Comments of the Pharmaceutical Research and Manufacturers of America
Docket No.: PTO-P-2016-0041
January 18, 2017

Comments of the Pharmaceutical Research and Manufacturers of America Responding to the United States Patent and Trademark Office's *Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility*

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits these comments in response to the United States Patent and Trademark Office's ("USPTO's") *Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility*, 81 Fed. Reg. 71485-71489 (October 17, 2016) ("Federal Register Notice").

PhRMA's member companies are leading research-based pharmaceutical innovators devoted to developing new and improved medicines that allow patients to live longer, healthier, and more productive lives. PhRMA's membership ranges in size from small emerging companies to multinational corporations that employ tens of thousands of Americans, and encompasses both research-based pharmaceutical and biotechnology companies. The U.S. biopharmaceutical sector supports a total of 4.4 million jobs throughout the economy, and directly employs more than 854,000 Americans.[1] The industry's overall economic impact is substantial, accounting for nearly $1.2 trillion in economic output.[2] We offer the comments below from the perspective of research-based biopharmaceutical companies who depend on the patent system for the development of new drugs and biologics.

PhRMA appreciates the USPTO's ongoing outreach to stakeholders on subject matter eligibility matters and is grateful for the opportunity to comment on these issues.

Comments

The U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business research and development ("R&D"), representing about 17% of dollars spent on all R&D by U.S. businesses.[3] Biopharmaceutical companies operating in the U.S. invested more than $70 billion in R&D in 2015, and PhRMA members invested an estimated $58.8 billion in R&D 2015.[4] Medicines developed by the biopharmaceutical sector have produced large improvements in health across a broad range of diseases. The rapid growth of

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[1] TEConomy Partners, LLC, *The Economic Impact of the U.S. Biopharmaceutical Industry: National and State Estimates*, at 1, 11, May 2016, http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceuticaul-industry-economic-impact.pdf.

[2] *Id.* at 1, 10.

[3] PhRMA analysis of National Science Foundation, Business Research, Development, and Innovation Survey (BRDIS) 2011, 2014.

[4] PhRMA, *2016 PhRMA Annual Membership Survey*, at 5, T.1., 2016, http://phrma-docs.phrma.org/sites/default/files/pdf/annual-membership-survey-results.pdf.

biomedical knowledge has created opportunities for profound advances against our most complex and costly diseases. Inventions made by PhRMA members provide significant public health benefits and provide consumers with life-saving medicines. However, developing a new medicine takes between 10 and 15 years of work and costs an average of $2.6 billion of investment in R&D.[5] Only two of every ten marketed drugs return revenues that exceed or match the R&D investment.[6]

Growing understanding of the underlying genetic and biological factors causing diseases is enabling a new era in targeted health care. Through personalized, or precision medicine, physicians and researchers are better able to direct patient care along the full spectrum of health care, from risk assessment and prevention to detection, diagnosis, treatment, and disease management. In recent years, we have seen tremendous advances in personalized medicine. In 2015, more than 25% of new drug approvals were personalized medicines, with 35% of 2015 cancer approvals alone being personalized medicines.[7] These medicines are shifting the treatment paradigm for patients, enabling increasingly precise assessment of which medical treatments and procedures will be best for each patient. By targeting treatments to patients most likely to benefit, personalized medicines represent an important tool, as they may reduce the use of unnecessary and often costly treatments or procedures.

Like innovators across the spectrum of American industries, biopharmaceutical companies make the substantial R&D investments that yield new and improved medicines in reliance on a legal regime that provides protection for any resulting intellectual property. In particular, PhRMA's members rely on patents to protect their inventions and provide an opportunity to recover their R&D costs and fund new research. Patents are critical for biopharmaceutical innovation given the research-intensive nature of this sector and the substantial upfront investment needed to discover and develop products that meet FDA approval requirements.[8]

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[5] Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, 47 J. Health Econ. 20-33, at 26 (2016).

[6] John A. Vernon et al., *Drug development costs when financial risk is measured using the Fama-French three-factor model*, 19 Health Econ. 1002-1005, at 1004 (2010).

