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FTC Challenges to Orange Book Listings: Considerations for Patent Holders

December 14, 2023

Meet the Speakers

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Agenda

The FTC's November 7 letters

FDA and the Orange Book Patent Listing Process

FTC and the District Court

What to do?

The FTC's November 7 letters

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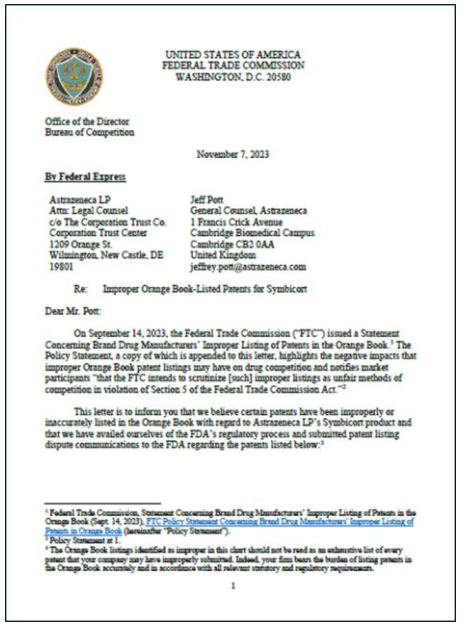
The Issue - the FTC's November 7 letters

Letters sent to 10 pharma companies:

- Astrazeneca LP, Abbvie, Inc., Teva Branded Pharmaceutical; Norton Limited, Mylan Specialty LP, Kaleo Inc., Impax Labs, Glaxo Smith Kline, Glaxo Group, and Boehringer Ingelheim
- Covered technology relates to "specific asthma and other inhaler devices, Restasis multidose bottles, and epinephrine autoinjectors, also commonly known as EpiPens"

FTC also notified FDA, pursuant to 21 C.F.R. § 314.53(f)(1), that the agency "disputes the accuracy or relevance of the listed information for these patents, which may require that the manufacturers remove the listing or certify under penalty of perjury that the listings comply with applicable statutory and regulatory requirements."

- Gives NDA holders 30 days to withdraw the patents, amend their listing, or certify that the patents are properly listed.



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Director
Bureau of Competition

November 7, 2023

By Federal Express

Astrazeneca LP
Attn: Legal Counsel
c/o The Corporation Trust Co.
Corporation Trust Center
1209 Orange St.
Wilmington, New Castle, DE
19801

Jeff Pott
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Re: Improper Orange Book-Listed Patents for Symbicort

Dear Mr. Pott:

On September 14, 2023, the Federal Trade Commission ("FTC") issued a Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book.[1] The Policy Statement, a copy of which is appended to this letter, highlights the negative impacts that improper Orange Book patent listings may have on drug competition and notifies market participants "that the FTC intends to scrutinize [such] improper listings as unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act."[2]

This letter is to inform you that we believe certain patents have been improperly or inaccurately listed in the Orange Book with regard to Astrazeneca LP's Symbicort product and that we have availed ourselves of the FDA's regulatory process and submitted patent listing dispute communications to the FDA regarding the patents listed below:[3]

[1] Federal Trade Commission, Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sept. 14, 2023), FTC Policy Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in Orange Book (hereinafter "Policy Statement").
[2] Policy Statement at 1.
[3] The Orange Book listings identified as improper in this chart should not be read as an exhaustive list of every patent that your company may have improperly submitted. Indeed, your firm bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements.

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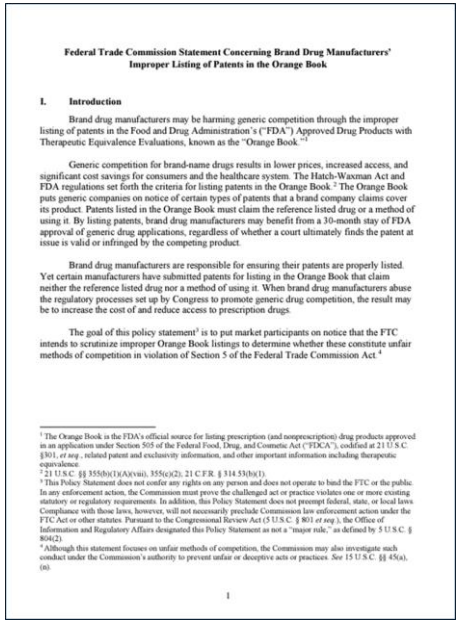

Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book

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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History and a Glance at the Future

Amicus Brief, *American Bioscience, Inc. v. BristolMyers Squibb Co.*, No. 00-cv-08577 (C.D. Cal. September 7, 2000)

- https://www.ftc.gov/sites/default/files/documents/cases/2000/09/amicusbrief.pdf

January 8, 2002 -- In re: Buspirone Patent Litig., MDL Docket No. 1410 (S.D.N.Y. 2002)

- https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-buspirone-antitrust-litigation/buspirone.pdf

April 23, 2002 – FTC's complaint and proposed Consent Agreement in *Bioavail v. Andrx* matter

- https://www.ftc.gov/sites/default/files/documents/cases/2002/04/bioavaildecision.htm

Amicus Brief, *SmithKline Beecham Corp. v. Apotex Corp*., No. 99-cv- 4304 (E.D. Pa. January 28, 2003)

- https://www.ftc.gov/sites/default/files/documents/amicus_briefs/smithkline-beecham-corp.v.apotex-corp./smithklineamicus.pdf

History and a Glance at the Future, continued

June 18, 2003, FDA amended 21 C.F.R. § 314.53 to clarify Patent Submission and Listing Requirements.

