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March 8, 2019

VIA EMAIL: Eligibility2019@uspto.gov

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22313

Attention: June E. Cohan, Senior Legal Advisor and Carolyn Kosowski, Senior Legal Advisor

Re: Docket No. PTO-P-2018-0053: 2019 Revised Patent Subject Matter Eligibility Guidance

Dear Director Iancu:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the enclosed views of PhRMA's members in response to the 2019 Revised Patent Subject Matter Eligibility Guidance. PhRMA's members appreciate the USPTO's efforts to provide clarity and instructions to Office personnel and the opportunity to submit comments on the Guidance.

Please feel free to contact me if you have any questions.

Respectfully submitted,

/S/

David E. Korn

Enclosure

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Comments of the Pharmaceutical Research and Manufacturers of America on the United States Patent and Trademark Office's *2019 Revised Patent Subject Matter Eligibility Guidance*
Docket No.: PTO-P-2018–0053

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits these comments in response to the United States Patent and Trademark Office's (the "Office's") *2019 Revised Patent Subject Matter Eligibility Guidance* (the "Guidance").[1] 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 $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.[2]

PhRMA supports the Office's efforts to provide clarity and instruction to Office personnel in the application of the *Alice/Mayo* two-step framework. We offer the comments below from the perspective of research-based biopharmaceutical companies who depend on the patent system for the development of new and improved medicines.

Comments

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

[1] 84 Fed. Reg. 50-57 (January 7, 2019) [hereinafter "Guidance"].

[2] TEConomy Partners, The Economic Impact of the US Biopharmaceutical Industry. Columbus, OH: TEConomy Partners; November 2017.

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.[3]

In previous comments, PhRMA raised concerns that the *Alice*/*Mayo* two-step framework has been arbitrarily and inconsistently applied, dampening incentives to develop future drugs and treatments.[4] As the Guidance notes, "[p]roperly applying the *Alice*/*Mayo* test in a consistent manner has proven to be difficult, and has caused uncertainty in this area of the law" such that, "[a]mong other things, it has become difficult in some cases for inventors, businesses, and other patent stakeholders to reliably and predictably determine what subject matter is patent-eligible."[5] PhRMA appreciates the Director's renewed efforts to address this problem with "policy direction and management supervision for the Office and for the issuance of patents"[6] that "increases certainty and reliability."[7] PhRMA understands that the Guidance reflects the Office's understanding of Section 101 as interpreted by recent case law, and is aimed at providing its personnel with a practical framework for applying that understanding.

The Guidance helpfully furnishes policy direction and helpful instruction to "[a]ll USPTO personnel"[8] on how to assess patent subject matter eligibility issues given the complex body of case law that courts have developed over the past several years. Interpreting prior decisional precedent, the Guidance provides specific considerations for identifying claims not "directed to" a judicial exception, ensuring "that the first step of the [*Alice*/*Mayo*] inquiry is a meaningful one, i.e., that a substantial class of claims

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[3] *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).

[4] Pharmaceutical Research and Manufacturers of America, Comments Responding to the United States Patent and Trademark Office's Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility, 7 (January 18, 2017), https://www.uspto.gov/sites/default/files/documents/comments_PHRMA_Jan182017.pdf.

[5] Guidance at 50.

[6] 35 U.S.C. § 3 (2011).

[7] Guidance at 55.

[8] *Id.* at 51.

are *not* directed to a patent-ineligible concept."[9] Specifically, the Guidance clarifies that a claim is not "directed to" a judicial exception that is "integrated into a practical application of the exception."[10] As the Guidance recognizes, the Supreme Court has acknowledged that "[a]t some level, all inventions embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."[11] For that reason, the Federal Circuit has explained that "it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether that patent-ineligible concept is what the claim is 'directed to.'"[12] The Guidance provides clarity as to how Office personnel are to make that assessment, and underscores the fact that simply reciting a judicial exception does not automatically render a claim "directed to" that exception.

In particular, PhRMA appreciates the Office's reiteration that "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.[13] Such elements "impose[] a meaningful limit on the judicial exception," rendering claims eligible at Step 2A.[14] For example, as the Office has previously observed, "[m]ethod of treatment claims (which **apply** natural relationships as opposed to being "directed to" them) were identified by the Supreme Court as not being implicated by its decisions in *Mayo* and *Myriad* because they 'confine their reach to particular applications.'"[15] PhRMA agrees with the Office: "'method of treatment' claims that practically apply natural relationships should be considered **patent eligible** under Step 2A."[16]

The 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. Such a discussion would be helpful for examiners, who apply § 101 to diagnostic method claims as well as method of treatment claims, and to other stakeholders relying on the patent system.

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[9] *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (emphasis in original).

[10] Guidance at 50; *see also id.* at 53 n.16 (collecting cases); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 596 (2013) ("Judge Bryson aptly noted that, '[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge.'").

[11] Guidance at 51 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012)); *accord Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1134 (Fed. Cir. 2018).

