My name is John Storella. I am currently a partner at the law firm of Storella & Witt in Berkeley, California. For more than thirty years, my practice has focused on biotechnology intellectual property. You can see my LinkedIn profile at linkedin.com/in/johnstorella. I write to address the issue of patent eligibility jurisprudence and, in particular, patent protection for diagnostic tests and precision medicine.

In short, I believe that Congress should make appropriate amendments to 35 U.S.C. §101 to extend patent eligibility to diagnostic tests, while relying on strict application of the written description and enablement requirements of 35 U.S.C. §112 to ensure appropriate claim scope. Congress also should consider amendment of 35 U.S.C. §271 to allow, in some instances, a finding of infringement even when different parties carry out different steps of a single patent claim. I make these recommendations understanding that patents represent a delicate social balance – too much protection stifles competition, too little inhibits the commercialization of valuable new technologies.

Since the Supreme Court's decision in *Mayo* v. *Prometheus* (569 U.S. 576 (2013)) ("*Mayo*"), it has been increasingly difficult for companies to obtain U.S. patents on diagnostic tests. This difficulty has had a negative impact on the development and commercialization of such tests. For example, certain of my clients have had delays in funding because investors expressed concern about the slowness and uncertainty of patents to issue. Also, the value of patents that do issue tend to be of narrow scope, and there is uncertainty as to whether these patents will provide meaningful exclusion of competitors in the market. Without patent protection, these companies are more likely to fail, and any investment in them to be wasted. The long-term impact will be a diminished number of new diagnostic tests on the market. Of course, the purpose of the patent system is to "promote the progress of science and the useful arts." (U.S. Constitution, Article I, Section 8.)

Let's being with terms. By "diagnostics" I mean the step of using objective measurements to make inferences about the state of a person's health. By "precision medicine" (sometimes called "personalized medicine"), I mean performing a diagnostic test on a patient, and, informed by the results of that test, administering a therapeutic treatment more specifically tailored to the patient.

A diagnostic test necessarily involves using a rule or algorithm to make inference: A finding of "X" in a subject infers condition "Y". This has been true since the beginning of medicine.

Around the first century, CE, the Roman physician, Celsus, identified the four cardinal signs of inflammation as “calor, dolor, tumor, and rubor” (warmth, pain, swelling and redness). Today’s diagnostic tests still rely on collecting data and, by executing a rule, inferring a state of health.

In *Mayo*, the Supreme Court held that a claim involving a diagnostic test was patent ineligible because it was directed to a “law of nature.” The Court said, “[T]o transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words ‘apply it.’” For the Court, the diagnostic rule is a “law of nature”, and executing the rule is “applying it”.

But this characterization does not do justice to the sophistication of modern diagnostics R&D. In a diagnostic discovery phase, large amounts of data may be collected. This could be measurements of thousands of proteins in sample of blood, or thousands of nucleic acid sequences from a tissue sample thousands of microbes in a feces sample. This information may require sophisticated bioinformatic processing to become intelligible. The algorithms that perform this processing can, themselves, may be novel and useful inventions. However, such inventions may not be patent eligible because of restrictions on patenting of computer algorithms. After processing, the data can be input into computers using machine learning (e.g., artificial intelligence) to create models that map the data to condition being diagnosed. The product of this phase is the diagnostic test. Under current patent eligibility jurisprudence, the very activity that produces a new, useful, and unobvious diagnostic test is not patent eligible because the process of diagnosis involves the execution of an algorithm.

Mayo does provide an out, of sorts, for patent eligibility. A claim to a diagnostic can be patentable if it includes steps involving more than “well-understood, routine, conventional activity.” This activity is understood to include steps that are up-stream of the diagnostic algorithm, for example, ways of measuring the analytes. Invention can lie in new methods of sample preparation, processing and measurement. However, frequently, this is a case of the tail wagging the dog: The key discovery is typically the diagnostic relationship, not how the test is physically carried out.

Another out is to include a therapeutic step after the diagnostic step. Methods of treatment are patent eligible. However, this approach suffers from two problems. First, the therapeutic step may involve the administration of a known drug. Unless the unobviousness of the diagnostic is considered, the claim could be subject to an obviousness challenge. Second, the doctrine of

divided infringement holds that a claim can only be infringed if the steps are performed by a single party. (See, e.g., *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015).) Such a method is typically carried out by two different parties, one that performs the diagnostic, and another that uses the result of the diagnostic to deliver the therapeutic. In this case, there is no one to sue.

Thus, we reach a conundrum. Regardless of the amount creative activity necessary to discover a novel diagnostic, regardless of its potential benefits to society, the invention is not patent eligible as long as the last step of the claim is "apply it."

The solution, then, is the change the law so that, at least for some exceptions, "apply it" suffices for patent eligibility. What might those exceptions be? I propose three for consideration:

- First, Congress might create an exception for medical diagnostic tests. That is, Congress could make patent eligible the application of a "law of nature" to produce a diagnostic result.
- Second, Congress might exempt diagnostic methods that cannot be performed by the human mind alone, that is, that require a computer to carry out. This will require a physical step (a computer) rather than a mental step (a human mind) to execute the diagnostic rule.
- Third, Congress might amend the law concerning divided infringement. Such an amendment might allow, under certain circumstances, the right to sue a first party who infringes part of a claim, if it is cooperating with a second party who infringes the rest of the claim.

Any changes in the law will produce ramifications that should be anticipated and addressed to the extent possible. In particular, expansion of patent eligibility could result in patents with scope so broad as to stifle further development. Therefore, such claims should be limited in scope. Limitations can be implemented by strict application of written description and enablement requirements. Written description requires a precise description of the invention. Enablement requires enabling the practice of the invention throughout its scope. Strict application of both of these rules could address the concerns expressed by the Supreme Court in *Mayo*: Tying up a doctor's subsequent treatment decision, inhibiting the development of more refined treatment recommendations, and broadly covering all processes that make use of correlations after measuring analytes, including later discovered processes using new methods.

No doubt, it will take the USPTO and the courts some time to settle on the contours of these doctrines in view of any expansion of patent eligibility. But this is what these institutions are good at.

In sum, Congress could jumpstart the development of diagnostic tests and precision medicine by proper and limited amendments to the patent law. The problem, and the contours of its solution, are clear.

Thank you for your consideration.