THE FEDERAL TRADE COMMISSION'S NEWEST CAMPAIGN: DRUG DEVICE DELISTING FROM THE ORANGE BOOK

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THE FEDERAL TRADE COMMISSION'S NEWEST CAMPAIGN: DRUG DEVICE DELISTING FROM THE ORANGE BOOK

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This article discusses the Federal Trade Commission's renewed offensive against drug-device patents listed in the FDA's "Orange Book," alleging that such listings improperly stifle generic competition. Framing this campaign as a sequel to the long-running "pay-for-delay" wars culminating in *FTC v. Actavis*, In addition, this article traces how the agency has targeted metered-dose inhaler patents and other delivery devices for delisting, culminating in *Teva v. Amneal*, where the Federal Circuit upheld an injunction compelling Teva to remove five inhaler patents.

The Federal Trade Commission ("FTC") has, since its inception,[2] had a responsibility (or mission[3]) to protect American consumers from anticompetitive acts, and particularly from antitrust harms.[4] The rub, of course, is deciding what constitutes anticompetitive behavior, particularly with regard to acts involving patents (which almost by definition are anticompetitive) and the scope of exclusion, including those involving regulations regarding patented drugs. These issues arose famously two decades ago in disputes over reverse payment settlement agreements (termed "pay for delay" by the FTC[5]) in Hatch-Waxman disputes (also known as "ANDA" litigation) between branded and generic drugmakers.[6] Similar contretemps have arisen in the past two years with regard to device patents for drug delivery that have been listed in the "Orange Book" kept by the Food and Drug Administration ("FDA") that identifies Hatch-Waxman related patents for approved drugs.[7]

It should be remembered that the reverse payment dispute was waged for almost a decade.[8] During that time only the Sixth Circuit (in a particularly egregious reverse payment settlement[9]) and the Third Circuit (in a case vigorously pursued by FTC[10]) agreed with the Commission's position (that such agreements were per se violations of the Sherman Act[11]), while the Eleventh,[12] Second,[13] and Federal[14] Circuits disagreed, providing that the exclusivity asserted by the branded drug manufacturers fell within the "scope of the patent."[15] Based on the circuit split arising with the Third Circuit decision in *In re K-Dur*[16] the Supreme Court granted certiorari in a case captioned *FTC v. Actavis*.[17] In a 5-3 decision (Justice Alito recusing) the Court held against FTC's position for *per se* antitrust violation but held that reverse settlement payment agreements should be scrutinized under an antitrust "rule of reason" analysis. The lower courts have applied this standard ever since[18], particularly with regard to "avoided patent litigation costs" being a reasonable basis for a branded drug company to provide a payment to a generic company, typically delaying market entry while settling ANDA litigation.[19] Most notably, only three private actions challenging alleged reverse payments have gone to

2 The Federal Trade Commission was created on September 26, 1914, when President Woodrow Wilson signed the Federal Trade Commission Act into law. The FTC opened its doors on March 16, 1915.

3 "The FTC's mission is protecting the public from deceptive or unfair business practices and from unfair methods of competition through law enforcement, advocacy, research, and education." https://www.ftc.gov/about-ftc/mission.

4 Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. 15 U.S.C. 1

5 Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 2 (2010), *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-howdrug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

6 K.E. Noonan, The Intersection of Patent Infringement and Antitrust Liability in Abbreviated New Drug Application Litigation, 2014 J. Disp. Resol.

7 *See* "FTC Announces Efforts to Police Pharmaceutical Companies' Patent Behavior," *Patent Docs* (September 19, 2023); "FTC Warns Pharma Companies It Means Business with Its Orange Book Listing Policy). *Patent Docs* (June 12, 2024); "Federal Trade Commission Continues Efforts to Delist Drug Device Patents," *Patent Docs* (May 5, 2025).

