Federal Circuit Affirms Device Patent Delisting in *Teva v. Amneal*

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On December 20, 2024, the U.S. Court of Appeals for the Federal Circuit lifted its stay and affirmed a district court's order requiring Teva to delist five patents from the U.S. Food and Drug Administration (FDA) *Orange Book*.[1] The Federal Circuit's opinion noted that these patents claimed inhaler devices but did not claim albuterol sulfate, the active ingredient used in Teva's FDA-approved ProAir HFA Inhalation Aerosol product.[2]

The Federal Circuit concluded that, in order for a patent to be properly listed in the *Orange Book*, it must claim the drug from the applicant's submitted and approved drug application. Moreover, for a manufacturer to properly claim that drug, the patent must include the active ingredient. The Federal Circuit also discussed device patents at large and noted that when patents claim only the device components of a product approved in a drug application, they do not meet the listing requirement of claiming the active ingredient or drug for which the application was submitted.[3]

In this matter, Amneal Pharmaceuticals alleged that Teva improperly listed patents in the *Orange Book* and delayed the entry of generic products onto the market.[4] The U.S. District Court for the District of New Jersey agreed with Amneal and ordered that Teva delist its patents from the *Orange Book*. They noted that "the Inhaler Patents contain no claim for the active ingredient at issue, albuterol sulfate," but instead "are directed to components of a metered inhaler device." Teva appealed, and the Federal Circuit stayed the district court's order pending their resolution of the case, eventually lifting the stay and affirming the district court's delisting order. [5]

The Federal Circuit's ruling aligned with growing scrutiny from the Federal Trade Commission (FTC) over the potential misuse of *Orange Book* listings. In September 2023, the FTC issued a policy statement addressing the alleged improper listing of patents in the *Orange Book* by some drug manufacturers. The statement aimed to alert market participants that the FTC would be scrutinizing such listings to determine if they constituted unfair competition under Section 5 of

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[1] Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC Opinion, 24-1936, (Fed. Cir.) (December 20, 2024) [hereinafter Opinion], p.38.

[2] *Id.*, p. 33

[3] Ibid.

[4] Opinion, p.2

[5] Opinion, p.3

the FTC Act. The FTC noted that improperly listed patents could discourage investment in competing products, delay generic drug entry, and increase healthcare costs.[6]

In November of that year, the FTC challenged over 100 patents and notified 10 drug companies, leading some to delist the contested patents while others argued they were properly listed.[7] The patents challenged included the five patents at issue in Teva's case against Amneal.[8] By April 2024, the FTC had challenged an additional 300 patents and sent new warning letters to 10 more drug companies regarding patents on various brand-name drugs, including those for asthma and injectable treatments such as Ozempic and Saxenda.[9]

The FTC filed an Amicus Brief on March 22, 2024, arguing that Teva improperly listed patents in the *Orange Book* and urged the court to order the listings to be removed. The FTC questioned whether Teva's listed patents meet the requirements for being listed in the *Orange Book* and considered whether they are an example of illegal monopolization. The FTC argued that "device patents that do not mention any drug in their claims do not meet the statutory criteria for *Orange Book* listing, and a device patent that is improperly listed in the *Orange Book* must be delisted."[10] On December 20, 2024, the FTC announced its agreement with the Federal Circuit's decision to request Teva to delist its inhaler patent listings from the *Orange Book*.[11]

Background: Teva and Amneal

Teva, established in 1901 in Israel, is a pharmaceutical company that specializes in generic drugs and develops specialty and biopharmaceutical treatments.[12] The company has a portfolio

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[6] Patent Listing in FDA's Orange Book, Congressional Research Service (December 27, 2024), *available at* https://crsreports.congress.gov/product/pdf/IF/IF12644#:~:text=By%20statute%2C%20a%20company%20seeking,such%20drug%20for%20which%20approval

[7] Patent Listing in FDA's Orange Book, Congressional Research Service (December 27, 2024), *available at* https://crsreports.congress.gov/product/pdf/IF/IF12644#:~:text=By%20statute%2C%20a%20company%20seeking,such%20drug%20for%20which%20approval

