No. 24-1936

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., TEVA PHARMACEUTICALS USA, INC.

Plaintiffs-Appellant,

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LTD., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS, INC.

Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey

Civil Action No. 23-cv-20964 (SRC), Judge Stanley R. Chesler

CORRECTED BRIEF OF 14 PROFESSORS OF MEDICINE AND LAW AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

Kristen A. Johnson
Lauriane Williams
HAGENS BERMAN SOBOL SHAPIRO LLP
One Faneuil Hall Square, 5th Floor
Boston, MA 02109
Telephone: 617-482-3700
Facsimile: 617-482-3003

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 24-1936

Short Case Caption Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC

Filing Party/Entity Professors of Medicine and Law: William B. Feldman, M.D., D.Phil., M.P.H.; Aaron S. Kesselheim, M.D., J.D., M.P.H.; S. Sean Tu, J.D., Ph.D.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 09/11/2024

Signature: /s/ Kristen A. Johnson

Name: Kristen A. Johnson

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
William B. Feldman, M.D., D.Phil., M.P.H., Harvard Medical School		
Aaron S. Kesselheim, M.D., J.D., M.P.H., Harvard Medical School		
S. Sean Tu, J.D., Ph.D., West Virginia University College of Law		
See full list of signatories at Section 5.		

☑ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☑ Additional pages attached

Kristen A. Johnson Hagens Berman Sobol Shapiro LLP		
Lauriane Williams Hagens Berman Sobol Shapiro LLP		

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☐ No ☑ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

I. IDENTITY AND INTEREST OF *AMICUS CURIAE*[1]

Amici are professors of law and medicine who focus their research and teaching on the drug approval process, pharmaceutical pricing and policy, patent law, and the use and health outcomes of prescription drugs. A full list of amici is referenced at Section V.

The first three signatories, William B. Feldman, M.D., D.Phil., M.P.H., Aaron S. Kesselheim, M.D., J.D., M.P.H., and S. Sean Tu, J.D., Ph.D guided the research, drafting, and editing of this brief. They are members of the Program on Regulation, Therapeutics, and Law ("PORTAL") and its parent organization, the Division of Pharmacoepidemiology and Pharmacoeconomics of Harvard Medical School and Brigham & Women's Hospital. PORTAL brings together researchers, analysts, and trainees from the fields of medicine, law, epidemiology, and health policy to critically evaluate emerging issues on the regulation, use, and reimbursement of therapeutics

[1] Amici and their counsel are the sole authors of this brief. No party or counsel for a party authored any piece of this brief or contributed any money intended to fund its preparation or submission. (Amici are William B. Feldman, M.D., D.Phil., M.P.H., Aaron S. Kesselheim, M.D., J.D., M.P.H., S. Sean Tu, J.D., Ph.D., Jerry Avorn, MD, Reed F. Beall, PhD, Robyn T. Cohen MD, MPH, Ravi Gupta, MD, MSHP, Thomas R. Radomski, MD, MS, Reshma Ramachandran, MD, MPP, MHS, Rita F. Redberg, Benjamin N. Rome, MD, MPH, Joseph Ross, MD, MHS, S. Christy Sadreameli, MD, MHS, Olivier J. Wouters, PhD. Counsel are Kristen A. Johnson and Lauriane Williams, Hagens Berman Sobol Shapiro LLP). Fed. R. App. P. 29(a)(4)(E). Further, all parties have consented to the filing of this brief. Fed. R. App. P. 29(a)(2).

(prescription drugs and medical devices).[2] PORTAL is one of the largest non-industry-funded research centers in the US devoted to pharmaceutical use, costs, regulations and outcomes.[3]

In recent years, the program has carried out a series of studies to better understand how pharmaceutical manufacturers develop their drug patent portfolios.

Amici submit this brief to provide the Court with the public policy context necessary to understand the impact of improper listings of device patents in the Orange Book on drug pricing and the availability of less-expensive pharmaceutical alternatives.[4]

[2] *See* PORTAL Program on Regulation, Therapeutics, and Law, About PORTAL - PORTAL: Program on Regulation, Therapeutics, and Law (portalresearch.org).

[3] Testimony of William Feldman, *Patent Thickets and Product Hops: How Congress Could Reward Legitimate Innovation While Facilitating More Timely Generic Competition*, United States Senate Judiciary Committee May 21, 2024, 1-12 https://www.judiciary.senate.gov/imo/media/doc/2024-05-21_-_testimony_-_feldman.pdf at 3.

[4] *See* 21 U.S.C. § 355(b)(1), (c)(2).

II. INTRODUCTION[5]

The Drug Price Competition and Patent Term Restoration Act of 1984,[6] (the "Hatch-Waxman Act") established the framework for generic drug approvals.[7]

The Hatch-Waxman Amendments consisted of two different titles. "Title I authorized the approval of duplicate versions of drug products, approved under section 505 of the act, under an ANDA [Abbreviated New Drug Application] procedure. Title II authorized the extension of patent terms for approved new drug products (including antibiotics and biological drug products), some medical devices, food additives, and color additives. Congress intended the two titles to provide a careful balance between promoting competition among brand-name and duplicate or

[5] We provide this background information as context for the argument below. As the parties and other Amici address the legal and regulatory framework, including the requirements for what patents must, and must not, be submitted for listing in the Orange Book, we do not further explore those issues here.

[6] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360 (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No.108-173, 117 Stat. 2066 (2003).

[7] Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, HASTINGS LAW JOURNAL, Volume 60, Issue 1, Article 6, 171–175 (2008) (Hatch-Waxman Act "effectively created the modern generic pharmaceutical industry"), https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=3715&context=hastings_law_journal, at 175.

'generic' drugs and encouraging research and innovation."[8] The statutory and regulatory framework established by Title I applies only to drugs, not medical devices.

The Hatch-Waxman Act requires FDA to publish the patent information submitted for each NDA (New Drug Application), which the FDA does in its Approved Drug Products with Therapeutic Equivalence Evaluations publication (commonly known as the "Orange Book").[9] The Orange Book includes a section titled "Prescription and OTC Drug Product Patent and Exclusivity Information;" there is no corresponding patent and exclusivity section for medical devices.