8 Noonan, 2014 J. Disp Resol. *Id.*

9 *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003)

10 *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3rd Cir. 2012); see also, "The Federal Trade Commission Finally Wins One," *Patent Docs* July 18, 2012

11 See In the Matter of Abbott Labs., A Corp., & Geneva Pharm., Inc., A Corp., C-3946, 2000 WL 681849, at *6 (F.T.C. May 22, 2000); In the Matter of Schering-Plough Corp., A Corp., Upsher-Smith Labs., A Corp., & Am. Home Products Corp., A Corp., 9297, 2001 WL 418903, at *1 (F.T.C. Apr. 2, 2001)

12 *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005).

13 *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, F.3d 98, 104-06 (2d Cir. 2010).

14 *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008).

15 See *Joblove v. Barr Labs. Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 216 (2d Cir. 2006)(Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.).

16 *In re K-Dur Antitrust Litig., ibid.*

17 *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

18 See for example *Watson Laboratories, Inc. v. Forest Laboratories, Inc.*, 101 F.4th 223 (2d Cir. 2024) (Bystolic), where the Court held that the challenged payments (goods and services, including an API supply agreement) were nothing but a "fair value for goods and services obtained as a result of arms-length dealings" and were not pretextual (Id. at 231). Notably, the Second Circuit rejected the FTC's position, set forth in its amicus brief, that such supply agreements and "side deals" were inherently anticompetitive (Id. at 239-240).

19 See K.E. Noonan, Antitrust Issues in ANDA and Biosimilars Litigation," Chapter 5, *Antitrust Issues in Intellectual Property Law*, 2nd ed. (The Intellectual Property Law Association of Chicago Antitrust Committee, Lyerla, B., ed.), American Bar Association Publishing Co., 2023.

trial since *Actavis—In re Nexium Antitrust Litig.* (D. Mass.),[20] *In re Opana ER Antitrust Litig.* (N.D. Ill.),[21] and *In re HIV Antitrust Litig.* (N.D. Cal.),[22] and all three trials resulted in favorable verdicts for defendants.

The current crusade began with statements from then-Commission chair Lina Khan that the FTC is "using all the tools we have to bring down drug prices and reduce barriers to generic competition."[23] The FTC's attitude seems to be that if something *might* be happening then to proceed as if it is, stating that "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'" (emphasis added). The targets of these efforts were device patents, listed in the Orange Book, for administering drugs[24] and/or containing dosage counters for patients to accurately keep track of administered doses (and reducing or eliminating the frequency with which patients are left with insufficient doses when needed).[25] These efforts were embodied in letters targeting ten pharmaceutical companies: AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, Impax Laboratories, Kaleo, Mylan Specialty, and subsidiaries of Glaxo-Smith Kline and Teva Pharmaceuticals. The letters alleged (uniformly) that "[w]rongfully listed patents can significantly drive up the prices Americans must pay for medicines and drug products while undermining fair and honest competition,"[26] although it is unclear whether there is any factual basis for this statement (i.e. that there is any data that listing these patents has had this effect).[27] Calling Orange Book device patent listings "bogus patent filings"[28] and "junk patents,"[29] the letters informed recipients that it had chosen to pursue these companies disputing "the accuracy or relevance of patent information submitted" to FDA for Orange Book listings.[30] However, the Commission's letters also informed recipients that the Commission "retain[s] 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."[31] These actions also included referring the matter to the Department of Justice for "further investigation" (including criminal prosecution under the statue) "[i]f 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."

One instance where these efforts have been successful involved litigation by Teva Pharmaceuticals against Amneal Pharmaceuticals over five patents claiming inhalers for Teva's ProAir® HFA (albuterol sulfate) Inhalation Aerosol product (see Table I).

20 No. 1-12-02409 (D. Mass. Dec. 5, 2014).

21 2016 US Dist Lexis 23319 (ND Ill 25 February 2016).

22 *In re HIV Antitrust Litig.*, 3:19-cv-02573-EMC (N.D. Cal. June 30, 2023).

23 "Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," Matter No. P233900 (September 14, 2023 (https://www.ftc.gov/legal-library/browse/federal-trade-commission-statement-concerning-brand-drug-manufacturers-improper-listing-patents).

24 See for example U.S. Patent No. 9,586,101.

25 See for example U.S. Patent No. 11,395,805.

26 FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book, https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book.

