TESTIMONY OF NATALIE DERZKO, COVINGTON & BURLING LLP

ON BEHALF OF

THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

BEFORE THE SENATE COMMITTEE ON THE JUDICIARY,

SUBCOMMITTEE ON INTELLECTUAL PROPERTY

I. Introduction

Chairman Tillis, Ranking Member Coons, and Members of the Subcommittee, thank you for inviting me to participate in today's hearing regarding the state of patent eligibility in the United States. Addressing issues of patent eligibility as they relate to innovations in medical diagnostics and nature-based products is important to fostering continued medical advances for patients. I appreciate the opportunity to explore this topic with you.

Today I am here on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which represents the country's leading innovative biopharmaceutical research companies. These companies are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.

PhRMA is committed to ensuring the continued health and competitive strength of a biomedical research and development ("R&D") ecosystem that fosters innovation, incentivizes competition, and benefits U.S. consumers. Strong and predictable intellectual property ("IP") protections are essential to the United States' economic well-being, and signal to other jurisdictions the critically important economic benefits of IP. The substantial investments related to biopharmaceutical R&D also fuel the U.S. economy. The IP-intensive biopharmaceutical industry supports a total of more than 4.7 million jobs across the U.S. economy and contributes $1.3 trillion in economic output when direct and indirect effects are considered.[1]

PhRMA appreciates the Subcommittee's leadership in exploring how best to reform patent subject matter eligibility to ensure that the patent system encourages and stimulates continued innovation, including medical innovation.

My testimony below covers a few topics. Part II explores the importance of providing patent protection to foster continued medical innovation. Part III discusses the purpose and function of Section 101 of the Patent Act. Part IV considers the uncertainties created by judicial

[1] TEConomy Partners, *The Economic Impact of the US Biopharmaceutical Industry: 2015 National and State Estimates*, at 7–8 (Oct. 2017).

elaboration on Section 101. Lastly, Part V provides comments on the proposed legislative amendment.

II. The Importance of Providing Patent Protection to Foster Continued Medical Innovation

The discovery and development of new drug therapies and diagnostic tools are crucial to public health. Advancements in science and technology are changing the way we define disease, develop drugs, and prescribe treatments. The protections afforded by the federal patent laws are central to providing appropriate incentives to innovation needed to overcome the staggering costs and risks of developing new products and therapies.

Armed with a greater understanding of disease biology, it has become evident that a patient's response to treatment—with respect to both safety and efficacy—is greatly dependent upon his or her unique molecular profile. 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. Personalized medicines allow the tailoring of medical treatments to the individual characteristics of patients. This tailoring allows physicians to target specific treatments to patient subpopulations who will benefit, sparing expense and side effects for broader patient populations who would not benefit.[2] In 2015, more than 25 percent of new drug approvals were for personalized medicines, with 35 percent of 2015 cancer approvals alone being for personalized medicines.[3]

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 the patients most likely to benefit, personalized medicines serve as an important tool to reduce the use of unnecessary and often costly treatments or procedures. These personalized medicines guide health care decisions toward "the most effective treatment for a given patient and, thus, improve care quality while reducing the need for unnecessary diagnostic testing and therapies."[4]

The benefits of personalized medicines include:[5]

---

[2] *See* National Research Council, *Toward Precision Medicine: Building a Knowledge Network For Biomedical Research and a Wew Taxonomy of Disease*, at 12 (Nat. Acads. Press 2011).

[3] *See* Personalized Medicine Coalition, *2015 Progress Report: Personalized Medicine at FDA*, at 1, http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/2015_Progress_Report_PM_at_FDA1.pdf.

[4] Geoffrey S. Ginsburg & Kathryn A. Phillips, *Precision Medicine: From Science to Value*, Health Affairs 694, 694–701 (May 2018).

[5] *See* Francis S. Collins, "The Future of Personalized Medicine," 5 *NIH Medline Plus: The Magazine* 2, 2–3 (Winter 2010).

- Improving the ability to detect and prevent disease, allowing for earlier determination of whether treatment is needed and preventing use of unneeded treatments;

- Identifying more quickly the most optimal therapy for a patient;

- Helping to avoid adverse drug reactions and reducing side effects;

- Improving quality of life and improving treatment options for patients; and

- Providing improved methods of administration.

The development of personalized medicines also results in improved efficiency in the health care system, by avoiding unneeded treatments, ensuring patients get the right treatment, and preventing disease and side effects. Personalized medicine also has the potential to help contain long-term health care spending in various ways, as shown in the following examples:

- A study[6] of patients with metastatic cancer of diverse subtypes, where half received genomic testing and targeted therapy (precision medicine) and half received standard chemotherapy or best supportive care, found that those patients receiving the personalized medicine had progression-free survival rates of almost twice that of those receiving standard therapy. The average progression-free survival was 22.9 weeks for patients receiving precision medicine and 12 weeks for patients in the control group. Patients in the precision treatment group were charged $4,665 per week, while patients in the control group were charged $5,000 per week. This study indicates that personalized cancer medicine may improve survival for patients with refractory cancer without increasing health care costs.

