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**Comments of the Pharmaceutical Research and Manufacturers of America Responding to the United States Patent and Trademark Office's Patent Eligibility Jurisprudence Study Request for Information (Docket No. PTO-P-2021-0032)**

**October 15, 2021**

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits these comments in response to the United States Patent and Trademark Office's (USPTO's) Request for Information for its Patent Eligibility Jurisprudence Study, 86 Fed. Reg. 36257–36260 (July 9, 2021) (Federal Register Notice).

PhRMA represents the country's leading innovative biopharmaceutical research companies, which 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 $1 trillion in the search for new treatments and cures, including an estimated $91.1 billion in 2020 alone. The biopharmaceutical industry is committed to working every day to discover and develop new treatments and cures for patients battling diseases like Alzheimer's, heart disease, and, most recently, COVID-19. This is made possible by America's system of intellectual property (IP) protections. Strong and predictable IP protections in the United States 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. IP-intensive manufacturing industries drive economic progress and collectively support 57.6 million American jobs[1] and the biopharmaceutical industry supports a total of more than 4.4 million jobs, contributing $1.1 trillion in economic output when direct and indirect effects are considered.[2]

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. 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.

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[1] PhRMA, IP in the Economy, *available at* https://www.phrma.org/Advocacy/Intellectual-Property.
[2] TEConomy Partners, LLC, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2017 National and State Estimates*, at 1, 11, 12, December 2019, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Economic-Impact-US-Biopharmaceutical-Industry-December-2019.pdf.

## 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] Medicines developed by the biopharmaceutical sector have produced large improvements in health across a broad range of diseases. The rapid growth of 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. Numerous examples of this can be found in the fight against COVID-19 where America's biopharmaceutical companies have brought the world hope by delivering safe and effective vaccines and treatments to patients in record time. But developing a new medicine generally takes between 10 and 15 years of work and costs an average of $2.6 billion of investment in R&D.[4] Only two of every ten marketed drugs return revenues that exceed or match the R&D investment.[5]

We have entered a new era in healthcare thanks to scientists' ever-increasing understanding of the underlying genetic and biological factors causing diseases. Through targeted therapies and personalized medicine (i.e., precision medicine), physicians and researchers are better able to direct patient care along the full spectrum of healthcare, from risk assessment and prevention to detection, diagnosis, treatment, and disease management. In recent years, we have seen tremendous advances in personalized medicine. Since 2015, more than 25% of new drug approvals were personalized medicines, with 42% of new molecular entities approved in 2020 being personalized medicines for the treatment of cancer.[6] 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 can guide healthcare 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."[7]

Like innovators across the spectrum of American industries, biopharmaceutical companies make substantial R&D investments that yield new and improved products in reliance on a stable legal regime that provides protection for any resulting intellectual property. In particular, PhRMA's members rely on a legal regime that provides clear, strong, and predictable protection for intellectual property when making the substantial R&D investments that yield

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[3] *Id.* at 3.
[4] 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).
[5] 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).
[6] Personalized Medicine Coalition. 2020 progress report: Personalized medicine at FDA. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM_at_FDA_The_Scope_Significance_of_Progress_in_2020.pdf.
[7] Geoffrey S. Ginsburg & Kathryn A. Phillips, *Precision Medicine: From Science to Value*, Health Affairs 694, 694–701 (May 2018).

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 in the biopharmaceutical space given the substantial regulatory requirements that must be met for the development of new treatments.

However, the evolution of patent subject matter eligibility law in the United States is concerning because of its negating impact on patent protection afforded to innovations within critical areas of biotechnological development.[8] PhRMA is concerned that the jurisprudence regarding 35 U.S.C. § 101 has led to the patent system not protecting certain important innovations that benefit patients. As such, the jurisprudence has become misaligned with the U.S. Constitution by failing to "promote the progress of science and useful arts."[9] These developments could stifle the innovation required to produce new treatments for patients.

PhRMA's comments below are twofold. Part I addresses USPTO's request for public comment on the impact of subject matter eligibility decisions issued by the U.S. Federal Judiciary on the general marketplace. Part II addresses USPTO's request to share experiences regarding the application of subject matter eligibility requirements in other jurisdictions, including China, Japan, Korea, and Europe, and considers how those experiences differ from experiences in the United States.

## I. Impact of Subject Matter Eligibility on the General Marketplace

### A. Uncertainty Negatively Impacts the Global Strength of U.S. Intellectual Property and the U.S. Economy

Questions 10–12 of the USPTO's request for public comment concern how the current state of patent subject matter eligibility jurisprudence in the U.S. impacts: (1) the global strength of U.S. intellectual property; (2) the U.S. economy as a whole; and (3) the global strength of U.S. intellectual property and the U.S. economy with respect to, *inter alia*, precision medicine, diagnostic methods, and pharmaceutical treatments. PhRMA addresses each below.

