June 4, 2019

The Honorable Thom Tillis, Chairman
Subcommittee on Intellectual Property
Committee on the Judiciary
U.S. Senate
224 Dirksen Senate Office Building
Washington, D.C. 20515

The Honorable Chris Coons, Ranking Member
Subcommittee on Intellectual Property
Committee on the Judiciary
U.S. Senate
152 Dirksen Senate Office Building
Washington, D.C. 20515

Dear Chairman Tillis and Ranking Member Coons,

The Coalition Against Patent Abuse (CAPA) is a bipartisan coalition of stakeholders who believe that fixing abuses of the patent system, including patent thicketing and product hopping, are fundamental to bringing access to affordable medicines to Americans. Our members are U.S. PIRG, Institute for Liberty, Citizen Outreach, R Street Institute, AHIP, Consumer Action, Lincoln Network, Knowledge Ecology International, Campaign for Sustainable Rx Pricing, Association for Accessible Medicines, Kaiser Permanente, Innovation Defense Foundation, Blue Cross Blue Shield Association, Service Employees International Union, and the Society for Patient Centered Orthopedics.[1]

The rising cost of prescription drugs in the U.S. cannot be addressed while major drug companies continue to game the patent system to prevent drug price competition, resulting in government-granted monopolies which do not represent either innovation or the best interests of public health. Essentially, patent abuse and extensions of regulatory monopolies not only keep drug prices high, they also slow innovation and prevent timely access to better, affordable medicines to save and enhance patients' lives. As such, we are deeply concerned with your draft Section 101 proposal. That proposal would overrule 150+ years of carefully crafted Supreme Court precedent on patent eligibility and would open the floodgates to further abuses of the patent system.[2]

[1] The views expressed are solely on behalf of the Coalition Against Patent Abuse members signed below.

[2] https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act

Patents, like all forms of intellectual property, are term-limited exclusive rights provided for in Article 1, Section 8, Clause 8 of our Constitution.[3] Our Founders recognized the need to protect inventors' exclusivity over their work, but also understood that issuing overly-broad monopolies would be detrimental to American progress. Over the past two centuries, Congress has thoughtfully crafted legislation that incentivizes innovation but also ensures consumers have access to their works and information using a fair and certain process with definite limits on length and scope of granted monopolies.

Section 101 of the Patent Act has undergone multiple revisions and clarifications by Congress and the Supreme Court. Currently, Section 101 provides that patents may only be granted for "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[4] As the Supreme Court has repeatedly recognized, laws of nature, abstract ideas, and natural phenomena—the basic facts of life that cannot be invented by anyone—are not patent eligible subject matter.[5] We greatly caution against any modification to Section 101 for the reasons articulated in this letter.

As an initial matter, the draft legislation would indisputably increase drug prices and further disrupt current policies that appropriately balance innovation and competition.[6] Patents are only intended to provide a monopoly for twenty years from the date of filing. Because the drug research and approval process requires time and investment, carefully-negotiated legislation like the Hatch-Waxman Act has provided mechanisms for companies to have certain lengths of guaranteed exclusivity.[7] This policy has resulted in an average of 12.5 years of exclusivity from the time the drug was introduced to the market to the time generic competition occurs.

However, a recent study of the twelve top selling drugs confirms that companies are obtaining far longer exclusivity periods.[8] For example, AbbVie has filed 247 patent applications to cover a single drug, Humira, and has received over 130 patents that would block competition for a total of 39 years. AbbVie settled patent challenges by allowing generic competition in the U.S. in 2023—a much later date than in Europe, where biosimilar competition is already occurring. And that competition has been enormously successful—AbbVie has had to slash prices by as much as 80% in some countries to compete. By contrast, AbbVie raised the price of Humira in the U.S. by 6.2% in January.

Humira is one of many examples. For every drug in the study, the branded company had a patent strategy to extend its monopoly to over 30 years using granted U.S. patents. The longest attempted monopoly, on lifesaving cancer drug Herceptin, totals 48 years. Herceptin has been on the market since 1998.

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[3] Article I, Section 8, Clause 8, of the United States Constitution grants Congress the enumerated power "To 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."

