June 18, 2019

The Honorable Thomas Tillis
Chairman, Subcommittee on Intellectual Property
Committee on the Judiciary
U.S. Senate
Washington, D.C. 20510

The Honorable Christopher Coons
Ranking Member, Subcommittee on Intellectual Property
Committee on the Judiciary
U.S. Senate
Washington, D.C. 20510

Dear Chairman Tillis and Ranking Member Coons:

On behalf of the Section of Intellectual Property Law of the American Bar Association (the “Section”), I write to supplement the Section’s views with respect to the hearing held on June 11, 2019 on The State of Patent Eligibility in America: Part III. The views expressed herein are presented on behalf of the Section of Intellectual Property Law. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the Association.

As Scott Partridge, Immediate Past Chair of the Section, noted during his testimony on June 5, the American Bar Association (ABA) is the legal profession’s leading national voluntary bar organization, with more than 400,000 members around the United States and the world. The ABA, the Section of Intellectual Property Law (ABA-IPL) is one of the largest intellectual property organizations in the world and the oldest substantive Section of the ABA. Since 1894, we have advanced the development and improvement of intellectual property laws and their fair and just administration. As the forum for rich perspectives and balanced insight on the full spectrum of intellectual property law, the Section of Intellectual Property Law serves within the ABA as a highly respected voice within the intellectual property profession, before policy makers, and with the public.
The Section is providing these supplemental views to the Subcommittee with respect to the reform proposal that has been proposed by Senators Tillis and Coons and Representatives Collins, Johnson, and Stivers. As noted by Mr. Partridge, the Section believes that the reform proposal is a simple and elegant solution to the current unworkable and detrimental state of §101 jurisprudence. However, given that one of the primary objectives of this legislative reform effort is to provide certainty and predictability to patent eligibility law to thereby reestablish appropriate incentives to innovation in all fields of technology, we have several changes that we believe will lessen the risk of misinterpretation going forward. We also wanted to provide some useful information to counter inaccurate statements made during these hearings with respect to the patenting of human genes.

I. Proposed Changes to the Legislative Proposal

The first suggested change we propose is to delete the redundancy between the definition of “useful” and the introductory phrase of Section 101 (a). Both use the expression “invention or discovery.” We suggest that the definition of “useful” in the new proposed Section 100 (k) be revised as follows: “The term “useful” means a specific and practical utility in any field of technology through human intervention.”

A second change we propose is to add Section 100 to the first paragraph of the Additional Legislative Provisions. We recommend the sentence read “The provisions of Sections 100 and 101 shall be construed in favor of eligibility.” We suspect that this is a simple oversight. Since the definition of “useful” in Section 100 is a key change to the law of patent eligibility under Section 101, both sections ought to be included in the first sentence of the Additional Legislative Provisions.

With respect to Section 112, it is important to address the use of the term “element” in that section and the different term “limitation” in Section 101(b) and the Additional Legislative Provisions (last paragraph). The term “element” has a long history and has been used in Section 112 since at least the 1952 Patent Act. Thus, we would not recommend changing the word “element” in Section 112 to “limitation” because of potential unintended consequences. Courts might think that Congress intended to change existing 112 law beyond the amendment now being proposed to Section 112 (f). However, the word “limitations” might be viewed as a term that has a broader perspective in that an element might have language within it that could be viewed as a limitation. That would be an appropriate view to take of the changes being suggested in Section 101. Thus, our recommendation would be to make two minor changes to Section 101(b) and the last paragraph of the Additional Legislative Provisions—1) namely, to change “any claim limitation” in Section 101(b) to “any claim element or limitation.
thereof,” and, 2) in the last paragraph of the Additional Legislative Provisions, change “individual limitations” to “individual elements or limitations thereof.”