[8] *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 596 (2013) (holding that because an isolated DNA sequence is naturally occurring, it is not patent eligible); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 99 (2012) (finding method claims directed to a diagnostic assay for determining the proper dose of a drug based on a patient's metabolite levels ineligible).

[9] Article I Section 8 | Clause 8 of the United States Constitution indicates that [the Congress shall have power] "[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."

Judge Michel described "the uncertainty surrounding the law of eligibility [as] the number one problem in our patent system today."[10] The uncertainty flows from the Supreme Court's decisions in *Mayo* and *Alice* which set forth 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."[11] Under this analysis, the court must first "determine whether the claims at issue are directed to one of those patent-ineligible concepts," i.e., laws of nature, natural phenomena, and abstract ideas.[12] 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.'"

Courts have struggled with a consistent and predictable application of the test for patent subject matter eligibility. Judges are the ultimate arbiters of patent eligibility determinations, but they themselves have repeatedly expressed confusion on how to apply the law. Federal Circuit Judge Todd M. Hughes wrote:

> "I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents. Such standards could permit patenting of essential life-saving inventions based on natural laws while providing a reasonable and measured way to differentiate between overly broad patents claiming natural laws and truly worthy specific applications."[13]

Federal Circuit Judge Richard Linn also expressed his concern over the tension between Section 101 and the judiciary's interpretation: "But 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."[14] And courts have characterized the judicial exemptions for laws of nature and natural phenomena as interchangeable. In *Athena*, the Federal Circuit stated that a method for diagnosing myasthenia gravis was directed to a law of nature, while also describing the diagnostic method for determining fetal characteristics by analyzing cell-free fetal DNA in maternal blood samples in *Ariosa* as a natural phenomenon.

Nearly all innovation in biopharmaceuticals could be said to relate to laws of nature and natural phenomena in some way, but the uncertainty surrounding the application of the *Mayo* test has led to disappointing patent subject matter eligibility outcomes in the field of diagnostic

[10] Testimony of Judge Paul R. Michel (Ret.) United States Court of Appeals for the Federal Circuit, *The State Of Patent Eligibility In America:* Hearing Before the United States Senate Subcomm. on Intellectual Property, Comm. on the Judiciary, 116th Cong. (June 4, 2019) at 17.
[11] *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014)
[12] *Id.* at 217.
[13] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs. LLC*, 915 F.3d 1333, 1337 (Fed. Cir. 2019) (Hughes, J., concurring in denial of rehearing *en banc*).
[14] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1381 (Fed. Cir. 2015) (Linn, J., concurring).

methods. While diagnostic claims have not been deemed as *per se* patent ineligible,[15] they have been rejected time and time again by the Federal Circuit in the wake of *Mayo*.[16] This is true even though the Federal Circuit has 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."[17]

Conversely, method of treatment claims that utilize a natural phenomenon or a law of nature have been correctly found worthy of patent protection. The Federal Circuit based part of its determination that claims describing a method for treating schizophrenia by basing the dosage on the patient's genotype were patent eligible in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*[18] by differentiating the claims from the claims in *Mayo*. The *Vanda* court pointed out that "the claims in *Mayo* were not directed to a novel method of treating a disease. Instead, the claims were directed to a diagnostic method . . . ."[19] Likewise, the court concluded that claims directed to a method of treating pain in patients with impaired kidney function in *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.* were not directed to a law of nature since "the claims here are directed to a *treatment* method, not a detection method."[20] And in *Ino Therapeutics LLC v. Praxair Distribution Inc.*, the Federal Circuit confirmed the patent subject matter eligibility of method of treatment claims generally but distinguished the claims at issue (reciting a method of treating patients who are candidates for inhaled nitric oxide treatment) from those in the *Vanda* and *Endo* cases and found those claims at issue in *Ino* to be patent ineligible since they were directed to a natural phenomenon.[21]

The uncertainty surrounding the application of Section 101 described has real-world consequences—consequences that the USPTO has recognized in its request for comments.

