FDA commissioner, two senators raise concerns about patent abuse by pharmaceutical companies

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In a bid to address the high cost of medicines, Food and Drug Administration Commissioner Janet Woodcock wrote the U.S. Patent and Trademark Office to express concern about moves that companies use to extend their monopolies as well as suggestions for curtailing some of these practices.

The Sept. 10 letter was sent in response to an executive order[5] issued last June by President Biden to lower prescription drug prices, notably by promoting more competition through greater access to generics and biosimilar medicines. The Biden administration has targeted the rising cost of medicines as a key initiative and various proposals are winding their way through Congress.

Patents, in particular, have increasingly become a contentious topic in the wider debate over the rising cost of prescription medicines in the U.S. The issue reflects concerns that drug makers have increasingly been granted patents that arguably add little to medical innovation, but extend their monopolies that not only forestall lower-cost competition but also permit ongoing price hikes.

For her part, Woodcock echoed such concerns in her letter.

"We believe that rewarding innovation should not improperly forestall access to lower cost medicines. We fully acknowledge that the regulatory structure surrounding drugs is complex, and not all of the gaming of the system is related to patents or their issuance. Certain uses of the patent system, however, have been criticized as allowing companies to inappropriately impede" generics and biosimilars, she wrote[8] to acting PTO Director Andrew Hirshfeld.

Toward that end, a coalition of advocacy and nonprofit groups three months ago noted the White House has yet to nominate a new PTO director and see this as an opportunity to overhaul the approach[9] to issuing patents that may sometimes prevent Americans from accessing needed medicines. The Biden administration has yet to nominate anyone, though.

"The PTO looks to Europe and industry for advice on patent quality, but the agency needs to look closer to home. Agencies need to talk to each other. The FDA has extensive knowledge of the particular drug and the state of the art in the industry, which could help the PTO," said Robin Feldman, director of the Center for Innovation at University of California Hastings, and co-author of a recent paper[10] in Nature Biotechnology that proposed greater coordination among agencies, among other things.

More specifically, Woodcock pointed to the practice of filing follow-on patents that create what are known as patent thickets, another way of describing numerous — sometimes, dozens — of patents that make it time-consuming and costly for other companies to successfully win the right to sell a lower-cost version of the patented medicine. AbbVie (ABBV), for instance, has been widely cited as a textbook case[11] for nearly 250 patent applications filed for its best-selling Humira arthritis treatment.

Woodcock also cited "evergreening," which refers to additional patents for an existing medicine that claim to add a new formulation or methods for using a medication, but without providing any significant innovation. She noted that a paper[12] written three years ago by Feldman in the Journal of Law & Biosciences found 78% of drugs listed from 2005 through 2015 in the FDA Orange Book – a database of patents – were for existing medicines, not new ones entering the market.

Still another area of concern is "product hopping," in which a drug maker makes modest reformulations to a medicine, such as different dosing, without offering substantive therapeutic advantages. The company then launches its updated version and removes the older drug from the market before a generic copy becomes available, which forces patients to switch to its newer medicine. Actavis, an AbbVie unit, tried such a gambit[13]. Drug makers believe patients are more likely to remain on a newer medicine even after a lower-cost generic becomes available.

To fulfill the mandate set out by the executive order, Woodcock suggested a few steps that both the FDA and the PTO could take. These included working with PTO examiners as they review patent applications as well as joint training for reviewing patent extensions. She also raised the idea of using data from the Patent Trial and Appeal Board, a PTO unit that hears patent challenges, to hasten availability of generic drugs. We asked the PTO for comment and will update you accordingly.

Woodcock was not the only one reaching out to the PTO last week to express concerns about patent abuse by the pharmaceutical industry.

In a Sept. 9 letter[14], two senators complained to Hirshfeld about companies that submit "significantly" different information to different agencies. Specifically, they noted that patent applications submitted to the PTO may contain contradictory information sent to the FDA about such claims as a patent for a novel invention. When such instances occur, they suggested the PTO should not only reject the application but, if there was "bad intent," then sanctions may be warranted.

"We seek to understand the circumstances around such statements, as such a practice could undermine both patent quality and competition. To improve the system, we write today to request that the PTO consider necessary measures requiring patent applicants to disclose additional information during the patent examination process," wrote Sen. Patrick Leahy (D-Vt.) and Sen. Thom Tillis (R-N.C.), both of whom are members of the Senate Judiciary Committee, which oversees the PTO.

The missives were seen as confirmation that the role played by the PTO in the pharmaceutical pricing debate is gaining traction, according to Priti Krishtel, a co-founder and co-executive director of the Initiative for Medicines, Access & Knowledge. The nonprofit led the coalition that recently urged the White House to name a new PTO director that would embrace this issue and, as part of its work, examined the large number of patent applications filed by AbbVie for Humira and by Merck (MRK) for its Keytruda cancer treatment[15].

"There is a growing recognition by policymakers that in order to solve the drug pricing problem long-term, we must solve the drug patent problem. This growing recognition is also bipartisan: for Senators Leahy and Tillis to acknowledge this link together is a turning point in the conversation," she wrote us. "While both the FDA letter and the Leahy-Tillis letter are a step in the right direction, we need actionable change by policymakers to provide relief to American patients and families."

About the Author

Ed Silverman[2]

Pharmalot Columnist, Senior Writer

Ed covers the pharmaceutical industry.

ed.silverman@statnews.com [16]
@Pharmalot [3]

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