- In 2002, a mutation in the BRAF gene was identified and found to be present in about 50 percent of all melanomas. This gene mutation leads to the overproduction and spread of cancer cells. This discovery led to the development and FDA approval of three new targeted drugs that are improving the overall survival rate for patients, when compared to treatment with chemotherapy. Three new immunotherapies are also changing the treatment landscape by targeting proteins that prevent the immune system from attacking cancer cells.[7]

---

[6] *See* Derrick S. Haslem et al., *A Retrospective Analysis of Precision Medicine Outcomes in Patients with Advanced Cancer Reveals Improved Progression-Free Survival Without Increased Health Care Costs*, 13 J. Oncology Prac. e018 (Feb. 2017), https://www.ncbi.nlm.nih.gov/pubmed/27601506.

[7] *See* American Cancer Society, *Targeted Therapy for Melanoma Skin Cancer*, at 1 (Mar. 2015), http://www.cancer.org/cancer/melanoma-skin-cancer/treating-targeted.html.

- Five-year survival rates for patients with metastatic colon cancer have improved in recent years, in large part due to medical innovations in gene testing that have directed the development of new targeted medicines that improve patient survival. Scientists have identified the molecular receptor on colorectal cancer cells that causes them to multiply (epidermal growth factor receptor, or EGFR). New medicines that specifically target these receptors are improving survival outcomes. Continued research revealed that the presence of a specific mutation in a particular gene (KRAS) is associated with resistance to cetuximab, an EGFR inhibitor. Testing for the KRAS gene allows for better targeting of EGFR-targeted therapy and leads to improved patient survival.[8]

- Biomarkers can be used to guide treatment decisions for cancer patients, leading to better health care outcomes and cheaper treatments for patients. For example, the use of biomarkers to inform prostate cancer treatment resulted in substantial cost savings.[9] The use of biomarkers to improve the accuracy of bronchoscopy for lung cancer diagnosis reduced the need for invasive procedures by 28 percent at 1 month and 18 percent at 2 years.[10]

Like innovators across the spectrum of American industries, biopharmaceutical companies rely on a legal regime that provides clear, strong, and predictable protection for intellectual property when making the substantial R&D investments that yield new and improved medicines. Companies developing diagnostics and medical devices, just like innovators in other biomedical fields, rely on patents to protect their inventions and to provide an opportunity to recover their R&D costs and fund new research. Patents foster continued R&D investments across the R&D ecosystem and are particularly important given the substantial regulatory requirements that must be met for the development of new treatments.

While there have been substantial investments in diagnostics and other areas in recent years, the evolution of patent subject matter eligibility law in the United States has likely had a chilling effect on critical areas of research needed to address some of our most costly and challenging diseases. PhRMA has previously expressed concerns that the current jurisprudence is not protecting important advances for patients, and thus could stifle the future innovation required to produce new treatments for patients. The uncertainty of the current framework, as interpreted by the courts, makes it hard for an inventor to know which inventions will be patentable or not.

---

[8] *See* National Cancer Institute, *Surveillance, Epidemiology, and End Results (SEER) Program: SEER Cancer Statistics Review (CSR) 1975-2016*(Apr. 15, 2019), http://seer.cancer.gov/csr/1975_2016/; National Cancer Institute SEER Program, *SEER Stat Fact Sheets: Colon Stat Facts: Colorectal Cancer*, http://seer.cancer.gov/statfacts/html/colorect.html (both pages accessed June 1, 2019).

[9] *See* Jennifer M. Lobo et al., *Cost-Effectiveness of the Decipher Genomic Classifier to Guide Individualized Decisions for Early Radiation Therapy After Prostatectomy for Prostate Cancer*, 15 Clinical Genitouriney Cancer e299–309 (June 2017).

[10] *See* David Feller-Kopman et al., *Cost-Effectiveness of a Bronchial Genomic Classifier for the Diagnostic Evaluation of Lung Cancer*, 12 J. of Thoracic Oncology 1223, 1223–32 (2017).

As such, the current framework is not providing effective protection for inventions that we, as a society, should incentivize and protect. If such advancements cannot be protected under the patent system, this could dampen incentives to develop future drugs and treatments.

PhRMA is concerned that the current Section 101 jurisprudence is not protecting and incentivizing future life-saving medical innovation, to the detriment of both the industry and the public-at-large. As just one example, taxol, a compound derived from the bark of the Pacific Yew tree, has anti-cancer properties. The discovery and development of taxol's utility in cancer treatment should provide a basis for patent protection in the United States. The importance of natural product-based therapies such as taxol has been well documented. Researchers have found that natural products can play an important role in developing new treatments for human diseases.[11]

Patent law needs to promote research and to reward inventive activity that meets the statutory standards with patent protection, as intended by the Constitution and reflected in the history of the Patent Act. Under the current state of the law, it seems that the concept of "discovery" is effectively being read out of the statute, even though it stems directly from the Patent Clause of the U.S. Constitution. Important scientific discoveries relating to natural products and diagnostics may no longer be patentable under the current jurisprudence. The term "discovers" in Section 101 provides a basis for patent eligibility, and the courts should protect such discoveries.

