July 9, 2018

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Madison Building
600 Dulany St.
Alexandria, VA 22313-1450

Re: **Comments Regarding Docket No. PTO-P-2018-0036,**
"Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board"

Dear Director Iancu:

We are stakeholders representing an array of consumer, industry and public interests who are concerned with the high cost of prescription medications. A significant portion of these high drug costs can be attributed to anti-generic strategies that extend the effective exclusivity period by seeking multiple low-quality patents covering the use of a drug whose initial patent is set to expire. In many cases, these follow on patents have been found to be invalid or improperly granted.

For this reason, we write to express our concerns over the U.S. Patent and Trademark Office's ("PTO" or the "Office") Notice of Proposed Rulemaking entitled "Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board." We believe that such a change from the broadest reasonable interpretation ("BRI") standard to the *Phillips* standard used in litigation is unnecessary because, as the Office has previously successfully convinced the Supreme Court, proceedings before the Patent Trial and Appeal Board ("PTAB") are not litigation. Additionally, we are concerned that such a change will frustrate the purpose of the PTAB and reduce the PTAB's ability to correct mistakes in the issuance of patents that were improperly granted. Such a change could reward bad behavior before the PTO in seeking patents on "inventions" that are not novel or non-obvious and would harm consumers through improperly extended drug monopolies.

America's Patients Benefit from an Effective IPR Process

The United States has chosen to regulate the prescription drug market so that innovators are rewarded for the discovery of a new drug with a limited duration monopoly. After the conclusion of this monopoly, generic competitors can enter the market and drive costs down for patients. This system balances the competing interests of providing affordable medication for patients while also providing incentives for the discovery of new medication. This balance is critical and relies on a system that only rewards true innovation and not patent office gamesmanship. Otherwise, drug companies will have an incentive to extend their monopolies from a limited duration to an indefinite duration through strategies that flood the PTO with weak patent applications covering already successful medications until new patents are granted protecting old drugs. We believe that Inter Partes Review ("IPR") and other post-grant reviews provide a necessary check on the patents issued by the PTO to ensure that those patents have been properly granted.

The prices of prescription medications are a driving force behind ever increasing healthcare expenditures. In 2016, Americans spent $323 billion on prescription medications, and drug spending is expected to reach over $580 billion by 2021.[1] Although pharmaceutical cost increases may be due to a number of factors, the added expense of brand-name medications contributes significantly to the high cost of prescription drugs. In 2016, brand-name drugs represented 11 percent of the drugs dispensed but 74 percent of the total drug costs, amounting to $239 billion.[2] The high cost of brand-name drugs can create significant financial burdens for consumers, causing them to have to choose between treatment or living expenses.[3] In 2012, Consumer Reports found that 18 percent of consumers with prescription drug coverage declined to fill their medications due to cost, while 45 percent of consumers without prescription drug coverage did not fill a prescription due to cost.[4] This is a major reason why President Trump has made lowering drug prices a top priority.[5]

Improved access to generic medications helps to combat the high price of prescription medications. In 2016 alone, generic medications saved consumers $253 billion, or approximately $5 billion a week.[6] In recent years, prices for brand-name drugs have continued to climb while prices for their generic counterparts decrease.[7] The FDA has found that effective entry of generic competitors reduces the price of drugs by 80 percent or more.[8] President Trump, HHS Secretary Alex Azar, and FDA Commissioner Scott Gottlieb are all committed to advancing policies that increase competition, and stop anti-generic strategies pursued by some brand-name drug manufacturers.[9]

The PTO is one place where brand-name drug manufacturers pursue anti-generic strategies. Many have raised concerns that the 19-hour average time allotment given to patent examiners

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[1] US prescription drug spending as high as $610 billion by 2021: Report, CNBC (May 4, 2017, 6:12AM), https://www.cnbc.com/2017/05/04/us-prescription-drug-spending-as-high-as-610-billion-by-2021-report.html.
[2] AAM 2017 Generic Drug Access & Savings in the U.S., https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.
[3] Carolyn Y. Johnson, *Expensive specialty drugs are forcing seniors to make hard choices*, Washington Post (Nov. 10, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/11/10/expensive-specialty-drugs-are-forcing-seniors-to-make-hard-choices/?noredirect=on&utm_term=.3f85d932f03e; Bill Walsh, *The Tier 4 Phenomenon: Shifting the High Cost of Drugs to Consumers*, AARP at 3 (2009), *available at* https://assets.aarp.org/rgcenter/health/tierfour.pdf (finding that high drug costs can cause consumer to "forgo basic living expenses").
[4] *Sluggish Economy Forces Americans to Cut Corners to Pay for Medications: Those without Prescription Drug Coverage Nearing Crisis Point*, Consumer Reports (2012), https://www.consumerreports.org/cro/2012/09/sluggish-economy-forces-americans-to-cut-corners-to-pay-for-medications/index.htm.
[5] Paige Minemyer, *Trump unveils 'American Patients First' plan to bring down drug costs*, Fierce Healthcare (May 11, 2018), https://www.fiercehealthcare.com/regulatory/trump-unveils-american-patients-first-plan-to-bring-down-drug-costs.
[6] AAM 2017 Generic Drug Access & Savings in the U.S., https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.
[7] See Stephen Schondelmeyer and Leigh Purvis, Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans,2006 to 2013 (2015), https://www.aarp.org/content/dam/aarp/ppi/2015/trends-in-retail-prices-of-generic-prescription-drugs.pdf (finding that "retail prices for 280 generic prescription drugs widely used by Medicare beneficiaries fell by an average of 4.0 percent in 2013, [while] the retail prices for 227 brand name prescription drugs most widely used by Medicare beneficiaries increased by an average of 12.9 percent").
[8] U.S. Food & Drug Admin., Generic Competition and Drug Prices, https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.
[9] *See, e.g.*, Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition, FDA (May 17, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm.