The FDA's regulations implementing this section of the Hatch-Waxman Act provide that NDA holders must submit certain kinds of patents claiming drugs, or methods of using drugs, for listing in the Orange Book:

> An applicant … must submit the required information … for each patent that claims the drug or a method of using the drug that is the subject of the NDA [new drug application] or amendment or supplement to it…. For patents that claim a drug product, the applicant must submit information only on those patents that claim a drug product, as is defined in § 314.3, that is described in the pending or approved NDA.[10]

---

[8] *Abbreviated New Drug Application Regulations*, 57 Fed. Reg. 17950, 17951 (Apr. 28, 1992).

[9] 21 U.S.C. § 355(b)(1), (c)(2).

[10] 21 C.F.R. § 314.53(b)(1); *see also* 21 U.S.C. § 355(b)(1)(A) (an applicant "shall submit . . . as part of the application . . . (viii) the patent number and the expiration date of each patent . . . that (I) claims the drug for which the applicant submitted the application and is . . . a drug product (formulation or composition) patent. . . .").

Submitting patents for listing in the Orange Book has consequences for both the submitting NDA holder and the company seeking to market a generic version. The would-be competitor referencing the brand company's NDA must provide a "certification" for each listed patent "which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval. . . ."[11] When the generic manufacturer chooses to challenge patents that have not yet expired, by filing what's termed a "paragraph IV certification,"[12] it sets of a series of potential steps. First, if the brand-name manufacturer sues the ANDA applicant within 45 days of receiving a paragraph IV certification, the FDA is prevented from approving the generic for two-and-a-half years (the "30-month stay.")[13] This is a powerful incentive for NDA holders to list patents in the Orange Book that do not belong. Delaying competition from less-expensive generic products can result in consumers and other purchasers spending *billions* more for the branded product than they otherwise would have.[14] Second, if the ANDA applicant is successful its challenge, the first generic (the

[11] 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). In some circumstances, not relevant here, they may submit what is referred to as a section viii or "carve out" statement instead. *See* 21 U.S.C. § 355(j)(2)(A)(viii). The regulations, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(12)(iii), similarly authorize omission of both patented and exclusivity-protected uses.

[12] A "paragraph IV" certification asserts that the brand company's patent is invalid or will not be infringed by the generic drug. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[13] 21 U.S.C. § 355(c)(3)(C) (NDAs); 21 U.S.C. § 355(j)(5)(B)(iii) (ANDAs).

[14] Generic Pharmaceutical Association, *Generic Drugs Continue to Deliver Billions in Savings to the U.S. Healthcare System, New Report Finds*, Oct. 2016, http://www.

"first-filer") manufacturer may be entitled to six months of exclusivity as the only ANDA-approved generic on the market (if other requirements are met).[15] This is a powerful incentive for companies to challenge Orange Book listed patents. During that period, because of the absence of competition, both the generic drug price and the first-filer's revenues are significantly higher than they would be when there are additional generic competitors.[16]

III. ARGUMENT

A. Improper listing of device patents in the Orange Book is one strategy among many that inhaler manufacturers have employed over the past several decades to delay generic competition.

Inhalers are the mainstay of treatment for asthma and chronic obstructive pulmonary disease (COPD). Modern inhalers have been available since the 1950s, and most of the active ingredients they use have been approved for over 25 years.[17] But

---

prnewswire.com/news-releases/generic-drugs-continue-to-deliver-billions-in-savings-to-the-us-healthcare-system-new-report-finds-300347698.html.

[15] 21 U.S.C. § 355(j)(5)(B)(iv). The brand-name company may sell an authorized generic under its 505(b)(1) NDA during this six-month period. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54-55 (D.C. Cir. 2005).

[16] Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, August 2011, Executive Summary at i, https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[17] Letter from Bernard Sanders, U.S. Senator, et al., to Richard Francis, CEO, Teva Pharm. Indus. Ltd. (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Teva.pdf at 5 (citing William B. Feldman et al., *Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-*

despite having been on the market for decades, brand-name manufacturers have continued to sell most inhalers at high prices without the threat of direct competition.[18] After a small number of generic albuterol inhalers were approved in the 1990s, which were later removed from the market for containing chlorofluorocarbons (CFCs), the first inhaler to face generic competition was Advair Diskus (fluticasone-salmeterol) in 2019.[19]

Delays in generic competition have reduced patient access and led to unnecessary health care spending.[20] These products remain expensive, in part because

---

2020, HEALTH AFFAIRS. Volume 41, Issue 6, 787, 789 (2022), https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01874; Stephen W. Stein & Charles G. Thiel, *The History of Therapeutic Aerosols: A Chronological Review*, JOURNAL OF AEROSOL MEDICINE AND PULMONARY DRUG DELIVERY, Volume 30, Issue 1, 20, 28–35 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278812/; Carson Vaughan, *The History of the Asthma Inhaler*, SMITHSONIAN MAGAZINE, Sept. 2020, https://www.smithsonianmag.com/innovation/history-asthma-inhaler-180975511/).

[18] Feldman WB, Tu SS, Alhiary R, Kesselheim AS, Wouters OJ, *Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021*, JAMA, Jan 3, 2023, Volume 329, Issue 1, 87–89. https://jamanetwork.com/journals/jama/fullarticle/2800037 at 87.

[19] Wang Z, Ahluwalia SK, Newman B, Dhapare S, Zhao L, Luke MC, *Medication Cost-Savings and Utilization of Generic Inhaled Corticosteroid (ICS) and Long-Acting Beta-Agonist (LABA) Drug Products in the USA*, THERAPEUTIC INNOVATION & REGULATORY SCIENCE JOURNAL, Mar. 2022, Volume 56, Issue 2, 346–357, https://pubmed.ncbi.nlm.nih.gov/35118630/ at 347 ("In early 2019, Wixela™ Inhub™ (fluticasone propionate and salmeterol xinafoate) inhalation powder (ANDA 208891) became the first generic DPI approved in the USA referencing the brand-name Advair Diskus® fluticasone propionate and salmeterol xinafoate inhalation powder.").

[20] Feldman WB, Tu SS, Alhiary R, Kesselheim AS, Wouters OJ, *Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021*. JAMA. Jan 3, 2023,

brand-name manufactures have obtained numerous patents on inhalers, including on their delivery devices,[21] resulting in substantial out-of-pocket costs for patients.[22]

Today, only 5 brand-name inhalers face any independent generic competition[23]—this is despite the Food and Drug Administration approving more than 50 brand-name inhalers for asthma and COPD since 1986.[24] No inhaler for asthma or COPD today faces competition from more than 3 generic competitors.[25] Brand-name inhaler manufacturers have employed several key strategies to preserve their revenue streams.