- limits to one per ANDA or 505(b)(2) application the maximum number of statutory 30-month stays of approval to which an innovator will be entitled when it submits multiple patents for the same NDA.
- Patents claiming *packaging*, *intermediates*, or *metabolites* must **not** be submitted for listing.
- Patents claiming a different polymorphic form of the active ingredient described in the NDA must be submitted if the NDA holder has test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA.
- Makes changes to the patent information required to be submitted and provides declaration forms for submitting that information to FDA, both with the NDA and after NDA approval; and
- Does not require claim-by-claim listing on the declaration form except for method-of-use patents claiming approved methods of use.

Part of a bigger recent initiative? Government agency activity

2013 - *FTC v. Actavis, Inc*., 570 U.S. 136 (2013)

- reverse payment settlements in patent infringement litigation can sometimes violate the antitrust laws

2015 - *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015); *FTC was also a plaintiff*

- company's payments to generic manufacturers were sufficiently large to give rise to inference that payments were intended to induce them to stay off market

2020 - *FTC v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020)

- sham litigation and reverse payments

Part of a bigger recent initiative? Government agency activity

2020 – present: FTC comments in connection with proposed business deals / transactions

Orange Book Transparency Act of 2020

- Required the FDA to solicit public comment regarding the "types of patent information that should be included on, or removed from, the Orange Book and to transmit to Congress a summary of such comments and actions the Agency is considering taking, if any, in response to such public comment by January 5, 2022."
- No action to date by FDA or Congress

***Impax Lab'ys., Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021)**

- evidence supported finding by FTC using rule-of-reason analysis that reverse payment settlement threatened competition in violation of Sherman Act

July 22, 2022: USPTO issued a Notice clarifying the "duty of reasonable inquiry" and "duty of disclosure" owed to the USPTO as those duties relate to information and "statements material to patentability" that are received from or submitted to the FDA.

- See Federal Register, Vol. 87, No. 145, July 29, 2022.

Part of a bigger recent initiative? Government agency activity

November 10, 2022 -- Amicus Brief, Jazz Pharms., Inc. v, Avadel CNS Pharms. No. 1:21-cv- 00691 (D. Del. Nov. 2022) (Doc. No. 22-3),

- https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf

November 20, 2023 -- FTC's amicus filing in *Mylan v Sanofi* (C.A. No. 23-836-MRH – Western District of Pennsylvania)

"FTC takes no position on Mylan's specific factual allegations"

"The FTC takes no position on whether the specific patents at issue in this case were properly listed."

Part of a bigger recent initiative? Government agency activity

September 2023 – FTC policy statement warning drug manufacturers against improperly listing certain drugs patents in the Orange Book.

- Goal was 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."
- "Listing patents in the Orange Book that do not meet the statutory listing criteria may constitute an unfair method of competition in violation of Section 5 of the FTC Act"
- "[I]mproper listing of patents in the Orange Book may also constitute illegal monopolization."
- "Individuals who submit or cause the submission of improper Orange Book patent listings, including those who certify compliance under 21 C.F.R. § 314.53(c)(2)(ii)(R), may be held individually liable. Further, if the FTC encounters false certifications filed under 21 C.F.R. § 314.53(c)(2)(ii)(R) that may constitute a potential criminal violation for the submission of false statements,34 the Commission may refer such cases to the U.S. Department of Justice for further investigation.

November 7, 2023 – FTC's letter to pharma companies

December 7, 2023 -- Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

- When an invention is made with federal assistance, the federal government may exercise its “march-in” rights to license the patented invention to another party, even when the patent owner disagrees.

Overview

- **The Orange Book and FDA's listing process**
- **Cases discussing listing of patents in the Orange Book**
- **What to do – both going forward as well as looking at previous listing decisions**

FDA and the Orange Book Patent Listing Process

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What is in the Orange Book?

The Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), lists

> (1) drug products approved on the basis of safety and effectiveness, which have not been withdrawn for either of those reasons, by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and
>
> (2) patent and exclusivity information related to approved drug products.

Biologic products, compounded drugs, and drug products that are not the subject of an approved NDA or ANDA, among others, are not listed in the Orange Book.

Why are Patents Listed in the Orange Book?

Timing of approval of 505(b)(2) and Abbreviated New Drug Applications (ANDAs)

Patent and Exclusivity Protections for the Reference Listed Drug (RLD) listed in the Orange Book

- Paragraph I Certification – no Orange Book-listed patents
- Paragraph II Certification – the Orange Book-listed patents have expired
- Paragraph III Certification - the generic applicant does not seek to market its generic product until the Orange Book-listed patent expires
- Paragraph IV Certification - the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA or 505(b)(2) application is submitted)
- Section viii Statement - the patent does not claim a use for which the ANDA or 505(b)(2) applicant is seeking approval

The information contained in the Orange Book allows the generic applicants to easily reference and identify patents that may prevent/delay their generic products' approval.

Benefits of Listing in the Orange Book

Paragraph IV Certification = "Artificial" Act of Patent Infringement

- Generic applicant - Notice of Paragraph IV Certification within 20 days of FDA acknowledgment letter
- Patent owner initiates patent infringement action within 45 days of notice
- 30-month stay of approval of the 505(b)(2) application or ANDA while the litigation is pending is available to timely listed patents

Which Patents are Listed in the Orange Book?

Any unexpired 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

(1) claims the drug substance (active ingredient) or the drug product (formulation or composition) that is the subject of the NDA (or amendment or supplement) or

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

- NDA applicants are required to amend NDA applications if a patent that claims the drug or a method of using the drug is issued after the filing date, but before approval of the application.
- NDA applicants are required to timely list patents that claim the drug or a method of using the drug is issued after the approval date of the NDA.

What Patents are Listed in the Orange Book?