The biopharmaceutical industry and other industries are investing in research today that may not be patentable in the future. This uncertainty may also have a profound impact on the long-term stability of the life sciences enterprise in the U.S. and the availability of lifesaving medicines in the future. If a company cannot rely upon the patent system to help protect its R&D, it is disincentivized to invest. Inventors and investors are also discouraged from investing time and money in the field, as neither knows which areas can or will result in patentable future inventions. Lack of investment and inventive human capital could slow the pace of medical advances in medical diagnostics and other areas.

III. The Purpose and Function of Section 101

The legal and policy debates surrounding Section 101 concern what kind of subject matter is eligible for patent protection in the United States. If an invention qualifies as patent-eligible subject matter, it may be patented—so long as it meets certain other requirements found in the Patent Act. These include requirements that the invention be new, useful, nonobvious, and sufficiently described.

As noted recently by the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("USPTO") Andrei Iancu, "the progress we have made in the past 200 years is absolutely unparalleled in human history and most of that

[11] *See, e.g.*, David J. Newman & Gordon M. Cragg, Natural Products as Sources of New Drugs over the 30 Years from 1981 to 2010, 75 *J. Nat. Prods.* 311, 330 (2012).

has been backed by patents."[12] That progress is due to recognition by the Framers of our Constitution of the importance of robust IP protections, empowering Congress in Article 1, Section 8 of the Constitution "[t]o 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."

Section 101 states that patent protection is available for any invention or discovery of a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." Congress wrote Section 101 with intentional breadth. The wide scope of patentable subject matter, as reflected first in the 1793 Patent Act and extending through each subsequent re-codification, reflects Thomas Jefferson's view that "ingenuity should receive a liberal encouragement."[13]

The scope of Section 101 is intended to be broad and to encompass a wide range of inventions, operating as a coarse filter that broadly permits patenting of useful subject matter within the statutory categories it enumerates and serving a threshold gatekeeping function separate from the patentability conditions of Sections 102, 103, and 112.[14] Section 101 is also intended to operate with flexibility, allowing the patent system to meet "the revelations of . . . onrushing technology."[15] As the Supreme Court has explained, "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[16]

Over time, though, the Supreme Court has added judicial exceptions to these statutory categories. Pursuant to the Supreme Court's patent subject matter eligibility jurisprudence, inventions are not eligible for patenting if they claim natural phenomena, laws of nature, or abstract ideas.[17] These exceptions are not found in the statute, and were introduced by the Supreme Court

---

[12] Andrei Iancu, Director of the USPTO, "The State of Care: Innovation and Access" (July 2018).

[13] *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980) (quoting 5 Writings of Thomas Jefferson 75-76 (H. Washington ed. 1871)); *see also Diamond v. Diehr*, 450 U.S. 175, 182 (1981); PTO, Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, 75 Fed. Reg. 43,922, 43,926 (July 27, 2010) (describing § 101 as "coarse filter").

[14] *See, e.g.*, *Chakrabarty*, 447 U.S at 308-09; 75 Fed. Reg. at 43,926.

[15] *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972).

[16] *Chakrabarty*, 447 U.S. at 309 (quoting S. Rep. No. 1979, 82nd Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82nd Cong., 2d Sess., 6 (1952)).

[17] *See, e.g.*, *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) ("'A patent will be good, though the subject of the patent consists in the discovery of a great, general, and most comprehensive principle in science or law of nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained.'") (quoting *Household Co. v. Neilson*, Webster's Pat. Cases, 683 (1843)); *Le Roy*, 55 U.S. at 175 ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."); *Corning v. Burden*, 256 U.S. 252, 268 (1853) ("[I]t is well settled that a man cannot have a patent for the function or

to prevent patent holders from monopolizing the basic building blocks of innovation.[18] For example, these exceptions would prevent someone from patenting the formula "$E=mc^2$." These exceptions, however, were intended to be applied "narrowly."[19] In particular, for inventions related to the pharmaceutical and life science industries, the Supreme Court has explained that the "relevant distinction" is "between products of nature . . . and human-made invention."[20] Put another way, if human ingenuity is applied to create a process involving natural laws or objects, that invention should be patentable under Section 101.[21]

Because the Patent Act is technology-neutral, the patent eligibility issue does not exclusively affect the biopharmaceutical sector—it is an important issue across R&D-intensive industries. Clear and certain rules for patent eligibility will help ensure that the United States retains its role as a global leader in innovation, and will help keep key industries and jobs in the United States.