Volume 329, Issue 1, 87–89, https://jamanetwork.com/journals/jama/fullarticle/2800037.

[21] Demkowicz BJ, Tu SS, Kesselheim AS, Carrier MA, Feldman WB. *Patenting Strategies on Inhaler Delivery Devices.* CHEST, August 2023, Volume 164, Number 2, 450–460. https://pubmed.ncbi.nlm.nih.gov/36842533/ at 451 (citing Feldman WB, Gagne JJ, Kesselheim AS. *Trends in Medicare Part D inhaler spending: 2012-2018*. ANNALS OF THE AMERICAN THORACIC SOCIETY. 2021, Volume 18, Number 3, 548–550).

[22] *Id.* (citing Patel B, Mayne P, Patri T, et al. Out-of-pocket costs and prescription filling behavior of commercially insured individuals with chronic obstructive pulmonary disease. JAMA HEALTH FORUM. May 2022, Volume 3, Number 5 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9142864/).

[23] Letter from Bernard Sanders, U.S. Senator, et al., to Richard Francis, CEO, Teva Pharm. Indus. Ltd. (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Teva.pdf.

[24] Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. Author Manuscript, *Patents and Regulatory Exclusivities On Inhalers For Asthma And COPD, 1986-2020*, https://pubmed.ncbi.nlm.nih.gov/35579925/ at 5 (published in final edited form in HEALTH AFFAIRS. June 2022, Volume 41, Number 6, 787–796); Feldman WB, Kesselheim AS. *How the makers of inhalers keep prices so high.* WASHINGTON POST. June 1, 2023.

[25] Reddy S, Beall RF, Tu SS, Kesselheim AS, Feldman WB. *Patent Challenges And Litigation On Inhalers For Asthma And COPD*. HEALTH AFFAIRS. Mar. 2023, Volume 42, Number 3, 398–406. https://pubmed.ncbi.nlm.nih.gov/36877911/ at 398, 404.

Releasing new product in old classes. The last inhaler approved by the FDA with a new mechanism of action was Atrovent (ipratropium) in 1986.[26] Every inhaler approved in the almost forty years since then has used the same mechanism of action as products already on the market, albeit with differing formulations or active ingredients.[27]

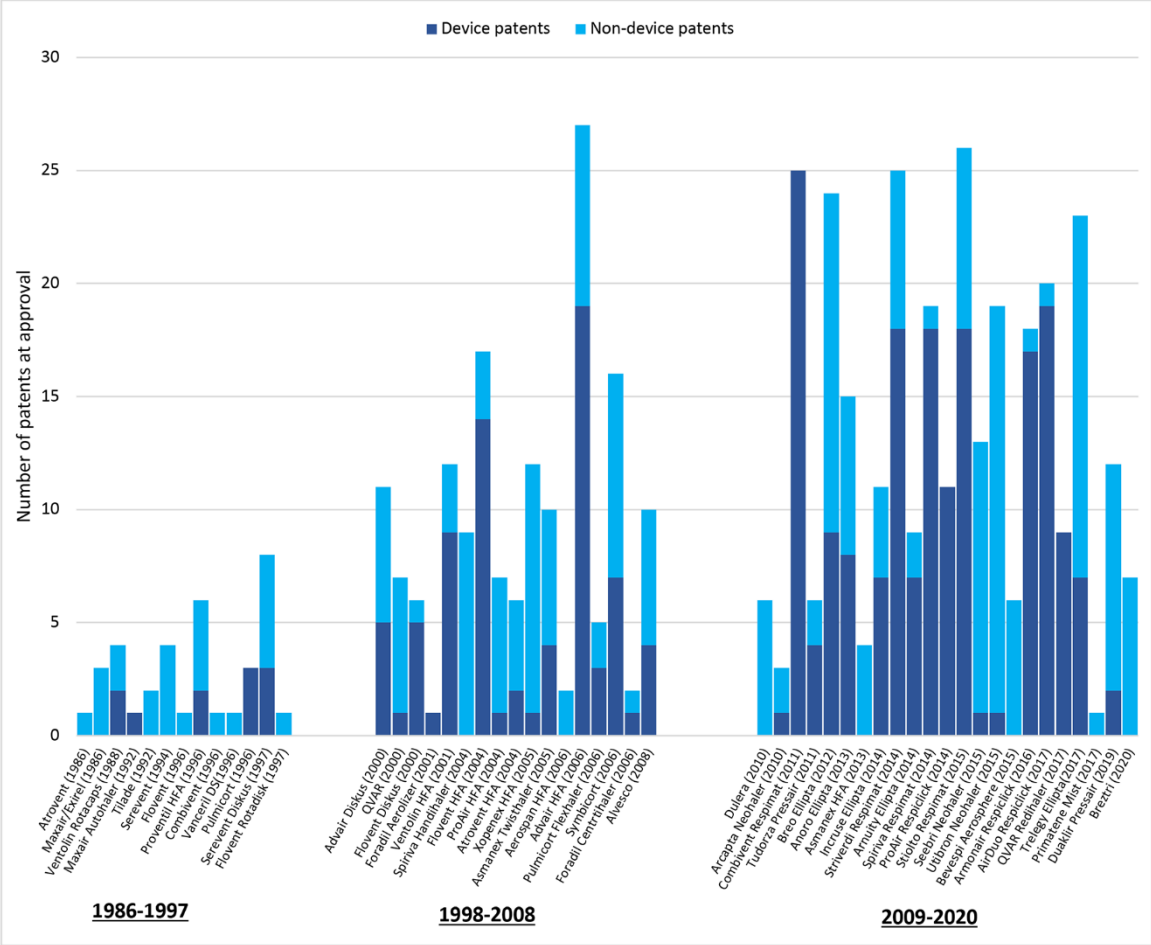
Dense patent thickets. The median number of patents filed before FDA approval for inhalers treating asthma and COPD increased from 2 for products approved between 1986 and 1997, to 9 for those approved between 1998 and 2008, and to 12 for those approved between 2009 and 2020.[28]

[26] Center For Drug Evaluation and Research, *Application Number 21-527*, Medical Review(s), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021527s000_MedR.pdf at 1.