If the patent claims the approved method of use, but does not cover the approved indication or condition of use in its entirety, only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product may be listed.

If the patent claims the approved method of use, but the claimed use is broader than the indication or other approved condition of use in the labeling, only the specific approved method of use that is described in FDA-approved product labeling may be included in the use code.

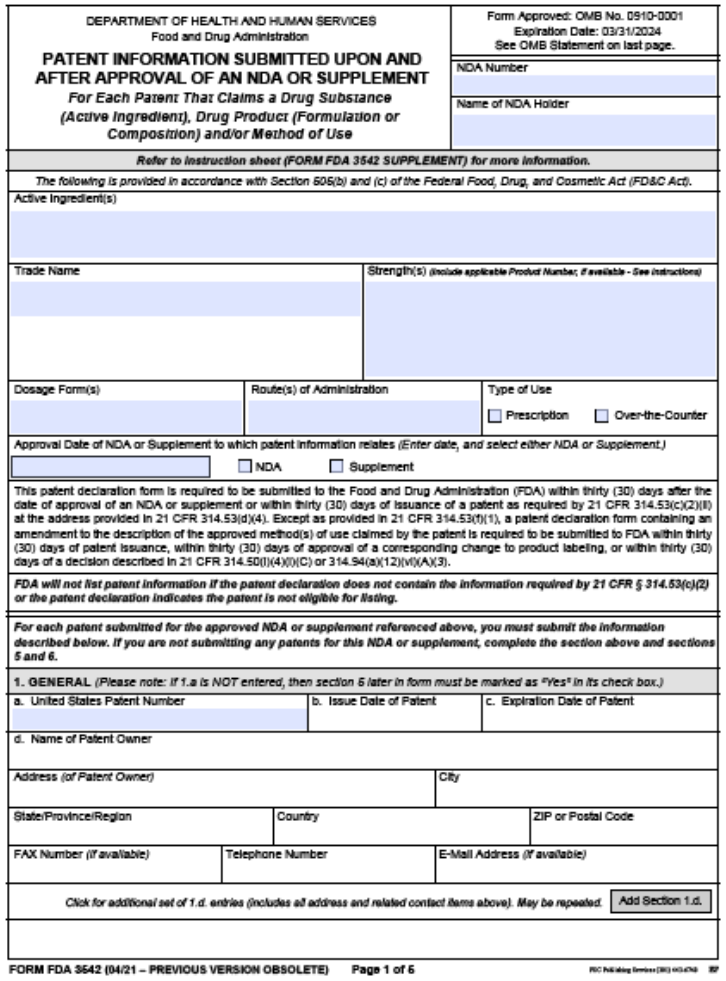
What Patents are Listed in the Orange Book?

Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not listable.

How are Patents Listed in the Orange Book?

The NDA applicant submits form FDA 3542a (pre-approval with the NDA filing) and FDA 3542 (within 30 days of approval or within 30 days of patent issuance after approval).

If the NDA holder submits the patent information after the date on which a substantially complete generic application is submitted, a 30-month stay of approval is not available for the Paragraph IV litigation based on that late listed patent.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation or Composition) and/or Method of Use

Form Approved: OMB No. 0910-0001
Expiration Date: 03/31/2024
See OMB Statement on last page.

NDA Number

Name of NDA Holder

Refer to instruction sheet (FORM FDA 3542 SUPPLEMENT) for more information.

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Active Ingredient(s)

Trade Name

Strength(s) *(Include applicable Product Number, if available - See instructions)*

Dosage Form(s)

Route(s) of Administration

Type of Use
☐ Prescription ☐ Over-the-Counter

Approval Date of NDA or Supplement to which patent information relates *(Enter date, and select either NDA or Supplement.)*
☐ NDA ☐ Supplement

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) within thirty (30) days after the date of approval of an NDA or supplement or within thirty (30) days of issuance of a patent as required by 21 CFR 314.53(c)(2)(ii) at the address provided in 21 CFR 314.53(d)(4). Except as provided in 21 CFR 314.53(f)(1), a patent declaration form containing an amendment to the description of the approved method(s) of use claimed by the patent is required to be submitted to FDA within thirty (30) days of patent issuance, within thirty (30) days of approval of a corresponding change to product labeling, or within thirty (30) days of a decision described in 21 CFR 314.50(l)(4)(i)(C) or 314.94(a)(12)(vi)(A)(3).

FDA will not list patent information if the patent declaration does not contain the information required by 21 CFR § 314.53(c)(2) or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the approved NDA or supplement referenced above, you must submit the information described below. If you are not submitting any patents for this NDA or supplement, complete the section above and sections 5 and 6.

1. GENERAL *(Please note: If 1.a is NOT entered, then section 5 later in form must be marked as "Yes" in its check box.)*

a. United States Patent Number

b. Issue Date of Patent

c. Expiration Date of Patent

d. Name of Patent Owner

Address *(of Patent Owner)*

City

State/Province/Region

Country

ZIP or Postal Code

FAX Number *(if available)*

Telephone Number

E-Mail Address *(if available)*

Click for additional set of 1.d. entries (includes all address and related contact items above). May be repeated. Add Section 1.d.

FORM FDA 3542 (04/21 – PREVIOUS VERSION OBSOLETE) Page 1 of 6

FDA’s Role in patent listing

- FDA's role in patent listing is "purely ministerial" and does not involve substantive review of patents
- FDA does not have the expertise or authority for reviewing patents and assessing patent challenges
- FDA has stated that it does not have the ability for reviewing patent listings due to lack of resources
- It would lead to disputes and increased litigation against the FDA

FDA's Role in Patent Listing

In 2003, FDA amended 21 C.F.R. § 314.53 to clarify the types of patents that must and must not be submitted for listing in the Orange Book.