IV. Uncertainties Created by Judicial Elaboration on Section 101

In recent years, the Supreme Court and Federal Circuit have addressed the application of these judicial exceptions to Section 101 on numerous occasions. As described below, these decisions have created significant uncertainties in the patent landscape, particularly for diagnostic patents.

In 2012, the Supreme Court decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[22] finding that a method claim directed to a diagnostic assay for determining the proper dose of a drug based on a patient's metabolite levels was drawn to a law of nature and therefore invalid under Section 101.[23] The Court concluded that the claimed method—which indicated a correlation between certain metabolite levels in the blood and the need to increase or decrease dosage—amounted to nothing significantly more than detecting a law of nature and engaging in well-understood, routine, conventional activity. As the Supreme Court explained in *Mayo*, though, the claims there were unpatentable because "the steps add nothing of significance to the natural laws themselves. Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws."[24] Additionally, in *Mayo* the Court set forth a "framework," confirmed in *Alice Corporation*

---

abstract effect of a machine, but only for the machine which produces it."); *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498, 507 (1874) ("An idea of itself is not patentable.").

[18] *See Gottschalk*, 409 U.S. at 67 (explaining that the judicial exceptions "are the basic tools of scientific and technological work").

[19] *Bilski v. Kappos*, 561 U.S. 593, 609 (2010).

[20] *Chakrabarty*, 447 U.S. at 313.

[21] *See, e.g.*, *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939).

[22] 566 U.S. 66 (2012).

[23] *See id.* at 92.

[24] *Id.* at 87.

Pty. Ltd. v. CLS Bank International[25] (discussed below), as the governing "framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts."[26]

The Supreme Court's 2013 decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*[27] held that, because an isolated DNA sequence is naturally occurring, it is not patent eligible, whereas a cDNA sequence reverse-transcribed from mRNA is not naturally occurring and thus is patent eligible.[28] The Court in *Myriad* explained that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."[29] Numerous decisions have used this statement to justify invalidation of a patent covering a seemingly novel discovery under Section 101.

The Supreme Court's 2014 decision in *Alice* relied on the framework set forth in *Mayo* to invalidate patents directed to mitigating settlement risk in financial transactions by using a computer system as a third-party intermediary.[30] The Supreme Court's framework for determining whether claims are directed to a patent-ineligible concept under Section 101 includes two steps. Citing *Mayo*, the *Alice* Court described the framework as first "determin[ing] whether the claims at issue are directed to one of those patent-ineligible concepts," i.e., laws of nature, natural phenomena, and abstract ideas.[31] If so, then the *Alice* framework's second step further requires "an 'inventive concept'—i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.'"[32] Applying this framework, the Court concluded that the claimed business method for using a third-party intermediary to mitigate settlement risk was ineligible because it amounted to nothing significantly more than the abstract idea of "intermediated settlement," performed on a generic computer.

Application of these principles by courts has been unpredictable, in large part due to overbroad and inconsistent application of the judicial exceptions by district courts and the Federal Circuit. Many Section 101 cases tend to hold patents ineligible on the theory that the patent claims do little more than describe a judicial exception and append a simple instruction to "apply it" with well-known, routine, and conventional techniques or generic computer implementation. Courts'

---

[25] 573 U.S. 208 (2014).

[26] *Alice*, 573 U.S. at 217.

[27] 569 U.S. 576 (2013).

[28] *See id.* at 596.

[29] *Id.* at 591.

[30] *Alice* is distinct from *Mayo* and *Myriad* in that it pertains to the "abstract ideas" portion of Section 101's implicit exception for "'[l]aws of nature, natural phenomena, and abstract ideas.'" *Alice*, 573 U.S. at 216 (quoting *Myriad*, 569 U.S. at 589).

[31] *Id.* at 217.

[32] *Id.* at 217–18 (quoting *Mayo*, 566 U.S. at 73).

application of this framework has created uncertainty about what can be patented, denying patent protection to many worthy and deserving inventions.

This legal patchwork has impacted the development of personalized medicines, where diagnostic technology can be important. Notably, the Supreme Court has never said that diagnostic claims are *per se* patent ineligible. Yet, since *Mayo*, the Federal Circuit has repeatedly found diagnostic claims to be ineligible, thereby putting into question the scope of patent protection available to meritorious diagnostic inventions.[33] *Mayo* made clear, though, that where additional limitations in a claim reflect novel features, these features "provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."[34]

The Federal Circuit has confirmed the eligibility of method of treatment claims that utilize a law of nature or natural phenomenon, most recently in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*[35] and *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*[36] The claims in *Vanda* describe a method for treating schizophrenia by basing the dosage on the patient's genotype, and the claims in *Endo* describe a method for using a painkiller to treat pain in patients with impaired kidney function. The inventions described by the patents in these cases represent novel, practical methods for treating disease, through a patent-eligible application of a natural law relevant to the disease at issue, and are precisely the types of inventions that should be patent eligible under Section 101.