[27] Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. Author Manuscript, *Patents and Regulatory Exclusivities On Inhalers For Asthma And COPD, 1986-2020*. https://pubmed.ncbi.nlm.nih.gov/35579925/ ("The only inhaler to enter the US market during the study period [1986-2020] with a new mechanism of action was ipratropium (Atrovent), which was approved in 1986.") at 4.

[28] *Id.* at 12 *See* infra Figure 1 ("This figure includes patents granted to inhalers that were filed prior to FDA approval. The median number of pre-approval patents grew from 2 per inhaler (interquartile range [IQR] 1–5) from 1986-1997 to 9 per inhaler (IQR 6–12) from 1998-2008 and 12 per inhaler (IQR 6.5–19.5) from 2009-2020.").

Figure 1: Patents per inhaler at FDA approval, 1986-2020[29]



Filing patent applications after FDA approval[30]. Manufacturers can apply for patents at any time before or after a product is approved by the FDA and then list those patents in the Orange Book. Some of these patent applications cover new modifications to a product (e.g., a dose counter). Others are obtained via a special type of application to the US Patent and Trademark Office (USPTO), called a

[29] *Id.*

[30] When talking about the dates on which patents are filed, we are referring to the date when patent applications were submitted to the USPTO.

continuation, in which a patent holder adds new applications to a prior submission by offering minor clarifications or additions without substantial change to the underlying invention. Manufacturers of 25 brand-name inhalers (47%) received patents on products that were filed as part of applications made to the USPTO after FDA approval.[31] These newly added patents extended the duration of protection on 12 inhalers by a median of 6 years.[32]

Growth in numbers of device patents. Inhalers represent one of the largest classes of drug-device combinations by market share in the United States.[33] Device patents are defined as those that cover the delivery vehicle required for administration of an active pharmaceutical compound (in this case the inhaler) or component parts of that delivery vehicle (for example, the nozzle of an inhaler). Manufacturers rely on device patents to enforce market exclusivity on brand-name inhalers. Of the 53 brand-name

---

[31] Testimony of William Feldman, *Patent Thickets and Product Hops: How Congress Could Reward Legitimate Innovation While Facilitating More Timely Generic Competition*, United States Senate Judiciary Committee May 21, 2024, 1-12, https://www.judiciary.senate.gov/imo/media/doc/2024-05-21_-_testimony_-_feldman.pdf at 7.

[32] *Id.*

[33] Demkowicz BJ, Tu SS, Kesselheim AS, Carrier MA, Feldman WB. *Patenting Strategies on Inhaler Delivery Devices.* CHEST, Aug. 2023, Volume 164, Issue 2, 450–460, https://pubmed.ncbi.nlm.nih.gov/36842533/ at 451(citing Beall RF, Kesselheim AS. *Tertiary patenting on drug-device combination products in the United States*. NATURE BIOTECHNOLOGY, Feb. 2018, Volume 36, Number 2, 142–145; Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. Author Manuscript *Patents and Regulatory Exclusivities On Inhalers For Asthma And COPD, 1986-2020*, https://pubmed.ncbi.nlm.nih.gov/35579925/).

inhalers for asthma and COPD approved by FDA between 1986 and 2020, 39 had at least one device patent listed in the Orange Book.[34] More than half of all patents listed on inhalers with the FDA since 1986 have covered their delivery devices, including 137 distinct device patents overall.[35] Of these 137 device patents, 77% made no mention of active ingredients or their molecular structures, and 72% made no mention of any relevant prespecified feature connecting the device patent to the drug product.[36] For the 39 brand-name inhalers with one or more device patents listed in the Orange Book, device patents extended the duration of market protection by a median of 5.5 years (interquartile range, 0.0-10.5 years) beyond the last-to-expire non-device patent.[37]

Device hops. While drug manufacturers obtain lengthy market dominance on inhalers through patents and exclusivities, they obtain even longer durations of protection from generic competition through "device-hopping." This strategy entails placing the same active ingredient(s) into a new device with new patents and

---

[34] Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. Author Manuscript, *Patents and Regulatory Exclusivities On Inhalers For Asthma And COPD, 1986-2020*. https://pubmed.ncbi.nlm.nih.gov/35579925/.

[35] *Id.*

[36] *Id.*

[37] Demkowicz BJ, Tu SS, Kesselheim AS, Carrier MA, Feldman WB. *Patenting Strategies on Inhaler Delivery Devices.* Chest, Aug. 2023, Volume 164, Issue 2, 450–460, https://pubmed.ncbi.nlm.nih.gov/36842533/at 450, *see* infra Figure 4.

exclusivities that provide longer protection.[38] Amici's study of the 53 brand-name inhalers for asthma and COPD approved by FDA between 1986 and 2020 demonstrated that inhaler manufacturers employed this strategy on 15 different originators (leading to 19 follow-on brand-name products).[39] While some of these device tweaks were in response to a ban on ozone-depleting CFCs, which early inhalers contained, the majority were unrelated to the ban.[40]

Among inhalers with device hops, manufacturers received a median of 28.1 years of protection from competition following approval of the originator product to the last-to-expire exclusivity or patent for follow-ons.[41] This strategy can work because generic versions of a brand-name reference inhaler are only approved for a specific brand-name product (i.e., one specific drug-device combination). Thus, when brand-name manufacturers release a new version of an inhaler (with a new drug application), generic versions of the older product are not interchangeable with the

---

[38] Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. Author Manuscript, *Patents and Regulatory Exclusivities On Inhalers For Asthma And COPD, 1986-2020*. https://pubmed.ncbi.nlm.nih.gov/35579925/ at 6.

[39] *Id.*

[40] *Id.* at 7 ("Some of these incremental adjustments to inhalers occurred in response to the FDA banning CFC-containing products between 2008-2013, which was strongly supported by the pharmaceutical industry […] While the CFC ban may have helped extend the market exclusivities obtained by brand name manufacturers, many of the incremental adjustments to inhalers during the study period were not directly related to the ban. Approximately two-thirds of the device hops involved moves to different types of inhalers (metered-dose, dry-powder, and soft mist products) rather than moves from CFC- to HFA-containing products.").

