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Orange Book Is The New Spat: FTC Seeks Removal Of 'Improperly' Listed Medical Device Patents

by Brian Bossetta

The US Federal Trade Commission wants to clean up the FDA's Orange Book by purging medical device patents that the commission says should not be in the listing. The FTC argues improper patents in the Orange Book block lower-cost generic equivalents from coming to market. *Medtech Insight* spoke to attorney Sara Koblitz about the FTC's delisting push.

The Federal Trade Commission has challenged more than a hundred medical device patents listed in the Food and Drug Administration's Orange Book, claiming the improper listings stifle competition and further increase the price of drugs.

The Orange Book — officially the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" — is the agency's authoritative guide to approved prescription drugs.

Along with publishing all FDA-approved medications, the Orange Book includes a drug's active ingredients, dosage forms, strengths and approval dates, as well as information on therapeutic equivalence for generics.

Additionally, the book includes pertinent patent information for the listed drugs.

But as Sara Koblitz, director at the law firm Hyman, Phelps & McNamara, told *Medtech Insight*, the Orange Book also lists medical devices such as inhalers and injectors that deliver drugs. These device patents, however, are not listed separately in the Orange Book but as part of the patented drug.

"If the drug is used with the device, then the device can be listed with the drug," Koblitz said.

Patent Protection

Koblitz further explained that listing device patents in the Orange Book provides companies with pre-approval enforcement of their patents, which allows them to bring patent infringement litigation against a potential competitor before that competitor's product has been approved.

For example, as Koblitz pointed out in a recent *FDA Law Blog* post, Teva Pharmaceutical initiated pre-launch patent litigation against Amneal Pharmaceuticals in March for infringement of five of its Orange Book-listed patents related to Teva's combination product, ProAir HFA, which is the brand name of the drug albuterol sulfate used with a metered dose inhaler.

> *"Wrongfully listed patents can significantly drive up the prices Americans must pay for medicines and drug products while undermining fair and honest competition." — Lina Khan*

In response to Teva's patent litigation, Amneal filed a counter claim seeking a declaratory judgment of non-infringement and asked the court to invalidate the five Teva patents and have them removed from the Orange Book. Amneal further sought relief from "allegedly anticompetitive conduct in violation of state and federal antitrust laws."

The FTC, Koblitz pointed out, filed an amicus brief in that suit arguing that the Teva patents "do not claim" any FDA-approved drug.

In her blog, Koblitz cites the FTC's view: "Device patents that do not mention any drug in their claims do not meet the statutory criteria for Orange Book listing, and a device patent that is improperly listed in the Orange Book must be delisted."

Last month, the District Court of New Jersey *ruled* Teva's patents were improperly listed and ordered their removal from the Orange Book.

Moreover, the court also ruled that Teva's patents, which only covered the inhaler component of the ProAir HFA drug, are not properly listed either.

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Koblitz quotes the court's opinion: "The inhaler patents do not claim the drug for which the applicant submitted the application."

As Koblitz later explained, this means that while the court acknowledged that the definition of a drug is broad enough to include the device used to deliver it — in this case the inhaler — the court also found the definition too narrow to establish the claim on the inhaler patents without specifying the drug used with the inhaler.

In other words, because the FDA identified "albuterol sulfate HFA inhalation aerosol" as the drug on Teva's new drug application (NDA) to the agency, albuterol sulfate must be claimed in the inhaler patent for it to be eligible for Orange Book listing.

Teva has appealed the ruling.

More Aggressive Posture

In November 2023, the FTC sent letters to 10 of the biggest pharmaceutical companies, including Teva, challenging more than one hundred patents of brand-name asthma inhalers, epinephrine autoinjectors, and other combination products as improperly or inaccurately listed in the Orange Book.

The FTC also notified the FDA that it disputes the accuracy of these patents.

"The FTC has now taken the position that device patents that do not include the specific drug product that is delivered by that device shouldn't be listed," Koblitz said, noting this issue is one the FDA would rather not deal with and has kicked down the road for some time.

"The FDA has never opined on it," she added. "They've been asked the question since 2005 and have refused to answer. So, everybody has been listing their device patents assuming they are integral to the use of the drug product listed in the book."

But while the FDA has not been clear on the patent question, the FTC now has.

Anticompetitive

As part of its more aggressive posture, the FTC, Koblitz said, has decided that a company listing a device patent that does not include the specific drug that goes with that device is anticompetitive.

In announcing its action against the 10 pharma companies, FTC Chair Lina Khan said wrongfully listed patents not only drive up prices but undermine "fair and honest competition" as well.

> *“These patents are valid patents. Just because they don't claim a drug substance doesn't mean there's anything wrong with the patents themselves.” — Sara Koblitz*

While some companies have complied with the FTC’s request to remove their patents from the Orange Book, others have refused, Koblitz noted.

And of those, Koblitz said Teva has taken the firmest stance in resisting the commission. As recently reported in the *Washington Post*, the FTC has launched an investigation into the company for its refusal to delist several of its inhaler patents.

What’s important for the device industry, in Koblitz’ view, is the value the FTC places on device patents.

“The framing of these patents is that they are junk or sham patents,” she said, adding that this terminology, which is catching on in Congress, is harmful to the medical device industry.

“These patents are valid patents,” Koblitz added. “Just because they don't claim a drug substance doesn't mean there's anything wrong with the patents themselves.”

Regardless of how successful Teva is in standing up to the FTC or how things shake out in various challenges in court, Koblitz believes the commission is going to keep pushing.

“The FTC has been submitting amicus briefs in these run-of-the-mill patent disputes that often occur for drug-device combination products stating that the patents never should have been listed in the Orange Book in the first place,” Koblitz said. “They are being extraordinarily aggressive. So, I don't see this going away anytime soon.”

Medtech Insight has reached out to Teva for comment.