[7] Personalized Medicine Coalition. 2015 progress report: Personalized medicine at FDA. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/2015_Progress_Report_PM_at_FDA1.pdf. Accessed April 2016

[8] *See* Claude Barfield & John E. Calfee, *Biotechnology and the Patent System: Balancing Innovation and Property Rights* at 1–2 (AEI Press 2007), https://www.aei.org/wp-content/uploads/2013/12/-biotechnology-and-the-patent-system-book_121440333605.pdf ("Without patent protection, investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk."); *see generally* Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, at 2 (2014), http://phrma-docs.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf; Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849 (2002).

PhRMA's comments below are twofold. Part I responds to the USPTO's request for public comment on the USPTO Subject Matter Eligibility Guidelines from Roundtable 1. Part II responds to the USPTO's request for public comment on topics covered in the Federal Register Notice under the heading "Exploring the Legal Contours of Patent Subject Matter Eligibility" from Roundtable 2.

I. Topics from Roundtable 1: USPTO Subject Matter Eligibility Guidelines

PhRMA applauds the USPTO's efforts to react to and provide timely guidance about recent case law regarding subject matter eligibility under 35 U.S.C. § 101. The USPTO's quick response time in adding new case law to the guidance has been most helpful and PhRMA hopes the USPTO will continue this endeavor.

PhRMA offers a few suggestions for improving the May 2016 Life Sciences examples in response to Question 2 of the Roundtable 1 topics in the Federal Register Notice.

***Example 28*.** PhRMA urges the USPTO to reconsider its subject matter eligibility analysis with respect to claim 3 of Example 28, which recites "[a] vaccine comprising: Peptide F; and a pharmaceutically acceptable carrier." The analysis provided in this example suggests that claim 3 is not subject matter eligible because, under the broadest reasonable interpretation of the claim, each component of the claim is a "product of nature" exception, and the claim does not amount to significantly more than each "product of nature" by itself. The example also states that using a carrier in a peptide vaccine does not further limit the claim because the combination of the peptide and a carrier was well-understood, routine and conventional in the field. However, this stems from an incomplete consideration of the claim as a whole, as explained below.

PhRMA submits that the recited claim is subject matter eligible when considered under the two-step analysis articulated in *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (citing *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012)). Under the first step, the recited claim is directed to a *vaccine*, which is a patent eligible manufactured composition of matter, comprising Peptide F and a pharmaceutically acceptable carrier. The claim is directed to a vaccine, not just to a peptide and a carrier such as water that produce an immunogenic response in a patient. It is directed to a man-made composition. The analysis in the example improperly discounts the value of the claimed vaccine and thus reaches the wrong assessment on the first step of the subject matter eligibility analysis. The importance of the "directed to" analysis to resolve subject matter eligibility issues under 35 U.S.C. § 101 is emphasized in the Federal Circuit's decision in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1047–50 (Fed. Cir. 2016). The claims in *CellzDirect* were directed to an improved process of preserving hepatocytes, which relied on the natural law of the hepatocytes' ability to survive multiple freeze-thaw cycles. *CellzDirect*, 827 F.3d at 1045, 1048. The court noted that the invention is "a constructive process, carried out by an artisan to achieve 'a new and useful end,' [and] is precisely the type of claim that is eligible for patenting." *Id.* at 1048. The invention "employed [a] natural discovery to create a new and improved way of

preserving hepatocyte cells for later use." *Id.* Similarly, the vaccine in claim 3 of Example 28 should be patentable because it is directed a new and useful product.

Further, under the second step of the analysis, a vaccine does not arise from well-understood, routine, conventional activity, but rather represents significantly more than the patent ineligible concepts of a peptide and a carrier such as water that produce an immunogenic response. For step two, the *CellzDirect* decision emphasizes the importance of viewing the claim "as a whole, considering [its] elements 'both individually and 'as an ordered combination.'" *See CellzDirect*, 827 F.3d at 1051; and *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1298). When viewing claim 3 of Example 28 as a whole, even under the broadest reasonable interpretation of the claim provided in the example, it is apparent that the claim recites significantly more than two individual "product of nature" components. Instead, looking at the claim as a whole, the claim recites a new, man-made combination of natural products which must produce a vaccinating immune response. The claim, therefore, should also be found to be subject matter eligible under the second step of the subject matter eligibility analysis.

