

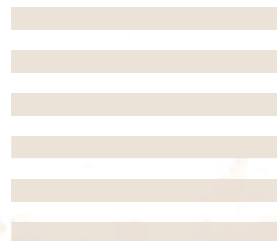


Why is the FTC Seeing Red over FDA's Orange Book Listings?

December 20, 2023

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General Information

- A recording of today's presentation will be circulated following the event
- **CLE:**
 - A CLE Code will be provided later in the presentation
 - CLE credit is available to attendees of the live presentation only
- **QUESTIONS:**
 - Add your questions to the Q+A Section

The views expressed are solely those of the speakers in the context of this discussion. No views should be imputed to employers, clients or others.



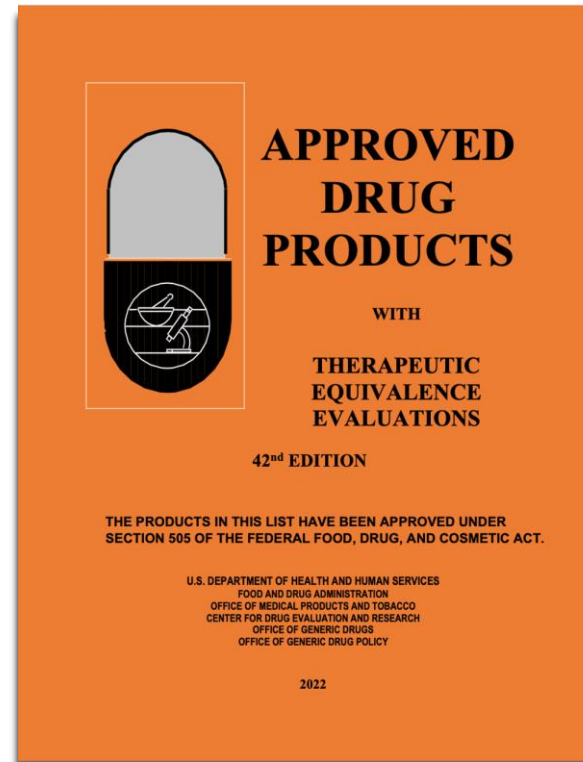
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1. Listing patents in the Orange Book
2. *Jazz Pharms. v. Avadel CNS Pharms*
3. FTC's September Policy Statement and November Actions
4. FTC: competition issues under Section 5 of the FTC Act, 15 U.S.C. § 45

The Orange Book

Includes:

- **FDA-approved drug products**
 - Proprietary name
 - Generic name
 - Dosage
- **Related patent information**
 - Patent numbers
 - Patent expirations
 - NOT all relevant patents
- **Exclusivity information**



Filer's Response

■ Abbreviated New Drug Application (ANDA) and 505(b)(2) pathways

Bioequivalent to RLD

- Streamlined FDA approval
- **Rely on safety & efficacy data** from Innovator's Reference Listed Drug (RLD)

Not Bioequivalent; adds new studies

■ Must Include **Patent Certification**:

- I – No patent info in *Orange Book*
- II – Listed patent(s) expired
- III – Approve Generic at expiry only
- IV – Patent is invalid / not infringed

Paragraph IV Litigation



Paragraph IV Certification = Act of Patent Infringement

35 USC § 271(e)(2)(A)

Prompt suit: Automatic 30-month stay of FDA approval.

(≥ ~6.5 years after initial NDA approval of NCE)

Court adjusts stay if fail “to reasonably cooperate in expediting the action.”

21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

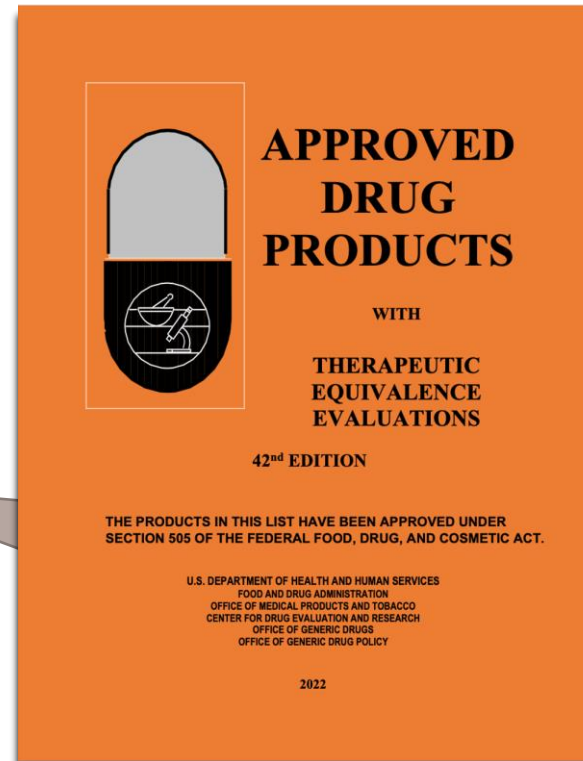
FDA Review and Patent Litigation Progress in Parallel

