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What To Watch As The FTC Targets Drug Patent Listings

By **Ryan Davis**

Law360 (May 30, 2024, 5:40 PM EDT) -- The Federal Trade Commission has been scrutinizing patents listed by drugmakers on a key federal database, warning several companies that their listings are improper and drive up drug prices. Here's a look at what the agency and others could do next.

The commission raised concerns in a September policy statement about patents being improperly listed in the U.S. Food and Drug Administration's Orange Book, which identifies approved drugs and the patents that the manufacturers say cover them.

In November, the FTC sent warning letters to 10 drugmakers identifying more than 100 "junk patents" it said were improperly listed, mostly covering drug delivery devices like inhalers or injectors rather than the drugs themselves.

The commission has argued that wrongly listed patents delay generic drugs from entering the market, keeping the price of branded drugs artificially high. Some letter recipients delisted their patents, but others did not.

The FTC sent additional letters in April, targeting 300 more patents owned by 10 companies, including Boehringer Ingelheim, maker of the chronic obstructive pulmonary disease Striverdi, and Novo Nordisk, maker of the injectable weight loss drug Ozempic. Recipients of those letters have until June 8 to respond.

Regarding the recipients of the first letters, an FTC official told Law360 that "we are discussing next steps for the companies that ignored our warning letters and did not remove their patents. The FTC does not make empty threats."

Jonathan Turpin of Locke Lord LLP said that given the FTC's actions and statements, "the obvious question is then, 'What's next?'"

"FTC in their policy statement identified several potential next steps that they could take, that they believe are available to them," he said. "And so how exactly they go about that I think is the unanswered question."

Preetha Chakrabarti of Crowell & Moring LLP said she will be watching for the commission's next move because "it's interesting for the FTC to be so in the weeds and involved in patents," and scrutinizing what patents cover is "not something the FTC does every day."

"Are they going to take more aggressive action? Do they have the resources to do that?" she said. "They are trying to fry a lot of fish right now, across many industries and many aspects of what's under the authority that the FTC has."

Experts said several actions could follow the letter campaign — by the FTC and others.

FTC Enforcement

The FTC's letters said they were sent under the FDA's dispute resolution process for improper Orange Book listings, but the FDA maintains that it doesn't have jurisdiction to address patent listings itself.

So when drugmakers argue that their patents are properly listed, it is up to the FTC to decide whether to take further action. The letters said that "may include investigating this conduct as an unfair method of competition."

If the FTC takes that route, it would be hard-fought and expensive, experts said, and would put its theories that the patents are wrongly listed and harm competition to the test.

"They would have to really make some sort of argument that it's anticompetitive to have them improperly listed, which would be a little bit of a novel sort of argument," said Melissa Wasserman, a professor at the University of Texas School of Law.

The commission detailed its position in a March brief in a case where Teva Pharmaceuticals accused Amneal Pharmaceuticals of infringing asthma inhaler patents, which Teva refused to delist after receiving a FTC letter last year.

FDA regulations require that listed patents cover either a drug substance or a drug product. Drugmakers argue that inhalers and other delivery devices are drug products, but the FTC said such patents are not tied to a specific drug and cannot be listed.

"In 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," the brief said.

The FTC said that is important because Hatch-Waxman Act infringement suits on Orange Book-listed patents trigger a 30-month stay of approval of a generic drug during litigation, which the commission says blocks competition and increases drug prices.

The FTC says it's clear drug-device patents shouldn't be in the Orange Book, but others say the statute is murky. A 2023 U.S. Government Accountability Office report said many stakeholders believe FDA guidance is insufficient to determine which device patents should be listed. Drugmakers could thus argue their listings were in good faith, and they aren't liable for unfair competition.

If the FTC prevailed in court, it could seek damages or an order requiring patents to be removed. Experts said that would benefit generic-drug makers, though some questioned how much effect it would have.

Chakrabarti said she could see the FTC's perspective that removing patents from the Orange Book "could potentially increase competition or make the burden lighter for those trying to enter the market."

Delisting patents does not invalidate them, but means they can't be used by branded drugmakers for a 30-

month stay of generic approval, and generic-drug makers don't need to show they are invalid or not infringed before they launch.