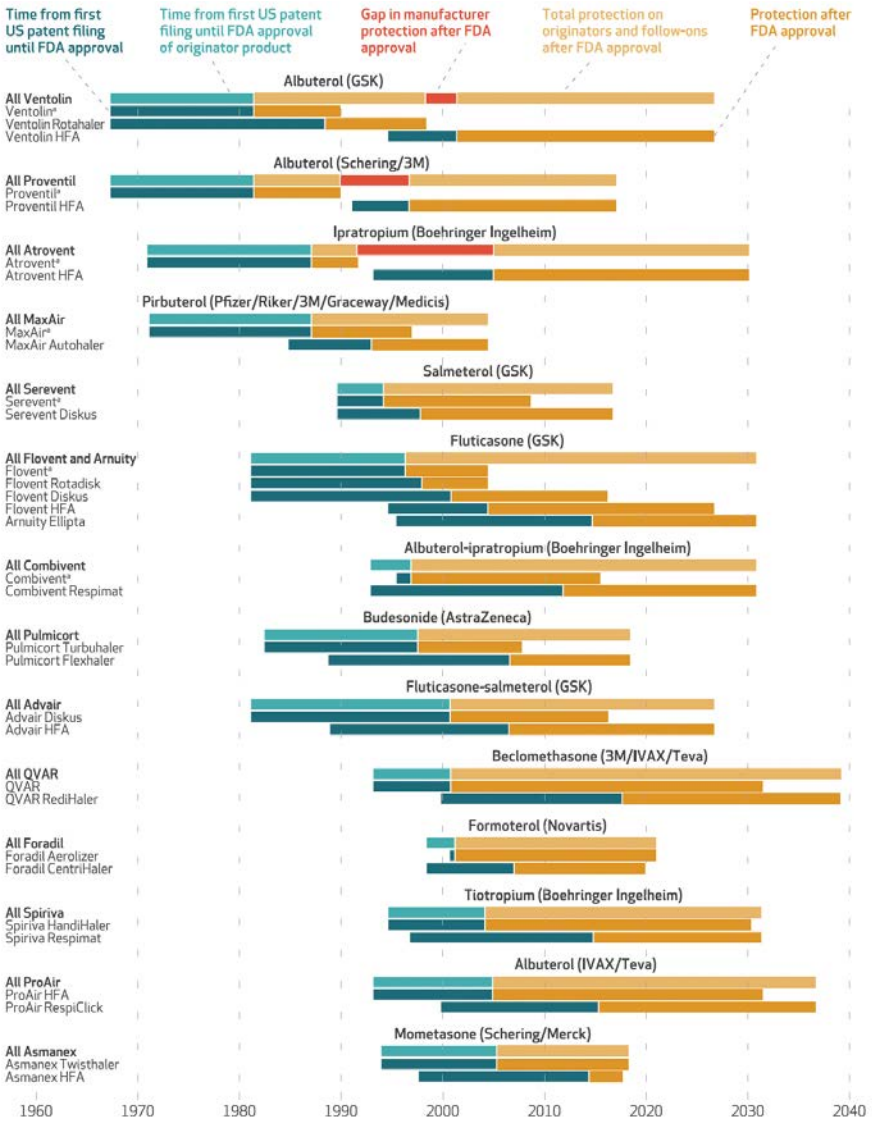
[41] *Id.* at 6.

new product and cannot automatically be substituted at the pharmacy for that new product.[42] Product hops to new albuterol inhalers generated approximately $14 billion in U.S. sales between 2007 and 2021.[43]

[42] *Id.*

[43] Wouters OJ, Feldman WB, Tu SS, *Product Hopping in the Drug Industry - Lessons from Albuterol*, NEW ENGLAND JOURNAL OF MEDICINE. Sept. 2022, Volume 387, Issue 13, 1153–1154 https://pubmed.ncbi.nlm.nih.gov/36155425/ at 1154 (*See* graph *Net Sales of Brand-Name Albuterol Inhalers in the United States, 1992-2021).*

Figure 2: Extensions of patent protection for brand-name inhalers for asthma and COPD through device-hopping[44]



The practices outlined above have proven lucrative for brand-name inhaler manufacturers. From 2000-2021, manufacturers earned $178 billion on brand-name

[44] Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. *Patents and Regulatory Exclusivities On Inhalers For Asthma And COPD, 1986-2020*. HEALTH AFFAIRS. June 2022, Volume 41, Number 6, 787–796. https://pubmed.ncbi.nlm.nih.gov/35579925/ at 793.

inhalers, including more than 60% after patents on the active ingredients had expired.[45]

B. Teva has adopted all of the strategies outlined above on ProAir HFA (albuterol)

For ProAir HFA, the listing of improper device-only patents is one strategy among many that has been employed to delay generic competition. Teva has adopted all of the strategies outlined above on ProAir HFA (albuterol).

ProAir was a new product in an old class. Albuterol is a selective β_2 agonist that was first approved in 1981.[46] The original albuterol inhalers contained CFCs, and generic CFC-based albuterol inhalers had entered the US market by the mid-1990s.[47] Revenue on brand-name products had substantially dropped by the 2000s.[48] Teva then

---

[45] Feldman WB, Tu SS, Alhiary R, Kesselheim AS, Wouters OJ, *Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021*, JAMA, Jan. 2023, Volume 329, Issue 1, 87–89, https://jamanetwork.com/journals/jama/fullarticle/2800037.