Looks at “hypothetical” Infringement – based upon proposed Rx label

The Orange Book

Includes:

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 - Proprietary name
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 - Dosage
- **Related patent information**
 - Patent numbers
 - Patent expirations
 - NOT all relevant patents
- **Exclusivity information**



Listable:

- Composition of Matter, e.g.:
 - API
 - Ingredients
 - Formulation
- Method of Treatment / Administration ([Use Codes](#))

Not listable:

- Synthetic methods
- Intermediates
 - *Packaging
 - *Metabolites

Statutory and Regulatory Criteria

- Within 30 days of approval, an NDA holder is required to file with their application or supplement:
 - the patent number and expiration date of each patent for which a claim of patent infringement could ***reasonably be asserted*** if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that:
 - (1) ***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
 - (2) ***claims a method of using such drug*** for which approval is sought or has been granted in the application
- Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.
- FDA will not list or publish patent information if it is not provided on Form 3542 or if the patent declaration does not contain the required information or indicates the patent is not eligible for listing.
- Patent information for patents issued after the date of approval of the NDA must be submitted to FDA within 30 days of the date of issuance of the patent.

FDA's Ministerial *Orange Book* Role

■ FDA does not substantively review listed patent information

- “There can be no question that the FDA's reading ... is reasonable. Indeed, that provision's **requirement that the FDA ‘shall file’ the patent information** submitted by NDA holders is most naturally read to suggest that **Congress intended for the FDA to play a purely ministerial role**. ... the FDA is required only **to ensure** that each NDA applicant has **submitted either a list of patents** claiming its drug **or** a declaration that there are **no patents to be listed**.”

aaiPharma Inc. v. Thompson, 296 F.3d 227, 238-40 (4th Cir. 2002)

- “The FDA has adopted a regulation, 21 C.F.R. § 314.53(f), which implements its view of the allocation of statutory responsibilities. ... **the regulation codifies the FDA’s position that its duties with respect to Orange Book listings are purely ministerial**.”

Apotex v. Thompson, 247 F.3d 1335, 1347 (Fed. Cir. 2003)

FDA's Orange Book Listing Form 3542

- Must submit within statutory timeframe
- Subsections for drug substance, drug product, method of use
 - Each subsection has a checklist describing when FDA **will not** list patents
 - E.g. “FDA will not list the patent in the Orange Book [...] if the answer to question 3.1 is ‘No’...”
 - Method of use subsection requires connection of patent claim to approved method of use in product label
- NDA holder or NDA holder’s agent/attorney must sign Form 3542 and declare, under penalty of perjury, that the for represents an “accurate and complete submission of patent information”

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT <i>For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation or Composition) and/or Method of Use</i>		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(i)(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.		

FDA and Orange Book Listings

- June 2020 FDA Letter responding to **5 Requests for Advisory Opinions** re listing patents in *Orange Book* on (1) **drug delivery systems**, or (2) **protective packaging**.
 - “FDA recently issued a Federal Register notice ... FDA intends to consider [these] issues ... together with comments received on the Federal Register notice and will not separately address the requests for advisory opinions. Accordingly, ... FDA is denying these requests for advisory opinions and inviting the requestors to submit any further comments to the docket associated with the Federal Register notice ...”

Letter from Douglas C. Throckmorton, CDER FDA, to GlaxoSmithKline, et al., FDA-2005-A-0476, FDA-2006-A-0063, FDA-2007-A-0099, FDA-2011-A-0363, and FDA-2012-A-1169 (June 1, 2020).

