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Teva v. Amneal Ruling Interprets Orange Book Listing Statute, Affirms Delisting of Device Patents

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On December 20, 2024, the US Court of Appeals for the Federal Circuit released its opinion in *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, affirming a lower court decision that Teva must delist five patents from the US Food and Drug Administration (FDA) Orange Book that claim inhalers for metered dose inhalation but do not recite the active ingredient within Teva's FDA-approved ProAir HFA Inhalation Aerosol, albuterol sulfate.[1]

The court summarized its analysis as follows:

> To list a patent in the Orange Book, that patent must, among other things, claim the drug for which the applicant submitted the application and for which the application was approved. And to claim that drug, the patent must claim at least the active ingredient.

The Federal Circuit also addressed device patents specifically, holding that "patents claiming just the device components of the product approved in an NDA do not meet the listing requirement of claiming the drug for which the applicant submitted the application."

Background

Teva sued Amneal for patent infringement under the Hatch-Waxman Act after receiving notice Amneal sought to sell a generic version of Teva's ProAir HFA inhaler product. Teva's ProAir HFA is a drug device combination product that was approved by FDA as a drug, pursuant to a New Drug Application (NDA).

Among other patents, Teva asserted five patents listed in the Orange Book against Amneal that claim aspects of the inhalation device and that do not recite any active ingredient, let alone the albuterol sulfate active in Teva's product (referred to by the court as the "Inhaler Patents"). Indeed, it was undisputed before the district court that "no claim in any of the Inhaler Patents discloses albuterol sulfate."[2]

Amneal asserted counterclaims seeking to delist the Inhaler Patents and, in early motion practice, moved for judgment on the pleadings that Teva improperly listed those five patents in the Orange Book. In granting Amneal's motion, Judge Stanley Chesler of the US District Court for the District of New Jersey reviewed and interpreted the statute governing what patents an NDA holder must list in the Orange Book. This "Listing Statute" – 21 US Code § 355(b)(1)(A)(viii), amended in 2021 – reads:

> Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application …
>
> > (viii) the patent number and expiration date of each patent for which a claim of patent infringement 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 –
> >
> > > (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or
> > >
> > > (II) claims a method of using such drug for which approval is sought or has been granted in the application.

Judge Chesler ordered Teva to delist the Inhaler Patents from the Orange Book because they "do not claim the

drug for which the applicant submitted the application." Teva appealed, and the Federal Circuit stayed the delisting order pending its decision in the case.

The Federal Circuit decision

The Federal Circuit dug into the Listing Statute in deciding the case. The main question it decided was whether the Listing Statute permits, as Teva put it, "the listing of only a small class of patents claiming at least the active ingredient," or instead permits – and in fact mandates – listing a patent "if the claimed invention is found in any part of [an] NDA product." In affirming the district court, the appellate panel rejected each of Teva's arguments in favor of the latter position.

First, the court rejected Teva's view that claiming and infringing mean the same thing. Teva argued that a patent "claims the drug" within the meaning of the Listing Statute if the claim reads on the approved drug. Accordingly, Teva asserted it properly listed the Inhaler Patents in the Orange Book because those patents' claims for a dose counter and canister read on the ProAir HFA. However, the court reasoned that to read the Listing Statute as Teva proposed – a statute that "identifies infringing and claiming as two distinct concepts" – "would create a stunning example of statutory redundancy" based on the language of the statutory text. Instead, the court concluded "[t]he more natural reading is that, in order to be listed, a patent must claim both the drug and be infringed by the NDA Product." In reaching this position, the court differentiated the concepts of claiming (i.e., of inventions) and infringement, pointing out that "[i]nventors claim what they invent, but infringement occurs when others make, use, or sell the invention without authorization."

Second, the court rejected Teva's argument that any component of an article that can treat disease meets the statutory definition of "drug" in the Listing Statute. To support this argument, Teva relied on the broad definition of the word "drug" in the Federal Food Drug and Cosmetic Act (FDCA). The Federal Circuit noted that if Teva's position prevailed, the Inhaler Patents would meet the requirements of the Listing Statute because they claim contain components of the ProAir HFA. In rejecting this argument, the court reviewed two definitions of "drug" provided by the FDCA:

- "'The first is 'articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.' 21 U.S.C. § 321(g)(1)(B)."
- "The second is 'articles intended for use as a component of any article specified in clause … (B).' Id. § 321(g)(1)(D) (emphasis added)."

Although the court noted that at first glance this argument has some appeal, it found that when looking at the FDCA in a broader statutory context, the FDCA supports that a patent claims a drug when a patent claims at least the active ingredient identified in the application. For example, the FDCA provides a distinct approval pathway for devices as compared to drugs.

Looking at the distinguishing features for what qualifies as a "drug" versus a "device," the court found that "the touchstone of the distinction" was that a device excludes an active ingredient. Here, even though ProAir HFA was approved as a drug device combination product under an NDA, it still maintains its drug and device subparts. The Inhaler Patents did not claim the drug, only inhaler device components, and were not properly listable in the Orange Book.

Third, the court refused to remand the matter back to the district court for claim construction per Teva's request. The court stated that even if it adopted Teva's proposed construction, the claims of the Inhaler Patents would not claim the active ingredient, albuterol sulfate, and thus would not qualify for listing in the Orange Book.

What remains

Touching on a hot-button issue in light of the Federal Trade Commission's recent letter campaign, Amneal also brought five antitrust counterclaims against Teva premised on Teva's improper Orange Book listings and alleged sham litigation. Teva moved to dismiss these antitrust counterclaims for failure to state a legally cognizable claim for relief under Rule 12(b)(6). Judge Chesler denied Teva's motion as to all five counterclaims. It will be interesting to see whether Amneal pursue these counterclaims as the case proceeds before the district court.

Notes

1. No. 24-1936, -- F.4th --, 2024 WL 2923018 (Fed. Cir. Dec. 20, 2024).
2. *Teva Branded Pharm. Prods. R&D v. Amneal Pharms. of N.Y., LLC*, 2021 US Dist. LEXIS 102503 (D.N.J. June 10, 2024).

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