Further, the logic of *Mayo* and *Myriad* has led courts to continue to draw distinctions indicating that diagnostic patents should be ineligible for patent protection under the current state of the case law. The Federal Circuit has explicitly distinguished between the patent eligibility of method of treatment claims and diagnostic claims in recent cases. For example, in *Vanda*, the court justified its conclusion that Vanda's asserted claims for a method of treating patients with schizophrenia by basing the dosage on the patient's genotype were patent eligible in part by concluding: "the claims in *Mayo* were not directed to a novel method of treating a disease. Instead, the claims were directed to a diagnostic method . . . ."[37] Similarly, in *Endo*, the court held that a method of treatment claim for treating patients with impaired kidney function was eligible as not directed to a law of nature, because "the claims here are directed to a *treatment* method, not a detection method."[38]

---

[33] *See, e.g., In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 763 (Fed. Cir. 2014); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017); *Roche Molecule Sys., Inc. v. CEPHEID*, 905 F.3d 1363 (Fed. Cir. 2018).

[34] *Mayo*, 566 U.S. at 77.

[35] 887 F.3d 1117 (Fed. Cir. 2018)

[36] 919 F.3d 1347 (Fed. Cir. 2019).

[37] *Vanda*, 887 F.3d at 1134. Even in light of this conclusion, however, the Supreme Court has requested the government's views on a certiorari petition challenging the eligibility of these method of treatment claims under Section 101.

[38] *Endo*, 919 F.3d at 1356 (emphasis in original).

Two recent examples from the Federal Circuit highlight many of the issues courts are facing in determining the eligibility of diagnostic patents under the framework outlined in *Mayo* and *Alice*. For example, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,[39] the Federal Circuit concluded that a patent covering a diagnostic method for determining fetal characteristics by analyzing cell-free fetal DNA in maternal blood samples was ineligible.[40] This method covered a major advancement in prenatal diagnostics, providing physicians with a less invasive, less risky method for determining fetal characteristics. Writing separately, Judge Linn explained that, in light of the fact that "*no one* was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers," and in fact that "the maternal plasma used to be routinely discarded," he found it "hard to deny that [the] invention is truly meritorious."[41] Judge Linn concluded that, "[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."[42]

Recently, in *Athena Diagnostics, Inc. v. Mayo Collaborative Services LLC*,[43] in a split decision, the Federal Circuit concluded that claims for a method for diagnosing myasthenia gravis were patent ineligible because the claimed method—which involved detecting the presence of antibodies to a particular protein—was directed to a natural law and added nothing but conventional techniques. In this case, the inventors created new man-made reagents for use in detecting a naturally occurring antibody to diagnose a subset of myasthenia gravis patients that could not have been detected using previous diagnostic methods. In finding these claims ineligible, the majority recognized that "the public interest is poorly served by adding disincentive[s] to the development of new diagnostic methods," and that "providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts."[44] The majority concluded, however, that:

> [W]hether or not we as individual judges might agree or not that these claims only recite a natural law . . . the Supreme Court has effectively told us in *Mayo* that correlations between the presence of a biological material and a disease are laws of nature . . . and [p]urely conventional or obvious [pre]-solution activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.[45]

These cases, along with other cases that apply the framework the Supreme Court laid out in *Mayo* and *Alice*, highlight several additional problems with the current state of Section 101 jurisprudence that create inconsistency and unpredictability for patents in the life science and

---

[39] 788 F.3d 1371 (Fed. Cir. 2015).

[40] *See id.* at 1378.

[41] *Id.* at 1381 (emphasis in original).

[42] *Id.*

[43] 915 F.3d 743 (Fed. Cir. 2019).

[44] *Id.* at 753 n.4.

[45] *Id.* (internal quotations and citations omitted).

biotechnology spaces. First, these cases highlight that courts oftentimes simplify the analysis dictated under step 1 of *Mayo*. Instead of analyzing whether the claim provides a technical improvement over the solutions found in the prior art, or whether the claim improves the operation of previously-used methods, courts oftentimes perform the step 1 analysis by merely comparing the claims to those in *Mayo* and *Myriad*, without asking whether the claim makes a technological improvement to the way a diagnostic or laboratory technique was performed, prior to the invention. In *Athena*, for example, the panel did not determine whether the asserted claims recite a technological improvement over prior methods of diagnosing myasthenia gravis, through use of a man-made reagent.

Second, relevant to these examples, courts have confused and conflated the judicial exceptions for laws of nature versus natural phenomena. For example, the Federal Circuit concluded that the diagnostic method at issue in *Ariosa* was directed to a natural phenomenon, while the court found that the diagnostic method in *Athena* was directed to a law of nature. This fact highlights that courts still struggle with application of the judicially-created exceptions to life science and biotechnology patents.