The preamble to the final rule addressed comments about patents claiming packaging and devices or containers that are 'integral' to the drug product

- Patents claiming packaging or containers must not be submitted
- FDA did not expressly address device-related patents
  - Whether the patent claims the finished dosage form of the approved drug product e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients

FDA's Role in Patent Listing

- Since the 2003 amendments, several drug companies have sought advisory opinions on Orange Book listing requirements of patents claiming drug delivery device and packaging.
    - The FDA has failed to adequately respond to the requests thus far. Thus, there is no clear advice yet from the FDA about the eligibility criteria of patents claiming drug delivery devices.
- In 2016, FDA issued a final rule to implement certain provisions of the The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which revised the requirements related to the submission of patent information.
    - If a patent is eligible for listing based on claiming the drug substance and the drug product, an applicant would only be required to identify one of these two bases for listing.

FDA’s Role in Patent Listing

- In 2020, partially based on the advisory opinions sought from the drug companies, FDA requested comments on the types of patents currently listed in the Orange Book.

- FDA also stated that it is “aware that some NDA holders have submitted patents for listing in the Orange Book, including certain types of device-related patents and REMS-related patents, for which there may be uncertainty regarding whether these are in fact the type of patents that must be submitted.”

- FDA sought comments on the "listing of patents that claim a device constituent part of a combination product approved under section 505 of the FD&C Act (e.g., a drug delivery device); the listing of patents that claim a device whose use is referenced in approved drug labeling; the listing of patents associated with an established REMS; and the listing of patents associated with digital applications (e.g., clinical decision support software, software as a medical device)."

FDA’s Role in Patent Listing

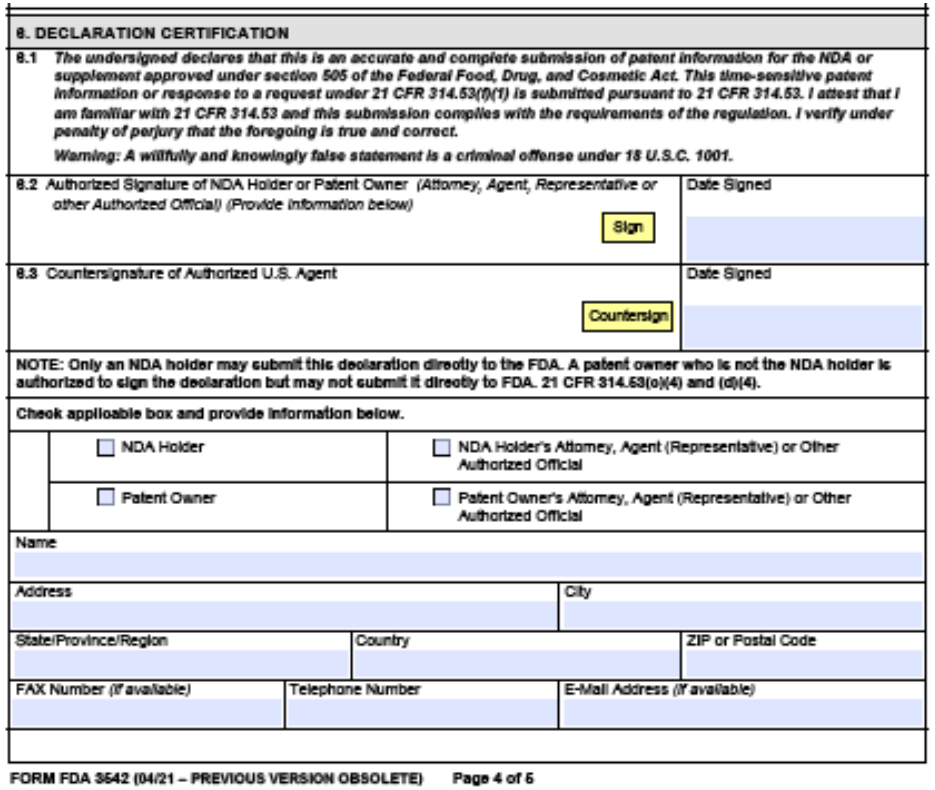
In 2021, the President signed into law the Orange Book Transparency Act of 2020, which required the FDA to solicit public comment regarding the "types of patent information that should be included on, or removed from, the Orange Book and to transmit to Congress a summary of such comments and actions the Agency is considering taking, if any, in response to such public comment by January 5, 2022."

In its report to Congress, FDA stated that it will create a multidisciplinary working group to "evaluate whether additional clarity is needed regarding the types of patents, patent information, or other patent-related information that should be included in, or removed from, the Orange Book, consistent with the current statutory requirements for patent listing in the FD&C Act."

Further FDA action is still pending.

Wrongfully Listing Patents in the Orange Book

- The 3542 form is submitted with a certification under penalty of perjury that the information is correct
- Patent listing dispute
- Patent listing counterclaim in an infringement action
- Antitrust claim



8. DECLARATION CERTIFICATION

8.1 *The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information or response to a request under 21 CFR 314.53(f)(1) is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.*

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

8.2 Authorized Signature of NDA Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide information below)* — Sign — Date Signed

8.3 Countersignature of Authorized U.S. Agent — Countersign — Date Signed

NOTE: Only an NDA holder may submit this declaration directly to the FDA. A patent owner who is not the NDA holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

- ☐ NDA Holder
- ☐ NDA Holder's Attorney, Agent (Representative) or Other Authorized Official
- ☐ Patent Owner
- ☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name