27 See, Morris & Park, "What the FTC Gets Wrong About the FDA's Orange Book," C-IP2. November 18, 2024 (https://cip2.gmu.edu/2024/11/18/what-the-ftc-gets-wrong-about-the-fdas-orange-book/).

28 "By filing bogus patent listings, pharma companies block competition and inflate the cost of prescription drugs, forcing Americans to pay sky-high prices for medicines they rely on." https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

29 "By challenging junk patent filings, the FTC is fighting these illegal tactics and making sure that Americans can get timely access to innovative and affordable versions of the medicines they need." *Ibid.*

30 21 C.F.R. § 314.53(f)(1)(i)(A).

31 FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book, *Ibid.*

U.S. Patent No. 8,132,712	U.S. Patent No. 9,463,289
1. A dose counter for a metered-dose inhaler, the counter comprising: an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery; a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear; wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.	1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.
U.S. Patent No. 9,808,587	**U.S. Patent No. 10,561,808**
1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.	1. A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.
	U.S. Patent No. 11,395,889
	1. An incremental dose counter for a metered dose inhaler having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having a main body, an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the actuator is in a non-depressed position, and wherein the incremental dose counter further comprises a second anti-back member configured to restrict motion of the output member in a direction opposite to the count direction when the actuator is disengaged from the output member by a bump surface.

(**Table** I)

These patents were directed to metered dose inhalation of this asthma drug, and Amneal argued (supported by an *amicus curiae* brief from FTC) that these patents were improperly listed. The district court, in an opinion borrowing heavily from the FTC's *amicus* brief, held on Amneal's motions on the pleadings that these patents were indeed improperly listed, as not being directed to an FDA-approved drug nor method of using such a drug for treating a disease or disorder, and granted an injunction compelling Teva to delist these patents.[32]

On appeal,[33] Teva made two arguments: the first based on a legal and technical definition of how the term "drug product" is defined in the statute, and the second on whether the district court erred procedurally, including whether claim construction was required to properly determine the first question. Before the Federal Circuit both these arguments failed, wherein the Court held that the statute[34] mandated that Orange Book listings were limited to the patent number and expiration date of "any patent which *claims the drug for which the applicant submitted the application* or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" (emphasis added).[35] Significantly, the Federal Circuit opinion noted that "[t]he attractiveness of the thirty-month stay might arguably provide an NDA holder significant incentives to improperly list patents in the Orange Book as purporting to claim the drug, even if they do not actually claim the drug. And this concern is not illusory."[36] The conventional recognition of the benefits of these provisions in the Hatch-Waxman Act (such as the notice function provided thereby to generic drug makers and the public) seem not to be recognized in this policy calculus. In a press release the FTC hailed this decision as a justification of their position.[37]

Teva dutifully delisted the five patents subject to the district court's injunction affirmed by the Federal Circuit, but the response from the other targeted pharma companies has been truly a mixed bag, as shown in Table II (where delisted patents are illustrated by strikethrough). These results may not be surprising, as a close look at the frequency with which these patents have been asserted in ANDA litigation shows that most of them have never been so asserted. Of the 61 patents identified in the first round of FTC's letters (presumably indicating some level of differentiation to select somewhat to particularly egregious examples of bad behavior), 34 have never been asserted and eight others have been asserted in only five ANDA cases. The anomaly are 19 patents asserted in 209 cases, with the majority of these being directed to Ozem-

32 *Teva Pharms. Inc. v. Amneal Pharms. Inc.*, No. 2:2023cv20964 (D.N.J. 2024); see also Noonan, "Teva Pharms. Inc. v. Amneal Pharms. Inc. (D.N.J. 2024), *Patent Docs* October 7, 2024.

33 *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC*, 124 F.4th 898 (Fed. Cir. 2024).

34 *Ibid.* at 906.

35 *Ibid.* (emphasis in opinion).

36 *Ibid.* at 905; see also *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012)(that "[i]n the late 1990's, evidence mounted that some brands were exploiting this statutory scheme to prevent or delay the marketing of generic drugs [with the] submission of inaccurate patent information to the FDA").