Third, courts have struggled with conflating the principles of patent eligibility under Section 101, with the principles codified in Sections 102, 103, and 112 of the Patent Act. The current statute's language in Section 101 requiring that an invention be "new and useful" does not require a novelty or obviousness analysis; in fact, the Supreme Court has explained in *Diamond v. Diehr*[46] that the question "of whether a particular invention is novel is wholly apart from whether the invention falls into a category of statutory subject matter."[47] The "new and useful" language in the statute is intended to be only "a general statement of the type of subject matter that is eligible for patent protection 'subject to the conditions and requirements of this title.'"[48] Nor should the inquiry into whether an invention is directed to a judicial exception be used as a way to invalidate overbroad claims, which are properly examined under the principles of Section 112.

Other types of life science patents on medical innovations, such as vaccines and antibiotics, may also face challenges based on the uncertain landscape of Section 101 jurisprudence. Vaccines and antibiotics reflect innovative uses of natural substances. Inventions of this type are not simply products of nature and are not comparable to the claims in *Mayo* that were found unpatentable by the Supreme Court because the claimed steps added nothing to what is found in nature. Antibiotics and vaccines are human-made compositions requiring human ingenuity and intervention to be designed and developed into functional treatments, and thus should be eligible for patenting. The availability of strong patent protection is important for continuing to encourage investment into, and innovation of, novel and beneficial vaccines and antibiotics. Vaccines and antibiotics should not be categorically challenged under Section 101.

[46] 450 U.S. at 175.

[47] *Id.* at 190 (internal quotation and citation omitted).

[48] *Id.* at 189 (quoting § 101).

In January 2019, the USPTO issued the 2019 Revised Patent Subject Matter Eligibility Guidance ("2019 Guidance").[49] The 2019 Guidance provides helpful direction to USPTO personnel on several issues related to patent subject matter eligibility, including considerations for identifying claims not "directed to" a judicial exception. Specifically, the 2019 Guidance clarified the Patent Office's perspective that a claim is not "directed to" a judicial exception if it is "integrated into a practical application of the exception."[50] For example, according to the 2019 Guidance, "an additional element that applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition" signals integration into a practical application.[51] The 2019 Guidance, however, does not discuss how additional elements might be included in a diagnostic method claim to signal integration of a judicial exception into a practical application for such claims and thus patent subject matter eligibility. The 2019 Guidance also does not solve the problems created by courts' inconsistent applications of the judicial exceptions. Further, because the USPTO is constrained by Supreme Court and Federal Circuit case law, the positive aspects of this 2019 Guidance—for example, its emphasis that examiners should evaluate whether the claim "as a whole" integrates the judicial exception into a practical application[52]—can only do so much to improve the uncertainty caused by the Supreme Court's jurisprudence. Further, the courts are not bound to follow the 2019 Guidance and a more robust fix will have to come from Congress.

The current jurisprudence on subject matter eligibility reflected in the *Mayo* analysis has become overly restrictive on what is patentable in the biopharmaceutical area. Ultimately, nearly all innovation in biopharmaceuticals can be said to relate to laws of nature and natural phenomena in some way. Courts have struggled with consistent and predictable application of the *Mayo*/*Alice* test in the life science space, which has made it difficult to reliably predict which subject matter will be found patent eligible. As cautioned by the Supreme Court in *Myriad*, "too broad an interpretation of [the] exclusionary principle [against patents on naturally occurring things] could eviscerate patent law."[53] Additionally, the Patent Office has explained that "[t]he legal uncertainty surrounding Section 101 poses unique challenges for the USPTO, which must ensure that its more than 8500 patent examiners and administrative patent judges apply the *Alice*/*Mayo* test in a manner that produces reasonably consistent and predictable results across applications, art units and technology fields."[54] All stakeholders in the patent system should be mindful of jurisprudential developments regarding Section 101 to prevent this evisceration from occurring. These issues have been particularly challenging for predicting the eligibility of diagnostic patents. As explained

[49] 84 Fed. Reg. 50 (Jan. 7, 2019) [hereinafter "2019 Guidance"]; *see generally* PhRMA, Comments on the USPTO's 2019 Revised Patent Subject Matter Eligibility Guidance (Mar. 8, 2019), https://www.uspto.gov/sites/default/files/documents/eligibility2019 comments_c_phrma_2019mar08.pdf.

[50] 2019 Guidance at 50.

[51] 2019 Guidance at 55 (citing *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066–68 (Fed. Cir. 2011).

[52] 2019 Guidance at 54.

[53] 569 U.S. at 590.

[54] 2019 Guidance at 50.

below, the proposed legislation is a promising avenue for course-correcting patent subject matter eligibility in the United States.

