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The US FTC issues a policy statement reflecting that it intends to scrutinize improper Orange Book listings and take actions against companies and individuals that improperly list patents in the Orange Book

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US FTC, *FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'*, Press Release, 14 September 2023
US FTC, *Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book*, Policy Statement, 14 September 2023

Howard Morse | Cooley (Washington)
David Burns | Cooley (Washington)
Sanya Sukduang | Cooley (Washington)
Jon Cousin | Cooley (Washington)
Natasha Leskovsek | Cooley (Washington)

e-Competitions News Issue Preview

FTC Issues Antitrust Warning Against 'Improper' Orange Book Patent Listings*

The US Federal Trade Commission (FTC) recently ***issued a policy statement*** "to put market participants on notice that the FTC intends to scrutinize improper Orange Book listings" and take "actions against companies and individuals that improperly list patents in the Orange Book."

Aggressive and broad in scope, the FTC's statement:

- Suggests the FTC views "improper" Orange Book listings to be essentially per se antitrust violations, unlawful regardless of the reasonableness of the listing.
- Targets existing as well as new Orange Book listings.
- Threatens enforcement against companies and "responsible individuals."
- Asserts that the FTC will refer matters to the Department of Justice for investigation of criminal violations for the

submission of false statements.

- Indicates the FTC may scrutinize a firm's history of improperly listing patents during a merger review.

Pharmaceutical manufacturers are well-advised to take steps to put themselves in position to fend off any aggressive FTC investigation or enforcement, as we discuss further below.

Orange Book listings are mandated by statute

The Hatch-Waxman Act provides that pharmaceutical manufacturers "shall" list in the Orange Book all patents that "could reasonably be asserted" if a person not licensed by the owner of the patent engaged in the manufacture, use or sale of the drug, and that claim the drug, a formulation or composition containing the drug, or a method of using the drug. [*1*]

These public listings put generic drug applicants on notice of the patents that may be infringed by generic entry. In fact, drug manufacturers must submit a signed verification that the submitted patent information is "accurate and complete."

Companies seeking to market generic drugs must certify against any Orange Book-listed patents for the reference listed drug. If a generic makes a "paragraph IV" certification that any Orange Book-listed patent is invalid or will not be infringed, the innovator company may bring an infringement suit and, if it does so within 45 days, the statute imposes a 30-month stay on the Food and Drug Administration (FDA) approving the generic drug while the patent litigation proceeds.

The Hatch-Waxman Act, including the 30-month stay, reflects legislative judgment balancing policies to encourage generic competition while preserving incentives to invest in innovation. Listing a patent in the Orange Book and suing for infringement, however, can have significant consequences for the timing of generic entry, and hence can raise antitrust issues.

Although the FDA manages the Orange Book, its long-standing position has been to serve only a "ministerial role," on the basis that it lacks the resources and expertise to assess whether patents are properly listed or otherwise police Orange Book listings in any substantive way.

By contrast, the FTC has in the past challenged Orange Book listings that it contends resulted in delayed generic entry. In 2002, for example, the ***FTC charged and settled allegations*** that Biovail delayed a generic entrant by enforcing an Orange Book-listed patent that Biovail was "aware" did not claim the formulation of the reference drug. The facts at issue, however, were extreme: In addition to Biovail's alleged knowledge that the patent was not properly listable, Biovail had acquired the patent from a third party, and listing it triggered a second 30-month stay, after the generic had already defeated Biovail's first patent suit and obtained tentative approval. (Such multiple 30-month stays generally are no longer possible.)

The FTC also has filed a number of amicus briefs relating to Orange Book listings, including in 2022 taking the position that patents related to distribution systems – such as a patent covering a risk evaluation and mitigation strategy (REMS) program mandated by the FDA – are not properly listable.

Significant open issues remain

The FTC's statement seeks to deter Orange Book listings, believing they "contribute to high drug prices," but in doing so ignores existing case law and well-established antitrust principles, potentially leaving the FTC vulnerable if it actually brings suit on the theories articulated in the statement.

Perhaps most egregiously, the FTC seems to contend that "improper" Orange Book listings are essentially per se antitrust violations, and subject to challenge regardless of the reasonableness of the decision to list the patent, and regardless of the competitive effects of the particular listing.

This position, however, runs headfirst into the precedents, which recognize that mere improper listing does not violate antitrust law. For example, in its 2020 ***In re Lantus*** decision, the US Court of Appeals for the First Circuit – citing precedent from other regulatory contexts – held that there should be no antitrust liability if an improper listing "was the result of a reasonable, good-faith attempt to comply with the Hatch-Waxman scheme." In ***Organon v. Mylan*** , a district court dismissed an antitrust counterclaim where there was a "reasonable basis" for Orange Book listing because the statute was "capable of two equally plausible interpretations."