Example 29. PhRMA encourages the USPTO to reconsider its subject matter eligibility analysis with respect to claim 2 of Example 29, which is directed to diagnosing and treating an autoimmune disease called julitis. In particular, the determination that claim 1 is subject matter eligible, but claim 2 is not eligible is illogical. Although claim 2 does not formally depend from claim 1, it contains the same elements as claim 1 and adds a further limitation. That is, claim 1 recites "a method of detecting JUL-1 in a patient . . . comprising . . . a. obtaining a plasma sample from a human patient; and b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody." Claim 2 recites a "method of diagnosing julitis in a patient" with the same steps as in claim 1 and an additional step of "diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample detected." Example 29 also explains that the applicant has discovered that the presence of JUL-1 in a person's body is indicative that the person has julitis. Pursuant to standard claim construction principles, under the circumstances described in the example, if claim 1 is found to be subject matter eligible, then claim 2, which recites the same steps plus an additional step, should also be found to be subject matter eligible. The recited preambles of "a method of detecting JUL-1 in a patient" of claim 1 and "a method of diagnosing julitis in a patient" in claim 2 are not so different that they should provide the basis for diverging subject matter eligibility results.

Examples such as this one, where one claim is patentable but another almost identical claim is not, re-enforces the arbitrary nature of the *Mayo* two-step test, as discussed further below. We believe revising the Examples as discussed above will provide needed clarity to the field while remaining consistent with existing law.

II. Topics from Roundtable 2: Exploring the Legal Contours of Patent Subject Matter Eligibility

A. Impact of Judicial Interpretation of Section 101: Scope of the Problem

In this section, we consider the impact of judicial interpretation of section 101. In Question 1 of the Roundtable 2 topics set forth the Federal Register Notice, the USPTO asked the public to comment on how the Supreme Court's interpretation of 35 U.S.C. § 101 in the past several years has affected the enforcement of patents and the development of subject-matter eligibility law. The biopharmaceutical ecosystem has been negatively impacted by the evolution of patent subject matter eligibility law in the United States. This section presents technical examples that provide a glimpse of current and developing § 101 jurisprudence that is potentially problematic for this industry, followed by a discussion that highlights some of the challenges with current § 101 jurisprudence from legal and policy perspectives.

Technical Examples: PhRMA highlights the following examples to show our concern about where the § 101 jurisprudence may be heading. This list is by no means exhaustive, but these examples illustrate some of the problems that the current § 101 jurisprudence is creating in the pharmaceutical industry.

- For many observers, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), provides a poignant example depicting how § 101 jurisprudence has led to the invalidation of a patent protecting worthy inventive activity. In that case, a patent to a method for detecting cell-free fetal DNA ("cffDNA") in maternal serum or plasma samples, was invalidated under § 101 because there was no inventive concept in Step #2 of the *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) analysis. The invention was a major advancement in prenatal diagnostics, providing a less invasive method to determine fetal characteristics that was less risky to the mother and to the pregnancy than what was previously available. Despite this, the court found that the claimed method was directed to a natural phenomenon (the cffDNA) and only applied well-understood, routine, conventional steps to detect the cffDNA, invalidating the claims as ineligible subject matter. *Ariosa*, 788 F.3d at 1376–78. The outcome of this case provides an extreme example of the breadth of the *Mayo* test. Even Judge Linn in his concurrence expressed concern and dissatisfaction with the outcome. Judge Linn agreed that "[i]t is hard to deny that Sequenom's invention is truly meritorious," and "[b]ut for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible." *Id.* at 1381. Judge Linn's comments echo our concern. Although the patented invention represented an important contribution to society, the current § 101 regime did not maintain patent protection for such an invention.

- In our second illustrative example, *Endo Pharmaceuticals Inc. v. Actavis Inc.*, No. 14-1381, 2015 WL 7253674 (D. Del. Nov. 17, 2015), the court adopted the Magistrate