[8] FTC Files Amicus Brief in Asthma Inhaler Patent Dispute, FTC (March 22, 2024), *available at* https://www.ftc.gov/news-events/news/press-releases/2024/03/ftc-files-amicus-brief-asthma-inhaler-patent-dispute

[9] Patent Listing in FDA's Orange Book, Congressional Research Service (December 27, 2024), *available at* https://crsreports.congress.gov/product/pdf/IF/IF12644#:~:text=By%20statute%2C%20a%20company%20seeking,such%20drug%20for%20which%20approval

[10] Brief for the FTC as Amicus Curiae, p. 2, in Teva v. Amneal, No. 24-1936 (2024), *available at* https://www.ftc.gov/system/files/ftc_gov/pdf/ftc_brief_as_amicus_curiae_teva_amneal.pdf.

[11] FTC Statement on Appellate Court Decision Ordering Delisting of Teva Inhaler Patents, FTC (December 20, 2024), *available at* https://www.ftc.gov/news-events/news/press-releases/2024/12/ftc-statement-appellate-court-decision-ordering-delisting-teva-inhaler-patents

[12] Improving health since 1901, Teva, *available at* https://www.tevapharm.com/our-company/teva-history/.

of over 3,600 medicines and produces approximately 76 billion tablets and capsules a year. Teva has over 53 manufacturing facilities in over 33 countries and employs approximately 37,000 employees.[13]

Amneal began as a start-up generics company in 2002 and later developed into a specialty pharmaceutical company. The company is headquartered in Bridgewater, New Jersey.[14] Amneal has developed, manufactured, and distributed a portfolio of over 280 generic and specialty pharmaceuticals, primarily within the U.S. The company employs over 7,800 employees.[15]

The FDA's Drug Approval Process

Generally, the Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 governs how the FDA approves and regulates medical products. Before a company can market and sell its drug, regulations require the company to submit a new drug application (NDA). The NDA must provide a complete description of the components and manufacturing process for the drug, proposed labeling, information on which patents claim the drug, and other information. If the application shows the drug is safe and effective, the FDA will likely approve the drug.[16]

In 1984, Congress enacted the Hatch-Waxman Act, which revised the FDCA. The act resulted in changes to the process for approving generic products, with the aim of bringing them to market faster while still encouraging companies to invest resources in developing new drug products. One major change the act brought about was the introduction of an abbreviated new drug application (ANDA). The ANDA process for generics allows the company to show bioequivalence[17] instead of having to conduct new, costly clinical trials to prove the safety of a drug. Rather, the generic manufacturers can rely on clinical studies and data generated by other manufacturers to prove that the drug is safe.[18]

Separately, the FDA oversees a publication called the *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is more commonly referred to as the *Orange Book*. The *Orange*

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[13] Company Info: Teva in Facts and Figures, Teva, *available at* https://www.tevapharm.com/our-company/teva-facts-figures/.

[14] Our Story, Amneal, *available at* https://amneal.com/about/our-story/.

[15] Amneal at-a-glance, Amneal, *available at* https://amneal.com/about/our-story/amneal-at-a-glance/.

[16] Opinion, pp.3-4

[17] The FDA defines bioequivalence as the following: "Two products are considered to be bioequivalent when they are equal in the rate and extent to which the active pharmaceutical ingredient (API) becomes available at the site(s) of drug action." Bioequivalence, U.S. Food & Drug Administration, *available at* https://www.fda.gov/animal-veterinary/abbreviated-new-animal-drug-applications/bioequivalence

[18] Opinion, p.4

Book includes all the small-molecule drugs approved by the FDA to be marketed in the United States, information on the approved drugs (such as dosages and forms), and the FDA's therapeutic equivalence evaluations. The latter are the approved products that are pharmaceutically equivalent as well as bioequivalent to an existing approved product, such as the generic form of a brand-name drug. Moreover, the *Orange Book* provides information on patents and exclusivities that can protect a brand-name drug from generic competition.[19]

