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The FTC and the Orange Book: Considerations for Patent Owners

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Meet the Speakers

Karrie Wheatley
Principal

wheatley@fr.com

Greg Booker
Principal

booker@fr.com

Agenda

- Overview of the FTC Orange Book Statement
- Actions FTC Has Taken Since Issuing the OB Statement
- What's Happening at the Federal Circuit?

Overview of FTC Orange Book Statement

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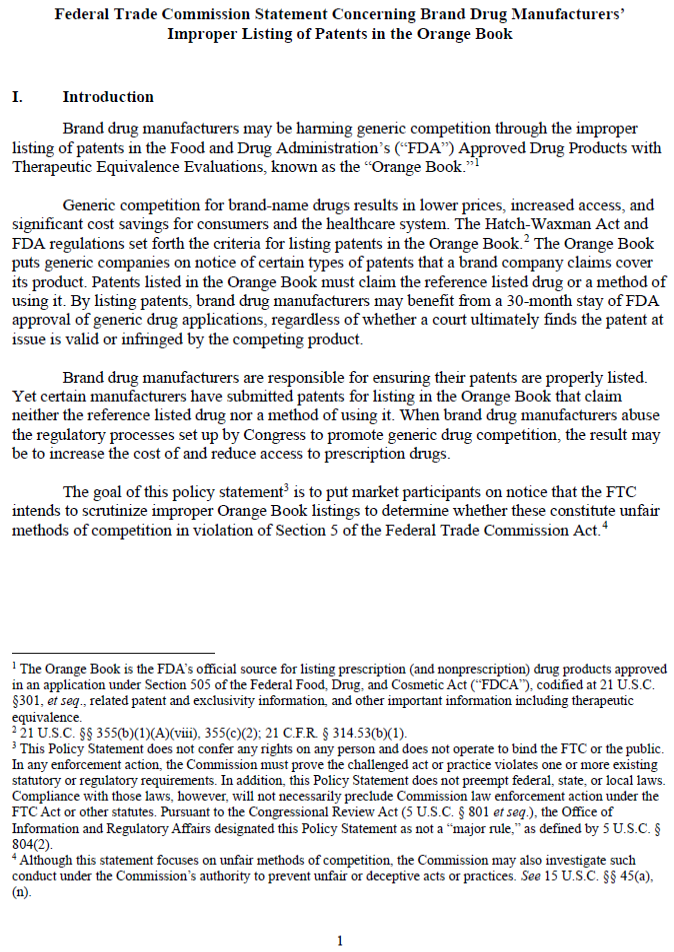
FTC Issues Notice Concerning "Improper Listing" Of Orange Book Patents



Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book

I. Introduction

Brand drug manufacturers may be harming generic competition through the improper listing of patents in the Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations, known as the "Orange Book."[1]

Generic competition for brand-name drugs results in lower prices, increased access, and significant cost savings for consumers and the healthcare system. The Hatch-Waxman Act and FDA regulations set forth the criteria for listing patents in the Orange Book.[2] The Orange Book puts generic companies on notice of certain types of patents that a brand company claims cover its product. Patents listed in the Orange Book must claim the reference listed drug or a method of using it. By listing patents, brand drug manufacturers may benefit from a 30-month stay of FDA approval of generic drug applications, regardless of whether a court ultimately finds the patent at issue is valid or infringed by the competing product.

Brand drug manufacturers are responsible for ensuring their patents are properly listed. Yet certain manufacturers have submitted patents for listing in the Orange Book that claim neither the reference listed drug nor a method of using it. When brand drug manufacturers abuse the regulatory processes set up by Congress to promote generic drug competition, the result may be to increase the cost of and reduce access to prescription drugs.

