A New Breed Of Antitrust Challenges To FDA's Orange Book

By **Benjamin Greenblum** (April 17, 2020)


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The U.S. Food and Drug Administration's Orange Book has been a bedrock of pharmaceutical patent disputes in the decades since it was first published.

Companies list patents that they assert cover their products, putting potential competitors on notice of the intellectual property they will have to navigate to bring a generic equivalent to market. At this, at least, the Orange Book has been a great success.

Questions have lingered, however, about the mechanics behind the publication: What kinds of patents are required to be listed, which are permitted to be listed, and how are patents to be categorized and described when listed?

The FDA has promulgated regulations on these seemingly straightforward questions, which of course, have only spurred more controversy. The FDA, for its part, will not answer many of these questions; it has typically stood back, insisting it has no patent expertise and that its role in publishing the Orange Book is purely ministerial.

Where there is unresolved controversy, litigation is often not far behind, and so it is that a new breed of antitrust litigation has sprung up: Competitors and private payors alike have claimed that improper Orange Book listings have overextended branded drug exclusivity, delayed generic entry and harmed competition in pharmaceutical markets.

Two recent rulings highlight the issues posed by such antitrust claims and reflect the challenges that courts face in applying antitrust law to sort out the controversies that the FDA has ducked.

In re: Actos Antitrust Litigation

In re: Actos Antitrust Litigation,[1] pending in the U.S. District Court for the Southern District of New York, involves Takeda Pharmaceutical Co. Ltd.'s diabetes product, Actos. In the early 2000s, Takeda listed certain of its Actos patents in the Orange Book as covering both the drug product as well as methods of use.

Plaintiffs, direct and indirect purchasers of the product, claim that, in fact, those patents only claim methods of use and should not have been listed as also claiming the drug product. Takeda contends that under FDA regulations, it was actually required to also apply both classifications to the patents.

Plaintiffs insist the issue is not a semantic one: Where a drug is protected only by a method of use patent, they say, potential competitors can attempt to avoid certifying that the patent is invalid or not infringed by representing to the FDA that they will not seek approval for the patented method of use. That maneuver may in turn avoid the statutory 30-month stay on FDA approval of the competitor's product.

Thus, the Actos plaintiffs claim that Takeda's improper listing of its patents as covering more than methods of use forced potential competitors to sit out of the market for the duration of a 30-month stay, allegedly delaying cheaper versions of the drug.

Takeda moved to dismiss the antitrust claims, arguing that under its interpretation of the Orange Book rules, it was required to list the patents as covering the drug product. The district court held that, in fact, both Takeda and plaintiffs had misread the listing statute and that Takeda's patent listing was only partially incorrect — albeit, sufficiently incorrect so as to have potentially delayed generic competition.

The district court acknowledged the possibility that Takeda's interpretation was reasonable, in part because other courts had arguably read the statute as Takeda had.[2] The district court further conceded that other antitrust courts in other Orange Book listing cases had addressed the issue of reasonableness in this context at the motion to dismiss stage, offering the potential to avoid costly and protracted antitrust discovery over a close regulatory question.[3]

Indeed, the district court was sufficiently uncertain of its own interpretation of the statute that it certified the issue for interlocutory review; it found an absence of controlling authority on a novel and complex issue that "may have important ramifications for other companies in the pharmaceutical industry."[4]

Despite this record and contrary precedents, in Actos the district court nevertheless held that whether Takeda acted in good faith would need to be addressed in discovery.[5]

Thus the motion to dismiss was denied, and unless the U.S. Court of Appeals for the Second Circuit intervenes, the case enters discovery, potentially exposing Takeda to treble damages for the way it described its patent in the Orange Book.

In re: Lantus Antitrust Litigation

In re: Lantus Antitrust Litigation,[6] pending in the U.S. District Court for the District of of Massachusetts, concerns a different diabetes product: an insulin injector pen manufactured by Sanofi-Aventis. Sanofi had listed a particular patent in the Orange Book as covering the drug product, despite the fact that the patent allegedly covered the delivery device instead of the drug itself. Several competitors challenged Sanofi's patent, but ultimately settled, including by agreeing to pay royalties to Sanofi on the sale of competing products.