Address | City

State/Province/Region | Country | ZIP or Postal Code

FAX Number *(if available)* | Telephone Number | E-Mail Address *(if available)*

FORM FDA 3542 (04/21 – PREVIOUS VERSION OBSOLETE) Page 4 of 5

Patent Listing Disputes

- 21 C.F.R. § 314.53(f)(1) describes a process for patent listing disputes
  - Disputing the accuracy or relevance of patent information published in the Orange Book
    - FDA sends a statement of the dispute to the NDA holder
  - NDA holder's response to patent listing disputes
    - NDA verifies correctness, or withdraws or amends the patent information or use code within 30 days
- FDA updates the Orange Book Patent Listing Dispute List

Patent Listing Dispute List

Patent Listing Disputes

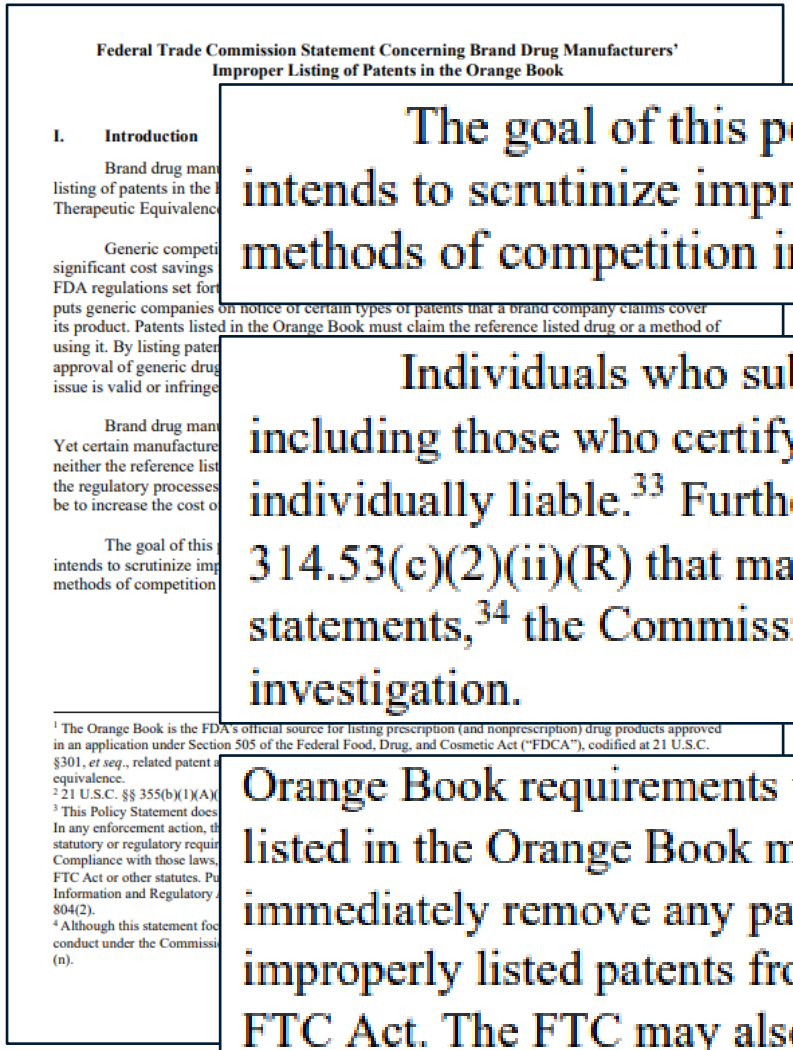
Current through December 08, 2023

Established Drug Product Name	NDA Number	NDA Holder	Strength(s)	Relevant U.S. Patent Number(s)	Type of Patent Claim	Original Use Code (if applicable)	Revised Use Code (if applicable)	Due Date for NDA Holder Response	NDA Holder Response Date	Dispute Outcome
cyclosporine	050790	Abbvie	0.05%	8292129, 8561859, 9669974, 9676525	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
budesonide; formoterol fumarate dihydrate	021929	Astrazeneca	0.08mg/INH; 0.0045mg/INH	7587988, 8387615, 8528545, 8616196, 8875699	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
albuterol sulfate; ipratropium bromide	021747	Boehringer Ingelheim	EQ 0.1mg base/INH; 0.02mg/INH	7284474, 7396341, 7837235, 7896264, 8733341, 9027967	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
ipratropium bromide	021527	Boehringer Ingelheim	0.021mg/INH	8474447	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
tiotropium bromide	021395	Boehringer Ingelheim	EQ 0.018mg base/INH	7694676, 9010323	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
tiotropium bromide	021936	Boehringer Ingelheim	EQ 0.00125mg base/INH	7284474, 7396341, 7837235, 7896264, 8733341, 9027967	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
fluticasone propionate	021433	Glaxo Grp Ltd	0.044mg/INH	7500444	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
fluticasone propionate; salmeterol xinafoate	021254	Glaxo Grp Ltd	0.115mg/INH; EQ 0.021mg base/INH	7500444	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
albuterol sulfate	020983	Glaxosmithkline	EQ 0.09mg base/INH	7500444	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
fluticasone furoate	205625	Glaxosmithkline	0.1mg/INH	8113199, 8161968, 8534281, 8746242	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
epinephrine	201739	Kaleo Inc	EQ 0.15mg/ delivery	7731686, 7731690, 7749194, 8016788, 8920377, 8926594, 9238108, 10960155	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	12/6/2023	Patent Listing Updated
epinephrine	020800	Impax	EQ 0.15mg/ delivery	7905352, 10166334	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	11/21/2023	Patent Listing Updated
epinephrine	019430	Mylan Specialty LP	0.15mg/delivery, 0.3mg/delivery	7449012, 7794432, 8048035, 9586010	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
beclomethasone dipropionate	207921	Norton Waterford	0.04mg/INH	8132712, 10022509, 10022510, 10086156, 10561808, 10695512, 11395889	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
albuterol Sulfate	021457	Teva Branded Pharm	EQ 0.09mg base/INH	8132712, 9463289, 9808587, 10022509, 10022510, 10086156, 10561808, 10695512, 11395889	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
albuterol Sulfate	205636	Teva Branded Pharm	EQ 0.09mg base/INH	8651103, 8978966, 9216260, 9463288, 9731087, 9782550, 9782551, 10022510, 10124131, 10561808, 10569034, 10765820, 11000653, 11266796, 11351317, 11357935, 11439777, 11464923	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending
beclomethasone dipropionate	020911	Teva Branded Pharm	0.04mg/INH	9463289, 9808587, 10022509, 10022510, 10086156, 10561808, 10695512, 11395889	Disputes Not Related to Use Code	N/A	N/A	12/16/2023	Pending	Pending