Generic-drug makers can still be sued over patents not in the Orange Book after their product enters the market, though such cases don't come with an automatic injunction and may be more challenging for patent owners, attorneys said.

If a branded drug only lists device patents in the Orange Book, their removal "would be extremely effective" in speeding up generic approval, said Turpin. But "there are other scenarios you can imagine where it might not have an effect," like if other patents trigger the stay.

More Patent Delistings

Michael Carrier, a professor at Rutgers Law School, said "the FDA is unclear as to precisely what patents should be listed," and companies could ignore the letters because the FTC doesn't technically enforce Orange Book listings.

"But they may seek to avoid bad publicity and the possibility (even if far from certain) of an FTC lawsuit challenging the listing (perhaps amidst an array of potentially anticompetitive conduct) by withdrawing ... patents from the Orange Book, as happened with the last round of letters," he said by e-mail. "A very positive outcome for the FTC is this withdrawal."

While it's unclear that the FTC will take enforcement action, by sending the letters, "the clear message is, 'We are going to come after you,'" said Michael Risch, a professor at Villanova University's Charles Widger School of Law.

"They are probably also sending the warning saying, 'Stop doing it, and stop doing it in the future,' because they're trying to avoid having to bring a million actions against all of the manufacturers," he said.

Lawsuits by Others

The FTC might also hope that its letters provide a road map for litigation by others challenging patent listings, like generic-drug makers or direct purchasers, said Arti Rai, a professor at Duke University School of Law.

The commission may have a plausible case, but "antitrust cases take time and money to litigate, and the FTC is not necessarily as well-heeled as perhaps a competitor might be or maybe a set of insurance companies," she said.

Health and welfare funds followed the FTC's lead in April with a proposed class action against Boehringer over inhaler patents the company didn't delist after receiving the commission's warning letter. The suit claims the improperly listed device-only patents let the company monopolize the market for its respiratory drugs.

The FTC's policy statement highlighted a similar suit. In 2020, the First Circuit ruled that Sanofi-Aventis shouldn't have listed an injector patent for its long-acting insulin product Lantus on the Orange Book, reviving a dismissed antitrust suit that remains ongoing.

Generic-drug makers have also filed suits targeting Orange Book patent listings, and until the FTC got involved, "that was kind of where all the action was," Turpin said.

Since the FDA does not police listings, "it's up to third parties, typically generic companies, to challenge improperly listed patents," he said. "FTC taking an interest has, I think, accelerated things, but it's not a completely untested area."

FDA Actions

Regardless of what the FTC does, experts said the FDA could get more involved in patent listings, either by policing submissions or clarifying the regulations.

The agency has long said it plays only a "ministerial" role with the Orange Book because it doesn't have patent expertise, "so one thing you might think this may do is incentivize them to take a more active role in reviewing the patents that are listed," Wasserman said.

"To me, a lot of this could be solved if the FDA just took a little bit more of an aggressive stance," she added. That could involve bringing on experts or collaborating with the U.S. Patent and Trademark Office to determine if patents listed by drugmakers cover things that are permitted under the law, she said.

Experts said it could also be helpful for the FDA to more clearly define which patents can be listed. The agency's January agenda of guidance it is preparing to release this year included an item about patent listings without additional details.

An FDA spokesperson said the agency "is working on new guidance on submission of patent information for listing in the Orange Book, planned for publication in calendar year 2024. We do not have further information to provide at this time."

Potential Legislation

There's also room for Congress to act. At a hearing this month, senators expressed **concern** about the role of patents in drug prices, including those on delivery devices being listed in the Orange Book.

A Congressional Research Service report this month listed actions Congress could take on the issue, such as clarifying statutes governing patents that can be listed in the Orange Book, and expanding procedures for challenging listings. In addition, lawmakers could review if the 30-month stay should apply only to certain patents, like those on active ingredients but not drug-delivery devices, the report said.

Since lawmakers have shown interest, "no doubt the FDA is getting some pressure from Congress to think about doing more than it has been doing in the last few decades," Rai said.

"I think that this set of issues is going to continue to be live and important, even if the FTC does not end up specifically pursuing its own antitrust cases," she said.

--Editing by Adam LoBelia.