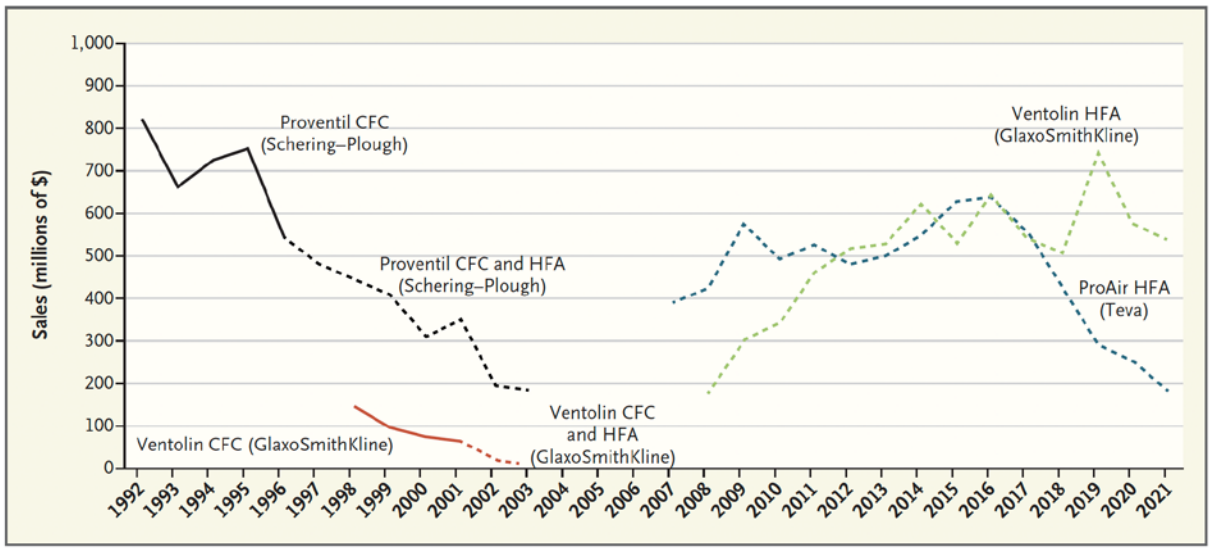
[46] Wouters OJ, Feldman WB, Tu SS, *Product Hopping in the Drug Industry — Lessons from Albuterol*, THE NEW ENGLAND JOURNAL OF MEDICINE, Sept. 29, 2022, Volume 387, Issue 13 https://pubmed.ncbi.nlm.nih.gov/36155425/ at 1153.

[47] Department of Health and Human Services Food and Drug Administration 21 CFR Part 2 [Docket No. 2003P-0029] RIN 0910-AF18 Use of Ozone-Depleting Substances; Removal of Essential-Use Designations, A Proposed Rule by the Food and Drug Administration on 06/16/2004, https://www.federalregister.gov/documents/2004/06/16/04-13507/use-of-ozone-depleting-substances-removal-of-essential-use-designations ("generic albuterol CFC MDIs first came on the market in 1995 and 1996").

[48] Wouters OJ, Feldman WB, Tu SS, *Product Hopping in the Drug Industry - Lessons from Albuterol*, THE NEW ENGLAND JOURNAL OF MEDICINE. Sept. 2022, Volume 387, Issue 13, 1153–1156, https://pubmed.ncbi.nlm.nih.gov/36155425/ at 1153-54.

launched an albuterol inhaler with hydrofluoroalkanes (HFA) that, along with a similar product by GlaxoSmithKline, resulted in substantial revenue (Figure 3).[49]

Figure 3: Net sales of brand-name albuterol inhalers in the United States, 1992-2021[50]



("Annual revenue from sales of brand-name albuterol inhalers was on the decline in the 1990s (when sales data first became publicly available), and it had dipped below $200 million by the early 2000s").

[49] Wouters OJ, Feldman WB, Tu SS, *Product Hopping in the Drug Industry - Lessons from Albuterol*, THE NEW ENGLAND JOURNAL OF MEDICINE, Sept. 2022, Volume 387, Issue 13, 1153–1156, https://pubmed.ncbi.nlm.nih.gov/36155425/ at 1154.

[50] *Id.* ("Sales figures are from annual reports to investors published on company websites or 10-K forms filed with the Securities and Exchange Commission; these documents contained data on product sales net of any discounts or rebates. Teva's sales figures reflect sales in the United States and Canada and include sales of ProAir RespiClick and ProAir Digihaler from 2015 onward. No information was available on sales of Proventil CFC and HFA in 1998, so we imputed an amount corresponding to the midpoint between sales in 1997 and 1999. Data on sales of Proventil HFA were unavailable in most years after 2003 and are therefore not shown. Ventolin was sold by Glaxo Wellcome in 1998 and 1999; GlaxoSmithKline was formed in 2000 through the merger of Glaxo Wellcome and SmithKline Beecham. Yearly average exchange rates were used to convert foreign currencies to U.S. dollars; all amounts were

Dense patent thickets. Teva has submitted 17 patents for listing in the Orange Book for ProAir HFA since the product was first approved in 2004.[51]

Filing patent applications after FDA approval. More than half of all patents listed on ProAir HFA were filed in applications submitted to the USPTO after the drug had received approval from the FDA (10 patents, 59%).[52]

Device patents. More than 70% (12/17) of patents listed in the Orange Book on ProAir HFA were on the delivery device of the product.[53] None mentioned the active ingredient (albuterol) in the product on which the patent was listed. Device patents making no mention of active ingredients extended patent protection on ProAir HFA by more than 8 years.[54] Teva's ProAir Respiclick/Digihaler secured an even longer period of extension from device patents with no mention of active ingredients or molecular structures, reaching more than 20 years.[55]

---

inflation-adjusted to 2021 dollars with the use of the U.S. consumer price index. CFC denotes chlorofluorocarbon, and HFA hydrofluoroalkane.").

[51] Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations,* Patent and Exclusivity for: N021457 https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=021457&Appl_type=N.

[52] *Id.*

[53] *Id.*

[54] Demkowicz BJ, Tu SS, Kesselheim AS, Carrier MA, Feldman WB, *Patenting Strategies on Inhaler Delivery Devices.* CHEST*,* August 2023, Volume 164, Number 2, 450–460, https://pubmed.ncbi.nlm.nih.gov/36842533/ at 454.

[55] *Id.* ("8.3 years of device patent-related protection on ProAir HFA…").

Device hops. ProAir HFA was originally approved in 2004.[56] Teva received approval for ProAir Respiclick in 2015[57] (and later reformulated under the same New Drug Application as ProAir DigiHaler in 2018), both dry powder versions of the metered-dose inhaler ProAir.[58] These dry powder inhalers were not required to demonstrate clinical benefit over the metered-dose version in order to obtain FDA approval; they were, however, protected by numerous patents on aspects of the delivery device. Patents listed in the Orange Book on ProAir RespiClick expire in 2032,[59] and patents listed on ProAir Digihaler expire in 2041 (although the latter product was recently discontinued).[60]

---

[56] Feldman WB, Tu SS, Alhiary R, Kesselheim AS, Wouters OJ. *Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021*. JAMA. Jan. 3, 2023, Volume 329, Issue 1, 87–89, https://jamanetwork.com/journals/jama/fullarticle/2800037 at 88.