To be sure, there may be instances where a patent is intentionally listed improperly simply to obtain the 30-month stay. But in other instances, there may be legitimate uncertainty about Orange Book listing requirements or the outcome of any future patent enforcement. And the harm almost always flows directly from the filing of the patent litigation, not by the Orange Book listing itself. In these circumstances, the precedents do not support per se antitrust liability for listing a patent, both because courts take into account the reasonableness of the decision to list and because likelihood of success is not a criterion for being listed. [*2*]

It remains to be seen whether the FTC – consistent with its past practices – will focus its enforcement on the egregious cases, or also challenge good faith, reasonable listings ultimately found to be improper.

The FTC also suggests it may challenge improper Orange Book listings irrespective of any enforcement or invocation of the 30-month stay, theorizing that "listings may disincentivize investments in developing [a generic]." Pharmaceutical manufacturers therefore should consider antitrust risks when listing a patent that may not meet the statutory criteria and when filing suit. However, mere Orange Book listing – in the absence of any patent enforcement – is much less likely to actually delay or deter generic entry. And in the absence of such evidence, there should be no legal or economic basis for antitrust condemnation.

It is notable that the FTC's statement – and even more so its ***press release*** – focuses on improper Orange Book listings as an "unfair method of competition" under Section 5 of the FTC Act. As support, the FTC cites its own (highly controversial) ***November 2022 Section 5 policy statement***, which argues that Section 5 reaches a wide swath of conduct not unlawful under the Sherman Act. It is not at all clear, however, that an FTC challenge under Section 5 that does not meet the requirements for monopolization under Sherman Act would be upheld by a court.

The FTC further flouts the fact that companies are under statutory command to list patents, and that under-listing can itself be harmful. Indeed, as recognized in Lantus, failure to list can "itself arguably have an anticompetitive effect by depriving potential competitors of notice and of the other procedural benefits." This was in part why the First Circuit rejected the plaintiffs' position – which the FTC appears to mirror – that an improper listing violates antitrust law regardless of its reasonableness.

Key considerations for innovator pharmaceutical manufacturers

The FTC statement certainly warrants attention. Even while the FTC's ability to obtain monetary relief is limited, the FTC can impose "cease and desist" orders. And many companies will not want to incur the cost of defending an FTC investigation or the adverse publicity that could result from an enforcement action, even if the company might prevail in litigation. Moreover, state attorneys general and private plaintiffs may attempt to leverage the FTC's statement to seek damages for alleged improper listings, although those entities would have to establish actual harm to obtain monetary relief.

We've outlined three key considerations for pharmaceutical manufacturers below.

Be aware of significant antitrust risks from listing/enforcing patents that do not satisfy statutory criteria

There is no doubt that intentionally listing a patent that clearly does not meet the statutory criteria and filing an infringement action on such patent, for the purpose of delaying or deterring generic entry, raises significant antitrust risks. Such action is likely to attract antitrust counterclaims from the generic applicant in addition to potential FTC scrutiny. Listing such a patent alone may carry antitrust risk insofar as it delays or deters generic entrants.

Audit existing and new Orange Book listings for compliance with current guidance

In light of these risks, and the FTC's renewed attention on these issues, pharmaceutical manufacturers should consider auditing existing Orange Book listings, and vet future listings, to ensure that any patent listed in the Orange Book meets the statutory criteria for listing and covers the product for which approval is sought or has been granted. In particular, pharmaceutical manufacturers should confirm their listings are up to date with current guidance, such as with respect to patents related to distribution systems (e.g., REMS). If a listed patent does not meet the statutory criteria, or is known to be invalid, it should be de-listed.

Document good faith rationale for listing decisions

To the extent there is ambiguity regarding whether a patent is properly listable, it is advisable to document the good faith rationale for listing the patent. Companies should be cognizant to avoid creating documents that could be inaccurately read to suggest that a listed patent does not meet the statutory criteria and is in the Orange Book solely to delay generic entry.

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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[1] The statute imposes additional requirements regarding patents that should be listed. For example, formulation patents must claim the formulation described in the New Drug Application, and method-of-use patents must claim an indication for which approval was granted.

[2] In a similar vein, the statement neglects to even mention the potential *Noerr-Pennington* issues at play. ***Some courts*** have held that *Noerr-Pennington* – which protects petitioning the government – does not apply to Orange Book listings because the FDA's role is "non-discretionary." ***Other courts***, however, have suggested that Orange Book listings in advance of a generic firm's certification do not cause harm independent of filing the infringement lawsuit required to obtain a 30-month stay, which is protected by *Noerr-Pennington*.