and the freedom to operate in areas where that protection does not extend or no longer remains. As Justice Breyer commented, "Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten." *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc*., 548 U.S. 124, 127 (2006) (Breyer, J., dissenting). Particularly in light of the *Prometheus* decision sitting atop decisions such as *Fisher* and *Ariad*, it is the Sections' view that the limitations on patenting in the biomedical arena require no further tightening of the reins.

The decision on Myriad's patents relating to the BRCA gene in *Ass'n for Molecular Pathology* understandably raised – and will continue to raise – strong emotions. Should a newly developed genetic test be used by all who could benefit from it? The simple question raises surprisingly complex considerations.

- How can patients for whom the test is indicated be better educated so that more than 50% actually take the test once recommended?
- How can insurance coverage for all diagnostic testing procedures be more rapidly and universally secured? Indeed, how can those who today have no health insurance better access new therapies and diagnostic tests?
- Even with a test that may be more than 99% accurate, what can be done to assure that technologies of this type continue to be improved – to provide ever-greater confidence for physicians and peace of mind for patients that the right information about their condition will lead to the best individualized treatment plan for them?

While patents and the patent law may raise policy issues, it is clear that patents relating to individual diagnostic or therapeutic innovations are but a transient consideration, at least relative to the more far-reaching issues impacting access to healthcare. In a few years, the Myriad BRCA-related patents will be history, but, almost without question, each of the crucial "access" issues discussed above will likely remain unresolved.

Recommendations

Congress has asked the United States Patent and Trademark Office to solicit public comment and to report on the appropriate relationship between DNA patents and exclusive licensing of genetic diagnostic tests, on the one hand, and public health needs and patient accessibility, on the other. The simplest answer for the Office to provide Congress may be that patents play an important role in creating the opportunity for access to an innovative diagnostic test, but many and varied factors are at work in a complex healthcare system that dictate whether access in fact exists for an individual patient once that opportunity has been created.

The Sections share the belief that both the Congress and the courts should stay the current course in striking the proper balance in the operation of the patent system. Under the Leahy-Smith America Invents Act, for example, Congress not only continued the rigorous requirements that limit the availability and reach of patents, but offered the public an important new role in assuring that patents that issue – and remain in force – meet the rigor imposed by the patent statute.

In the future, both before and after a patent issues, the public can now participate in the patenting process. Indeed, under the new post-grant review procedure, a member of the public can raise any issue of patent validity that an infringer could raise in court as a defense against the patent in the PGR.

Congress has also wisely chosen inaction where the courts have stepped in to address an issue of possible imbalance. As one example, despite prompting to do otherwise, Congress has refrained from legislating on top of the Supreme Court decision in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). It declined addressing through statutory modification the judicial caveats on the availability of injunctions cases where patent infringement is found.

Congress has to date elected not to address the *eBay* holding that, in certain situations, permits the continued, unlicensed practice of a patented invention once a judgment of infringement has been entered. It has not otherwise sought to add to the patent statute new provisions that would either tolerate such post-judgment patent infringement or, alternatively, compel the patent owner to license what otherwise would be infringing activity.

Again, the issue of balance is at play. The United States has long upheld a rule that treats patent rights as exclusive rights, but countenances exceptions in exceptional situations. As the Sections see this issue, nothing thus far in gene-related or genetic testing-related patenting would appear to justify statutory tinkering.

Continuing to allow the courts, case by case, to address key patenting issues through the judicial process would appear to be especially desirable for gene-related inventions *at the present time*. Why so?

Today, not only is the entire human genome of many human beings "prior art," but the same is true of tens of thousands of individual human and non-human genes and gene sequences. Those who express a desire to have "freedom of action" from future patenting with respect to individual human genes, the sequencing of human genetic material, or the human genome itself, should take perfect comfort from the fact that Congress has assured such freedom under the novelty and non-obviousness requirements for patentability. Indeed, these tests for novelty and inventiveness have long been the central limiting features on the availability of patents.

