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FTC Continues to 'Dispute' Orange Book Device Patent Listings, But Still No Antitrust Enforcement

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Over the last eight months, the US Federal Trade Commission (FTC) has focused on what it characterizes as "improper" Orange Book listings and the impacts of such listings on generic entry.

Most recently, on April 30, 2024, the FTC initiated a second round of patent listing disputes – this one targeting more than 300 device patent listings for 20 medicines approved to treat diabetes, obesity, asthma, chronic obstructive pulmonary disease (COPD) and hypoglycemia, covering injectors, inhalers and nasal sprays. The FTC sent letters to the companies listing patents urging them to withdraw their listings from the Orange Book.

This action follows an FTC policy statement, in which the agency announced it would consider "improper" Orange Book listings to be antitrust violations, and a first round of listing "disputes" initiated by the FTC in November 2023 that focused on inhaler products and epinephrine injector pens.

The FTC's actions have drawn the attention of members of Congress, who have urged companies targeted by the FTC to delist their patents, notwithstanding the absence of guidance about whether these types of patents are properly listed pursuant to the statute. A recent Congressional Research Service report questioned "whether additional clarity [from Congress] is needed on the types of patents that may be listed."

Antitrust enforcement on the horizon?

The FTC's actions do not compel delisting and are not antitrust enforcement actions. Rather, the FTC has sent letters to the listers pursuant to US Food and Drug Administration (FDA) regulations that permit anyone to question an Orange Book listing. Targeted companies then have 30 days to elect to either delist or maintain their listings.

In response to the November 2023 listing disputes, a handful of companies did delist some patents. The majority, however, recertified and maintained their patent listings, arguing that their patents satisfy the statutory listing criteria and, therefore, are in fact statutorily required to be listed. In letters to Congress, these companies defended their listings as not causing any real-world anticompetitive effect. To date, the FTC has not brought any antitrust enforcement actions against these companies.

A key question going forward is whether the FTC ultimately brings antitrust cases. In its policy statement, the FTC took the position that improper listings are illegal, regardless of the reasonableness of the decision to list or its competitive effects. If the FTC were to bring litigation on this basis without additional evidence, it would likely face significant challenges.

Of course, the FTC may well be investigating to identify and prioritize fact patterns on which to base future antitrust enforcement. The strongest antitrust cases would be where the FTC is able to prove both that a patent was intentionally improperly listed and a causal link between the improper listing and delayed or deterred generic entry.

In the meantime, it is clear that the FTC continues to devote considerable resources to this issue. The FTC has, among other things, recently submitted amicus briefs in lawsuits against Sanofi in the US District Court for the Western District of Pennsylvania and against Teva in the US District Court for the District of New Jersey, advocating that improper listings "thwart competition" and are "actionable under the antitrust laws."

And, at a recent White House event, FTC Chair Lina Khan spoke about what she characterized as "bogus patents" listed in an "obscure registry" used to "delay or block" generics. The FTC, however, is not questioning patent validity, only whether patents are properly listed, and listing patents – which is required by statute – is

designed to facilitate generic entry by providing notice of relevant patents. Moreover, generic entry is often tied to patent expiration, not the act of listing in the Orange Book.

Is this just about device patents?

As was the case with the FTC's first round of patent listing disputes, in this most recent round, the FTC is focused on device patents that do not claim the specific drug. The FTC has by now made clear its view that device patents that do not mention the drug are not listable, notwithstanding the long-standing ambiguity on this issue, the practice of listing these types of patents and the FDA's historic refusal to provide guidance.

In light of the FTC's focus on device patents that do not claim the drug, innovator companies that have marketed drug-device combination products, or that are developing such products, should assess whether any device patents may be vulnerable to FTC scrutiny. Companies that are still developing intellectual property should consider claiming relevant drugs when drafting and prosecuting device patents.

Pharmaceutical companies also should recognize that the FTC appears likely to broaden its lens beyond device patents to include additional categories of patents it views as improperly listed. FTC personnel have flagged, for instance, patents claiming manufacturing processes, packaging and distribution systems, such as REMS (Risk Evaluation and Mitigation Strategies), as potentially being the focus of future listing disputes, as we discuss in this November 2023 client alert. The FDA also has committed to "continue to engage with the FTC to identify and address potential efforts to impede competition."

What else do I need to know?

We have detailed key considerations in earlier alerts on this topic (see this October 2023 alert and this November 2023 alert).

In the current environment, the FTC's focus on this issue warrants attention from pharmaceutical companies that have listed patents or that are prosecuting patents that may fall into a category the FTC deems not proper for Orange Book listing.

Cooley's antitrust, patent and Hatch-Waxman teams are available to advise on these and other issues at the intersection of antitrust and pharmaceutical patent enforcement.

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