37 FTC Statement on Appellate Court Decision Ordering Delisting of Teva Inhaler Patents, December 20, 2024 (https://www.ftc.gov/news-events/news/press-releases/2024/12/ftc-statement-appellate-court-decision-ordering-delisting-teva-inhaler-patents).

bic, Saxenda, and Victoza; whether this exemplifies over-exuberance, bad acting, or justifiable protection of devices providing patient-specific advantages remains to be determined.

Few (if any) of the patents challenged by the FTC recite claims directed to specific drugs to be used with them.[38] This is strategic, because it permits the patents to be listed for however many drugs can benefit from them. It is also has the negative consequence that the patents can (and have) been branded as not complying with the statute with regard to Orange Book listings being directed to specific drugs and formulations of drugs having been shown to be safe and effective for treating specific diseases and disorders.[39] To the extent to which these devices were shown to be useful with specific drugs there may be an opportunity to file, by narrowing reissue, such claims directed to embodiments comprising the device coupled with the drug (which are the combinations that received regulatory approval).

While the fervor with which the FTC is pursuing companies guilty of "bad acting" with regard to Orange Book listings may be motivating and maybe exhilarating to the pursuers, fervor is rarely accompanied by nuance and such nuances exist here.[40] One ready example would be the benefits attendant on dose meter devices that can reduce or prevent patients from inadvertently having fewer doses than they need to rely upon. It can be readily understood that such circumstances can be upsetting if not life-threatening, and their application to asthma drugs such as albuterol sulfate is consistent with the needs and benefits of these devices for treatment of sporadic symptoms of that disease. Other possibilities are drug devices that administer drugs having very narrow windows for proper dosing (for example, wherein small variations delivering too little drug make treatment ineffective, whereas administering too much of the drug can produce disagreeable or even life-threatening results). Such devices can increase patient compliance, reduce negative outcomes, and prevent harm to patients. Preventing Orange Book listing could reasonably reduce incentives to develop them and thus harm the very members of the public for whom the FTC is striving to help by keeping drug costs low (ignoring the multiplicity of factors involved in those costs while focusing, as the Commission is wont to do on patents).

Company	Challenged patents (NDA-approved product)
Amphastar Pharma	~~10,894,133 (Baqsimi)*~~
Covis Pharma GmbH	8,051,851 (Tudorza Pressair), 8,051,851 (Duaklir Pressair)
Mylan Specialty/Viatris	7,449,012 (Epipen, Epipen Jr), 7,449,432 (Epipen, Epipen Jr), 8,048,035 (Epipen, Epipen Jr), 9,586,101 (Epipen, Epipen Jr)
Novartis Pharma	8,182,838 (Seebri, Utibron)
Teva Pharmaceuticals	~~8,132,712; 9,463,289; 9,808,587; 10,561,808; 11,395,889 (ProAir® HFA Inhalation Aerosol_(~~all delisted); 8,651,103 (AirDuo Respiclick, AirDuo Digihaler, ArmonAir Respiclick, ArmonAir Digihaler), 8,714,149 (AirDuo Respiclick, AirDuo Digihaler, ArmonAir Respiclick, ArmonAir Digihaler), 8,978,966 (AirDuo Respiclick, AirDuo Digihaler, ArmonAir Respiclick, ArmonAir Digihaler), 9,216,260 (AirDuo Respiclick, AirDuo Digihaler, ArmonAir Respiclick, ArmonAir Digihaler), 9,463,288 (AirDuo Respiclick, AirDuo Digihaler, ArmonAir Respiclick, ArmonAir Digihaler), 9,731,087 (AirDuo Respiclick, AirDuo Digihaler, ArmonAir Respiclick, ArmonAir Digihaler),9,782,550 (AirDuo Digihaler), 9,782,551 (AirDuo Digihaler, ArmonAir Digihaler), 10,022,510 (AirDuo Respiclick, AirDuo Digihaler, ArmonAir Respiclick, ArmonAir Digihaler), 10,124,131 (AirDuo Respiclick, AirDuo Digihaler, ArmonAir Respiclick, ArmonAir Digihaler haler), 10,569,034 (AirDuo Digihaler, ArmonAir Digihaler), 10,765,820 (AirDuo Respiclick, AirDuo Digihaler, ArmonAir Respiclick, ArmonAir Digihaler), 11,000,653 (AirDuo Digihaler, ArmonAir Digihaler), 11,266,796 (AirDuo Digihaler, ArmonAir Digihaler), 11,351,317 (AirDuo Digihaler), 11,357,935 (AirDuo Digihaler, ArmonAir Digihaler), 11,439,777 (AirDuo Digihaler, ArmonAir Digihaler), 11,464,923 (AirDuo Digihaler, ArmonAir Digihaler)
GSK/Glaxo	~~8,113,199, '8,161,968, and '8,534,281 (for ARNUITY ELLIPTA)(all delisted); 7,500,444 (for ADVAIR HFA, FLOVENT HFA, and VENTOLIN HFA)(all delisted)~~
Kaleo Inc.	~~7,731,686; 7,731,690; 7,749,194; 8,016,788; 8,920337; 8,926,594; 9,238,108; 10,960,155; 7,918,823, 9,056,170, 9,259,539, and 9,278,182)(for AUVI-Q epinephrine autoinjector~~)(all delisted)