[12] *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc*, 827 F.3d 1042, 1050 (Fed. Cir. 2016); *Vanda*, 887 F.3d at 1134.

[13] Guidance at 53 (citing *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066–68 (Fed. Cir. 2011); *Vanda*, 887 F.3d at 1135).

[14] Guidance at 54.

[15] USPTO Memorandum of June 7, 2018, Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals* [hereinafter "*Vanda* Memorandum"] (emphasis in original) (citing *Vanda*, 887 F.3d at 1135 (quoting *Mayo,* 566 U.S. at 87)); *see also Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, No. 2017-2508, 2019 WL 453489, at *6 (Fed. Cir. Feb. 6, 2019) ("claiming a new treatment for an ailment, albeit using a natural law, is not claiming the natural law.").

[16] *Vanda* Memorandum at 2 (emphasis in original).

In particular, the Guidance could helpfully address additional elements that would distinguish an eligible diagnostic method claim from claims like those recently held ineligible in *Athena Diagnostics, Inc. v. Mayo Collaborative Services*.[17] PhRMA would welcome further guidance and updated examples explaining how Step 2A applies to life science claims other than method of treatment claims, such as diagnostic claims and composition claims.

Further, the Guidance rightly emphasizes that examiners should evaluate whether the claim "as a whole" integrates the judicial exception into a practical application.[18] For example, as explained in the Office's *Vanda* Memorandum, the Federal Circuit in *Vanda* "evaluated the claims as a whole . . . when determining that the claim was not 'directed to' the recited natural relationship."[19] Evaluating claims "as a whole" ensures that claims integrating judicial exceptions into practical applications are properly deemed eligible at Step 2A.

Importantly, the Guidance helpfully observes that "revised Step 2A specifically excludes consideration of whether the additional elements represent well-understood, routine, conventional activity"—an analysis reserved for Step 2B.[20] For example, as the Office has explained, "it is not necessary for 'method of treatment' claims that practically apply natural relationships to include nonroutine or unconventional steps to be considered **patent eligible** under 35 U.S.C. § 101."[21] Rather, nonroutine or unconventional elements may render "a claim that does not 'integrate' a recited exception" eligible at Step 2B.[22] PhRMA applauds the Office's clear demarcation of § 101 Supreme Court jurisprudence and of the *Alice*/*Mayo* analytical framework, which should enable issuance of high-quality patents by helping the patent examining corps make accurate, efficient, and consistent § 101 determinations.

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[17] *Athena*, 2019 WL 453489, at *1.

[18] Guidance at 54; *accord Mayo*, 566 U.S. at 80 (explaining that the Court in *Diamond v. Diehr*, 450 U.S. 175 (1981), "found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole.").

[19] *Vanda* Memorandum 2 (noting also that "[t]he importance of evaluating the claims as a whole in Step 2A was also emphasized by the Federal Circuit in previous cases, such as *Finjan Inc. v. Blue Coat Systems, Inc.*, 879 F.3d 1299 (Fed. Cir. 2018), and *Core Wireless Licensing S.A.R.L., v. LG Electronics, Inc.*, 880 F.3d 1356 (Fed. Cir. 2018)."); *see also Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253, 1262 (Fed. Cir. 2017) ("Step one of *Alice* . . . directs us to examine and determine the character of each claim as a whole."); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1312–13 (Fed. Cir. 2016) ("[T]he claims are considered in their entirety to ascertain whether their character as a whole is directed to excluded subject matter . . . . [A] court must look to the claims as an ordered combination, without ignoring the requirements of the individual steps."); *Enfish*, 822 F.3d at 1335 ("[T]he 'directed to' inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether "their character as a whole is directed to excluded subject matter.").

[20] Guidance at 55.

[21] *Vanda* Memorandum at 2 (emphasis in original).

[22] Guidance at 56.

PhRMA also appreciates the Guidance's instruction that examiners analyzing the "abstract idea" exception "(a) Identify the specific limitation(s) in the claim under examination (individually or in combination) that the examiner believes recites an abstract idea; and (b) determine whether the identified limitation(s) falls within the subject matter groupings" provided by the Guidance.[23] Anchoring the "abstract idea" exception in discrete categories synthesized from case law determinations helps ensure that examiners heed the Supreme Court's warning that "too broad an interpretation of this exclusionary principle could eviscerate patent law."[24] These categories help examiners readily discern whether or not a claim recites an abstract idea as informed by the full range of applicable law.

Conclusion

PhRMA thanks the Office for reaching out to stakeholders regarding its *2019 Revised Patent Subject Matter Eligibility Guidance*. The Office's willingness to engage with stakeholders will result in a patent system that answers the Constitution's call to "promote the Progress of Science and useful Arts."[25] To that end, PhRMA welcomes further dialogue with the Office on patent subject matter eligibility issues.

[23] *Id.* at 54.

[24] *Myriad*, 569 U.S. at 590; *Mayo*, 566 U.S. at 71; *accord Vanda*, 887 F.3d at 1134 (citing *id.*).

[25] U.S. CONST. art. I, § 8, cl. 8.