[57] Demkowicz BJ, Tu SS, Kesselheim AS, Carrier MA, Feldman WB. *Patenting Strategies on Inhaler Delivery Devices*. CHEST, Aug. 2023, Volume 164, Issue 2, 450–460, https://pubmed.ncbi.nlm.nih.gov/36842533/ at 453.

[58] Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. Author Manuscript, *Patents and Regulatory Exclusivities On Inhalers For Asthma And COPD, 1986-2020*. https://pubmed.ncbi.nlm.nih.gov/35579925/.

[59] *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations,* Patent and Exclusivity for: N205636 (Product 001), https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=205636&Appl_type=N.

[60] *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations,* Patent and Exclusivity for: N205636 (Product 002), https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=002&Appl_No=205636&Appl_type=N.

Teva reached a settlement with Perrigo following its ANDA in 2012 in which Perrigo agreed to delay release of its generic inhaler until 2016 (with limited supplies through 2018).[61]

As with other inhaler manufacturers, these strategies proved lucrative for Teva. The company earned $7.7 billion from 2004-2021 on ProAir products[62] containing an active ingredient (albuterol) first approved in 1981, which has been off patent for more than 3 decades.

C. The major question in *Teva vs. Amneal* concerns improper patent listings of device-only patents in the Orange Book. This practice is widespread among inhalers, and thus the decision in *Teva vs. Amneal* could have far-reaching impact for respiratory drugs.

As noted above, of the 137 unique device patents listed on inhalers approved from 1986-2020, 77% made no mention of active ingredients, and 72% made no mention of any feature that might connect the patent to its product (active ingredients, therapeutic class, asthma, COPD, emphysema, chronic bronchitis, or the lungs).[63] For the 39 brand-name inhalers with device patents, these patents extended

---

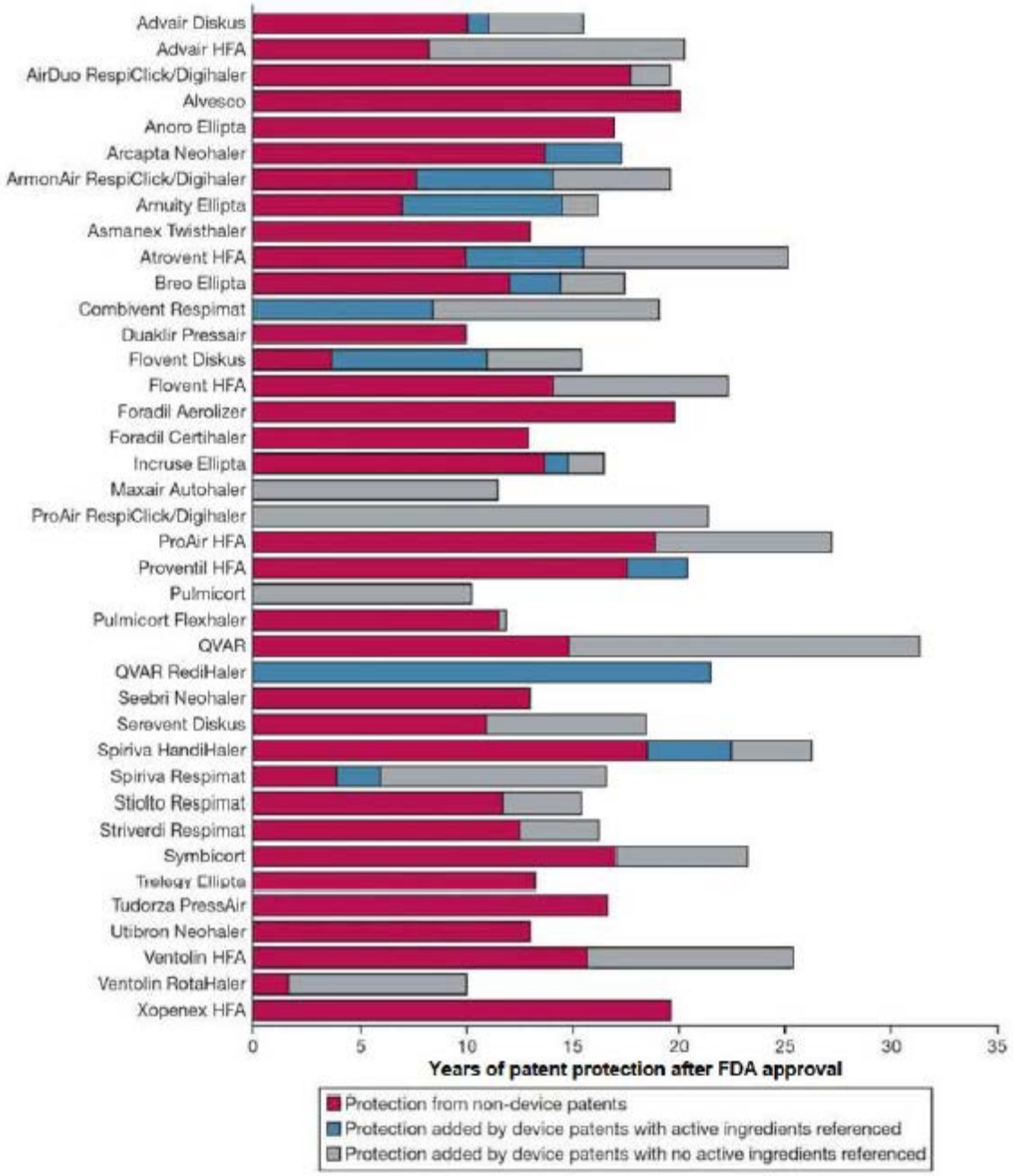
[61] Business Wire, *Teva Reaches Settlement in ProAir® HFA Patent Case*, https://www.businesswire.com/news/home/20140620005338/en/Teva-Reaches-Settlement-in-ProAir%C2%AE-HFA-Patent-Case.

[62] This includes both ProAir HFA and Respiclick, although the overwhelming majority was ProAir HFA. *See also* Research Letter, *Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021*, JAMA, Jan. 3, 2023, Volume 329, Issue 1, at 88.

