Exhibit H

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).

II. Statutory and regulatory background

In 1984, Congress passed the Hatch-Waxman Act[5] to encourage generic drug competition, establishing an abbreviated regulatory pathway for speedy approval of generic equivalent drugs through the filing of an abbreviated new drug application ("ANDA").[6] Alternately, a company seeking to market a modified ("follow-on") version of an existing brand drug—such as with a "new indication or new dosage form"—can file an application pursuant to Section 505(b)(2).[7]

As part of the Hatch-Waxman framework, brand drug manufacturers are required to submit information to the FDA about certain types of patents covering the products described in their new drug application ("NDA"). "The purpose of listing a patent in the Orange Book is to put potential generic manufacturers on notice that the brand considers the patent to cover its drug."[8] The Orange Book patent list is the statutory mechanism for identifying and potentially resolving certain patent disputes while 505(b)(2) applications[9] and ANDAs are still under review by the FDA.

Under 21 U.S.C. § 355, as amended by the Orange Book Transparency Act of 2020,[10] the brand manufacturers must submit for listing a patent 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.[11]

"Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted. . . ."[12]

A drug company that seeks to market a generic or follow-on version of a brand drug for which there are patents listed in the Orange Book must provide a "certification" with respect to each listed patent "which claims the listed drug . . . or which claims a use for such listed drug for

---

[5] Pub. L. No. 98-417, 98 Stat. 1585 (1984). *See also* H.R. REP. NO. 98-857, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.
[6] *See* 21 U.S.C. § 355(j)(2)(A)(iv).
[7] *Fed. Trade Comm'n v. AbbVie Inc*., 976 F.3d 327, 339 (3d Cir. 2020) (discussing 21 U.S.C. § 355(b)(2)). Like an ANDA applicant, a 505(b)(2) applicant can rely on the FDA's finding of safety and effectiveness for the brand drug product and need only "produce some data, including whatever 'information [is] needed to support the modification(s).'" *Id.* (quoting 21 C.F.R. § 314.54(a)).
[8] *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig*., 333 F. Supp. 3d 135, 149 (E.D.N.Y. 2018).
[9] As used herein, "505(b)(2)" refers to Section 505(b)(2) of the FDCA, codified at 21 U.S.C. § 355(b)(2).
[10] Pub. L. No. 116-290, 134 Stat. 4889 (2021).
[11] 21 U.S.C. § 355(b)(1)(A)(viii). *See also* 21 U.S.C. §§ 355(c)(2), 21 C.F.R. § 314.53 (submission of patent information). Only the patent information submitted under section §355(c)(2) is listed in the Orange Book. A patent that is identified as claiming a method of using such drug shall be filed pursuant to section §355(c)(2) for listing in the Orange Book only if the patent claims a method of use approved in the application.
[12] 21 U.S.C. § 355(c)(2).

which the applicant is seeking approval."[13] If the Orange Book listed patents are not expired, the generic company can file a "paragraph IV" certification stating the generics' view that the brand company's patent is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[14] A paragraph IV certification generally triggers an immediate right for the brand company to sue for infringement,[15] which if done timely, generally results in an automatic, 30-month stay of any approval of the generic company's ANDA or 505(b)(2) application by the FDA.[16]

NDA holders[17] 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.[18]

III. Improper listing of patents in the Orange Book may harm competitive conditions in pharmaceutical markets

Brand manufacturers' listing in the Orange Book patents that do not meet the statutory listing criteria undermines the competitive process and may constitute an unfair method of competition in violation of Section 5 of the FTC Act.

Improper Orange Book listings may have played a role in distorting pharmaceutical markets for decades. The Supreme Court has observed that since the late 1990s there has been evidence that some brand drug companies were exploiting the Orange Book listing process "to prevent or delay the marketing of generic drugs."[19] The FTC examined the potential anticompetitive effect of improper Orange Book listings as part of a 2002 study, in which it identified numerous instances in which the 30-month stay was used to block competition.[20] The same year, the FTC charged Biovail Corporation for, among other things, wrongfully listing a

---

[13] *Id*. at § 355(j)(2)(A)(vii).

[14] *Id*. at § 355(j)(2)(A)(vii)(IV). If the generic is not contending the patents are invalid or not infringed, it would simply file a "paragraph III" certification signifying it will wait to come to market until patent expiry. *Id*.