Only certain types of pharmaceutical patents can be listed in the *Orange Book*. A company applying for FDA approval of a new drug must include in its NDA any patent that (1) is an active ingredient patent or a formulation patent that claims the relevant drug or (2) a patent that claims a method of using the drug for which approval is being sought. If the FDA approves the drug, the NDA's patent information and any updates are listed in the *Orange Book*. FDA regulations state that patents claiming processes, packaging, metabolites, or intermediates must not be included in an NDA. As a result, these types of patents should not be listed.[20]

The FDA does not actively check the patent information in NDAs to confirm that the listed patents claim the drug or a method of using the drug. The agency notes that it takes on a "ministerial" role regarding *Orange Book* patents; its role is only to list the patent information provided by drug companies without necessarily verifying the validity of the patents themselves.[21]

Under the Hatch-Waxman Act, a drug company can seek FDA approval for the generic version of an approved brand-name drug by filing an ANDA. An ANDA must provide one of four certifications, considering every patent listed in the *Orange Book*: Paragraph I certifies that no patents are listed for the drug in question; paragraph II certifies that all the patents included in the *Orange Book* for the drug are expired; paragraph III certifies that the ANDA filer does not provide a challenge to the patents listed; and paragraph IV certifies that the filer of the ANDA challenges the patents listed as invalid or inapplicable.[22]

The FDA can approve ANDAs with paragraph I or II certifications instantaneously, and if the generic applicant makes a paragraph III certification, then the FDA cannot approve the ANDA

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[19] Patent Listing in FDA's Orange Book, Congressional Research Service (December 27, 2024), *available at* https://crsreports.congress.gov/product/pdf/IF/IF12644#:~:text=By%20statute%2C%20a%20company%20seeking,such%20drug%20for%20which%20approval

[20] Ibid.

[21] Ibid.

[22] Ibid.

until the relevant patents have expired. If the generic applicant makes a paragraph IV certification, however, and the NDA filer subsequently sues for patent infringement, this results in a 30-month stay. This means the FDA cannot approve the ANDA for 30 months unless the relevant court resolves the patent dispute before the stay is over. As such, it is in the interest of NDA holders to submit an exhaustive list of all relevant patents in the *Orange Book*.[23]

The Facts of the Case

The product at issue in *Teva v. Amneal* was Teva's ProAir HFA Inhalation Aerosol, which the FDA approved on October 29, 2004. The product is primarily used for the treatment or prevention of bronchospasm associated with reversible obstructive airway disease in adults and children aged 12 or older. The ProAir HFA, delivered in canisters containing 200 doses each, combines the active ingredient albuterol sulfate with the propellant ethanol and an inhaler device to deliver the medication.

Although the ProAir HFA was approved by the FDA as a drug, it includes both the active ingredient albuterol sulfate and the device (or the physical machinery) of the metered-dose inhaler. The FDA reviews and approves metered-dose inhalers as drugs because the primary mode of therapeutic action is derived from the active ingredient, which in this case is albuterol sulfate.[24]

Teva listed nine non-expired patents in the *Orange Book* for its ProAir HFA. Five of these patents were central to the case and generally focused on the device components of the inhaler—such as the dose counter—and addressed various problems related to dose counting. However, none of the patents explicitly claimed the active ingredient albuterol sulfate.[25]

Amneal filed an ANDA to market a generic version of Teva's ProAir HFA, which uses albuterol sulfate, the same active ingredient as Teva's product. In response to Teva's listing of multiple patents in the *Orange Book* claiming its ProAir HFA product, Amneal filed a paragraph IV certification asserting that its generic product did not infringe on the nine listed patents. Amneal notified Teva of this certification on August 24, 2023. Following Amneal's paragraph IV certification notice, Teva initiated a lawsuit against Amneal, claiming infringement of six of the

[23] Ibid.