V. Comments on the Proposed Legislation

PhRMA appreciates the Committee's efforts to reform Section 101 and believes that reform of Section 101 is appropriate at this time. We appreciate this opportunity for dialogue and engagement on this issue, as well as the Committee's recognition that a potential solution should apply across the technology spectrum. As described below, PhRMA believes the proposed legislation offers numerous promising concepts for further discussion.

A. The Proposal Maintains the Current Statutory Categories

As discussed, courts have skewed the Section 101 inquiry by broadly applying judicially-created exceptions. In doing so, they have introduced uncertainty into the patent system and the life sciences R&D environment in terms of diagnostics, personalized medicines, and other innovations that represent advances in diagnosis, prevention, and treatment for patients. The proposed legislation seeks to address these uncertainties by maintaining the current statutory categories of eligible subject matter and ensuring that courts will not confuse the statutory analysis as they have in the past. PhRMA believes the proposed legislation on subject matter eligibility would ensure that inventive activities are more appropriately recognized by the patent system.

Given the numerous risks associated with research and development, innovators must be able to rely on stable and consistent application of patent laws. Adopting the proposed changes regarding subject matter eligibility would increase predictability in the patent system, incentivizing innovation and enabling greater investment in critical life-saving inventions. The proposed legislation would return Section 101 to its proper function: operating as a coarse filter that identifies eligible categories of subject matter: processes, machines, manufactures, or compositions of matter, or useful improvements thereof. This broad categorical approach also provides sufficient flexibility for adapting to future technological advances.

Returning Section 101 to its threshold gatekeeping function addresses the unpredictability that the "judicial exceptions" injected into the patent system. Rather than relying on courts to weed out ineligible claims by applying amorphous judicial exceptions—and dulling innovation incentives in the process—the proposal allows other parts of the Patent Act to serve their prescribed purposes. Well-understood, routine, and conventional claims are dealt with under Sections 102 and 103, and issues of overbroad claiming under Section 112.

B. The Proposal Guards Against Future Judicial Intervention

In view of its history of judicial interventions, it is necessary to ensure that Section 101 continues to function as a coarse filter for the enumerated categories of subject matter rather than devolving again into a hazy line-drawing exercise that conflates the threshold question of eligibility with the patentability conditions of other sections. Several aspects of the proposal address this concern.

1. The Proposal Prevents Application of Judicial Exceptions and Avoids Enumerating a List of Statutory Exceptions

First, the proposal explicitly mandates that no implicit or judicial exceptions be used to assess eligibility under Section 101, and abrogates cases establishing or interpreting those exceptions. This language guards Section 101 against renewed judicial intervention. Courts would not be free to rely on the prior judicial exceptions—natural phenomena, law of nature, and abstract idea. Nor would they be free to create new judicial exceptions.

PhRMA supports the drafters' decision to not enumerate statutory exceptions to patentability. Avoiding a list of statutory exceptions protects Section 101's threshold gatekeeping function and helps keep the pathway of patent protection open for meritorious inventions, subject to meeting the other patentability requirements.

2. The Proposal Prevents Conflating Section 101 with Sections 102, 103, and 112

Second, the proposal clearly distinguishes the Section 101 eligibility inquiry from the patentability conditions of Sections 102, 103, and 112. PhRMA supports the proposal's language noting various terms courts have used to conflate these inquiries, requiring that eligibility determinations be made without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional, or routine; the state of the art at the time of the invention; or any other considerations relating to Sections 102, 103, or 112.

Issues of novelty, nonobviousness, and sufficient disclosure do not bear on whether a claimed invention falls within the enumerated categories of eligible subject matter. Rather, they are properly analyzed under the clearer standards governing Section 102, 103, and 112. For example, as the Supreme Court explained in *Diamond v. Diehr*, the question "of whether a particular invention is novel is wholly apart from whether the invention falls into a category of statutory subject matter."[55] That is because the "new and useful" language in Section 101 is by its own terms only "a general statement of the type of subject matter that is eligible for patent protection 'subject to the conditions and requirements of this title.'"[56] Highly "[s]pecific conditions for patentability follow" in the subsequent provisions, and Congress plainly intended those to control any determination of whether the invention is new or useful.[57] Many years later, the Supreme Court's *Mayo* decision ignored these important distinctions. PhRMA therefore supports the choice to remove the word "new" from the current statutory language of Section 101. This feature of the proposal further ensures that courts will not conflate the threshold eligibility inquiry with the novelty requirement of Section 102 in an attempt to reinvigorate the "inventive concept" step of the *Mayo*/*Alice* test.

---

[55] *Diehr*, 450 U.S. at 190 (emphasis added; internal quotation and citation omitted).

[56] *Id.* at 189 (quoting § 101).

[57] *Id.*; *see also id.* at 191, 193 n.15.

3. The Proposal Requires Analyzing Claims As a Whole

Third, the proposal safeguards the threshold gatekeeping function of Section 101 by requiring that claimed inventions be considered "as a whole, without discounting or disregarding any claim limitation." That requirement prevents courts from conducting an implicit novelty inquiry by sectioning claims into old and new elements, or ignoring individual elements deemed well-understood, routine, or conventional.