- *Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments, 85 Fed. Reg. 33,169, 33,170 (June 1, 2020).*
- **[1]** *Request for Advisory Op. by GlaxoSmithKline, FDA-2005-A-0476 (formerly 2005A-0015) (Jan. 10, 2005);* **[2]** *Request for Advisory Op. by AstraZeneca, FDA-2006-A-0063 (formerly 2006A-0318) (Aug. 10, 2006);* **[3]** *Request for Advisory Op. by AstraZeneca, FDA-2007-A-0099 (formerly 2007A-0261) (June 21, 2007);* **[4]** *Request for Advisory Op. by Forest Lab's, Inc., FDA-2011-A-0363 (May 12, 2011);* **[5]** *Request for Advisory Op. by Novo Nordisk Inc., FDA-2012-A-1169 (Nov. 26, 2012).*

Orange Book Transparency Act of 2020

- OBTA requires brand sponsors to notify FDA if any claim of a patent has become canceled or invalidated by a final decision from the Patent Trial and Appeal Board and request that the patent listing be amended or withdrawn.
- *“FDA intends to create a multidisciplinary working group within the Agency 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.”*
 - FDA Report to Congress
- GAO interview of stakeholders
 - About ½ believe that FDA should play more active role to ensure patent information in OB meets listing requirements
 - Most agreed that FDA should clarify which device-related patents should be listed

PUBLIC LAW 116-290—JAN. 5, 2021

134 STAT. 4889

Public Law 116-290
116th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act regarding the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and for other purposes.

Jan. 5, 2021
[H.R. 1503]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Orange Book Transparency Act of 2020”.

Orange Book
Transparency Act
of 2020.
21 USC 301 note.

SEC. 2. ORANGE BOOK MODERNIZATION.

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—

(1) IN GENERAL.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended to read as follows:

“(b)(1)(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

“(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

Reports.

“(ii) a full list of the articles used as components of such drug;

List.

“(iii) a full statement of the composition of such drug; “(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

“(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

“(vi) specimens of the labeling proposed to be used for such drug;

Assessments.

“(vii) any assessments required under section 505B; and “(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

“(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

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

Disputing an Orange Book Patent Listing

Orange Book Questions and Answers Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

July 2022
Generic Drugs

Q18. Can a patent listing be disputed?

A18. Yes. Section 314.53(f)(1) outlines a process through which a person other than the NDA holder can dispute the accuracy or relevance of patent information published in the Orange Book, as well as the process for the relevant NDA holder to respond to such disputes. If any person either “disputes the accuracy or relevance of patent information submitted to the Agency” and published by the Agency in the Orange Book or “believes that an NDA holder has failed to submit required patent information, that person must first notify the Agency in a written or electronic communication titled ‘314.53(f) Patent Listing Dispute.’”

Congressional Interest

"The agency should close loopholes in the patent system that pharmaceutical companies have exploited to rake in billions in profits."

"Pharmaceutical companies, especially brand-name companies, have routinely abused the Orange Book system by improperly listing patents to block the introduction of lower-cost generics"

Congress of the United States

Washington, DC 20515

August 28, 2023

Dr. Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

We are writing to you about the U.S. Food and Drug Administration's (FDA's) responsibilities in addressing the anti-competitive business practices that pharmaceutical companies use to keep drug prices high.¹ Big Pharma companies have abused their monopoly power to jack up prices for life-improving drugs, "straining the healthcare system"² and forcing patients to suffer the consequences, often going without necessary medications due to high costs and rising debts.³

As the agency that is "responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable,"⁴ the FDA approves and regulates medical products such as drugs, biologics, and devices.⁵ The FDA also maintains the Orange Book, which contains a complete list of FDA-approved drug and related patent and exclusivity information, which sponsors of brand-name drugs can use to delay generic competition.⁶ The agency should close loopholes in the patent system that pharmaceutical companies have exploited to rake in billions in profits.

As part of the existing drug approval process, the FDA requires brand-name drug companies to list patents in the Orange Book. The Orange Book covers drug substances (active ingredient), drug product (strength, dosage form, and formulation), and method of use (indication).⁷ After approval, the FDA

¹ American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf

² Initiative for Medicines, Access, and Knowledge (I-MAK), "Overpatented, Overpriced," September 2022, <https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf>

³ Patients for Affordable Drugs, "Ten Reasons Why We Need Lower Drug Prices Now," July 2022, <https://patientsforaffordabledrugs.org/wp-content/uploads/2022/07/P4AD-July-2022-Price-Hikes.pdf>

⁴ U.S. Food and Drug Administration, "What We Do," March 28, 2018, <https://www.fda.gov/about-fda/what-we-do>

⁵ U.S. Food and Drug Administration, "What does FDA regulate?" January 18, 2022, <https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate>

⁶ U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," June 9, 2023, <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>; U.S. Government Accountability Office, "Generic Drugs," March 2023, <https://www.gao.gov/products/gao-23-105477>

⁷ U.S. Government Accountability Office, "Generic Drugs," March 2023, p. 6, <https://www.gao.gov/products/gao-23-105477>

"This creates an incentive for companies to intentionally list 'sham' patents in the Orange Book as a way to hold off generic competition for at least 2.5 years, regardless of the outcome of any litigation."