The new Section 112(f) needs to be read in the context of Williamson v. Citrix Online, LLC. Williamson reaffirmed en banc that the test for whether a claim element is structural, rather than functional, is whether “the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.” Williamson is and remains the test in view of new 112(f). The only change there is that new 112(f) widens this inquiry to elements not expressed as a combination. Today, a claim element, including the presence or absence of the words “means for” or “step for,” would be construed under Phillips as a question of law, applying the Williamson test set out above. Under new Section 112(f) this remains the same. New Section 112(f) does not overrule the Williamson presumption but makes it clearer that it is unnecessary to the construction of the claim.

Section 112(f) serves as a safe harbor for functionally defined claim elements. However, the ABA-IPL Section recognizes the theoretical potential for a conflict with Section 112(a), if the provisions are not read together. That is, under Section 112(f) the literal claim scope includes the equivalents of the structures disclosed in the patent specification. Plainly, those equivalents are not literally described in the patent specification and therefore could be argued to render the claim invalid under Section 112(a). Although theoretically possible, under current law, Section 112(f) and Section(a) have not operated in this manner. There is simply no basis in the amended text of Section 112(f) to suggest that it would be going forward. Nevertheless, the Section would support a simple legislative provision that provides, “the determination that a claim is sufficiently disclosed under Section 112 must be made by disregarding equivalents under Section 112(f).”

II. Inaccuracies with Respect to the Patenting of Human Genes

We would like to provide the Subcommittee with facts surrounding the issue of gene patenting, as well as information with respect to the real competing interests and philosophical choices that the issue of gene patenting raises. Specifically, we are concerned by the statements made by witnesses during the hearing which seek to relitigate the Myriad case and the issues surrounding that case, using the same inaccuracies asserted during that litigation.

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1 792 F.3d 1339 (Fed Cir 2015).
22 Id. at 1349.
3 Association for Molecular Pathology v. Myriad Genetics, Inc. 569 U.S. 576 (2013).
We are most concerned by several statements asserted as fact that are incorrect. The first of these is that human genes are not patent eligible. In fact, they are and have been before and after the Supreme Court’s *Myriad* decision. The only difference the decision made is that patent eligibility is limited to a particular form of these genes, termed complementary DNA (cDNA). The proposed changes in the law will not affect patent eligibility of human genes.

Second, the issue of human gene patenting itself has been mooted by the passage of time: the Human Genome Project publicly disclosed almost all human genes (and the rest of the human genome) between 1998 and 2000. U.S. patents have a term defined as 20 years from their earliest filing date, and thus any patents on human genes have or will expire before the close of this Congress. Simply put, there are no human genes left to patent.

There was never any risk to scientific research by patenting genes. During the time Myriad had its patents in force more than 10,000 scientific research papers were published on the BRCA genes. Gene patents have not prevented academics from studying the genes for the purpose of better understanding them or finding new uses for them. We are not aware of any scientific researchers ever being threatened with infringement lawsuits; the only objection was to those actors replicating patented diagnostic assays and charging patients for the results, activities that were not research and were in direct competition with Myriad. We are likewise not aware of any patent infringement lawsuits filed against a university or non-profit research institution performing basic research on the BRCA genes or on any other genes. The overwhelming evidence is that patent infringement lawsuits or the threat of such lawsuits did not inhibit academic research, even regarding the BRCA genes, prior to the Supreme Court’s *Myriad* decision.

Contrary to testimony given during the hearings, no gene patent holder “owns” an individual’s genes, either in their chromosomal form nor as cDNAs. This is because claims have never been granted on “products of nature” as they exist in nature; the law require “human intervention” and therefore cannot read on the gene in its native state in the chromosome. It also ignores the constitutional and statutory prohibitions regarding having an ownership interest in a human being. These allegations produce more heat than light and impede sober consideration of this important issue.

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4 These genes contain the identical “informational” content of the genes as they exist in the human chromosome.

5 U.S. Const., amend. XIII.


Another incorrect assertion (or assumption) is that genetic information per se is patent eligible; it is not. Claims to human (or any organisms) genes do not encompass genetic information per se. On the contrary, these claims are limited as compositions of matter to genes as chemical compounds. While this misunderstanding requires correction, it does not require amending the statute because genetic information falls outside the scope of Section 101 of the 1952 Patent Act.