C. The Proposal's "Useful" Definition Codifies the Current Utility Standard

PhRMA also supports the proposal's definition of "useful." The utility requirement of Section 101 has long served a gatekeeping function—it is a threshold issue. Under the well-established utility standard as it exists today in case law, subject matter is useful when it provides a specific and substantial utility.[58] PhRMA understands the proposal's definition of "useful" using the terms "specific and practical utility" to codify that long-standing standard. Indeed, "[c]ourts have used the label[] 'practical utility' . . . in determining whether an invention offers a 'substantial'" utility."[59] This is "a shorthand way of attributing 'real-world' value to claimed subject matter"—i.e., that "'one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.'"[60] That definition has been an important and consistent standard in the U.S. patent system, and PhRMA supports maintaining it.

D. PhRMA Supports the Proposal's Technology Neutrality

The proposal's definition of "useful" also includes the concept of being neutral across fields of technology. PhRMA does not believe that inclusion of "in any field of technology" represents a change from the U.S. patent system's long-established policy of technological

---

[58] *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966) ("The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with *substantial utility*. Unless and until a process is refined and developed to this point—where *specific benefit exists in currently available form*—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.") (emphasis added); *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) ("Following *Brenner*, our predecessor court . . . and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101") (citing *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563 (Fed. Cir. 1996) ("Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed.")); *see generally*, MPEP 2107.

[59] *In re Fisher*, 421 F.3d at 1371.

[60] *Id.* (citing *Nelson*, 626 F.2d at 856) (emphasis omitted). The *Fisher* court went on to explain: "It thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." *Id.*

neutrality, which is also a requirement for compliance with the TRIPS agreement.[61] It is important to the pharmaceutical industry that Congress maintain a technology-neutral framework for patent eligibility, as differing standards in other fields would have impacts in the biopharmaceutical industry—for example, in areas that involve collaboration across disciplines or convergence of diverse technologies.

E. PhRMA Supports the Proposal's "Human Intervention" Component

The proposal also adds a human intervention component to the definition of "useful." These changes appear intended to address concerns about an overbroad definition of eligible subject matter. The "human intervention" approach to addressing those concerns is far superior to the "judicial exceptions" approach. It does not require drawing lines based on amorphous concepts like "natural phenomenon" and "law of nature"—concepts that could be found in any claimed invention.[62] Instead, the human intervention requirement would operate as a high-level filter to exclude only clearly ineligible claims—for example, claims that solely recite an unmodified, naturally-occurring substance as it exists independently in nature. Claims that involve human intervention, on the other hand, would satisfy the utility requirement so long as they have specific and practical utility, and would be patent eligible if they also fall into one of the enumerated categories of eligible subject matter. Those claims would be analyzed subsequently under Sections 102, 103, and 112.

The human intervention standard also accords with statements in some of the Supreme Court's pre-*Mayo* cases. As the Supreme Court indicated in *Chakrabarty*, the "relevant distinction" is "between products of nature . . . and human-made invention."[63] Thus, it is not possible to patent "the heat of the sun, electricity, or the qualities of metals,"[64] or the "law that $E=mc^2$" or the "law of gravity," or "a new mineral discovered in the earth or a new plant found in the wild."[65] But when human ingenuity is applied to create a process that involves these natural laws or objects, Section 101 is satisfied.[66]

F. Claims to Diagnostic Methods Which Involve Human Intervention and Have a Specific, Practical Utility Would Be Eligible under the Proposal

Diagnostic methods are one area of particular importance to providing continued medical advances to patients and incentivizing additional competition in various areas of biomedical innovation, and one which the line of cases following the Supreme Court's *Mayo* decision has particularly affected—as seen, for example, in the *Ariosa* and *Athena* cases. PhRMA agrees that Section 101 should be technology-neutral, and also believes that patent claims to diagnostic

---

[61] *See* TRIPS Agreement, Article 27.1.

[62] *Diehr*, 450 U.S. at 189 n.12 ("all inventions can be reduced to underlying principles of nature").

[63] *Chakrabarty*, 447 U.S. at 313.

[64] *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

[65] *Chakrabarty*, 447 U.S. at 309.

[66] *See, e.g.*, *Mackay*, 306 U.S. at 94.

methods would be eligible under the proposed language when they involve human intervention and have a specific, practical utility.

G. Section 112(f)

Finally, PhRMA's views regarding the proposed changes to the patent subject matter eligibility provision of Section 101 are described above. PhRMA takes no position on the proposed change to Section 112(f).

VI. Conclusion

PhRMA thanks the Senate Judiciary Committee for reaching out to stakeholders regarding Section 101 reform. Your engagement on this issue answers to the Constitution's call to "promote the Progress of Science and useful Arts." To that end, PhRMA welcomes further dialogue on Section 101 issues.