"The pharmaceutical patents in the Orange Book are considered some of the 'most valuable patents in the world,' but about 25 percent of active patents in the Orange Book have been invalidated in court."



1. Listing patents in the Orange Book
2. *Jazz Pharms. v. Avadel CNS Pharms*
3. FTC's September Policy Statement and November Actions
4. FTC: competition issues under Section 5 of the FTC Act, 15 U.S.C. § 45

Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC 60 F.4th 1373 (Fed. Cir. 2023)

- Narcolepsy Drug Xyrem® → “Date Rape Drug”
- NDA approval – REMS (prescribing / dispensing)
- ’963 patent (2014 listed in *Orange Book*):
 - “Jazz's single-pharmacy distribution system, which **controls access** to abuse-prone prescription drugs prescribed to **narcolepsy patients** through a **central pharmacy** and computer database by **tracking prescriptions, patients, and prescribers.**” (60 F.4th at 1376)
- Avadel 2020 §505(b)(2) NDA: FT218 *with* REMS
 - FDA: Required certification on ’963 patent
 - Jazz: Patent Suit *v. Avadel*
 - Avadel: Admin. Proc. Act. Suit *v. FDA*

Listable:

- Composition of Matter, e.g.:
 - API
 - Ingredients
 - Formulation
- Method of Treatment / Administration ([Use Codes](#))

Not listable:

- Synthetic methods
- Intermediates
 - * Packaging
 - * Metabolites

Jazz v. Avadel – Listing Challenge

- Challenging *Orange Book* Listings:
 - FDA-based challenge
 - Counterclaim to Hatch-Waxman patent suit

“... the applicant may assert a **counterclaim** seeking an order requiring the holder **to correct or delete the patent information** submitted by the holder ... on the ground that the patent does not claim either—
 (aa) the **drug** for which the application was approved; or
 (bb) an approved **method of using the drug.**” 21 U.S.C. §355(c)(3)(D)(ii)(I) (NDA); see §355(j)(5)(C)(ii)(I) (ANDA)

- Computer system **≠** Method of using the drug
- Dist. Ct.: Permanent Injunction to **delist '963 patent** from *Orange Book*
- Fed. Cir: Affirmed



Jazz v. Avadel – FTC Amicus Curiae

The strict statutory limits on Orange Book patent listings serve a vital purpose because **the listing process has significant implications for consumers and for competition.** ... [The] 30-month stay ... reflects Congress's intent to balance the interests of brand and generic drug manufacturers by facilitating the resolution of certain types of patent disputes before generic or 505(b)(2) products are introduced. **But when this stay is triggered by a patent that does not meet the statutory listing criteria, the stay merely blocks consumer access to a competing product that might reduce prices, improve quality, or both. Given the high cost of many drugs, even a short delay in competition can have enormous consequences for the public.**

Case 1:21-cv-00691-GBW Document 222-3 Filed 11/10/22 Page 1 of 27 PageID #: 4447

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

Civil Action No. 21-691-GBW

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

FEDERAL TRADE COMMISSION'S BRIEF AS *AMICUS CURIAE*

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Director
Bureau of Competition

ANISHA DASGUPTA
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1. Listing patents in the Orange Book
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FTC Policy – Sept. 14, 2023 Statement

- Supported by FDA
- “[P]harmaceutical companies ... could face legal action if they improperly list patents in the... ‘Orange Book’.”
- “Improperly listing patents in the Orange Book may harm competition from less expensive generic alternatives and keep prices artificially high, according to the policy statement. The FTC will scrutinize improper Orange Book patent listings as potential unfair methods of competition in violation of Section 5 of the FTC Act.”
- “... illegitimately delay or lock out generic manufacturers from entering the market, depriving Americans of access to lower-cost medicines and drug products ...”