There is plentiful evidence that the Supreme Court’s subject matter eligibility decisions, particularly Myriad, have not promoted progress and have affirmatively hampered innovation. The evidence: several hundreds of new drugs that are the fruit of the “biotechnology revolution” that are either on the market or in development, and the number of formerly deadly diseases with real-world interventions that have been developed that would not be patent-eligible under current law. The allegation that revising the Patent Act as proposed “will prevent the discovery of novel treatments for diseases including cancer, muscular dystrophy, Alzheimer's disease, heart disease, and other rare and common diseases” is belied by the history of the past thirty years, during which there has been discovery of treatments for many such diseases, supported by the patent system to permit these treatments to come to market.

Turning to the philosophy of the debate, the argument that patenting genes is somehow ethically wrong should be weighed against the consequences of continuing to apply the Court’s Myriad decision to prevent patenting any compound that is “merely” isolated from nature. Analysis of a 2010 study from the National Institutes of Health shows that the overwhelming majority of FDA-approved drugs in the 1981-2010 timeframe would be patent ineligible under the Supreme Court’s recent decisions, including 75% of antibacterial drugs and 80% of anti-cancer drugs. Prohibiting patenting of drugs “merely” isolated from nature (as the Supreme Court’s reasoning has been applied outside the

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9 The only support proffered by this argument’s proponents for the assertion that human gene patent ineligibility should lead to lower cost diagnostic tests is an article by a journalist, written the day the Supreme Court handed down its Myriad decision in 2013 (Andrew Pollack, After Patent Ruling, Availability of Gene Tests Could Broaden, NY TIMES (Jun. 13, 2013), https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html). There are no recent studies that confirm this hypothesis based in real-world evidence that the Myriad decision has led to lower cost diagnostics. And further arguments comparing the cost of Myriad’s tests with the decreasing cost of genomic sequencing during the time when Myriad’s patents were in effect compares apples and oranges: the Myriad test did not require whole genome DNA sequencing (which is where significant cost savings arose at that time).

context of human genes) also prohibits significant innovation in the development of important, life-saving drugs. Development of novel therapeutic agents, produced in reliance on the genomic information developed over the past half-century and a better understanding of the underlying biology of disease, is threatened by the Supreme Court’s recent eligibility decisions. Ironically, it might be easier under current patent law to patent a synthetic compound having therapeutic usefulness which is discovered by chance than to patent therapies directed by a better understanding of the underlying biological cause of the disease.

We believe that a proper appreciation of the facts will establish that the position arguing that the legislative proposal would reverse the Myriad decision is based on speculation, assumption, rhetoric, and a fundamental misunderstanding of the role of patenting in promoting innovation in our economy. We ask that the Subcommittee take the actual factual situation into consideration as it moves forward in reviewing the legislative proposal and determines the best way forward for reforming Section 101 of the Patent Act.

In closing, the Section appreciates the efforts that both of you and your staff have taken in recently sponsoring roundtables with stakeholders and in holding this important series of hearings to develop a legislative solution to address the ambiguity and uncertainty posed by the current Supreme Court jurisprudence on patent subject matter eligibility. Legislative reform is needed now to restore predictability to the patent system and to maintain incentives to invest in future cutting-edge technologies and discoveries. The proposal that has been drafted by yourselves and Representatives Collins, Johnson, and Stivers provides an important step forward in improving our patent system. We should be cautious about seeking perfection as some witnesses seemingly suggest, as that would risk the current window of opportunity in favor of a forever elusive dream of a perfect solution. The time to act is now.

Thank you for your attention to this important issue and for considering the views of the Section throughout the process. Please let us know if we can further assist your efforts as this process moves forward in the Senate and later this year in the House of Representatives.

Sincerely,

[Signature]

Mark K. Dickson
Chair, ABA Section of Intellectual Property Law