Before doing more – or recommending to Congress that more be done – the time has arrived to digest the recent decisions of the U.S. Supreme Court in deciding patent-eligibility under §101. As the Court unanimously concluded in *Prometheus*, "[W]e must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U.S.C. §§161-164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable." *Mayo Collaborative Services v. Prometheus Laboratories*, 566 U.S. ___, ___ (2012).

Although the Supreme Court's role is not to determine such policy questions, the Sections would submit that Congress – for the present at least – need not now undertake more than it has already done, especially in light of the new tools in the hands of the public under the AIA. Before acting hastily, Congress should at least wait to determine the actual impact of the *Prometheus* decision, especially in light of the highly unorthodox manner in which the inventor expressed the invention in its claims. It may prove to be the case that the Supreme Court's decision is largely benign for inventors, at least those whose patent claims are more carefully crafted – to more specific and concrete applications of the natural principles on which the invention rests. Moreover, in the near future, the Office will have the opportunity to hear – and promptly decide – key patent-eligibility issues under §101 in the new post-grant review procedures afforded under the AIA.

For all the above reasons, it would, thus, be unwise for Congress to act prematurely, seeking to "rescue" the biotechnology industry by easing the limitations in

§101. If nothing more than securing a better patent draftsman would suffice to obtain effective patent protection, a legislative remedy is clearly unwarranted.

It would be similarly premature for Congress to conclude that patent rights and exclusive patent licenses for validly patented gene-related inventions required some redress in order to assure that, during the transient period when a new therapy or diagnostic might be protected through patents, would-be copiers can compel the patent owner to permit market access.

To compel licensing of a patent in a manner that would remove genetic diagnostics from the economic incentives offered by patents, or to substantially degrade their value, should be based on evidence of a compelling public health interest that would be served, and, absent such, is inadvisable. To facilitate such copying of a patented innovation would work against the future innovativeness of American medical advances—hurting, in the long run, the patient populations such advances are crafted to serve.

In the end, the Office does not have the mandate to change the patent laws or to set public policy. Whether fully described and enabled DNA compounds, once determined to be both novel and non-obvious, and genetic diagnostic tests that are derived from such discoveries are §101 "patent-eligible" inventions is a matter for the courts to decide, applying a statutory standard that can be traced, virtually unchanged, back to 1793.

If the courts' holdings are in line with the Patent Act, but run contrary to public policy, then Congress may be forced to heed calls that it should address the situation. However, with respect to genetic diagnostic testing, and gene-related patents more generally, there is simply no case to be made that patents have been anything other than a partner in achieving mammoth technological advances that have remarkably improved the therapeutic and diagnostic options available to patients, including during the transitory period when patent protection exists and would-be copiers are kept at bay.

Thus, the most thoughtful approach to addressing the issues associated with gene-related inventions should recognize that patents, through the incentives they provide, *create the opportunity for access* to innovative therapies and diagnostics. Once the opportunity exists, a myriad of other economic and non-economic factors operate to limit effective access in fact. This is certainly the case with BRCA genetic testing.

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 US 722 (2002), the Supreme Court noted that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." On the other hand, when the courts determine the rigorous requirements for patenting laid out by Congress have not been met, then those inventions reside in the public domain and are free for all to use. Congress, for over 200 years, has crafted U.S. patent laws with a balancing of interests

between exclusivity rights for what lies strictly within those rigorous requirements for valid patenting and freedom to operate and compete for anything lying outside such boundaries. As long as the patent system is seen as driving investments that lead to biomedical innovation that create the opportunity for access to new therapies and diagnostic tools, that system should not be needlessly put at risk by tinkering with the transient protections a patented therapy or diagnostic might enjoy, especially in light of all the non-patent factors that may operate to compromise that access, both during the patent term and beyond.

We hope this response is helpful to the Patent and Trademark Office, and we would be happy to discuss our comments in greater detail should you so desire.

Sincerely,

Eric Y. Drogin
Chair, ABA Section of Science & Technology Law

Robert A. Armitage
Chair, ABA Section of Intellectual Property Law