Statement of FTC Chair Khan

The FDA tentatively approved Avadel’s extended-release version ... but by that time, Jazz, another pharma company, had sued Avadel for infringing Jazz’s “Risk

Evaluation and Mitigation

Strategies” (“REMS”) patent—a patent that had nothing to do with the drug itself or an approved method of using the drug. Jazz cited the Orange Book to automatically trigger the 30-month stay, blocking Avadel from the market.



FTC Action – Nov. 7, 2023

FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book

Improper listings may delay lower-cost generic drug competition, stall drug development, and stifle innovation

- “Today, the Federal Trade Commission (FTC) challenged **more than 100 patents** held by manufacturers of brand-name asthma inhalers, epinephrine autoinjectors, and other drug products **as improperly or inaccurately listed in ... the ‘Orange Book.’**
- “The Commission has also **notified FDA that it 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.
- “The **FTC sent notice letters to 10 companies**”

www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book; www.ftc.gov/legal-library/browse/warning-letters/81927

November 7, 2023 Notice Letter:

... certain patents have been improperly or inaccurately listed in the Orange Book ... We have opted to use the FDA's regulatory dispute process ... 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 Amicus Brief – Nov. 20, 2023

For Release

FTC Files Amicus Brief Outlining Anticompetitive Harm Caused by Improper Orange Book Listings

- FTC filed an amicus brief to address the anticompetitive harm that it alleges stems from improperly listed patents
- Antitrust case brought by Mylan alleging that Sanofi-Aventis affiliated entities have engaged in anticompetitive conduct to monopolize the market for injectable insulin glargine
 - Abuse of the FDA's Orange Book regulatory process: Mylan alleges Sanofi delayed and blocked Mylan's generic drug called Semglee from competing with Sanofi's branded insulin glargine drug Lantus by improperly listing several drugs in the Orange Book

<https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-files-amicus-brief-outlining-anticompetitive-harm-caused-improper-orange-book-listings>

FTC's Amicus Brief:

“When triggered by an appropriately listed patent, this 30-month stay reflects **Congress’s intent to balance the interests of brand and generic drug manufacturers** by facilitating the resolution of certain types of patent disputes before generic or other competing follow-on products are introduced. But when this stay is triggered by a patent that does not meet the statutory listing criteria, the stay merely delays consumer **access to a competing product that might reduce prices, improve quality and access, or both.**”



1. Listing patents in the Orange Book
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Section 5 of the FTC Act, 15 U.S.C. § 45

- Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful
 - Exclusive FTC jurisdiction

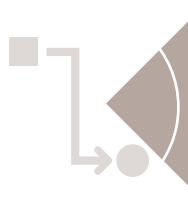
On July 9, 2021, the FTC withdrew the Statement of Enforcement Principles Regarding “Unfair Methods of Competition” Under Section 5 of the FTC Act previously issued by the FTC in 2015

On Nov. 10, 2022, the FTC issued a new Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act

- According to the FTC, the 2015 Statement abrogated its congressionally mandated duty to use its expertise to identify and combat unfair methods of competition *even if they do not violate a separate antitrust statute*
- According to the FTC, Section 5 *reaches beyond the Sherman and Clayton Acts* to encompass various types of unfair conduct that tend to negatively affect competitive conditions

Unfair Methods of Competition

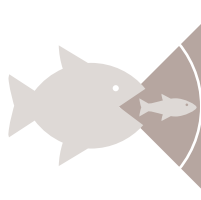
- Congress chose to leave it to the FTC to determine which practices fell into the category of “unfair methods of competition” rather than attempt to define through statute the various unlawful practices
- FTC claims a statutory mandate to combat incipient wrongdoing before it becomes likely to harm consumers or competition



Inquiry does not turn on whether the conduct caused actual harm in a specific instance



Instead, examines whether the conduct has a tendency to generate negative consequences; for instance, raising prices, reducing output, limiting choice, lowering quality, reducing innovation, impairing other market participants, or reducing the likelihood of potential or nascent competition



Does not require a separate showing of market power or market definition when the evidence indicates that such conduct tends to negatively affect competitive conditions



Dissent by Commissioner Wilson

“[I]nstead of providing meaningful guidance to businesses, the Policy Statement announces that the Commission has the authority summarily to condemn essentially any business conduct it finds distasteful.”