to review a patent leads to the issuance of low-quality patents that should not have been issued.[10] This is why Congress designed the IPR process: "'to protect the public' from improperly issued patents, which impose high social costs."[11] Indeed, many patents obtained to extend the exclusivity of a successful drug have later been found to be invalid.[12]

Abandoning BRI Disregards the Core Mission of IPR

The Office currently uses the "broadest reasonable interpretation" or "BRI" standard both in examination and in IPR. Congress mandated that the PTAB can only cancel patent claims during an IPR if the patent challenger proves that the claims are unpatentable by a preponderance of the evidence, consistent with the current BRI standard.[13] This standard of proof is lower than the clear and convincing *Phillips* standard used by district courts.[14] This is intentional, because Congress intended that the presumption of validity that applies to an issued patent in litigation should *not* apply when the Office itself is reconsidering its own prior action. Indeed, the agency defended the use of the BRI claim-construction standard for IPRs just two years ago.[15]

Changing the standard for IPR from BRI to *Phillips* would undermine the very rationale for IPR, a rationale that the Office repeatedly described before the Supreme Court: that IPR is intended as a reconsideration of the agency's own decisions and a correction of the agency's own mistakes.[16] The basic premise of IPR is that sometimes a claim survives examination even though, if the examiner had had the benefit of more information, it would not have issued. IPR allows a third party to bring that additional information to the Office's attention, and allows the Office to fix its mistake. It is not litigation and the PTO should not have to give the issued patent the same deference as that found in a court. This is because the PTO, as the issuing body, has the expertise and responsibility to review its own work. A generalist judge, without this expertise or responsibility, must rely on the PTO to have properly issued the patents before it, and is therefore required to presume the patent is valid unless proven otherwise.

Both Congress and the Supreme Court have been clear that IPR serves a significantly different function than that of the courts. The Supreme Court has emphasized that IPR "is 'a second look at an earlier administrative grant of a patent,'" and that it involves "the same statutory requirements" and "the same interests as the determination to grant a patent in the first instance."[17] And Congress' stated goal of post grant proceedings like IPR is to provide "a meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court."[18]

Therefore, the PTO should maintain the BRI standard in IPR so that the re-examination is made under the same standard as that used by the patent examiners to issue the patent. This

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[10] *E.g.*, Michael D. Frakes & Melissa F. Wasserman, *Revising Patent Examiner's Time Allocations*, Berkeley Technology Law Journal (Mar. 12, 2016), http://btlj.org/2016/03/revising-patent-examiners-time-allocations/.
[11] Br. for the Federal Resp., *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365 (2018)., at 20.
[12] *E.g.*, Joe Mullin, *Judge throws out Allergan patent, slams company's Native American deal*, Ars Technica (Oct. 16, 2017), https://arstechnica.com/tech-policy/2017/10/judge-throws-out-allergan-patent-slams-companys-native-american-deal/.
[13] 35 U.S.C. §§ 316(e), 326(e).
[14] 35 U.S.C. § 282.
[15] 81 Fed. Reg. 18,752.
[16] Br. for the Federal Resp., *Oil States*, *supra*, at 4, 16, 20, 23, 30, 36, 47.
[17] *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1374 (2018).
[18] H.R. Rep. No. 112–98(I) at 48 (2011), reprinted in, 2011 USCCAN 67, 78.

consistency is required to properly ensure that the patents that are enforced have been properly granted by the Office. Otherwise, PTAB could be forced to uphold a patent even if, under the standard that is and would still be followed in examination, the patent should not have issued.

Conclusion

We believe that caution should be taken before changing the IPR claim construction standard from the BRI standard used by examiners to the *Phillips* standard used in courts. We believe such a standard would be inconsistent with the goals of IPR and would only serve to reduce the quality of patents that are relied on by courts and the public. Such a reduction in quality would cause real harm to consumers in the form of higher drug prices, and would frustrate the goals of the current administration and Members of Congress on both sides of the aisle that are working towards providing much needed relief from high drug prices for American patients and taxpayers.

Sincerely,

America's Health Insurance Plans
Association for Accessible Medicines
BlueCross BlueShield Association
Citizen Outreach
Consumer Action
Institute for Liberty
Social Security Works