Litigation Precedent And Implications

FISH.

FTC Policy Statement Re OB Listing Raises Section 5 Power



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

I. Introduction

Brand drug manu
listing of patents in the
Therapeutic Equivalenc

Generic competi
significant cost savings
FDA regulations set fort
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 pater
approval of generic drug
issue is valid or infringe

Brand drug manu
Yet certain manufacture
neither the reference list
the regulatory processes
be to increase the cost o

The goal of this
intends to scrutinize imp
methods of competition

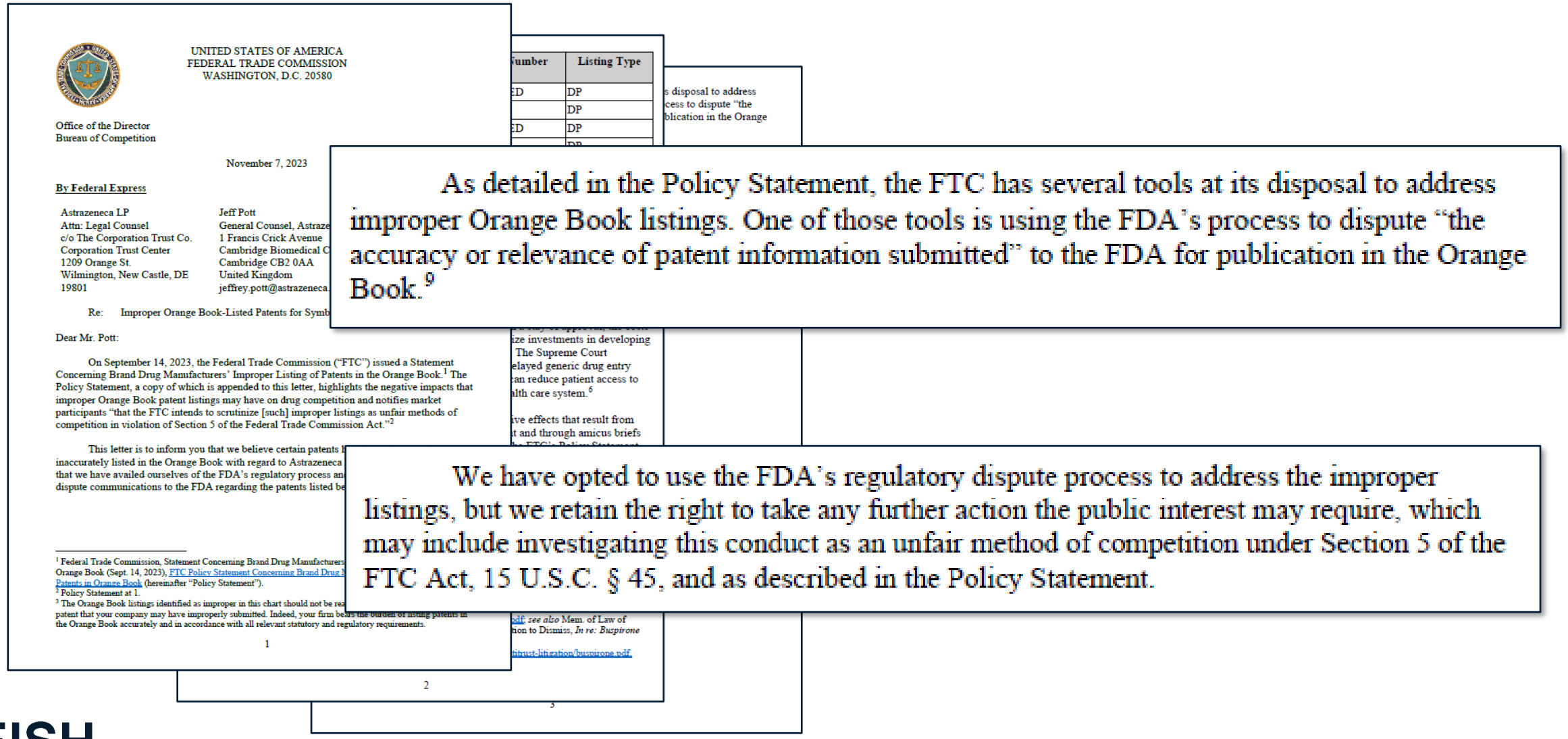
[1] The Orange Book is the FDA's official source for listing prescription (and nonprescription) drug products approved in an application under Section 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. §301, *et seq.*, related patent
equivalence.
[2] 21 U.S.C. §§ 355(b)(1)(A)(
[3] This Policy Statement does
In any enforcement action, th
statutory or regulatory requir
Compliance with those laws,
FTC Act or other statutes. Pu
Information and Regulatory
804(2).
[4] Although this statement foc
conduct under the Commissi
(n).

