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Following Recent Policy Statement, FTC 'Disputes' 100+ Patent Listings in FDA Orange Book

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The US Federal Trade Commission (FTC) sent letters on November 7, 2023, accusing 10 companies of improperly listing drug delivery device patents in the US Food and Drug Administration (FDA) Orange Book, stating that the FTC has taken steps to "dispute" these listings.

The FTC's statements suggest the potential for future antitrust enforcement actions against these companies, as well as for further disputes regarding a "wide array of patent listings."

The FTC's letters follow the agency's September 2023 policy statement announcing that "improper" Orange Book listings may be challenged "as unfair methods of competition" in violation of Section 5 of the FTC Act, as we described in this October 18 alert.

The letters come as the FTC is increasingly taking a position on these issues in private litigation – including a November 2023 amicus brief arguing that "improper" Orange Book listings can "constitute illegal monopolization" and cause harm extending beyond the 30-month stay, because they can "distort the competitive process."

We summarize the FTC's actions and offer key takeaways for innovator pharmaceutical manufacturers.

FTC's 'challenges' are not antitrust enforcement actions

The FTC's September 2023 policy statement outlined an aggressive view of the antitrust implications of Orange Book listings. The FTC implied that it views "improper" Orange Book listings as essentially per se unlawful under Section 5 of the FTC Act, subject to condemnation regardless of the reasonableness of the decision to list or the competitive effect of the specific listing.

The threat of antitrust enforcement may deter Orange Book listings, but it conflicts with existing case law and antitrust principles, leaving the FTC vulnerable if it were to bring antitrust challenges based on the theories articulated in the policy statement.

Indeed, while the FTC characterizes its recent letters as "challenging" 100+ Orange Book patent listings, it notably did not bring any Section 5 enforcement actions or other antitrust challenges against these Orange Book patent listings, nor did it initiate a process to compel delisting of any patent.

Instead, the FTC sent letters to the FDA, pursuant to FDA regulations that permit anyone to question a patent listing. The companies that have listed the patents in the Orange Book have 30 days to either remove the listings or recertify that the listings comply with statutory requirements.

Beyond initiating the dispute, the FTC will play no formal role in the process – and presumably neither will the FDA, which historically has played only a "ministerial" role in managing the Orange Book. If the companies targeted by the FTC letters recertify the patent listings, the patents will remain listed.

Since 2021, there have been more than a dozen other listings questioned, as tracked by the FDA. In more than half of those instances, no changes were made to the Orange Book.

Uncertainty regarding listing device patents

The Hatch-Waxman Act and related FDA regulations require new drug application (NDA) holders to list certain patents related to the company's approved drug products in the FDA's Orange Book, formally the "Approved Drug Products with Therapeutic Equivalence Evaluations."

The regulations require the listing of patents directed to the approved drug substance, the approved drug product and method-of-use patents covering the approved indication(s). For nearly two decades, if not longer, drug companies have sought the FDA's guidance on the listing of drug-device patents in the Orange Book, as these devices are frequently integral to the delivery of the drug and are approved as drug-device combinations.

Over this period, the FDA has continued to list drug-device patents but has refused to provide written guidance regarding the listability of these patents. The 2021 Orange Book Transparency Act required the FDA to solicit comments regarding the listing of device and other patents in the Orange Book. In response, the FDA received numerous comments from industry and others regarding the listing of device patents. In the face of these comments, the FDA has continued to list drug-device patents in the Orange Book but has yet to issue any written guidance directed at the listability of these patents.

The patent listings disputed in the recent FTC letters are directed to these types of drug-device patents. The FTC's claim that these patents are clearly unlistable stands in contrast to the FDA's long-standing practice of listing these patents in the Orange Book, along with the FDA's refusal to provide any express guidance regarding the listing of drug-device patents, notwithstanding decades of industry requests for clarity.