Judge's Report and Recommendation to dismiss a patent infringement action for failure to state a claim because it found that the patent claims were directed to patent ineligible subject matter. The patent was directed to methods of treatment requiring providing a patient with a therapeutically effective amount of oxymorphone based on how patients with renal deficiencies process the drug. The Magistrate Judge, and subsequently the court, found that the patent failed the *Mayo* analysis because the claims were directed to a natural law (the bioavailability of oxymorphone in light of the patient's creatinine clearance rate) and then only applied the natural law with known, routine steps. *Endo*, 2015 WL 7253674, at *2. The Supreme Court in *Mayo* had distinguished "a typical patent on a new drug or a new way of using an existing drug" from the subject matter ineligible claim in *Mayo*, since "the patent claims [in such a typical patent] do not confine their reach to particular applications of those laws. *Mayo*, 132 S. Ct. at 1302. Yet the fact that the invention was a method of treatment seemed to have no bearing on the court's analysis. As with the *Ariosa* example, PhRMA is concerned that the current jurisprudence is not protecting important advances for patients and thus could stifle future innovation to produce new drugs and treatments. Moreover, this patent eligibility analysis was conducted prior to claim construction, a critical step by which a Court can properly discern the meaning and scope of a patent claim from the perspective of the person having ordinary skill in the art. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005). The Magistrate Judge and the court denied patent protection to an important biopharmaceutical invention without even construing the claims.

- In *Boehringer Ingelheim Pharmaceuticals, Inc. v. HEC Pharm Co.*, No. 15-cv-5982 (D.N.J. Dec. 7, 2016), the court dismissed an infringement case because it found patent claims relating to the use of DPP-IV inhibitors for treating and/or preventing metabolic diseases, particularly diabetes, to be directed to ineligible subject matter under the *Mayo* analysis. The court explained that "claim 1 of the '156 patent, which recites a single instruction of administering the DPP-IV inhibitor to the targeted patient population, is directed to an abstract idea" and the additional features in the claims were routine and conventional. *Boehringer*, No. 15-cv-5982, at 18, 21. This is a surprising decision since a claim directed to a method of administering a compound to a patient is not an abstract concept and is generally perceived as an appropriate claim form for claiming methods relating to pharmaceutically active compounds. Moreover, as above, the court made its determination on a motion to dismiss without undertaking a claim construction analysis. This is a concerning decision which, if upheld, could dampen innovation incentives.

- In the area of patent prosecution, PhRMA understands that patent examiners have been rejecting patent applications for vaccines under § 101. As suggested earlier in Part I of these comments, vaccines require human ingenuity and intervention to be designed and developed into functioning vaccines, and yet they are facing scrutiny under § 101 as being natural products. Vaccines are important pharmaceutical

contributions to society and should not be categorically challenged under § 101. While there is no explicit policy in the USPTO's guidance or jurisprudence that specifically excludes vaccines from patentable subject matter, it seems that vaccine claims have been receiving increased scrutiny under § 101. The availability of strong patent protection is important to continue to encourage investment into and innovation of novel and beneficial vaccines.

From a legal perspective, PhRMA perceives several problems with the current § 101 jurisprudence and its future direction. First, patent ineligibility findings under § 101 are occurring without claim construction analysis. As evidenced by the examples above, the § 101 analysis is being determined without first fully defining the claimed invention through proper claim construction. This is problematic because how the invention is characterized is critical to the subject matter eligibility determination, especially when analyzing what a claim is directed to. It is also unfair to the patentee to not at least require the court to construe the claims before making a validity determination based on subject matter eligibility.

Second, the current § 101 jurisprudence has evolved into an analysis that appears inconsistent with broader legal constructs. Given the elements of the current § 101 analysis, analytical aspects of other patent requirements (such as novelty under § 102 and obviousness under § 103) are being imported into the § 101 analysis. In particular, the second step of the *Mayo* analysis, which asks whether the claims add significantly more to the law of nature, natural phenomena, or abstract idea, now inappropriately incorporates elements of novelty and obviousness analyses because a court looks at whether the additional limitations are well-known or routine. These considerations should not be imported into an analysis under § 101. If the invention is only adding well-known or routine steps, then it will likely be found invalid under either § 102 or § 103. Thus, the current analytical framework for § 101 is overbroad because other statutory sections exist to address these patent validity issues. Further, deciding patent invalidity purely under § 101 leads to consideration of these validity issues without the prerequisite development of a proper factual basis for the analysis. The complex and involved aspects of novelty and obviousness are best left to a full analysis under their respective sections and should not be shortchanged by being brought into the § 101 determination.

Third, the *Mayo* two-step framework has been arbitrarily and inconsistently applied. The uncertainty of the framework makes it hard for a patentee to know which inventions are patentable or not. As such, the framework is not providing effective protection for inventions that we, as a society, should incentivize and protect. As illustrated in the examples above, important pharmaceutical innovations are being found patent ineligible as a result of the *Mayo* test. If such advancements cannot be protected under the patent system, this could dampen incentives to develop future drugs and treatments.