[24] Opinion, p.12

[25] Opinion, pp.13-15

listed patents. Teva later amended its complaint to focus on the five specific patents referenced earlier. [26]

Amneal responded with several counterclaims, including antitrust violations, declaratory judgments of noninfringement and invalidity, and a request for an order to delist the five patents asserted by Teva. Amneal argued that Teva's infringement suit triggered a 30-month stay of the FDA's final approval of Amneal's ANDA. Amneal further alleged that if Teva had not listed these patents, it would have filed a paragraph I certification, which would not have resulted in a 30-month stay. In response, Teva moved to dismiss Amneal's antitrust and delisting counterclaims, which resulted in Amneal cross-moving for a motion for judgment on the pleadings, arguing that Teva did not properly list the asserted patents. [27]

The Initial Decision of the United States District Court for the District of New Jersey

On June 10, 2024 the district court ultimately denied Teva's motion to dismiss Amneal's counterclaims and granted Amneal's motion for judgment. Furthermore, the district court ordered Teva to delist their five asserted patents, concluding that the company improperly listed the asserted patents because they did not claim the active ingredient, albuterol sulfate, but were directed at components of the inhaler device.[28]

The district court rejected Teva's primary argument that a patent claims a product if it could be infringed by that product. It also dismissed Teva's claim that the patents were listed properly because they claimed components of the ProAir HFA (albuterol sulfate) Inhalation Aerosol.[29] The court noted that Teva's reasoning did not account for the statutory phrase "for which the applicant submitted the application," which requires the claim to explicitly include albuterol sulfate.

Teva then appealed the district court's interlocutory delisting order to the Federal Circuit. Following the appeal, the Federal Circuit issued a stay of the district court's order pending its review, thereby temporarily halting the requirement for Teva to delist the patents from the *Orange Book*. [30]

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[26] Opinion, p.15

[27] Opinion, pp.15-16

[28] Opinion, pp.2-3

[29] Opinion, p.16

[30] Opinion, pp.16-17

The Federal Circuit's Decision and Opinion

Teva argued that the district court erred by interpreting the listing provision too narrowly, limiting it to patents that claim the active ingredient. The company contended that a patent can be listed in the *Orange Book* if it claims any part of the NDA product. Specifically, Teva's ProAir HFA inhaler included features like an active ingredient, a dose counter, and a canister, and the patents in question claimed the dose counter and canister components—which, according to Teva, meant that its patents were properly listed in the *Orange Book*.

The Federal Circuit noted that Teva's argument relied on two key points: (1) that a patent "claims the drug" if the NDA product infringes the claim, meaning that the claimed invention is found in any part of the NDA product, and (2) that the FDA's broad definition of "drug" includes any component of an article intended to treat disease. Therefore, the court explained that Teva asserted that its patents, which claim components of the ProAir HFA, should be listed.[31]

The court rejected Teva's interpretation and stated that a patent claims the drug only if it "particularly points out and distinctly claims the drug as the invention." Simply describing the features of the approved drug is insufficient. Additionally, the court rejected the notion that a patent claiming any component of a drug is listable. Instead, a patent must claim at least the active ingredient that made the product approvable as a drug.[32]

Teva further argued that even if its statutory arguments were rejected, the Federal Circuit should remand for the district court to construe the claims. The Federal Circuit also rejected this argument, stating that even with Teva's proposed construction, the patents do not qualify for listing because they do not claim the active ingredient. The court upheld the district court's order to delist the patents and affirmed that only patents claiming the active ingredient can be listed in the *Orange Book*.[33]

The court delved into the above topics in more detail in its opinion. It first rejected Teva's interpretation of what it means to claim a drug and then explained why a listable patent is one that distinctly claims the relevant active ingredient. Lastly, the court evaluated Teva's argument that its patents include claims requiring the presence of an "active drug."[34]

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[31] Opinion, pp.17-18

[32] Opinion, p.18

[33] Opinion, pp.18-19

[34] Opinion, p.19

Teva's Interpretation of "Claims the Drug"

The court rejected Teva's argument that a patent claims the drug if it describes any part of the NDA product, emphasizing that the patent must claim at least the active ingredient. The court further rejected Teva's interpretation that the scope of what a patent "claims" is the same as the products that infringe a patent. Teva's argument was found to be defective by the court as it conflates two distinct statutory requirements: claiming and infringing.[35]

The court emphasized that the listing provision in the statute identifies "infringing" and "claiming" as separate requirements. Accepting Teva's interpretation would render parts of the statute redundant. As such, Teva's argument, that the specialized meanings of "claim" and "infringe" in patent law support its interpretation, was dismissed. The court emphasized that these terms have distinct meanings. Claims define the invention, whereas infringement occurs when someone unauthorized makes, uses, or sells the invention.[36]