The goal of this policy statement[3] is to put market participants on notice that the FTC intends to scrutinize improper Orange Book listings to determine whether these constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act.[4]

[1] The Orange Book is the FDA's official source for listing prescription (and nonprescription) drug products approved in an application under Section 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. §301, *et seq.*, related patent and exclusivity information, and other important information including therapeutic equivalence.
[2] 21 U.S.C. §§ 355(b)(1)(A)(viii), 355(c)(2); 21 C.F.R. § 314.53(b)(1).
[3] This Policy Statement does not confer any rights on any person and does not operate to bind the FTC or the public. In any enforcement action, the Commission must prove the challenged act or practice violates one or more existing statutory or regulatory requirements. In addition, this Policy Statement does not preempt federal, state, or local laws. Compliance with those laws, however, will not necessarily preclude Commission law enforcement action under the FTC Act or other statutes. Pursuant to the Congressional Review Act (5 U.S.C. § 801 *et seq.*), the Office of Information and Regulatory Affairs designated this Policy Statement as not a "major rule," as defined by 5 U.S.C. § 804(2).
[4] Although this statement focuses on unfair methods of competition, the Commission may also investigate such conduct under the Commission's authority to prevent unfair or deceptive acts or practices. *See* 15 U.S.C. §§ 45(a), (n).

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"The goal of this policy statement is to put market participants on notice that the FTC intends to scrutinize improper Orange Book listings to determine whether these constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act."

Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sept. 14, 2023) ("FTC Orange Book Statement"), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf at 1.

Two Statutory Categories for Orange Book Listing

(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;

(II) claims a method of using such drug for which approval is sought or has been granted in the application.

21 U.S.C. § 355

FTC's Enforcement Options

"The FTC intends to use its full legal authority to protect patients and payors, including Medicare and Medicaid, from business practices that tend to negatively affect competitive conditions. This includes taking actions against companies and individuals that improperly list patents in the Orange Book that do not meet the statutory listing criteria."

FTC Orange Book Statement at 5.

FTC's Enforcement Options

- Section 5 of the FTC Act (unfair competition)
- Investigate conduct under Commission's authority to prevent unfair or deceptive acts or practices. 15 U.S.C. §§ 45(a),(n)
- Monopolization claim
- Scrutinize OB listings during merger review
- Refer suspected improper OB listings by individual to the U.S. Department of Justice for further investigation

FTC Orange Book Statement at 5-6.

FTC's Stated Policy Concern

"Improper Orange Book patent listings may disincentivize investments in developing a competing product and increase the risk of delayed generic and follow-on product entry, reducing patient access to more affordable prescription drugs and increasing costs to the healthcare system."

FTC Orange Book Statement at 4.

FTC Reminder: NDA Holders are Responsible

"NDA holders are responsible for ensuring that Orange Book patent information is consistent with the listing requirements in 21 C.F.R. § 314.53, and subsection (c)(2)(ii)(R) requires the person who submits the patent information to attest under penalty of perjury that the submission complies with this regulation."

FTC Orange Book Statement at 3.

What Has the FTC Done?

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Overview of FTC Action

- September 14, 2023— FTC Orange Book Statement
- November 10, 2023— FTC sends warning letters to 10 pharma companies
- November 20, 2023— FTC files amicus brief in *Mylan Pharms., Inc. v. Sanofi-Aventis U.S. LLC* in W.D. Penn.
- March 22, 2024— FTC files amicus brief in *Teva Branded Pharms. Products R&D, Inc. v. Amneal Pharms of New York, LLC* in D.N.J.
- April 30, 2024 — FTC send warning letters to 10 companies

The Warning Letters

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FTC Sends Warning Letters to 10 Pharma Companies

November 2023

- Notified each company of the patents FTC viewed as improperly listed

NDA	Product Number	Product	Patent Number	Listing Type

- Informed the company that FTC opted to use the FDA's regulatory dispute process to address the allegedly improper listings

- Reserved the right "to take any further action the public interest may require," including investigating the listing as an unfair method of competition under Section 5 of the FTC Act, 15 U.S.C. § 45

FTC Sends Another 10 Warning Letters in April 2024

"By filing bogus patent listings, pharma companies block competition and inflate the cost of prescription drugs, forcing Americans to pay sky-high prices for medicines they rely on...By challenging junk patent filings, the FTC is fighting these illegal tactics and making sure that Americans can get timely access to innovative and affordable versions of the medicines they need."

-FTC Chair Lisa M. Khan

https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma (last accessed Dec. 10, 2024)

The Amicus Briefs

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Mylan Pharmaceuticals, Inc. v. Sanofi-Aventis U.S. LLC

- Mylan alleged that Sanofi improperly listed patents in the OB as covering injectable form of diabetes drug insulin glargine, commercially marketed in as Lantus SoloSTAR and Toujeo
- Mylan filed complaint bringing monopolization and attempt at monopolization claims under the Sherman Act, 15 U.S.C. § 2
- Sanofi moved to dismiss
- FTC filed amicus brief

Complaint, *Mylan Pharmaceuticals, Inc. v. Sanofi-Aventis U.S. LLC*, No. 2:23-cv-836 (W.D. Penn. May 2023), ECF No. 1.

