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The Current Status of FTC'S Orange Book Listings Challenge: A Mixed Bag

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On September 14, 2023, the U.S. Federal Trade Commission issued a "Policy Statement" declaring that "improper" pharmaceutical patent listings in the "Orange Book" of the U.S. Food and Drug Administration may constitute an unfair method of competition in violation of Section 5 of the FTC Act.[1] The FDA Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, identifies drug products approved by the FDA based on safety and effectiveness under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.[2] A pharmaceutical drug product must be listed in the Orange Book to be marketed in the United States.[3] The FTC's Policy Statement asserts that there are situations where "a generic company with a competing product facing an infringement suit based on a patent that was improperly listed in the Orange Book [could not] launch its product because the automatic stay would prevent the FDA from granting approval to market the product."[4] When the FTC released its Policy Statement, there were only three Commissioners all of whom were affiliated with the same political party, rather than a full, five-member commission.[5]

Soon after the FTC's initial Policy Statement, on November 7, 2023, the FTC announced its intention to challenge more than one hundred Orange Book listings as improper.[6] About six months later, on April 30, 2024, the FTC announced a second group of challenges to more than 300 Orange Book listings as inaccurate or improper.[7] After each announcement, the FTC sent patent listing dispute letters to the FDA pursuing removal or correction of the subject Orange

[1] FTC, Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book at 1 (Sept. 14, 2023) (hereinafter, "Policy Statement").

[2] *See* Section 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. § 301, *et seq*.

[3] *See* Congressional Research Service Report, Patent Listing in FDA's Orange Book (May 1, 2024).

[4] Policy Statement, *supra* note 1 at 4.

[5] *See* https://www.ftc.gov/about-ftc/commissioners-staff/commissioners.

[6] *See* Press Release, FTC, FTC Challenges More than 100 Patents as Improperly Listed in the FDA's Orange Book (Nov. 7, 2023) (hereinafter, "FTC November Patent Listing Challenges").

[7] *See* Press Release, FTC, FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs (Apr. 30, 2024) (hereinafter, "FTC April Patent Listing Challenges").

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Book listings.[8] This *Legal Backgrounder* examines the status of the Orange Book listings that the FTC has challenged.

The FDA's Delisting Mechanism for Patents Listed in the Orange Book

Patents in the Orange Book can be "delisted" by the New Drug Applicant ("NDA") holder (i.e., the patent owner).[9] If the NDA holder determines that a patent no longer meets the statutory requirements for listing, the NDA holder must promptly notify the FDA as to whether it will amend or withdraw the patent information from the Orange Book.[10] A patent listing may also be disputed by a person other than the NDA holder by notifying the FDA and disputing "the accuracy or relevance of patent information submitted to the Agency."[11] The patent listing dispute "must include a statement of dispute that describes the specific grounds for disagreement regarding the accuracy or relevance of patent information," which the FDA will then send to the NDA holder.[12]

The FTC's Recent Measures in Challenging Some Orange Book Listings

The FTC has had some measure of success participating as amicus curiae in private challenges to Orange Book listings.[13] The U.S. District Court for New Jersey recently found five Teva pharmaceutical patents improperly listed and ordered their removal from the Orange Book.[14] This litigation concerned patents for Teva's ProAir® HFA (albuterol sulfate) Inhalation Aerosol product, which had been discontinued.[15] "Amneal contend[ed] that the Inhaler Patents do not meet the requirement that they claim the relevant drug" and the FTC joined as amicus curiae to support this contention.[16] The court, relying in part on the FTC's amicus brief, concluded that "the Inhaler Patents do not claim the 'finished dosage form' of the approved drug product" and thus "do not claim 'the drug for which the applicant submitted the application.'"[17] The court has stayed the decision in *Teva* pending appeal, and the subject patents currently remain listed in the Orange Book.[18] The FTC has since opened its own investigation concerning these Teva patent listings.

To date, the FTC has not announced any other investigation or brought any enforcement actions concerning Orange Book listings. The overwhelming majority of patents declared by the FTC as improperly listed in the FDA's Orange Book remain listed and in force. Thus far,

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[8] *See* FTC November Patent Listing Challenges *supra* note 6; *see also* FTC April Patent Listing Challenges *supra* note 7.

[9] 21 CFR 314.53(f)(2)(iv).

[10] 21 CFR 314.53(f)(2)(i).

[11] 21 CFR 314.53(f)(1).