(**Table** II)

38 See, for example, most if not all of the patents set forth in Table II.

39 *Teva Pharms. Inc. v. Amneal Pharms. Inc., ibid.*

40 A pithy example (which illustrates these hazards) can be found in an amicus brief filed on behalf of Amneal in the appeal to the Federal Circuit stating that "Teva's patent claim is not a claim to "the drug for which the applicant submitted the application" any more than a patent on a spoon would be listable in the Orange Book because it is possible to take some medicines with a spoon." BRIEF OF 52 PROFESSORS OF LAW, ECONOMICS, AND MEDICINE AS AMICI CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE, p. 19.

It is unclear whether the current administration will continue to pursue the latest campaign (particularly in light of Commissioner Khan's departure at the close of the Biden Administration). There has been some evidence that this administration will not change course.[41] And it must be recognized that the political pressure to reduce drug costs has been evident in some of the tariff and other measures taken by the current administration. Indeed, earlier this year the Commission targeted another 200 device patents for improper listing.[42] This latest letter writing campaign emanating from the FTC has maintained the earlier rhetoric while adding 200 new patents targeted for delisting.[43] New FTC Chairman Andrew N. Ferguson stated in his press release that "The American people voted for transparent, competitive, and fair healthcare markets and President Trump is taking action. The FTC is doing its part. When firms use improper methods to limit competition in the market, it's everyday Americans who are harmed by higher prices and less access. The FTC will continue to vigorously pursue firms using practices that harm competition."[44] It can be expected that the pressure to limit the patents that can be Orange Book listed will continue, in view of Federal Circuit's recent imprimatur for delisting Teva's patents, but the effects on development of new device patents giving significant advantages to patients is unclear.

41 "The American people voted for transparent, competitive, and fair healthcare markets and President Trump is taking action. The FTC is doing its part," said FTC Chairman Andrew N. Ferguson (https://www.ftc.gov/news-events/news/press-releases/2025/05/ftc-renews-challenge-more-200-improper-patent-listings).

42 "The FTC sent warning letters to Novartis, Amphastar Pharmaceuticals, Mylan Specialty, Covis Pharma, and three Teva entities, and notified the Food and Drug Administration (FDA) that it disputes the appropriateness of more than 200 patent listings in the FDA's Orange Book across 17 different brand-name products." FDA Renews Challenge of More Than 200 Improper Patent Listings, May 21, 2025 (https://www.ftc.gov/news-events/news/press-releases/2025/05/ftc-renews-challenge-more-200-improper-patent-listings).

43 These letters can be accessed on the FTC website at https://www.ftc.gov/legal-library/browse/warning-letters/88289.

44 *Ibid.* The press release also touts the support by the Federal Circuit for delisting in Teva Pharms. Inc. v. Amneal Pharms. Inc., ibid.

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