“list of nefarious-sounding adjectives, many of which have no antitrust or economic meaning”

1

First criterion: conduct may be “coercive, exploitive, collusive, abusive, deceptive, predatory, or involve the use of economic power of a similar nature,” or “otherwise restrictive or exclusionary”

2

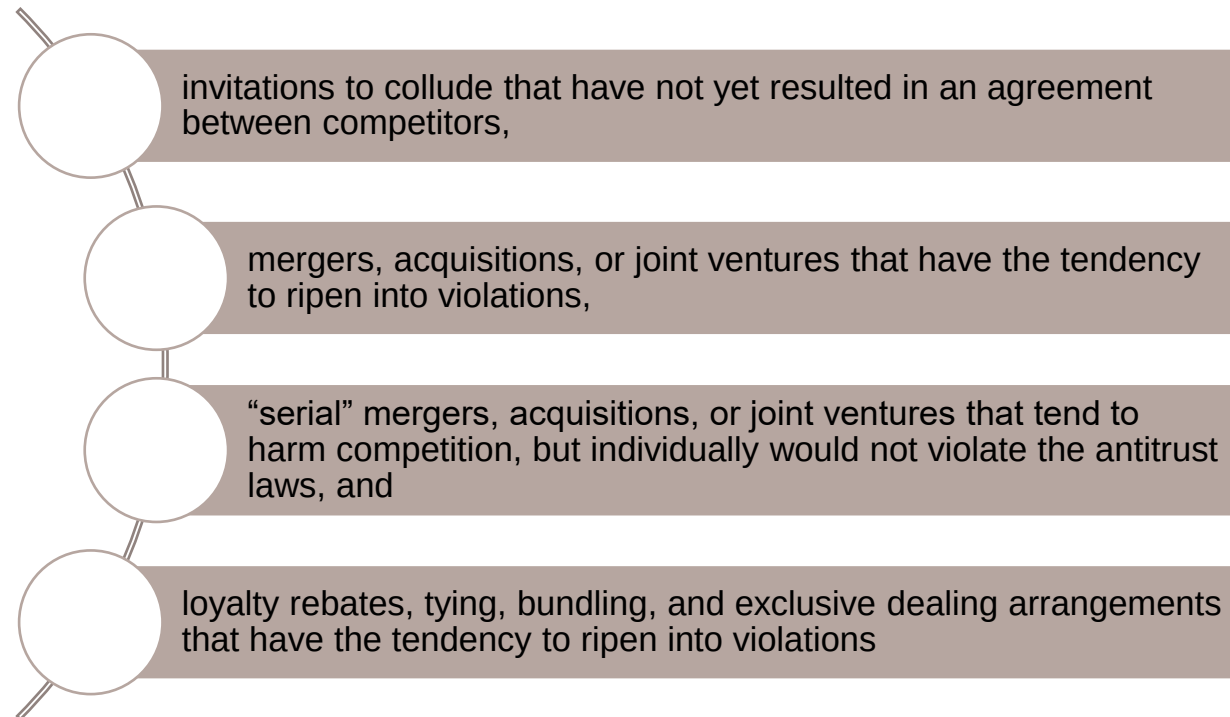
Second criterion: “the conduct must tend to negatively affect competition conditions” by “affecting consumers, workers or other market participants”



Sliding scale: when the indicia of unfairness are clear (first criterion), less is required to show a tendency to negatively affect competition (second criterion), and vice versa

Examples of Unfair Methods of Competition

- Practices deemed to violate the Sherman Act or the Clayton Act
- Conduct deemed to be an incipient violation of the antitrust laws



Examples continued . . .



- Conduct that violates “the spirit of the antitrust laws”
 - Fraudulent and inequitable practices that undermine the standard-setting process or that interfere with the Patent Office’s full examination of patent applications
- FTC’s 2022 Section 5 Policy Statement is part of a larger trend toward more vigorous and more expansive enforcement and thus an increased risk of antitrust enforcement
- Chair Lina Khan has warned that the FTC “will continue to use all our tools to protect Americans from illegal business tactics that are hiking the cost of drugs and drug products.”



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CLE CODE: FH2023

CLE approved in NY and CA

Please direct all CLE requests to Robert Burke at rburke@foleyhoag.com.

Upcoming Webinar on Jan. 24th

TOP IP CASES OF 2023

Who said there's no looking back? It is crucial to consider key takeaways from the most important IP cases in 2023 when planning for 2024.

Foley Hoag will present a 60-minute webinar on Wednesday, January 24, 2024, offering guidance on what we learned last year and what to prepare for in the new year. Our speakers will focus on developments in trademark, copyright, patent and trade secret law.

Register with the QR code below



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Questions?

Thank You



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