Mylan Pharmaceuticals, Inc. v. Sanofi-Aventis U.S. LLC

"[T]his harm can extend beyond the delay from the 30-month stay: improper listings can distort the competitive process by affecting the planning and incentives of potential competitors. Indeed, ***the prospect of a 30-month stay may deter rivals from developing lower-cost generic products, permanently depriving the market of competition and access to affordable medications.*** Improperly listing an ineligible patent, either on its own or alongside other anticompetitive conduct, may therefore constitute ***illegal monopolization***."

Brief for FTC as Amicus Curiae Supporting Plaintiffs at 3, *Mylan Pharmaceuticals, Inc. v. Sanofi-Aventis U.S. LLC*, No. 2:23-cv-20964-JXN-MAH (D.N.J. Mar. 22, 2024), ECF No. 61.

Teva Branded Pharm. Prods. R&D, Inc v. Amneal Pharmaceuticals of New York, LLC

- Teva sued under the HW Act for infringement of patents listed in connection to its ProAir® HFA (albuterol sulfate) Inhalation Aerosol ("ProAir® HFA")

- Amneal brought counterclaims seeking declarations ordering Teva to delist the patents at issue from the Orange Book and alleging violations of the Sherman Act and state antitrust laws

- Teva moved to dismiss; Amneal moved for judgment on the pleadings

- FTC filed for leave to file an amicus brief

Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC, No. CV 23-20964 (SRC), 2024 WL 2923018, at *9 (D.N.J. June 10, 2024)

Teva Branded Pharm. Prods. R&D, Inc v. Amneal Pharmaceuticals of New York, LLC

ORDERED that it is the Judgment of this Court that U.S. Patent Nos. 8,132,712, 9,463,289, 9,808,587, 10,561,808, and 11,395,889 have been improperly listed in the Orange Book in regard to the drug product that is the subject of NDA No. 021457; and it is further

ORDERED that, pursuant to 21 U.S.C. § 355(j)(5)(c)(ii)(I), Teva must correct or delete the relevant Orange Book patent information listings to reflect the Judgment of this Court.

Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC, No. CV 23-20964 (SRC), 2024 WL 2923018, at *9 (D.N.J. June 10, 2024)

Teva v. Amneal Appeal

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Outline

- NDA product
- Representative claim
- Listing Statute
- FTC’s Position
- Parties’ Arguments

NDA Product

- Teva's metered dose inhaler ("MDI") product, ProAir® HFA

- Drug-device combination product: an inhaler device that delivers a metered dose of the active ingredient albuterol sulfate in aerosol form

- FDA regulates the MDI as a drug and approved ProAir® HFA, including the inhaler, under the statute and regulations governing NDAs

Representative Patent Claim

Claim 1: An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,

the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

FTC & Defendant's Position

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Listing Statute

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.

FTC's Position

- In the Orange Book Transparency Act of 2020 ("OBTA") congress amended H-W Act to clarify that a non-method-of-use patent is listable only if:
  - (1) it is a "drug substance (active ingredient) patent or a drug product (formulation or composition) patent," *and* (2) it "claims the drug" for which the brand obtained approval from the FDA.

- Patents at issue are not "drug product" patents
  - Rather, they are drug-agnostic patents directed to mechanical devices—inhalers and dose counters—and do not claim any particular active ingredient or drug formulation

FTC's Position

- The term "drug product" originates in FDA regulations, which define "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more ingredients"

- The terms "drug product" and "dosage form" include an active ingredient

- A device patent that does not recite any species or genus of active ingredient in its claims is neither a drug substance nor a drug product

FTC's Position

- Drug-Agnostic device patents are not "drug product (formulation or composition)" patents

- Allowing drug-agnostic patents would enable minor device inventions unrelated to the actual medicine to trigger automatic 30-month stays

- "Formulation" and "composition" do not encompass mechanical devices

FTC's Position

- Not Listable: patents that are directed to ***devices*** that can be used as part of a combination drug-device product, without any reference to any particular pharmaceutical formulation or composition delivered by the device

- Listable: patents that claim a formulation comprising albuterol and HFA as a propellant

“reading on” the NDA drug is insufficient

- *Lantus*: patent on the drive mechanism of an injector pen did not “claim the drug” for which the brand’s application was approved because the patent “neither claims nor even mentions insulin glargine or the Lantus SoloSTAR”

- *Lantus*: a patent that claims a transmission system would “read on” a car that has that transmission, but one would not say that patent “claims” the car.