[12] *Id.*

[13] *See* Order on Motion to Dismiss, *Teva Branded Pharm. Prod. R&D, Inc. et al., v. Amneal Pharms. of N.Y., LLC, et al.*, No. 2:23-cv-20964 (D.N.J. June 10, 2024), ECF No. 88.

[14] *Id.*

[15] "Teva USA currently distributes an authorized generic of ProAir® HFA (albuterol sulfate) Inhalation Aerosol under NDA No. 021457 in the United States." *Id.* at 6.

[16] *See id.* at 6.

[17] *Id.* at 8.

[18] *See* Carla Baranauckas, *Teva Wins Pause of Order Ousting Patents from Orange Book*, Law360 (June 13, 2024).

only three companies, GlaxoSmithKline, Glaxo Group, and Kaléo Inc., have voluntarily delisted patents. GlaxoSmithKline voluntarily removed patents related to its Anoro Ellipta, Trelegy Ellipta, Arnuity Ellipta, and Ventolin HFA drug products.[19] Glaxo Group voluntarily delisted patents relating to Advair HFA, Flovent HFA, Incruse Ellipta, and Breo Ellipta.[20] Kaléo Inc., voluntarily delisted patents relating to its AUVI-Q and Naloxone Hydrochloride patents.[21] These companies, however, still maintain several patents that the FTC targeted for delisting.[22]

Financial Implications of Delisting Patents

The drug products targeted by the FTC's Orange Book challenges accounted for significant revenue earned by pharmaceutical companies in 2023. For example, the patents that GlaxoSmithKline voluntarily delisted relate to the following drugs: Anoro Ellipta, Trelegy Ellipta, Arnuity Ellipta, and Ventolin HFA. While any financial impact is uncertain and subject to many factors, in 2023 these drugs earned $293 million, $1.756 billion, $32 million and $436.23, respectively, in North American revenue for GlaxoSmithKline.[23] The patents that Glaxo Group voluntarily delisted relate to the following drugs: Advair products, Flovent products, Incruse Ellipta and Breo Ellipta. While any financial impact is uncertain and subject to many factors, in 2023 these drugs earned $372 million, $308 million, $85 million and $475 million, respectively, in North American revenue for Glaxo Group.[24] The revenue implicated by the Teva patents currently under investigation by the FTC is not publicly available because Teva Pharmaceuticals and its subsidiary Norton (Waterford) Ltd. do not publicly list their revenue by product. Rather than voluntarily delist, some companies have responded commercially to the FTC's challenge of Orange Book listings. Boehringer Ingelheim, for example, has capped out-of-pocket costs for inhalers at $35 for its drug products related to inhalers.[25]

Conclusion: A Mixed Bag

To date, the FTC has not taken any enforcement action concerning the Orange Book challenges the agency first announced in November 2023. The only subsequent delistings have been voluntary and most Orange Book listings challenged by the FTC remain in force. Unless and until the FTC proceeds with a litigated enforcement challenge of an Orange Book listing that results in a court decision, it remains to be seen whether the FTC's conduct in this area is even an appropriate exercise of the agency's power—given that all patents in the United States are issued by the U.S. Patent and Trademark Office, pharmaceutical products are additionally regulated by the FDA, and FDA regulations provide an effective mechanism for private parties, such as economically motivated generic competitors, to challenge the propriety of Orange Book listings.

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[19] Letter from Amy Chevalier Efantis, Vice President, Gov't Affairs & Pub. Policy, GlaxoSmithKline, to Elizabeth Warren, U.S. Senate, and Pramila Jayapal, U.S. House of Representatives (Jan. 12, 2024).

[20] *Id.*

[21] Letter from Ned Ruffin, Chief Legal & Compliance Officer, Kaleo, to Elizabeth Warren, U.S. Senate, and Pramila Jayapal, U.S. House of Representatives (Jan. 12, 2024).

[22] *See* FTC November Patent Listing Challenges *supra* note 6; *see also* FTC April Patent Listing Challenges *supra* note 7.

[23] Press Release, GlaxoSmithKline, GSK delivers strong 2023 performance and upgrades growth outlooks, 35 (Jan. 31, 2024) (converted to USD using GBP-USD rate as of July 18, 2024).

[24] *Id.*

[25] Press Release, Boehringer Ingelheim, Boehringer Ingelheim caps patient out-of-pocket costs for its inhaler portfolio at $35 per month (Mar. 7, 2024).

