

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

Comment of the Open Markets Institute

Introduction

Prescription drug prices are a major topic of public concern and discussion today. Senator Bernie Sanders has asked, “How can it be that Americans can walk into a drugstore and find that the prices they are paying for their prescription drugs can double, triple, or quadruple, literally overnight?”¹ Food and Drug Administration Commissioner Scott Gottlieb has pledged to make lowering prescription drug prices a priority for his agency.² Cases that have sparked public outrage include Mylan’s steady decade-long increase of the price of the EpiPen,³ Turing Pharmaceuticals’ 5000% overnight price hike on a sixty-year-old medication used by patients with HIV/AIDS and other conditions that weaken their immune systems,⁴ and the persistently high price of insulin.⁵ Unaffordable prescription drugs can strain already tight family budgets, hurt patient health, and cause premature death.⁶

Branded drug companies’ extension of their drug monopolies through aggressive patenting is a key contributor to the unaffordability of prescription drugs. Patent law provides an important incentive to innovate and promotes the public disclosure of new discoveries, including in the pharmaceutical sector. Branded companies, however, often obtain patents on not only the active ingredient in a drug, but also other modifications, such as a change in dosage, formulation, or form. Through this “secondary patenting,” drug companies can foreclose generic competition and extend their monopolies. This elimination of competition inflicts significant harm. Generic competition produces a substantial decrease in drug prices and thereby improves patient access to medicine. By suppressing generic competition,

¹ Bernie Sanders, *Sick of Big Pharma’s Greed*, U.S. NEWS & WORLD REP., Aug. 30, 2017, <https://www.usnews.com/opinion/articles/2017-08-30/bernie-sanders-take-on-big-pharma-and-lower-prescription-drug-prices>.

² Brett Norman, Sarah Karlin-Smith & Brent Griffiths, *Gottlieb Signals Priorities for FDA, Including Drug Pricing*, POLITICO, May 30, 2017, <https://www.politico.com/tipsheets/prescription-pulse/2017/05/30/gottlieb-signals-priorities-for-fda-including-drug-pricing-220567>.

³ Lisa Rapaport, *Another Look at the Surge in EpiPen Costs*, REUTERS, Mar. 27, 2017, <https://www.reuters.com/article/us-health-epipen-costs/another-look-at-the-surge-in-epipen-costs-idUSKBN16Y24O>.

⁴ Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES, Sep. 20, 2015, <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

⁵ Aimee Picchi, *The Rising Cost of Insulin: “Horror Stories Every Day”*, CBS, May 9, 2018, <https://www.cbsnews.com/news/the-rising-cost-of-insulin-horror-stories-every-day/>.

⁶ Liz Szabo, *As Drug Costs Soar, People Delay or Skip Cancer Treatments*, NPR, Mar. 15, 2017, <https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments>.

branded companies maintain monopolistic pricing, inflicting economic hardship on patients and their families and threatening patient health.

The Open Markets Institute welcomes the opportunity to comment on the U.S. Patent and Trademark Office’s (USPTO) proposed change to patent claim construction in *inter partes* and other trial proceedings before the Patent Trial and Appeal Board (PTAB). In construing patents in PTAB proceedings to decide challenges to patent validity, the USPTO proposes to replace the current “broadest reasonable interpretation” standard with the “ordinary and customary meaning” standard. The Open Markets Institute is concerned that the proposed change to the claim construction standard threatens to protect low-quality secondary drug patents against challenges to their validity in *inter partes* and post-grant review proceedings. By protecting trivial changes to existing drugs, these patents help create unjustified drug monopolies. The USPTO’s proposed rule could grant branded drug companies more power to use secondary patenting to exclude generic rivals from the market and, as a result, make even more prescription drugs unaffordable. Before finalizing this proposal, the USPTO must examine the consequences for prescription drug competition and patients. If the USPTO finds that the proposal would protect low-quality pharmaceutical patents against challenges to their validity, it must withdraw the proposed change to the claim construction standard in PTAB proceedings.