FTC's view on device patents and the Orange Book

The FTC has made clear that, in its view, "only patents that claim the active ingredient should be listed in the Orange Book," and that "drug-device patents that do not claim the active ingredient should not be listed." In a recent interview, the FTC deputy director who signed the drug delivery listing letters asserted that this is not "particularly controversial," as "the law is actually relatively clear" with "not a lot of ambiguity here in terms of what should and should not be listed."

The FTC further suggested that listing these types of patents violates antitrust law, and that the FTC "retains the right to take further action," including by investigating and bringing cases. If any of the targeted companies recertify their listings, the FTC may well attempt to use that as evidence the listing was maintained knowing the FTC believes it is improper.

Any future antitrust enforcement actions against these or other disputed patents, however, would require the FTC to develop substantially more evidence.

As an initial matter, while the FTC has now expressed the view that these types of drug-device patents should not be listed, the fact is that the FDA has remained silent regarding repeated requests from industry to provide clear guidance regarding the listability of drug-device patents and has continued to list these patents in the Orange Book. Moreover, the FTC is not an expert arbiter in determining statutory patent listing criteria for a fellow federal agency.

Even if certain drug-device patents are ultimately determined not to be listable, that would not necessarily mean the listing violates antitrust law, as the FTC suggests, for a number of reasons:

- The case law – in particular, the US Court of Appeals for the First Circuit's 2020 decision in *Lantus* – provides that there should be no antitrust liability if a listing was made "reasonably" and in "good faith." This precedent is based on the recognition that the requirement to list patents is not voluntary, but is statutorily mandated, and in the absence of clear guidance, companies should not be held liable for a good faith attempt to comply with a statutory scheme.
- Antitrust law is concerned with conduct that causes or threatens likely harm to competition. The FTC has expressed concern that improper Orange Book listings may delay or deter generic entry, but that is not plausible for at least some of the disputed patents. For example, where a disputed patent has not been used as the basis for obtaining a 30-month stay, or if there are additional patents listed in the Orange Book that are not disputed by the FTC, the listing of the disputed patent may not have

any effect on competition at all. This is especially the case considering that a patent holder can allege infringement regardless of whether a patent is Orange Book-listed.

The FTC normally investigates and marshals supporting evidence of an antitrust violation before going public with suggestions of wrongdoing. Here, the FTC has gone public while stating it "retains the right to take … further action [including] investigating the manufacturer's conduct."

Key considerations going forward

The FTC has long prioritized enforcement against conduct that delays or deters generic entry, and it is now clearly focused on Orange Book listings as a method to do so, arguing it is protecting "Americans from illegal business tactics that are hiking the costs of drugs and drug products."

In an interview following the FTC's announcement, the FTC deputy director said that the FTC "continue[s] to review other patent listings" and that this action is not "exhaustive." It thus appears likely that the FTC will continue to identify patents it views as improperly listed, such as patents covering manufacturing processes, packaging, REMS (Risk Evaluation and Mitigation Strategies) and other drug distribution systems, as well as device patents, and will publicize its efforts to target these listings.

Pharmaceutical companies should, therefore, be extra cautious to ensure they have a good faith basis for thinking their Orange Book listings satisfy the listing criteria.

As our October alert detailed, significant antitrust exposure would come from intentionally listing a patent that does not meet the statutory criteria and filing an infringement action on such patent to delay or deter generic entry. Such action is likely to attract antitrust counterclaims from the generic applicant – in addition to potential FTC scrutiny and class actions on behalf of purchasers – that may be difficult to defend.

FTC enforcement is much less likely to succeed in the absence of evidence that a particular listing was made in bad faith, and that the listing caused or is likely to cause generics to delay or forego entry. Under these circumstances, private claims also are much less likely, since conduct that does not actually impact generic entry would not result in antitrust injury and damages.

In the current environment, however, that does not mean the FTC will not act. Where there is ambiguity about an Orange Book listing, companies will need to balance the benefits of listing against the downsides. Considerations in this analysis include the strength of the legal basis for listing and associated documentary record, the potential for a protracted FTC investigation, including litigation and adverse publicity, even if the company may ultimately prevail, and the fact that companies can, of course, still assert infringement – even if a patent is not listed.

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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