[4] 35 U.S.C. § 101

[5] Current Supreme Court precedent clarifying § 101 is as follows: Human genes, isolated from the rest of the genome: *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S. Ct. 2107 (2013). Computerized financial transactions: *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). Medical diagnostic tests that correlate with adjustments of treatment: *Mayo Collaborative Servs. v. Prometheus Labs.,* Inc., 566 U.S. 66 (2012).

[6] https://www.judiciary.senate.gov/meetings/intellectual-property-and-the-price-of-prescription-drugs-balancing-innovation-and-competition

[7] https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity

[8] http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf

The draft legislation will permit drug companies to file more applications and seek even greater monopoly lengths. This will further disrupt the careful balance between innovation and competition, and raise costs for patients and those that indirectly share the cost of higher drug prices, like taxpayers who fund Medicare and Medicaid. Current Section 101 law has prevented patents on methods for determining safe dosages for patients based on known correlations between the results and the effectiveness of the drug.[9] Current law has also prevented patents on using genetic testing to predict which drugs will be effective based on known correlations between certain genes and response to certain medications.[10] These decisions would be abrogated by the draft legislation. These kinds of patents grant monopolies on scientific discoveries, prevent doctors from applying known best medical practices, and increase the ways in which companies can strategically renew their monopolies on important medications.

We believe that more patents of the type previously barred by the Supreme Court will only further harm patients and raise costs for all taxpayers. If anything, lower courts should be stricter in their application of the Supreme Court's Section 101 precedent. The Federal Circuit has refused to apply the Supreme Court's Section 101 decisions to cases involving using biological markers to provide patients with safer medication dosages. In one case, a patent was issued on a method 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 for patients with that gene. Generic competition on that drug was stifled because that testing was required by FDA.[11] In another case, a patent was upheld on a method of treating renal failure by administering lower doses of pain medication. The patented process involved administering the drug, taking some measurements, and then changing the dose based on the measurement.[12] These patents should not have been granted and increase the cost of safe medical treatment.

Worse, the Section 101 proposal is contrary to current legislative efforts to solve our country's high drug price problem. For example, Senators Cornyn and Blumenthal have introduced legislation that would curb branded companies' anticompetitive use of patents to prevent generics and biosimilar competition. Their legislation, S. 1416, the "Affordable Prescriptions for Patients Act of 2019", makes it clear that anticompetitive patent thicketing and product hopping are violations of the FTC Act.[13] This bill represents a first step towards stopping these abuses of our regulatory systems so that competition enters the market on time. If the Section 101 proposal is signed into law, it will undermine current efforts to clean up abuses of the patent system by opening the floodgates to more non-innovative patents that needlessly block competition. We implore the Committee to reject this proposal. The only beneficiaries of this legislation will be monopolistic bad actors.

We recognize that re-balancing the patent system is a complicated endeavor. However, the current Section 101 proposal is not the way it should be done. As you consider improvements to make medications affordable, we request that you consider the proposals that we wrote about in our previous letter to the Committee: strengthening IPR and improving patent quality.[14]

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[9] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).
[10] *Esoterix Genetic Laboratories LLC v. Qiagen Inc.*, 133 F. Supp. 3d 349, 359 (D. Mass. 2015).
[11] *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), petition for cert. pending, No. 18-817
[12] *Endo Pharms Inc. v. Teva*, __ F.3d __, 2019 WL 1387988 (Fed. Cir. Mar. 28, 2019).
[13] https://www.congress.gov/bill/116th-congress/senate-bill/1416
[14] https://www.capanow.org/media/2019/05/CAPA-Testimony-Final-Draft-Senate-Judiciary-May-2019.pdf

Thank you for your consideration and you move forward. If you have any questions or concerns, we are happy to discuss them with you and your staff.

Yours very truly,

America's Health Insurance Plans
Association for Accessible Medicines
Blue Cross Blue Shield Association
Campaign for Sustainable Rx Pricing
Coalition to Protect Patient Choice
Citizen Outreach
Innovation Defense Foundation
Institute for Liberty
Knowledge Ecology International
Lincoln Network
R Street Institute
Service Employees International Union
The Society for Patient Centered Orthopedics

CC: Chairman Lindsey Graham
Ranking Member Dianne Feinstein