Finally, there is nothing in the statute to support the judicial exceptions to patentability (i.e., laws of nature, natural phenomena, and abstract ideas). These are purely judge-made exceptions that limit patent protection for the full breadth of the "Science and

useful Arts" contemplated by the United States Constitution. The current narrow jurisprudence on subject matter eligibility reflected in the *Mayo* analysis has become too restrictive on what is patentable in the biopharmaceutical area. Ultimately, all innovation in this area relates to laws of nature and natural phenomena in some way and the *Mayo* analysis sweeps too broadly and invalidates important contributions to society in this area that the patent system was designed to protect. As noted by the Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, "too broad an interpretation of [the] exclusionary principle [against patents on naturally occurring things] could eviscerate patent law." 133 S. Ct. 2107, 2116 (2013). All stakeholders in the patent system should be mindful of jurisprudential developments regarding § 101 to prevent this from occurring.

From a policy perspective, PhRMA is concerned that the current § 101 jurisprudence is not protecting and incentivizing future innovation in the biopharmaceutical area, to the detriment of both the industry and the public at large, which relies on the industry to develop life-saving medicines and treatments. Pharmaceutical products take years to develop and perfect. The pharmaceutical industry is investing in research now that may not be patentable in the future. This uncertainty may also have a profound impact on the long-term stability of the industry and the availability of lifesaving medicines in the future. If a company cannot count on the patent system to help protect its research and development, it is a disincentive to devote the necessary resources to create such medicines. This also leads to uncertainty for investors and inventors in the field, as neither knows which areas to invest their time and money in to secure patentable future inventions. Lack of investment and inventive human capital could slow innovation in areas of the biopharmaceutical sector.

Some commentators during the Roundtable 2 meeting mentioned that trade secret law may be an alternative to patent protection given the current challenges of securing patent protection for some subject matter. However, this not only is an unrealistic option for the biopharmaceutical sector, but also could have negative implications from a public health perspective. Patent laws provide an incentive to disclose inventive technology that is beneficial to the public, whereas trade secret protection relies on maintaining the secrecy of the technology. With modern reverse engineering and federally mandated disclosures, pharmaceutical inventions are most appropriately protected by patent law and are hard to protect under trade secret law. Thus, trade secret protection is an inadequate substitute for patent protection. To the extent that developments in the law lead to increased reliance on trade secret protection, the result will likely be less disclosure of technologies and less of an incentive for innovation of important biopharmaceutical technologies for patients. If the biopharmaceutical sector does end up relying on trade secrets, companies may not be as incentivized to create new biopharmaceutical products, but rather could pursue technological advancements that can more readily be protected by trade secrets.

Further, the current § 101 jurisprudence is causing the United States to fall behind its competitor countries in terms of the breadth of patent protection that is available for innovation in the biopharmaceutical area. By not providing patent protections consistent with the international landscape of patentable subject matter, the United States has placed

its companies at an economic disadvantage. This affects the competitiveness of the United States patent system in the global market. Given the long tradition of innovation in the United States, United States patent law must recognize the importance of being at the forefront of providing appropriate patent protection for meritorious inventions resulting from human ingenuity.

Moreover, if an invention is patentable under foreign law, but that same invention is ineligible in the United States, this creates a problem because a company cannot protect its inventions worldwide. In a global economy, worldwide protection is important to successfully commercialize a biopharmaceutical product. The challenge created by the Supreme Court jurisprudence on § 101 issues has made it harder for companies to consistently rely on the U.S. patent system to protect their inventions. This deficiency in the U.S. patent system puts the United States at an economic disadvantage by failing to stimulate future innovation and research and development activity in the United States.

B. It might take legislative action to change the course of § 101 jurisprudence.

Question 2 under Statutory Categories of Patentable Subject Matter of the Federal Register Notice asked whether the patent statute should be amended to further define the statutory categories of invention, i.e., process, machine, manufacture, and composition of matter; and if so, to identify possible legislative changes. PhRMA acknowledges that courts to date have been unable to shape § 101 jurisprudence in a way that promises patent protection for meritorious life sciences inventions, and that if this continues, it may take an act of Congress to correct the current state of § 101 jurisprudence.

