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US FDA's Patent 'Concerns' Include Thickets, Product Hopping, And Evergreening

by M. Nielsen Hobbs

Senators press for sharing of FDA applications with PTO as Woodcock letter seeks collaboration on everything from PTAB to patent term extensions to 'possible misuse of the patent system.'

The US Food and Drug Administration is seeking to work with the Patent and Trademark Office on a variety of hot-button issues, but it seems unclear how much impact the collaboration will have on the intellectual property landscape for the pharmaceutical industry.

Nevertheless, the 10 September *letter* from acting FDA Commissioner Janet Woodcock to PTO's Drew Hirshfeld will only increase the attention on patent reform as mechanism for drug cost reductions, and if Congress makes any changes aimed at curbing the areas of concern that FDA identified, that could have major consequences for product sponsors.

The "areas of concern" that could delay generic or biosimilar competition identified by Woodcock in her letter include:

- Patent "thickets" created by filing continuation patents for inventions disclosed in earlier patents;
- "Evergreening" products through patenting post-approval changes to formulations, delivery mechanisms or additional methods of use; and
- "Product hopping" by which sponsors create a "modified drug product" that has "the practical effect of forestalling competition" because the market has moved on from the original product.

None of these concerns are new issues, and they are not accompanied by any specific reform suggestions, but Woodcock's letter is a reminder to industry that patents are on the administration's radar as it develops its own plans for drug pricing reforms while Congress debates Medicare negotiations.

The letter notes the value of patents to innovation but also worries about "possible misuse of the patent system." Woodcock tells Hirshfeld, "We would be interested in learning USPTO's perspective on these practices and whether it is considering means of limiting" them.

One intriguing suggestion in Woodcock's letter is an offer to "facilitate examiners' work by offering training of FDA public information and databases that may help US PTO locate pertinent references and determine whether particular documents constitute prior art."

FDA also wonders whether providing more time or resources to PTO examiners considering pharmaceutical patents "would help ensure the right balance of rewarding innovation and facilitating patents competition."

Another possibility for "joint training could include FDA and USPTO's roles in determining a product's eligibility for patent term extension."

Finally, Woodcock wants to know what impact the Patent Trial and Appeal Board on Orange Book-listed patents, and "how the PTAB framework might be optimized to support timely availability of generic drugs."

The Executive Order

Woodcock was directed to write the letter by President Biden's *Executive Order 14036*, "Promoting Competition in the American Economy," which also told HHS to develop its recently released drug pricing plan.

In addition to "enumerating and describing any relevant concerns" to PTO, FDA is instructed by the Executive Order to work with states and tribes on developing drug importation programs.

In a separate section, the Executive Order tells FDA to support biosimilar "adoption by providing effective educational materials and communications to improve understanding of biosimilar and interchangeable products." FDA is also instructed to work with the Federal Trade Commission to address "any efforts to impede generic drug and biosimilar competition, including but not limited to false, misleading, or otherwise deceptive statements about generic drug and biosimilar products and their safety or effectiveness."

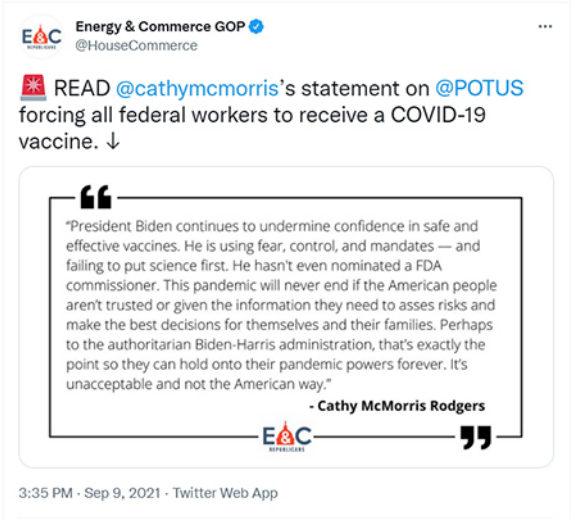
FDA and FTC already have some initiatives in this regard, but the Executive Order will likely help to enhance them. (Also see "*FDA/FTC's Hot Ticket: Biosimilar Workshop On How To Boost Market,*

From Education To Lawsuits" - Pink Sheet, 12 Mar, 2020.)