The court further explained that claims and infringement are analyzed differently. Claims focus on what the patent document specifies as the invention, while infringement is assessed by examining if an existing product meets the claim's limitations. Literal infringement exists when each claim limitation is found in the accused product. The court referenced case law and statutory provisions to clarify that a patent claims something by distinctly identifying it as the invention, whereas infringement involves determining if each element of the pre-existing claim is found in the accused product. The court concluded that whether Teva's NDA infringes its patents is separate from whether those patents claim the drug for which Teva submitted the application.[37]

Combination Products

Although Teva's ProAir HFA was approved as a combination product (drug and device), the court explained that device components alone do not qualify as a drug for the purpose of listing patents in the *Orange Book*. The approval pathway for a combination product does not transform the device parts into a drug, and the active ingredient must still be claimed.[38] Teva argued that a patent should be listed in the *Orange Book* if it claims any part of the NDA product.

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[35] Opinion, pp.20-21

[36] Opinion, p.21

[37] Opinion, pp.27-28

[38] Opinion, p.36

According to Teva, the statutory definition of "drug" under the FDCA includes any component intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. As a result, the company contended that patents claiming device parts of its NDA product should also be listed. The court rejected Teva's argument, stating that the FDCA's definition of "drug" must be understood within the broader statutory context. [39] The court emphasized that a patent must claim at least the active ingredient identified in the application to "claim the drug for which the applicant submitted the application." The presence of a safe and effective active ingredient is ultimately what makes a product FDA-approved as a drug. [40]

The FDCA distinguishes between drugs and devices based on their primary mode of action. Drugs are composed of complex chemical compounds or biological substances. In contrast, devices are defined by their mechanical nature. A device does not achieve its primary intended purpose through chemical action or metabolization, which are essential for drugs to achieve their intended purpose. This distinction informs the approval pathways and regulatory oversight for drugs and devices. The court emphasized that the active ingredient is central to the new drug approval process. The FDA evaluates the safety and efficacy of a drug based on its active ingredient under the conditions prescribed in the proposed labeling. Additionally, ANDAs must demonstrate that the active ingredient is the same as that of the listed drug. This focus on the active ingredient reinforces the requirement that patents must claim the active ingredient to be listed in the *Orange Book*. [41]

The court argued that while the FDA approved Teva's ProAir® HFA as a drug, the device parts of the combination product remain classified as devices. While the approval pathway used by the FDA depends on the primary mode of action, this does not transform the device components into a drug. As such, the court concluded that patents claiming only the device parts do not meet the listing requirement of claiming the drug for which the application was submitted and approved. [42]

Teva's Claim Construction

The court explained that Teva argued that "even if a patent must claim at least the active ingredient to be listed in the *Orange Book*, its patents do claim an active ingredient." Furthermore, Teva argued that each relevant patent does include one claim requiring the

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[39] Opinion, pp.33-36

[40] Opinion, p.37

[41] Opinion, pp.34-36

[42] Opinion, pp.35-36

presence of an "active drug." The court adopted this proposed construction from Teva for the sake of argument but found that a claim requiring "an active drug" is too broad to meet the requirement of distinctly claiming the approved drug with albuterol sulfate as the active ingredient. The court concluded that Teva's construction does not meet the legal standard of distinctly claiming the specific active ingredient in the approved drug product. Consequently, the court upheld the district court's order to delist the five asserted patents, as they determined that Teva's patents do not meet the criteria for listing in the *Orange Book*. [43]

The Federal Circuit's decision sets a precedent for the proper listing of patents, particularly medical device patents, in the *Orange Book*. This ruling reinforces the FTC's ongoing efforts to address potentially improper patent listings, as the agency has expressed concerns about the misuse of the *Orange Book* to delay generic drug entry. The decision not only impacts Teva but also suggests the importance for pharmaceutical companies to claim the active ingredient of the approved drug in their patents to avoid scrutiny from the FTC and other regulatory bodies.

[43] Opinion, pp.37-38