Subject: Comments by the Coalition Against Patent Abuse[1]
Docket Number: PTO-P-2021-0032

Allowing a more patent permissive interpretation of Section 101 would be extremely dangerous without first addressing anticompetitive uses of the patent system, termed patent abuse, to extend effective patent protection on important drugs. Section 101 serves as a gatekeeper that prevents patents on laws of nature and natural phenomenon that are often at the heart of patient treatments and diagnostics. Inventors can still get patents on inventive applications of this knowledge, but they can't patent the knowledge itself. The Supreme Court famously said "to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" *Mayo Collaborative v. Prometheus Labs., 566 US 66 (2012).*

Modern drug price and competition policy is based largely on the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, that went into effect in 1984. The Hatch-Waxman Act balanced the needs for competition with the needs to incentivize and encourage innovation. The needs of competition were addressed by providing accelerated pathways for generic competition and encouraging generic companies to challenge weak patents that are preventing entry. The needs of innovation were addressed by, among other things, allowing patent terms to be extended to account for the time spent in the drug approval process. The intention was to give drug innovators additional incentives to innovate and ensure that a lengthy FDA approval process wouldn't prevent them from enjoying an adequate monopoly period once the drug was on the market. This patent term extension is capped at 14 years, although there are other sources of exclusivities found in the law to encourage other types of behavior. The Biologics Price Competition and Innovation Act (BPCIA), which governs biologics and biosimilars, largely followed the philosophy of the Hatch-Waxman Act by granting a guaranteed 12 years of market exclusivity and establishing the system through which biosimilars could challenge patents and enter the market.

However, modern patent thicketing strategies have been developed to extend effective drug monopolies well beyond the 14 years contemplated by the Hatch-Waxman Act and some drugs even maintain their monopolies beyond the 20 year term of a patent. The Hatch-Waxman Act and BPCIA's provisions that enable the challenging of weak patents do little good when the volume of patents that need to be challenged are beyond what is feasible in terms of cost and time to litigate. Indeed, gaming of the patent system has progressed to the point that negative innovation - or the worsening of a product in response to patent incentives - has been

[1] A list of CAPA members may be found on the website https://www.capanow.org/. Opinions expressed herein reflect the views of the coalition but not necessarily those of the individual members.

documented. *See Negative innovation: when patents are bad for patients, https://www.nature.com/articles/s41587-021-00999-0.*

Section 101 has specifically been at issue in several important cases where competition and access to affordable healthcare was on the line. Examples:

- **Treating autoimmune disease** – A company was issued two patents on how to safely administer drugs to treat autoimmune disease. These patents described three steps: 1) administering the medication; 2) measuring how the drug was metabolized; and 3) using these measurements to determine if the dose is too high or too low. The Supreme Court said that the relationship between the concentration of certain metabolites in the blood and how the patient responded to the drug was an unpatentable law of nature and cancelled its monopoly. *Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).*
- **Detecting breast and ovarian cancer** – A company was issued a patent based on a discovery of the location of two genes that, if mutated, greatly increase the risk of breast and ovarian cancer. If valid, the patents would give the company exclusive right to isolate these genes. The Supreme Court found that DNA, even in segments, is an unpatentable product of nature. This ruling is important for research and patient diagnostics, allowing competition for both. *Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).*
- **Diagnosing neurological and cardiovascular disorders** – Two cases involved issued patents that covered methods of diagnosing medical disorders by detecting certain antibodies or proteins. The judges found that the fact that certain biological markers can indicate disorders are unpatentable laws of nature, and allowed competition on testing for these diseases based on this information. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019); Cleveland Clinic Found. v. True Health Diagnostics LLC, No. 2018-1218, 2019 WL 1452697, at *1 (Fed. Cir. Apr. 1, 2019).*
- **Assessing best treatment for cancer patients** – A patent was issued on a method of determining the best types of drugs to treat patients with lung cancer. The method was to examine a patient's genes for the presence or absence of certain nucleotides, and this measurement would help determine which cancer medications would be most effective. The court found this correlation was an unpatentable law of nature. *Esoterix Genetic Laboratories LLC v. Qiagen Inc., 133 F. Supp. 3d 349, 359 (D. Mass. 2015).*
- **Setbacks in drug safety** – The Federal Circuit has refused to apply the Supreme Court's 101 decisions to cases involving using biological markers to provide patients with safer medication dosages, upholding these patents as valid. In one case a patent was issued to better treat schizophrenia patients by testing for a certain gene that indicates the patient is a poor metabolizer, and then administering a lower dose if the patient has that gene. Generic competition cannot enter because the FDA requires the safety provided by this testing. In another case a patent was upheld on treating renal failure with lower doses of pain medication. The patented process involved administering the drug, taking some measurements, and then changing the dose based on the

measurement. *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018), petition for cert. pending, No. 18-817 and Endo Pharms Inc. v. Teva, __ F.3d __, 2019 WL 1387988 (Fed. Cir. Mar. 28, 2019).*

Any changes to Section 101 should not be sought before addressing issues with patent law that enable patent abuse, and any proposed changes must first be tested against a theoretical bad actor who would abuse those new provisions towards anticompetitive ends rather than furthering the state of innovation.