The Implications For Woodcock

It is impossible to look at FDA's letter to Hirshfeld and not think about how it is intended to be read by broader audiences, particularly Congress, where Woodcock's bid to become permanent commissioner has stalled after several senators questioned how closely aligned she is with product sponsors.

Expressing concerns about potential patent abuses could help Woodcock show that she is not captured by industry, but time may be running out to make that case, because unless Biden nominates someone for FDA commissioner by 16 November, Woodcock would need to step aside as acting commissioner. (Also see "*Like Sands Through The Hourglass, So Are The Days Of Woodcock's Acting FDA Commissionership*" - Pink Sheet, 21 Jun, 2021.)



Pressure continues to build on the administration to act quickly, and the lack of a confirmed commissioner is becoming a talking point for vaccine skeptics. (*See tweet.*)

The Democrats' one-vote margin in the Senate means that Biden is unlikely to risk antagonizing any Senator by nominating anyone they are offended by, so *FDA's recent moves on opioids* and now drug pricing will need to be persuasive if Woodcock hopes to get the nod.

FDA's Role In Drug Pricing

FDA, as it reiterates in the PTO letter, does not have direct authority on drug pricing, but "we play an indirect role in holding down prices by bringing efficiencies to the drug development and review process and by promoting robust competition for established drugs."

It's a role that FDA openly embraced when Scott Gottlieb was commissioner and has continued to emphasize.

Congress has also tried to adjust FDA's review mechanisms to speed generic entry and reduce drug spending, and under the Orange Book Transparency Act of 2020, the agency needs to solicit comments on what patent information should be listed. (Also see "*US FDA Mulls 'Orange Book' Listing For Device, REMS, Digital App Patents*" - Pink Sheet, 29 May, 2020.)

FDA's summary is due to Congress by 5 January 2022, and how the agency choses to frame

potential changes could go a long way to determining whether any such reforms are included in the must-pass user fee legislation next year.

FDA And PTO Need To Get The Same Info, Senators Say

Just as drug pricing reform is one of the few remaining policies with bipartisan support in America, patent adjustments are one of the few approaches to achieving the goal which also enjoys bipartisan support. (Also see "*Rx Patent Reform Gets Renewed Interest From GOP As Alternative To Price Negotiation* " - Pink Sheet, 17 Oct, 2019.)

Just a day before Woodcock's letter, Senate Judiciary Subcommittee on Intellectual Property Chair Senator Patrick Leahy (D-Vt.) and Ranking Member Thom Tillis (R-N.C.) *wrote to Hirsfeld* "requesting the PTO take steps to reduce patent applicants' making inappropriate conflicting statements in submissions to the PTO and other federal agencies."

The senators cited "inconsistent statements" submitted to FDA "to secure approval of a product – asserting that the product is the same as a prior product that is already on the market – can then be directly contradicted by statements" made to the PTO to secure a patent.

"When a certain piece of prior art is already being applied by the examiner, and the patent applicant has made statements about that prior art to another federal agency that establish that the invention claimed is not novel, making conflicting statements to the PTO should be cause for rejecting the application and, when made knowingly and with bad intent, potentially other sanctions," Leahy and Tillis write.

How big a problem the lack of sharing is in patent prosecution remains to be seen. The senators may have been inspired by the recent *Belcher Pharmaceuticals v. Hospira* case, where the Court of Appeals for the Federal Circuit upheld on 1 September the district court decision that the '197 patent related to Belcher's 505(b)(2) for an epinephrine injection is unenforceable due to inequitable conduct.

If PTO does issue a rule requiring sponsors to share their FDA submissions as part of their PTO applications, though, it will certainly add to their administrative burdens and complicate their patent defenses, if nothing else.