To achieve the desired changes to the current law, potential legislative action could have the following goals: 1) Simplify and return § 101 to a true threshold question; 2) ensure that the patent requirements from other sections of the Patent Act (i.e., §§ 102, 103, 112, etc.) are not imported into the § 101 analysis; and 3) provide patent protection for life sciences inventions created through human intervention. These goals could help address the legal and policy problems discussed above and help improve the patent system to protect and incentivize future biopharmaceutical innovation. We remain hopeful that the courts can address some of the concerning elements of § 101 jurisprudence and we will continue to monitor and consider jurisprudential developments in this area.

C. Patentable Subject Matter in the Life Sciences should include scientific discoveries, products isolated from their natural surroundings, and diagnostic methods.

In this last section, we briefly address several questions from the section of the Notice titled “Patentable Subject Matter in the Life Sciences” and offer the following suggestions.

First, Question 8 asked to define the meaning of the term ''discovery'' in sections 100 and 101, and comment on the extent that a ''discovery'' should be eligible for a patent. Whether technological developments are described as inventions or discoveries should not drive the determination of what is patentable subject matter. If a technological development leads to a beneficial or valuable product, society should incentivize such development by at least including it under the umbrella of patent eligible subject matter. This premise flows from the United States Constitution, Article I, Section 8, Clause 8, which reads "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The concept of patenting discoveries goes back to the first Patent Act of 1790, which stated "any person or persons . . . [who] have invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used . . . if they shall deem the invention or discovery sufficiently useful and important" will be granted "the sole and exclusive right and liberty of making, constructing, using and vending to others to be used, the said invention or discovery." Patent Act of 1790, Ch. 7, 1 Stat. 109-112 (April 10, 1790). The discovery language has remained in the statute ever since. *See* Amicus Brief of Professors Jeffrey A. Lefstin and Peter S. Menell at 5-14, Sequenom, Inc. v. Ariosa Diagnostics, Inc., No. 15-1182 (Apr. 20, 2016).

Yet, under the current state of the law, it seems that the concept of "discovery" is being read out of the statute, even though it stems from the U.S. Constitution. Important scientific discoveries relating to natural products may no longer be patentable. The term "discovery" in § 101 provides a basis for patent eligibility, and the courts should be protecting such discoveries. For example, the discovery that taxol, which derives from the bark of the Pacific Yew tree, has anti-cancer properties should provide a basis for patent protection in the United States. Patent law needs to promote such research and reward such inventive activity with patent protection, as intended by the Constitution and reflected in the history of the Patent Act.

Next, we address Question 10, which asked to what extent should products that have been isolated from their natural surroundings as a result of human ingenuity be eligible for a patent. We submit that isolated natural products should not be categorically excluded from eligible subject matter. These types of inventions were previously accepted as patent eligible subject matter before the Supreme Court's more recent decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). *See e.g.*, *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282 (Fed. Cir. 2010); *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979);*In re Kratz*, 592 F.2d 1169 (C.C.P.A. 1979); *In re Bergstrom*, 427 F.2d 1394 (C.C.P.A. 1970); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911); Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). Earlier case law and examination guidance should be revisited as a basis for finding certain types of invention patent eligible, focusing more on the practical application of natural laws and products. *See e.g.*, *Diamond v. Diehr*, 450 U.S. 175 (1981) (finding that a process for curing rubber using the natural law of the Arrhenius equation was eligible subject matter because the process became a specific, practical application of the natural law). Discovering and isolating useful

products from their surroundings is an inventive activity that should be recognized by the patent system.

Lastly, Question 11 asks to what extent should a ''diagnostic method'' be eligible for a patent. We submit that diagnostic claims should not be categorically ineligible. There is no jurisprudence stating that diagnostic inventions are not patentable. They are process claims and thus fall under an explicit patentable subject matter category. Diagnostics are important innovations of future medical treatments that should be recognized as patent eligible subject matter.

Conclusion

PhRMA thanks the USPTO for reaching out to stakeholders regarding the current state of subject matter eligibility law. The USPTO's willingness to engage with stakeholders during this process will result in an improved patent system. We also appreciate the USPTO taking an active role in considering the § 101 jurisprudence and its impact on the U.S. patent system and innovation more generally. PhRMA welcomes further dialogue from the USPTO on subject matter eligibility issues.