The judicial exemptions have created a patchwork legal system that threatens to undermine the strength and predictability of the U.S. patent system as a whole. In the fields of precision medicine and diagnostic methods, inventors are left wondering what inventions will be afforded patent protection. Indeed, former USPTO Director Andrei Iancu commented he

[15] However, Judge Moore, with whom Judges O'Malley, Wallach, Stoll, , joined, dissented from the denial of the petition for rehearing en banc in *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, *supra* note 13 at 1354 and wrote that "[w]e have turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible. That per se rule is 'too broad an interpretation of this exclusionary principle [which] could eviscerate patent law.'"
[16] *See, e.g.*, *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 763 (Fed. Cir. 2014); *Ariosa*, 788 F.3d 1371; *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); *see also* Colleen Chien & Jiun-Ying Wu, *Decoding Patentable Subject Matter*, 2018 PatentlyO Patent Law Journal 1, 10 ("Among medical diagnostic ('MedDx') applications, the 101 rejection rate grew from 7% to 32% in the month after *Mayo* and continued to climb to a high of 64% and to 78% among final office actions just prior to abandonment.").
[17] *Athena*, 915 F.3d at 753 n.4.
[18] 887 F.3d 1117 (Fed. Cir. 2018).
[19] 887 F.3d 1117,1134 (Fed. Cir. 2018).
[20] 919 F.3d 1347, 1356 (Fed. Cir. 2019).
[21] 782 Fed, Appx. 1001, 1008 (Fed. Cir. 2019) (not precedential). ("Here, by contrast, the invention is not focused on changing the physiological state of the patient to treat the disease. … Therefore, the claims here are readily distinguishable from other cases that actually integrate or leverage natural laws to an eligible method of treatment for a particular disease.")

"worr[ies] that the current state of Section 101 in patentable subject matter weakens the robustness of our IP system in the affected areas."[22]

Former Director Iancu's fears are well-founded. Without a robust patent system, inventors are left vulnerable to others seeking to copy their work. "Research, development, and creativity are time-consuming and expensive, but copying the successful results of these endeavors can be quick and easy."[23] This sense of vulnerability may force inventors to seek refuge in other jurisdictions that are perceived as more hospitable and reliable concerning patent eligibility and hence more stable in predictability of outcomes of patent enforcement. These other major patent systems foster a sense among innovators that their technologies can be better protected by foreign patents than by U.S. patents, as discussed further in Part II below.

Moreover, inventors have become doubtful that the judiciary can reset the course of patent subject matter eligibility determinations in the United States so that meaningful inventions are not found to be patent ineligible. The Federal Circuit has requested greater clarity in application of Section 101 eligibility as demonstrated above. But the Supreme Court has not answered the call.

The effect of this could perception be to encourage investment of risk capital in foreign locales to the detriment of innovation and its benefits to markets and employment in America. As Senator Thom Tillis (R-NC) observed: "Why would anyone in their right mind risk millions if not billions of dollars to develop a product when they have no idea if they're eligible for protection? From a business perspective, it simply isn't worth the risk for many endeavors."[24] Inventors may instead invest where they believe their inventions can be best protected.

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.[25] But if an invention is patentable under foreign law, and 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's jurisprudence on Section 101 issues has made it harder for companies

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[22] Interview by Gene Quinn with Hon. Andrei Iancu, Former Director, USPTO https://www.ipwatchdog.com/2018/05/15/iancu-part-2/id=97191/ (Apr. 27, 2018).
[23] David J. Kappos, *The Antitrust Assault on Intellectual Property*, 31 Harv. J. of L. & Tech. 665, 667 (2018).
[24] Richard Lloyd, *Unprecedented Congressional Engagement on Patent Eligibility Reform, but Don't Bet on a Rush to Legislation*, IAM (Jan. 6, 2019), https://www.iam-media.com/law-policy/series-congressional-hearings-point-unprecedented-engagement-101.
[25] *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).

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.

Pharmaceutical products take years to develop and perfect. It is concerning that companies may invest in research now that may not be patentable in the future due to the evolution of patent subject matter eligibility law in the United States. 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. This concern does not exist in the abstract, nor is it a hypothetical. It is a reality. A recent policy report by leading intellectual property law professor Mark Schultz found that "VC investment in pharmaceuticals went from a 7% share of all investments in 2004 to a 0.79% share in 2017."[26]

### B. Uncertainty Negatively Impacts the U.S. Public

Question 13 of the USPTO's request for public comment concern how the current state of patent eligibility jurisprudence in the United States affects the public. PhRMA addresses this question below.

Lack of investment and inventive human capital is likely to slow meaningful innovation in areas of the biopharmaceutical sector where patent protection is unavailable. This could lead to lost opportunities to improve healthcare outcomes for affected patient populations.

Prevention and diagnosis of the disease state are important aspects of patient care that could see less future innovation. That is, given the current treatment of diagnostic claims, no incentivization exists for inventors to improve upon or create improved methods for early detection of diseases. This is a problem since, in the case of cancer, improved methods of early detection have the potential to save millions of lives in the United States. Delayed diagnosis leaves patients vulnerable to more invasive treatment such as radiotherapy and could allow for the disease to progress to a state where it is more difficult to treat.