I. Through Secondary Patenting, Branded Pharmaceutical Companies Can Maintain Their Monopolies and Harm the Public

Branded drug companies often pursue an aggressive patenting strategy to maintain their monopolies. For branded companies, the loss of patent protection, especially on a “blockbuster drug,” can represent the loss of billions of dollars in annual revenues and profits.⁷ While patents are an important tool for promoting innovation in the drug sector, branded companies often obtain patents on drug features besides the active ingredient, a strategy known as secondary patenting.⁸ On branded drugs, the number of secondary patents often exceeds the number of patents on active ingredients.⁹ As an extreme example, AbbVie’s best-selling anti-inflammatory drug, Humira, is protected by a thicket of over 100 patents.¹⁰ For branded drugs with patents on an active ingredient, secondary patents extend patent protection by an average of 4 to 5 years.¹¹ For branded drugs without patents on an active ingredient, secondary patents are even more important and extend patent protection by an average of 9 to 11 years.¹²

Studies suggest that secondary patents frequently cover trivial changes to existing pharmaceutical drugs. Secondary patents attract more legal challenges to their validity than patents that cover the active

⁷ Doni Bloomfield, *Why Drugmakers Aren’t Sweating the Next Wave of Patent Losses*, BLOOMBERG, July 7, 2017, <https://www.bloomberg.com/news/articles/2017-07-07/why-drugmakers-aren-t-sweating-the-next-wave-of-patent-losses>.

⁸ Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 513-533 (2016); Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades*, 31 HEALTH AFF. 2286, 2288 (2012).

⁹ Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLOS ONE 1, 6 (2012).

¹⁰ Cynthia Koons, *This Shield of Patents Protects the World’s Best-Selling Drug*, BLOOMBERG BUSINESSWEEK, Sep. 7, 2017, <https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug>.

¹¹ Kapczynski et al., *supra* note 9, at 6.

¹² *Id.*

ingredient in a drug.¹³ This finding indicates that secondary patents are more likely to be low quality (not meeting the nonobviousness and novelty criteria for patentability). Examples of slight but profitable reformulations include “the makers of the antidepressant Prozac and the cholesterol treatment TriCor switch[ing] from capsule to tablet form.”¹⁴ These cases are not outliers: For branded drug companies, making such changes to a drug’s form is a common strategy to extend patent monopolies.¹⁵

Many secondary patents may fail to satisfy the basic logic of the patent laws and the intellectual property system. The founders established the patent system to enable innovators to obtain a term-limited private monopoly in exchange for making a socially valuable discovery and disclosing it to the public.¹⁶ Secondary patents, however, often simply allow branded drug companies to extend their monopoly without necessarily providing the public a therapeutic advance or other benefit in return.

Secondary patenting can undermine pro-competitive state laws on prescription drug dispensation. Under drug product selection laws in all states, pharmacists can or must substitute an equivalent lower-cost generic for the branded equivalent, unless the prescribing physician directs the pharmacist to dispense only the branded version.¹⁷ Competition at the point of sale is critical to ensuring affordable drugs. Generic substitution yields significant savings to individual patients and their families, and to the public. According to a study by the generic drug industry’s trade association, generic drug substitution produced cost savings of more than \$1.6 trillion between 2007 and 2016.¹⁸

Branded drug companies often use secondary patenting as part of a larger strategy to extend their prescription drug monopolies. In an “evergreening” or “product hopping” plan, branded companies reformulate an existing branded drug, obtain a secondary patent on new drug features, and market the new product to doctors and other prescribing providers.¹⁹ Because physicians who prescribe drugs do not bear the cost of drugs, they do not necessarily consider costs when selecting appropriate drugs for patients. Once a critical mass of providers prescribes the new patent-protected reformulation (for which no generic alternative exists), the branded company deprives pharmacists of the ability to substitute lower-cost generic versions at the point of sale.²⁰ To execute this product hop, branded drug companies have sometimes paid generic competitors to delay market entry so that the branded company has enough time

¹³ C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1386 (2013); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 328, 336-37 (2012).

¹⁴ Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1017 (2010).

¹⁵ Mike Hutchins, *Extending the Monopoly – How ‘Secondary Patents’ Can Be Used to Delay or Prevent Generic Competition Upon Expiry of the Basic Product Patent*, 1 J. GENERIC MEDS. 57, 67 (2003).