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]

Individuals who submit or cause the submission of improper Orange Book patent listings, including those who certify compliance under 21 C.F.R. § 314.53(c)(2)(ii)(R), may be held individually liable.[33] Further, if the FTC encounters false certifications filed under 21 C.F.R. § 314.53(c)(2)(ii)(R) that may constitute a potential criminal violation for the submission of false statements,[34] the Commission may refer such cases to the U.S. Department of Justice for further investigation.

Orange Book requirements under the law. Accordingly, NDA holders that currently have patents listed in the Orange Book must ensure that those listings comply with the law and should immediately remove any patents that fail to meet listing requirements. Failure to remove improperly listed patents from the Orange Book promptly may result in legal liability under the FTC Act. The FTC may also dispute patent listings through the FDA process set out in 21 C.F.R.

FTC Notice Letters Also Raise Section 5 Power



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Director
Bureau of Competition

November 7, 2023

By Federal Express

Astrazeneca LP
Attn: Legal Counsel
c/o The Corporation Trust Co.
Corporation Trust Center
1209 Orange St.
Wilmington, New Castle, DE
19801

Jeff Pott
General Counsel, Astraze
1 Francis Crick Avenue
Cambridge Biomedical C
Cambridge CB2 0AA
United Kingdom
jeffrey.pott@astrazeneca.

Re: Improper Orange Book-Listed Patents for Symb

Dear Mr. Pott:

On September 14, 2023, the Federal Trade Commission ("FTC") issued a Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book.[1] The Policy Statement, a copy of which is appended to this letter, highlights the negative impacts that improper Orange Book patent listings may have on drug competition and notifies market participants "that the FTC intends to scrutinize [such] improper listings as unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act."[2]

This letter is to inform you that we believe certain patents l
inaccurately listed in the Orange Book with regard to Astrazeneca
that we have availed ourselves of the FDA's regulatory process an
dispute communications to the FDA regarding the patents listed be

[1] Federal Trade Commission, Statement Concerning Brand Drug Manufacturers
Orange Book (Sept. 14, 2023), FTC Policy Statement Concerning Brand Drug I
Patents in Orange Book (hereinafter "Policy Statement").
[2] Policy Statement at 1.
[3] The Orange Book listings identified as improper in this chart should not be rea
patent that your company may have improperly submitted. Indeed, your firm bears the burden of listing patents in
the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements.

1

Number	Listing Type
ED	DP
	DP
ED	DP
	DP

s disposal to address
cess to dispute "the
blication in the Orange

ize investments in developing
The Supreme Court
elayed generic drug entry
an reduce patient access to
alth care system.[6]

ive effects that result from
t and through amicus briefs

pdf; *see also* Mem. of Law of
tion to Dismiss, *In re: Buspirone*

itrust-litigation/buspirone.pdf.

2

3

As detailed in the Policy Statement, the FTC has several tools at its disposal to address improper Orange Book listings. One of those tools is using the FDA's process to dispute "the accuracy or relevance of patent information submitted" to the FDA for publication in the Orange Book.[9]

We have opted to use the FDA's regulatory dispute process to address the improper listings, but we retain the right to take any further action the public interest may require, which may include investigating this conduct as an unfair method of competition under Section 5 of the FTC Act, 15 U.S.C. § 45, and as described in the Policy Statement.

FTC's Powers Under Section 5 of FTC Act

- Section 5(a) of the FTC Act**, 15 U.S.C. Sec. 45(a)**, prohibits, *inter alia*, "unfair methods of competition." **Unfair methods of competition** include any conduct that would violate the Sherman Antitrust Act or the Clayton Act.
- The FTC may initiate an enforcement action using either an administrative or judicial process if it has "**reason to believe**" that the law is being or has been violated. Violations of some laws may result in civil penalties, which are adjusted annually for inflation. ***Commission Rule 1.98, 16 C.F.R. Sec. 1.98.***
- **Section 13(b) of the FTC Act, 15 U.S.C. Sec. 53(b)**, authorizes the Commission to seek preliminary and permanent injunctions to remedy "any provision of law enforced by the Federal Trade Commission."

Example of FTC Using Section 5 Power

011 0094

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

BIOVAIL CORPORATION,
a corporation.

Docket No. C-4060

COMPLAINT

Pursuant to the provisions of the Federal Trade Commi
virtue of the authority vested in it by said Acts, the Federal Trad
that respondent Biovail Corporation has engaged in conduct tha
and Section 5 of the Federal Trade Commission Act, and it app
proceeding in respect thereof would be in the public interest, her
charges as follows:

Count 2 – Unlawful Monopolization in Violation of FTC Act § 5

54. Biovail has, and at all times relevant to this complaint has had, monopoly power in the market for Tiazac and generic bioequivalent versions of Tiazac in the United States.

55. Biovail engaged in acts to willfully maintain its Tiazac monopoly. These acts included, but were not limited to: (a) acquiring an exclusive license to the '463 patent for the purpose of listing it in the Orange Book; (b) wrongfully listing the '463 patent in the Orange Book as claiming Tiazac, in order to be eligible for an automatic 30-month stay of FDA approval for any generic Tiazac product; and (c) giving non-responsive answers to questions raised by the FDA about the propriety of listing the '463 patent in the Orange Book so as to avoid de-listing.