Defendant's Arguments

- OBTA was introduced in response to concern that brand companies were submitting patents for the purpose of blocking generic competition

- Committee Report commented on proliferation of the listing of device patents

- The FDCA prohibits the FDA from treating a device as if it were a drug, even though the term "drug" is broadly defined that it linguistically could include a device

Defendant's Arguments

- The Listing Statute requires a "drug product" patent to have at least one claim require the NDA drug substance to be present in the claimed invention
- The OBTA was intended to codify current regulations and practice regarding the types of patent information listed in the Orange Book; e.g. "drug product" refers to a product that necessarily contains a drug substance
- Because a "drug product" requires the presence of a drug substance, a "drug product" patent must require the presence of a drug substance in the claimed product

Defendant's Arguments

- Relies on *Lantus* for First Circuit holding a patent claims a device for use in an injector pen was not properly listed in the Orange Book for an insulin glargine injector pen, because the claims did not mention the drug

- Relies on *United Food* for the Second Circuit stating that a patent claim that fails to explicitly include the drug does not claim the drug

Patentee/Apellant's Position

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Patentee-Appellant's Statement of the Issue

STATEMENT OF THE ISSUES

1. Whether the statutory requirement to list in the Orange Book any patent that "claims the drug for which the applicant submitted [an NDA] and is a drug product (formulation or composition) patent" excludes drug product patents unless they recite, by name, the active ingredient in the drug product.

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Patentee-Appellant's Arguments

- FDA regulations define "drug product" as a finished dosage form
- "dosage form" is defined as "the physical manifestation containing the active ingredients that deliver a dose of the drug product"
- Patents claiming the "dosage form" must be listed (but patents on packaging cannot be listed)
- FDA expressly categorizes metered aerosols as a dosage form

Patentee-Appellant: What is a "drug"?

The FDCA expressly defines the term "drug" as:

> (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

Patentee-Appellant: What is a "drug"?

- The statute expressly defines "drug" to include not just the active ingredient, but the entirety—specifically including any component—of any article used for the treatment or prevention of disease or to affect any function of the body

- The term "drug" covers the entirety of the drug product and any component thereof—not just the active ingredient

- A patent claims a drug if it reads on any aspect of the drug product

Patentee-Appellant's Arguments

- The scope of what a patent "claims" must be determined through an infringement-type analysis

- The First Circuit in *Lantus* failed to consider the well-established patent-law meaning of "claims," instead equating "claims" with "mentions"

- The asserted patents read on ProAir HFA, and ProAir HFA is "the drug for which the applicant submitted the application"
  - Thus, the asserted patents "claim the drug for which the applicant submitted the application"
  - A "drug product" includes "finished dosage forms" – "metered aerosols" are "dosage forms"

Patentee-Appellant's Response to OBTA "claim the drug"

- Until 2020, the statute contained no reference to "drug substance" patents

- In the OBTA, Congress did not amend the phrase "claim the drug"; rather, it added a separate requirement that a listable patent be either a drug product patent, a drug substance patent, or a method patent

- The amendment did not alter the meaning of "claim the drug"

Patentee-Appellant's Arguments

- FTC's position would make patents claiming a genus of active ingredients not listable

- FTC's position would make patents that claim one of multiple active ingredients in combination products not listable

What is Listable?

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.

Claim:

A metered dose inhaler comprising

(a) HFA

Is This Listable?

(A) A metered dose inhaler comprising

(a) *Albuterol* and

(b) HFA

(C) A metered dose inhaler comprising

(a) [*large genus* that includes albuterol] and

(b) HFA

(B) A metered dose inhaler comprising

(a) [*small genus* that includes albuterol] and

(b) HFA

(D) A metered dose inhaler comprising

(a) an *active ingredient* and

(b) HFA

Karrie Wheatley
Principal
wheatley@fr.com

Greg Booker
Principal
booker@fr.com

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