¹⁶ The U.S. Constitution authorizes Congress to enact patent (and copyright) laws “[t]o 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.” U.S. CONST. art. I, § 8, cl. 8. Summarizing the writings of Thomas Jefferson on the patent system, the Supreme Court has stated that “[o]nly inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly.” *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966).

¹⁷ OFFICE OF THE ASSISTANT SEC’Y FOR PLANNING & EVALUATION, DEP’T OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS 3, app. A (2010), <http://aspe.hhs.gov/sites/default/files/pdf/76151/ib.pdf>.

¹⁸ ASSOC. FOR ACCESSIBLE MEDICINES, GENERIC DRUG ACCESS & SAVINGS IN THE U.S. 20, 39, <https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>.

¹⁹ Feldman & Frondorf, *supra* note 8, at 513-33.

²⁰ Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 N.D. L. REV. 167, 175-76 (2016).

to move the market to the reformulated version of the drug.²¹ Given the harm to patients and the public from this conduct, antitrust enforcers have sued branded drug companies for engaging in exclusionary product hopping.²²

Through the foreclosure of generic drug competition, branded companies can maintain monopolistic prices on prescription drugs for several additional years. To appreciate the harm to the public, consider the benefits from generic competition. When the first generic competitor to a branded drug enters the market, the price for the generic drug is, on average, 13% lower than the branded drug.²³ When a second generic maker enters the market, generic drug prices fall to roughly half of the branded drug's pre-generic entry price.²⁴ As the number of generic competitors increases, prices fall further: by the time ten generic rivals have entered the market, the generic price is generally 80% lower than the branded drug's pre-generic entry price.²⁵ As an example of this beneficial price competition, when Pfizer's Lipitor faced full generic competition, patients' median out-of-pocket costs for the generic version were nearly 85% lower than out-of-pocket costs for brand-name Lipitor.²⁶ When branded drug companies exclude generic equivalents through secondary patenting and product hopping, they block this price competition and preserve their power to charge monopolistic prices.

In addition to extracting more money from patients, the maintenance of prescription drug monopolies can hurt patient health. Due to the unaffordability of monopoly prescription drugs, patients may not follow their doctors' directions on use and even forgo taking a prescribed drug.²⁷ Patients struggling to meet their other obligations may place lower priority on their essential, but costly, prescription drug regimen. For instance, a person with diabetes may prioritize paying her monthly rent over taking her insulin as directed.²⁸ As this example illustrates, forgoing prescription drugs can have serious adverse effects on patient health, including premature death.²⁹

II. The USPTO Must Consider the Effects of the Proposal on the Quality of Secondary Patents in Pharmaceuticals

Improving patent quality is essential for addressing exclusionary conduct in the market for prescription drugs. By improving patent quality, branded pharmaceutical companies would have less freedom to abuse the patent system to perpetuate their monopolies. Higher standards of patentability would advance the core logic of the intellectual property system in pharmaceuticals (and other sectors). Branded drug companies could obtain patent protection for genuine advances but would not be able to acquire patent monopolies for minor changes to existing drugs. When low-quality patents are invalidated

²¹ For an example of how pay-for-delay strategies are used to facilitate product hopping, see Michael A. Carrier, *Provigil: A Case Study of Anticompetitive Behavior*, 3 HASTINGS SCI. & TECH. L.J. 441 (2011).

²² *E.g.*, *New York v. Actavis PLC*, 787 F.3d 638 (2015).

²³ Chintan V. Dave, Abraham Hartzema & Aaron S. Kesselheim, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 NEW ENG. J. MED. 2597, 2598 (2017).

²⁴ U.S. Food & Drug Admin., *Generic Competition and Drug Prices*, <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> (last visited Jul 5, 2018).

²⁵ Dave et al., *supra* note 23, at 2598.

²⁶ Jing Luo et al., *Effect of Generic Competition on Atorvastatin Prescribing and Patients' Out-of-Pocket Spending*, 176 J. AM. MED. ASSOC. INTERNAL MED. 1317, 1320-21 (2016).