FTC Has Utilized Judicial Enforcement

- *Fed. Trade Comm'n v. Roomster Corp.*, 654 F. Supp. 3d 244 (S.D.N.Y. 2023)
  - Plaintiff FTC alleges two counts of violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a)
- *Fed. Trade Comm'n v. Quincy Bioscience Holding Co., Inc.*, 646 F. Supp. 3d 518 (S.D.N.Y. 2022)
  - The FTC and the NY AG brought this alleging that defendants' advertising of Prevagen is false advertising in violation of Sections 5(a) and 12 of the FTC Act
- *Fed. Trade Comm'n v. Fleetcor Techs., Inc.*, 620 F. Supp. 3d 1268 (N.D. Ga. 2022)
  - Counts I through IV asserted violations of Section 5 of the FTC Act in connection with allegedly deceptive representations made by FleetCor
- *Fed. Trade Comm'n v. Ivy Cap., Inc.*, 340 F.R.D. 602, 605 (D. Nev. 2022)
  - The FTC initiated this action against movants for their roles in a telemarketing scheme in violation of section 5(a) of the FTC Act and several provisions of the Telemarketing Sales Rule
- *Fed. Trade Comm'n v. Shkreli*, 581 F. Supp. 3d 579, 624 (S.D.N.Y. 2022)
  - The FTC brought this action pursuant to authority given to it in the FTC Act. The FTC Act declares "[u]nfair methods of competition" to be unlawful, 15 U.S.C. § 45 (Section 5 of the FTC Act), and directs the FTC to prevent violations of the FTC Act. "Unfair methods of competition" under the FTC Act encompass violations of the Sherman Act.

FTC’s Policy Statement Insights On Thinking

- “Listing patents in the Orange Book that do not meet the statutory listing criteria may constitute an unfair method of competition in violation of Section 5 of the FTC Act.”
- “Improper listing of patents in the Orange Book as a method of competition. It is undertaken by a brand drug manufacturer and is not an inherent market condition.”
- “Improperly listing patents in the Orange Book can be unfair because it is not competition on the merits of drug quality or price, and it tends to negatively affect competitive conditions by impeding opportunities for generic rials to compete, thus limiting consumer choice.”
- “Improperly listing patents in the Orange Book can be an unfair method of competition is consistent with the FTC’s historical use of Section 5, which has reached ‘conduct resulting in direct evidence of harm, or likely harm to competition, that does not rely upon market definition.’”

Listing Challenges Raised in District Court

- ***Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)**
  - A use code is "patent information" under 21 U.S.C. § 355(j)(5)(C)(ii)(I) and therefore a generic can file a counterclaim challenging not only improper patent listing, but also improper use codes.
- ***Jazz Pharms., Inc. v. Avadel CNS Pharms*., LLC, 60 F.4th 1373, 1378 (Fed. Cir. 2023)**
  - Patent claimed a computer-implemented system for treating a patient with a drug. Court of appeals found that "systems" describe an apparatus as a whole; "methods" describe performance of steps. The statute only allows for listing patents claiming drugs or methods of using drugs. Patent delisted.
- ***In re Actos End-Payor Antitrust Litig., 417 F. Supp. 3d 352, 375 (S.D.N.Y. 2019), aff'd sub nom. United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd., 11 F.4th 118 (2d Cir. 2021)***
  - Antitrust plaintiffs alleging anti-competitive conduct do not need to show an improper Orange Book listing was made in bad faith. Showing a good faith basis for listing, of course, can be part of the defense to an allegation of anti-competitive conduct.
- ***United Food & Com. Workers Loc. 1776 v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 134–35 (2d Cir. 2021)**
  - Brand listed patents claiming drug combinations in Orange Book for drug with only a single active ingredient. Court of Appeals concluded that combination patents claim the combination, not substituent parts. Court further concluded that antitrust plaintiffs need not show that brand's interpretation of listing rules was unreasonable. Plaintiffs need only allege brand had market power, it incorrectly listed, and there was injury.

And Continue To Be Raised

- *Teva Branded Pharm. Inc. v. Amneal Pharm. LLC* No: 23-cv-20964 (D.N.J. Oct. 6, 2023)
- *GW Research Limited v. Teva Pharmaceuticals, Inc. et al*. No: 2-23-cv-00018 (D.N.J. Jan. 3, 2023)
- *Metacel Pharmaceuticals LLC v. Rubicon Research Private Limited* No: 2-21-cv-19463 (D. NJ Oct. 29, 2021)
- *In Re: Ozempic (Semaglutide) Patent Litigation* No: 1-22-md-03038 (D. Del. Aug. 5, 2022)
- Jazz *Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals* No: 1-22-cv-00941 (D. Del. July 15, 2022)
- *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc. et al* No: 1-18-cv-03632 (D.N.J. Mar. 15, 2018)

Reasonable Basis Standard Will Be Important

- *In re Actos End-Payor Antitrust Litig.,* 417 F. Supp. 3d 352, 373 (S.D.N.Y. 2019), aff'd sub nom. *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.,* 11 F.4th 118 (2d Cir. 2021)
  - Plaintiffs could not state a monopolization claim against an NDA holder, predicated on an allegedly improper Orange Book listing, where the defendant's interpretation of the listing statute was reasonable.
- *Organon Inc. v. Mylan Pharms., Inc., 293 F. Supp. 2d 453, 461 (D.N.J. 2003)*
  - Finding no liability where the NDA holder listed a patent claiming an “off-label” use of the drug because there was a “reasonable basis for the submission”

To Be Continued…

- What with the FTC do?
  - Initiate additional FDA processes?
  - Respond to companies who refuse to delist?
  - File an agency enforcement action or a judicial enforcement action?
- What will brand companies do?
  - Explore strategies on how and whether to respond to the FDA process?
  - List questionable patents or not?
  - Remove questionable patents or not?
  - Increase in opinions of counsel on the issue of listing?
- What will generic companies do?
  - More challenges using the FDA process?
  - More challenges in district court?
  - Let the FTC take charge?
- Will this increase certainty or make it worse?

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