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Kathi Vidal, Director
U.S. Patent and Trademark Office
Alexandria, VA 22314

October 14, 2022

Director Vidal:

On behalf of the U.S. PIRG (Public Interest Research Group) and our state affiliates, I am responding to the request for public comment from the office of PTO Director Kathi Vidal on July 25, 2022, concerning § 101 guidance included in the Manual of Patent Examining Procedure § 2106.

U.S. PIRG is a nonprofit advocate for the public interest. We speak out for a healthier, safer world which includes promoting policies that support the delivery of the high value healthcare we deserve. To succeed in this goal, we must address skyrocketing healthcare costs, including the cost of prescription drugs. We have been particularly concerned about barriers to entry of generic and biosimilar medications which create the competition needed to bring down the cost of prescription drugs. Additionally, PIRG plays an important role in watchdogging existing law (which includes Supreme Court precedent) in all matters of public policy. As such, the way that patents are evaluated and granted are of particular importance to our mission.

We commend the PTO's solicitation of public comment and to allow those most directly affected by PTO decisions, consumers, to weigh in on this issue. We write to urge you to revise the U.S. Patent & Trademark Office's (USPTO) patent-eligibility guidance in Section 2106 of the Manual for Patent Examining Procedure (MPEP).

Revisions to the MPEP's patent-eligibility guidance are necessary because the guidance currently contradicts controlling law—particularly the Supreme Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories*, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, *and Alice Corporation v. CLS Bank International*—and works to create barriers to competition in the pharmaceutical market. We urge you to revise the MPEP to realign USPTO guidance more closely to its goal of promoting scientific advancement for the benefit of the public.

Patent-eligibility directly impacts the way drugs are priced and whether competitors can enter the market which help drive down prices for patients. The public has an overwhelming interest in ensuring the PTO applies patent-eligibility law correctly, just as any state or federal agency has the responsibility to be accurate in its implementation of law. Limits on patent-eligible subject matter are essential to the patent system's ability to do what it was designed to do: "promote economic growth and a higher standard of living for all."[1] By safeguarding "the basic tools of scientific and technological work," patent-eligibility limits mitigate the 'considerable danger' that patents would otherwise inhibit innovation," which "would be at odds with the very point of patents, which exist to promote creation."[2]

When drug patents are inappropriately granted, it unnecessarily extends market exclusivity for the patent-holder and precludes innovation. For this reason, it is important that any guidance to be used by PTO staff and judges closely follows statutory and case law. Your office is appropriately concerned and justified in your consideration of reevaluating current guidance. According to the Government Accountability Office's (GAO) recent survey of Patent and Trial Appeal Board (PTAB) judges, 30 percent of responding judges stated that "the 2019 Revised Patent Subject Matter Eligibility Guidance *creates new tests* for evaluating whether an invention is eligible *that are not supported or established* by the applicable case law."(emphasis added)[3] Some judges specified that the MPEP's unsupported tests of patent-eligibility have the effect of "broaden[ing] the types of inventions that are patentable beyond the case law."[4] If this many of the PTO's own experts on the law are expressing concern, it is time to reassess the MPEP and revise it in ways that more clearly return to what is delineated and defined by statute and case law.

The Supreme Court established clear directions to test eligibility which should be reflected in the MPEP. The Supreme Court established a straightforward test[5] for

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[1] Letter from USPTO Director Kathi Vidal to FDA Commissioner Robert Califf, July 6, 2022, https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-22.pdf
[2] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (citations omitted)
[3] Government Accountability Office, Preliminary Observations on Oversight of Judicial Decision-making at 14, https://www.gao.gov/assets/gao-22-106121.pdf
[4] *Id.*
[5] *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014)

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determining whether a patent holder satisfies the Section 101 requirements of patentable subject matter .

> (1) Determine whether the claim at issue is directed to ineligible subject matter—i.e., a law of nature, natural phenomenon, or abstract idea; and if so,
>
> (2) Determine whether the claim contains elements that, individually or collectively, reflect an inventive concept that is eligible for protection—i.e., elements that do or are significantly more than the ineligible subject matter identified in step one as opposed to elements which are routine, conventional, well-understood, generic, or inherent to the ineligible subject matter itself.

The MPEP should closely align with that two step process and avoid unsupported variance from those directions. Rewriting guidance to meet this standard will assure patent examiners more consistently approach patent examinations using guidance supported by statute and case law. Appropriate revision will not only avoid confusing future patent applicants but importantly avoid extended and expensive litigation to correct patents that were inappropriately granted.

Thank you for your consideration of revisions to the MPEP. We urge you to take on this important work swiftly to ensure the public can benefit from enhanced quality of granted patents as defined in statute and case law.

Sincerely,

Patricia Kelmar
Health Care Campaigns Director