²⁷ *E.g.*, Carolyn Y. Johnson, *Expensive Specialty Drugs Are Forcing Seniors to Make Hard Choices*, WASH. POST WONKBLOG, 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=.a66477e11fd0.

²⁸ Picchi, *supra* note 5.

²⁹ Szabo, *supra* note 6.

in federal court or the PTAB, the public benefits can be substantial. For example, in the market for anti-hypertension medications, successful judicial challenges to the validity of relevant patents are estimated to have saved drug purchasers more than \$42 billion between 2000 and 2008.³⁰

Inter partes and post-grant reviews are important for tackling the unaffordability of prescription drugs. These proceedings can play a critical role in invalidating low-quality patents in all areas, including the pharmaceutical sector.³¹ Any member of the public (besides the owner of the relevant patent)³² can use *inter partes* and post-grant review to challenge the validity of patents. This open participation standard is essential in pharmaceuticals. While generic drug companies are most likely to have standing to challenge the validity of branded drug patents in federal court, they are not reliable challengers and cannot be viewed as proxies for the public interest. When litigating patent validity, generic drug makers have a history of entering into collusive pay-for-delay settlements with branded drug companies, which enrich both parties at the expense of the public.³³

The USPTO's proposal could worsen the problem of monopolistic secondary patenting on branded pharmaceuticals. The proposal would replace, in *inter partes* and post-grant review PTAB trial proceedings, the broadest reasonable interpretation standard for claim construction with the ordinary and customary meaning standard. By shrinking the scope of prior art against which a patent is read, the proposal could increase the likelihood that pharmaceutical patents that lack nonobviousness or novelty are upheld in *inter partes* and post-grant reviews. This proposed standard of claim construction could protect low-quality secondary patents on prescription drugs and even encourage branded drug companies to develop and patent more marginal changes to existing drugs. If this is true, the USPTO's proposal would produce longer effective drug monopolies, higher prescription drug prices, and more adverse effects on patient health.

Before finalizing this proposal, the USPTO must consider the implications for patent quality in pharmaceuticals. Specifically, it must determine whether the proposed claim construction standard could protect more secondary pharmaceutical patents of low quality. Branded drug companies, under the proposed claim construction standard, may be able to defend secondary patents that lack either novelty or nonobviousness, against challenges to their validity.

III. Conclusion

The Open Markets Institute thanks the USPTO for the opportunity to comment on this notice of proposed rulemaking. Through secondary patenting of trivial changes to existing drugs, branded drug companies can foreclose generic competition and extend their monopolies. In other words, patients and third-party payors are forced to bear the burden of monopoly without receiving a therapeutic benefit in exchange. Secondary patenting is a key reason that essential prescription drugs are unaffordable for many Americans.

³⁰ Lee Branstetter, Chirantan Chatterjee & Matthew J. Higgins, *Regulation and Welfare: Evidence from Paragraph IV Generic Entry in the Pharmaceutical Industry*, 47 RAND J. ECON. 857, 887 (2016).

³¹ Jonathan J. Darrow, Reed F. Beall & Aaron S. Kesselheim, *Will Inter Partes Review Speed U.S. Generic Drug Entry?*, 35 NATURE BIOTECH. 1139 (2017).

³² 35 U.S.C. §§ 311(a) & 321(a) (2018).

³³ FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 3 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>. In 2013, the Supreme Court held that these pay-for-delay agreements between branded and generic drug companies are subject to antitrust scrutiny. The Court, however, declined to treat them as presumptively illegal and held that they must be analyzed under the rule of reason. *FTC v. Actavis, Inc.*, 570 U.S. 136, 159-60 (2013).

The USPTO’s proposal could insulate low-quality secondary patents in pharmaceuticals from successful challenges to their validity in *inter partes* and post-grant reviews. Given that the affordability of prescription drugs is a life-or-death matter, the USPTO must examine the implications of its proposal for pharmaceutical patents, especially patents on drug properties besides active ingredients. If the USPTO determines that the proposed change to claim construction in PTAB proceedings would impair the ability of the public to challenge the validity of low-quality pharmaceutical patents, it must withdraw this proposal.