[15] There is no right to file an infringement suit in response to a paragraph IV certification if the patent was obtained by fraud on the United States Patent and Trademark Office or if the infringement suit would be objectively baseless. *See*, *e.g*., *AbbVie Inc.*, 976 F.3d at 361 ("[W]e must not immunize a brand-name manufacturer who uses the Hatch-Waxman Act's automatic, 30-month stay to thwart competition. Doing so would excuse behavior that Congress proscribed in the antitrust laws.").

[16] 21 U.S.C. § 355(j)(5)(B)(iii).

[17] For purposes of this statement the terms "brand drug manufacturer" and "NDA holder" are used synonymously.

[18] According to 21 C.F.R. § 314.53(c)(2)(ii)(R), NDA holders are required to submit a signed verification as part of Form FDA 3542 that states:

> The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information or response to a request under 21 C.F.R 314.53(f)(1) is submitted pursuant to 21 C.F.R. 314.53. I attest that I am familiar with 21 C.F.R. 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.

[19] *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012).

[20] FED. TRADE COMM'N., GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 39-52 (2022) www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

patent in the Orange Book to block generic competition in violation of the FTC Act.[21] Over the years, the FTC has filed amicus briefs in private litigations relating to the anticompetitive effects of improper Orange Book patent listings, including most recently in *Jazz Pharms., Inc. v. Avadel CNS Pharms.*[22]

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. Given the enormous profit margins of many branded drugs, even small delays in generic competition can generate substantial additional profits for brand companies at the expense of patients.

In the Hatch-Waxman framework, Congress struck a careful balance between preserving financial incentives for innovative drug development and accelerating the availability of follow-on lower-priced generics.[23] When brand companies improperly list patents in the Orange Book that do not meet the statutory criteria, it undermines the pro-competitive goals of Congress and risks significantly harming patients. By improperly listing a patent and timely filing an infringement suit, a brand can generally rely on the automatic stay to block FDA approval of a competing drug product, generally for 30 months, regardless of the validity or scope of the patent and regardless of whether the patent meets the statutory listing criteria. As a result, a generic company with a competing product facing an infringement suit based on a patent that was improperly listed in the Orange Book cannot launch its product because the automatic stay would prevent the FDA from granting approval to market the product. Patients suffer because they are deprived of the ability to choose between competing products and may be forced to pay inflated prices.[24]

---

[21] Decision and Order, *In re Biovail Corp*., FTC Dkt. No. C-4060 (Oct. 2, 2002).

[22] *See* Brief for Fed. Trade Comm'n as *Amicus Curiae*, *Jazz Pharms., Inc. v, Avadel CNS Pharms*. No. 1:21-cv-00691 (D. Del. Nov. 10, 2022) (Doc. No. 22-3) (arguing that a patent covering a system for implementing a REMS was not properly listed), https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf; Mem. of Law of the Federal Trade Commission as *Amicus Curiae*, *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-beechamcorp.v.apotex-corp./smithklineamicus.pdf; Mem. of Law of *Amicus Curiae* the Federal Trade Commission In Opposition to Defendant's Motion to Dismiss, *In re: Buspirone Patent Litig.*, MDL Docket No. 1410 (S.D.N.Y. Jan. 8, 2002), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-buspirone-antitrust-litigation/buspirone.pdf; Brief for Fed. Trade Comm'n as *Amicus Curiae*, *American Bioscience, Inc. v. Bristol-Myers Squibb Co*., No. 00-cv-08577 (C.D. Cal. September 7, 2000), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/american-bioscience-v.bristol-myers/amicusbrief.pdf.

[23] The FDA has noted that these requirements "reflect an attempt to balance two competing interests: Promoting competition between 'brand name' or 'innovator drugs' and 'generic' drugs and encouraging research and innovation." Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676 (June 18, 2003) (codified at 21 C.F.R. pt. 314).

[24] *See* Fed. Trade Comm'n Generic Drug Entry Study, *supra* note 20.

IV. The FTC will enforce the law against those companies and individuals who continue to improperly list patents in the Orange Book

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.

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.[25] First, the Commission views the 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.[26] Second, 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 rivals to compete, thus limiting consumer choice.[27] Further, recognizing that 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."[28] Accordingly, the FTC intends to scrutinize whether brand drug companies and responsible individuals are improperly listing patents in violation of Section 5.