The antitrust plaintiffs — direct purchasers of Sanofi's product — now claim that Sanofi improperly listed the patent as covering a drug product, thereby forcing potential competitors to endure the same 30-month stay on approval of the product as in Actos.[7] In moving to dismiss, Sanofi was able to point to a record of industry confusion on whether the type of patent at issue was in fact required to be listed in the Orange Book, as well as a record that the FDA has been unable or unwilling to resolve the confusion.

The district court agreed, dismissing the case because the FDA's listing requirement in this context posed an open question, and Sanofi's listing decision had been reasonable.[8]

The U.S. Court of Appeals for the First Circuit reversed in an opinion issued in February. While concluding that Sanofi had misread the statute and regulations, the court conceded "the complexity of th[e] endeavor," and allowed that in some circumstances, a failure to list a patent might itself be alleged to "have an anticompetitive effect by depriving potential competitors of notice and of the other procedural benefits that result from an Orange Book listing."[9]

Indeed, Sanofi had a fair point that the antitrust plaintiffs were arguably setting up a world

in which companies would bear strict liability for improper Orange Book submissions.[10]

But ultimately, as the Southern District of New York had suggested in Actos, the First Circuit held that Sanofi had not yet proven that the listing of the patent was "a good faith, reasonable attempt to comply with a regulatory scheme."[11] The court also noted in passing that Sanofi might choose to disclose "what if any legal opinions [it] sought and obtained before submitting the patent" to the Orange Book.[12]

Conclusions

Together, the Actos and Lantus decisions pose three unique issues.

First, despite that the regulatory rules of the road are sufficiently complex here that even different judges can construe them differently, even if a given patentholder's interpretation is reasonable on its face, that will not necessarily protect it from antitrust discovery on the question.

In a world in which the FDA frequently refuses to address disputes between competitors as to the proper listing of patents, and where patent holders can be attacked for failing to list patents they later assert in litigation, exposure to antitrust liability over a listing decision that a court might later determine — with the benefit of hindsight — was improper portends risks for Orange Book listing decisions.

Second, while both were decided at the pleadings stage, both Actos and Lantus contemplate potentially shifting to defendants the burden of proving their patent listings were reasonable, rather than forcing plaintiffs to prove the listings were unreasonable, i.e., that no reasonable patentholder would have made that listing decision.

If these courts were to decide to apply that construct at summary judgment or trial, it would be a marked departure from the way courts handle the analogous question of when, for example, litigation against a competitor is deemed so unreasonable as to constitute sham litigation and potentially exposes the litigant to antitrust liability. Under longstanding precedent, in that circumstance, it is the antitrust plaintiff that bears the burden of proving that the positions taken in the underlying litigation were objectively unreasonable.[13]

Third, both courts contemplated consideration of whether defendants acted in good faith in making the listing decision. This too would depart from the way courts have traditionally analyzed the analogous claim of sham litigation, where "[o]nly if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation."[14]

Unsurprisingly, decisions around how to list patents in the Orange Book are typically made by legal counsel, and so whether and to what extent these courts actually contemplate a subjective inquiry into the listing decision could tee up difficult questions around the attorney-client privilege.

The Second Circuit will soon decide whether to consider Actos on an interlocutory basis, and the First Circuit's remand instructions in Lantus give that district court some latitude to fashion the antitrust inquiry. Only time will tell what impact these decisions actually will have on Orange Book controversies and attendant antitrust litigation going forward.

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[1] In re Actos Antitrust Litigation, No. 13-CV-9244 (RA), 2019 WL 4805843 (S.D.N.Y. Sept. 30, 2019).

[2] Id. at *12.

[3] Id. at *6.

[4] 2020 WL 433710, at *2 (S.D.N.Y. Jan. 28, 2020).

[5] 2019 WL 4805843, at **14-15.

[6] In re Lantus Antitrust Litigation, No. 18-2086, 2020 WL 728628 (1st Cir. Feb. 13, 2020).

[7] Id. at *4.

[8] 284 F. Supp. 3d 91, 107 (D. Mass. 2018).

[9] 950 F.3d 1, 11, 13 (1st Cir. 2020).

[10] Id. at 11.

[11] Id. at 12.

[12] Id. at 13.

[13] E.g., Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 57 (1993).

[14] Id. at 60.