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FTC Focus: Exploring The Meaning Of Orange Book Letters

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This article is part of a monthly column that considers the significance of recent FTC antitrust announcements. In this installment, we discuss the agency's added scrutiny on pharmaceutical manufacturers' improper or inaccurate listing of patents in the Orange Book.

The Federal Trade Commission is busy. Big Tech challenges, new merger guidelines, a new noncompete ban. But through it all, it has never diverted its gaze from healthcare.

The merger guidelines and noncompete ban are part of that, certainly. But the FTC is going even deeper, targeting the very foundation of modern healthcare: patents.

Specifically, on April 30, the FTC announced it had "expanded its campaign against pharmaceutical manufacturers' improper or inaccurate listing of patents" in the Orange Book. It issued a second round of letters to 10 companies disputing "the accuracy or relevance" of 300 patent listings.

The FTC move reflects the position that the novel tactic will "promote competition" by removing at least some patent hurdles for would-be generic entrants. But taking a patent off the Orange Book does not invalidate the patent, so does it pave the way to generic entry or simply hide potential roadblocks?

The FTC move also reflects the position that brand drugs are listing more patents than technically required, to discourage generic entry. Of course, the contrary argument can be made, that by listing more potentially applicable patents, the process facilitates easier entry by giving generic entrants notice of all potential patent issues.

The Orange Book

Born in 1979, the Orange Book was intended to provide a comprehensive list of all prescription drug products approved by the U.S. Food and Drug Administration for safety and effectiveness, along with therapeutic equivalent evaluations, so states with substitution laws could have a single reference list based on common criteria. It was published with an orange cover.

Then came the Hatch-Waxman Act in 1984, which required brand drug manufacturers to submit information about certain types of patents in their applications to the FDA, and the FDA to make publicly available a list of approved drug products.

So the Orange Book included an addendum containing patent and exclusivity information. As the U.S. District Court for the Eastern District of New York described it in the 2018 decision In re: Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litigation: "The purpose of listing a patent in the Orange Book is to put potential generic manufacturers on notice that the brand considers the patent to cover its drug."[1]

If a generic manufacturer submits an application that implicates a listed patent, it can file what is called a paragraph IV certification with the FDA, stating it believes the patent invalid or will not be infringed.

That triggers an immediate right for the brand to sue for patent infringement, which can trigger an automatic 30-month stay of FDA approval for the generic application.

The FTC's Gripe

The FTC believes improper Orange Book listings "may constitute an unfair method of competition in violation of Section 5 of the FTC Act" or illegal monopolization by taking advantage of the automatic 30-month stay.[2]

The FTC once charged a company, Biovail Corporation, over two decades ago for improper Orange Book patent listings, but has otherwise largely contented itself to amicus briefs in private patent litigation.

Its tactics changed under the new administration. On Nov. 7, 2023, it issued letters challenging over 100 listed patents. And five months later, it sent the April letters challenging 300 more. To be clear, the FTC is not necessarily challenging the validity of the patents themselves, just whether they should be listed in the Orange Book.

The challenged listings largely apply to drug delivery system patents that do not claim a specific drug. The FTC says the Orange Book is supposed to be limited to a drug's active

ingredients or formulation.

The result? The FTC's letters are not an antitrust or enforcement action; they are pursuant to FDA regulations. Under applicable FDA regulations, when an Orange Book listing is challenged, the manufacturer has 30 days to withdraw or amend the listing or certify the listing complies with statutory and regulatory requirements.

Some of the patents targeted in November were removed, but others were not. Members of Congress have also joined the fray, encouraging companies to comply with the FTC's letters.

But the FTC's position is not necessarily clear-cut under the statute. A 2022 FDA report titled "The Listing of Patent Information in the Orange Book" and a 2023 report from the U.S. Government Accountability Office titled "Generic Drugs: Stakeholder Views on Improving FDA's Information on Patents" indicated that participants held varying views on which patents should be listed in the Orange Book, with some calling for clarification of the rules.

And on May 1, 2024, the Congressional Research Service questioned "whether additional clarity is needed on the types of patents that may be listed in the Orange Book."[3] Indeed, the FDA is currently working on updated guidance on which patents are required to be listed in the Orange Book.

Is There an Antitrust Claim?

In an amicus brief filed in March of this year in the case of Teva Branded Pharmaceutical Products R&D Inc. v. Amneal Pharmaceuticals Of New York, the FTC laid out its case for an antitrust claim based on Orange Book listings.[4]

In short, it asserts that improper Orange Book listings lead to delayed generic entry and consequently higher prices. But antitrust liability is based on comparison to the "but-for" world.

Remember that delisting a patent from the Orange Book does not necessarily affect the

validity of the patent itself. To claim a generic drug would have entered earlier "but for" the improper Orange Book listing, the FTC, or the plaintiff, would have to show that the brand would not have asserted infringement, instituted litigation or at least that the litigation would have been frivolous. While not impossible in an egregious case, that is a steep challenge.

The Upshot

To date, the FTC has not taken further action on its letters, though it has said it does not "issue empty threats." Perhaps the FTC is just going after low-hanging fruit in the first instance, but low-hanging fruit for the FTC is also low-hanging for a generic entrant.

There's no reason to believe a patent holder would delist a patent in response to a challenge from the FTC but not in a challenge from a generic entrant.

So what is the FTC saving generic entrants? Perhaps some paperwork. It may also be causing additional headaches for generics, because if a patent is legitimate but delisted from the Orange Book, a generic entrant may still face infringement litigation.

Still, there is no question the FTC is critically focused on Orange Book issues, and will only increase that focus going forward. There are a few learnings that can be applied from what the FTC has done so far.

First, the FTC is clearly focused on device patents that do not list a particular drug. Care should be taken with such patents when deciding whether to include in Orange Book listings. Indeed, this applies to any patent that is not specific to a particular drug.

But care should be taken both ways, because while the statute prohibits listing patents "not of the type" specified, it also creates an affirmative obligation to list those covered. Documentation of legitimate rationale for listing decisions will be important. The FTC's view is narrow, of course, but whether the FTC is correct is still an open question.

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[1] In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig. , 333 F. Supp. 3d 135, 149 (E.D.N.Y. 2018).

[2] https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.

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[3] https://crsreports.congress.gov/product/pdf/IF/IF12644.

[4] https://www.ftc.gov/system/files/ftc_gov/pdf/ftc_brief_as_amicus_curiae_teva_amneal.pdf.

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