The improper listing of patents in the Orange Book may also constitute illegal monopolization. Monopolization requires proof of "the willful acquisition or maintenance of [monopoly] power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[29] This requires proof that "the defendant has engaged in improper conduct that has or is likely to have the effect of controlling prices or excluding competition,"[30] and courts have recognized that improperly listing patents in the

---

[25] Fed. Trade Comm'n, Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act (Nov. 10, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf.

[26] *Id*. at 8 ("The conduct must implicate competition, but the relationship can be indirect. For example, misuse of regulatory processes that can create or exploit impediments to competition (such as those related to licensing, patents, or standard setting) constitutes a method of competition."). *See Charles Pfizer & Co. v. FTC,* 401 F.2d 574, 585 (6th Cir. 1968), *cert. denied*, 394 U.S. 920 (1969) (affirming Commission order holding that defendants violated Sec. 5 of the Federal Trade Commission Act where substantial evidence supported the Commission's findings that misrepresentations and withholding of material information misled Patent Office officials into granting a patent on tetracycline).

[27] Fed. Trade Comm'n Unfair Methods of Competition Policy Statement*, supra* note 25 at 8-9.

[28] *Id.* at 15 n.85 (citing *Fed. Trade Comm'n v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (finding of sustained effects legally sufficient even in absence of elaborate market analysis); *Toys "R" Us v. Fed. Trade Comm'n*, 221 F.3d 928, 937 (7th Cir. 2000) (finding "sufficient proof of anticompetitive effects [such] that no more elaborate market analysis was necessary"). *Cf. Fed. Trade Comm'n v. Staples, Inc.,* 970 F. Supp. 1066, 1075-6 (D.D.C. 1997) (relying in part on direct evidence that pricing for key products from office superstores lower where three such stores exist in same metropolitan area and higher where only one or two such stores present).

[29] *U.S. v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

[30] *PepsiCo, Inc. v. Coca-Cola Co*., 315 F.3d 101, 108 (2d Cir. 2002).

Orange Book may constitute an "improper means" of competition.[31] Accordingly, improperly listing patents in the Orange Book may also be worthy of enforcement scrutiny from government and private enforcers under a monopolization theory. Additionally, the FTC may also scrutinize a firm's history of improperly listing patents during merger review.[32]

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.

NDA holders must ensure that submitted patent information complies with all applicable 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. 314.53(f)(1), which allows any interested person to request correction of patent information published in the Orange Book.

Patents improperly listed in the Orange Book can significantly undermine fair competition and harm the American public. The FTC will continue to use all its tools to halt unlawful business practices that contribute to high drug prices.

---

[31] *In re Lantus Direct Purchaser Antitrust Litig*., 950 F.3d 1, 7 (1st Cir. 2020) (quoting *Town of Concord v. Bos. Edison Co*., 915 F.2d 17, 21 (1st Cir. 1990)). In *In re Lantus*, the First Circuit found a device patent covering an injector pen drive mechanism that drugmaker Sanofi submitted for listing in the Orange Book was improperly listed because the patent did not claim insulin glargine or the Lantus SoloSTAR product. *Id*. *See also United Food & Com. Workers Local 1776 v. Takeda Pharm. Co*., 11 F.4th 118, 134-136 (2d Cir. 2021).

[32] 15 U.S.C. § 18. *See also* Michael A. Carrier, *et al*., *Prior Bad Acts and Merger Review,* 111 GEO. L. J. 106 (2023).

[33] *See Fed. Trade Comm'n v. Shkreli*, 581 F. Supp. 3d 579, 637 (S.D.N.Y. 2022) (citing *Hartford-Empire Co. v. United States*, 323 U.S. 386, 407 (1945)); *Lorain Journal Co. v. United States*, 342 U.S. 143, 145 n.2 (1951) (officers and directors "participated in the conduct alleged to constitute the attempt to monopolize").

[34] 18 U.S.C. § 1001. FDA Form 3542—the form used by NDA holders to submit their patent information for listing in the Orange Book—warns those submitting patents for listing that "[a] willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001" directly beneath the declaration certifying to the accuracy and completeness of the submission. *See* FDA Form 3542, Section 6, https://www.fda.gov/media/133512/download.