Uncertainty as to patent protection for precision medicine may create further harm by discouraging further innovation in this area. Precision medicine holds promise for improving many aspects of health and healthcare. The benefits of precision medicines include:[27]

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[26] Mark F. Schultz, Alliance for U.S. Startups & Inventors for Jobs, *The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies* 4 (July 2020), https://static1.squarespace.com/static/5746149f86db43995675b6bb/t/5f2829980ddf0c536e7132a4/1596467617939/USIJ+Full+Report_Final_2020.pdf.

[27] *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.

Healthcare also plays an important role in the U.S. economy. The development of precision medicines and improved diagnostic treatments result in improved efficiency in the healthcare system, by avoiding unneeded treatments, helping ensure patients get the right treatment, and preventing disease and side effects. These inventions have the potential to help contain long-term healthcare spending in various ways:

- A study[28] 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 healthcare 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.[29]

[28] *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.
[29] *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.[30]

- Biomarkers can be used to guide treatment decisions for cancer patients, leading to better healthcare outcomes and cheaper treatments for patients. For example, the use of biomarkers to inform prostate cancer treatment has resulted in substantial cost savings.[31] The use of biomarkers to improve the accuracy of bronchoscopy for lung cancer diagnosis has reduced the need for invasive procedures by 28 percent at 1 month and 18 percent at 2 years.[32]

In order for improvements in patient well-being and public health to continue, it is important for U.S. technology policy, and the U.S. patent system in particular, to encourage rather than discourage innovation in these various areas.

## II. Subject Matter Eligibility Requirements Beyond the United States

Question 4 of the USPTO's request for public comment asks how experiences with patent subject matter eligibility requirements in foreign jurisdictions such as China, Japan, Korea, and Europe differ from those experiences in the United States. Below we share our understanding of patent subject matter eligibility requirements for natural products and diagnostic methods in these foreign jurisdictions.

Compared to the United States, the foreign jurisdictions identified in the question have deemed naturally occurring material as patent eligible subject matter. For example, in China, the China National Intellectual Property Administration ("CNIPA") considers claims directed to a gene or a DNA fragment to be *per se* eligible in China, and the process to obtain it may be patented provided certain criteria are met. In Korea, the Korean Intellectual Property Office

[30] *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).
[31] *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).
[32] *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).

("KIPO") considers isolated biological materials, cells, higher life forms, genetic sequences, and proteins to be patent eligible. [33] Likewise, in Europe, although there are some patentability exclusions (e.g., relating to cloning, germ line modification, or the use of human embryos), the European Patent Office ("EPO") considers the discovery of a natural phenomenon or naturally occurring product as patent eligible subject matter if the claimed invention is directed to the discovery's technical effect.[34] Moreover, in Japan, the Japanese Patent Office ("JPO") considers claims directed to medicines, vectors, medical materials, and methods of manufacturing the same to be patent eligible.

Unlike in the United States where diagnostic method patents have routinely been found not to be patent eligible, China, Japan, Korea, and Europe view diagnostic methods as being patent eligible under certain circumstances.

- In China, claims directed to diagnostic methods are patent eligible so long as the method does not lead to a diagnosis or health assessment—regardless if it is carried out separately from the body or performed on the body.[35]

- In Korea, methods of diagnosis are patentable in some forms, namely where the claims do not require the human body to carry out the invention. [36]

- A method of diagnosis may be patent eligible in Japan if the method is performed outside the human body, does not include the steps of medical doctors judging the physical condition of a human body for medical purposes, or is used to collect information from a human body.[37]

- The EPO will not grant patents covering diagnostic methods practiced on the human or animal body.[38] But a known substance or composition may still be patented for use in diagnostic methods if the known substance or composition has not previously been disclosed for use in any such method.[39] A subsequent diagnostic method employing a known substance or composition that has previously been used in a method may still be deemed patent eligible if the subsequent use of the substance in these methods is novel and inventive.

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[33] Min Son, *South Korea: Patentable subject matter—what's new?*, MANAGINGIP (Feb. 24, 2016), https://www.managingip.com/article/b1kbpbxgm85h99/south-korea-patentable-subject-matter-whats-new.
[34] Guidelines for Examination in the European Patent Office, Part G, Chpt. 2, §3.1, https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_1.htm, https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_1.htm.
[35] Article 25 of Patent Law of the People's Republic of China; CNIPA Guidelines for Patent Examination, Part II, Chapter 1, § 4.3.1.2.
[36] Son, *supra* note 33.
[37] Japanese Patent Office Examination Guidelines, Part III, Chpt. 1, § 3.
[38] European Patent Convention, Art. 53(c).
[39] European Patent Convention, Art. 54(4)

## 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 is an important step to improving the U.S. 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.

Respectfully submitted,

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