[63] Demkowicz BJ, Tu SS, Kesselheim AS, Carrier MA, Feldman WB. *Patenting Strategies on Inhaler Delivery Devices*, CHEST, Aug. 2023, Volume 164, Number 2, 450–460, https://pubmed.ncbi.nlm.nih.gov/36842533/, at 452.

the duration of market protection by a median of 5.5 years. The last-to-expire patent was a non-device patent on 11 inhalers (28%), a device patent referencing one or more active ingredients on 3 inhalers (8%), and a device patent referencing no active ingredients on 25 inhalers (64%). Patents in this latter category added 7.5 years of patent protection, including 21.4 years on Teva's ProAir RespiClick/DigiHaler, 16.5 years on Teva's QVAR, 12.0 years on GlaxoSmithKline's Advair HFA, 10.7 years on Boehringer Ingelheim's Spiriva Respimat, 10.2 years on AstraZeneca's Pulmicort, and 8.3 years on ProAir HFA (Figure 4).

Figure 4: Patent protection for inhalers with device patents[64]



[64] *See id.* at 456 ("Bar graph showing patent protection of inhalers with device patents, 1986 through 2020. This figure includes all brand-name inhalers with one or more device patents approved from 1986 through 2020 (n = 39). It shows how brand-name manufacturers have extended periods of patent protection by listing device patents in the Orange Book with no reference to active ingredients. The red

1. Delayed generic competition on inhalers keeps prices high, and high out-of-pocket costs, in turn, can lead to cost-related non-adherence.

More than 27 million people in the US have asthma.[65] Nearly 12 million have COPD.[66] Patients with both conditions rely on maintenance inhalers for daily use and rescue inhalers to manage acute symptoms.[67] List prices for these products can run more than $600 per month and, although payers negotiate rebates to lower costs for payers, net prices are still substantially higher than prices in other countries.[68]

---

bars represent patent protection obtained from nondevice patents. The blue bars represent added protection from device patents that list one or more active ingredients, beyond any protection from nondevice patents. The gray bars represent further protection from device patents that list no active ingredients, beyond any protection from nondevice patents or device patents that list active ingredients. FDA: Food and Drug Administration.").

[65] Testimony of William Feldman, Patent Thickets and Product Hops: How Congress Could Reward Legitimate Innovation While Facilitating More Timely Generic Competition, United States Senate Judiciary Committee, May 21, 2024, https://www.judiciary.senate.gov/imo/media/doc/2024-05-21_-_testimony_-_feldman.pdf at 6 (citing Asthma and Allergy Foundation of America, Asthma Facts, https://aafa.org/asthma/asthmafacts/).

[66] *Id.* (citing American Lung Association, *COPD Trends Brief: Prevalence*, https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-prevalence).

[67] *Id.* (citing Global Initiative for Chronic Obstructive Lung Disease (GOLD), *2024 GOLD Report*, https://goldcopd.org/2024-gold-report/; Global Initiative for Asthma (GINA), *2023 GINA Report, Global Strategy for Asthma Management and Prevention*, https://ginasthma.org/2023-gina-main-report/).

[68] *Id.* (citing NAVLIN database, https://data.navlin.com/alspc/).

Since modern inhalers first became available to US patients in the 1950s, they have become the primary treatment for asthma and COPD.[69] For the reasons discussed in this brief, however, after over 65 years on the market, they remain expensive[70] and contribute to substantial out-of-pocket costs for patients.[71] Because out-of-pocket costs are often tied to list prices and because those without insurance do not pay insurer-negotiated rates, high list prices can also threaten affordability for patients.[72] One in 6 patients with asthma[73] and 1 in 6 with COPD[74] reported cost-

---

[69] Demkowicz BJ, Tu SS, Kesselheim AS, Carrier MA, Feldman WB, *Patenting Strategies on Inhaler Delivery Devices*, CHEST, August 2023, Volume 164, Issue 2, 450–460, https://pubmed.ncbi.nlm.nih.gov/36842533/at 451(citing Global Initiative on Chronic Obstructive Lung Disease, *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: 2023 Report*, 2023, https://goldcopd.org/2023-goldreport-2/; Global Initiative for Asthma, *GINA 2022 Annual Report*, https://ginasthma.org/gina-reports/).

[70] *Id.* (citing Feldman WB, Gagne JJ, Kesselheim AS, *Trends in Medicare Part D Inhaler Spending: 2012-2018*, ANNALS OF THE AMERICAN THORACIC SOCIETY, 2021, Volume 18, Issue 3, 548–550).

[71] *Id.* (citing Patel B, Mayne P, Patri T, et al. *Out-Of-Pocket Costs and Prescription Filling Behavior of Commercially Insured Individuals with Chronic Obstructive Pulmonary Disease*, JAMA HEALTH FORUM, 2022, Volume 3, Issue 5, e221167).

[72] Testimony of William Feldman, *Patent Thickets and Product Hops: How Congress Could Reward Legitimate Innovation While Facilitating More Timely Generic Competition*, United States Senate Judiciary Committee, May 21, 2024, https://www.judiciary.senate.gov/imo/media/doc/2024-05-21_-_testimony_-_feldman.pdf at 6.

[73] Xia T, Qiu H, Yu B, Bi J, Gu X, Wang S, Zhang Y, *Cost-Related Medication Nonadherence in US Adults With Asthma: The National Health Interview Survey, 2013-2020*, ANNALS OF ALLERGY ASTHMA & IMMUNOLOGY, Nov 2023, Volume 131, Issue 5, 606–613, https://www.annallergy.org/article/S1081-1206(23)00518-5/abstract#:~:text=Of%20the%2026%2C539%20individuals%20with,to%202020%20(eFig%201).

[74] Wen X, Qiu H, Yu B, Bi J, Gu X, Zhang Y, Wang S. *Cost-Related Medication Nonadherence in Adults with COPD in the United States 2013-2020*. BMC PUBLIC HEALTH,

related non-adherence in the US from 2013-2020. Given the prevalence of these diseases, this amounts to more than 4 million people in the United States each year who cannot afford their inhalers and must therefore limit their use. By contrast, a recent study of patients with commercial insurance found that reducing out-of-pocket costs could promote better inhaler adherence.[75]

2. Generic competition is the key way to lower prescription drug prices in the US.[76]

In the US pharmaceutical system, brand-name companies set prices at whatever level they choose. Generic competition, however, can lead to substantial price drops, and an increased number of generic competitors is associated with a greater

---

Mar. 2024, Volume 24, Number 1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10956194/#:~:text=In%20this%20nationally%20representative%20study,medications%20due%20to%20medication%20costs.

[75] Agarwal SD, Metzler E, Chernew M, Thomas E, Press VG, Boudreau E, Powers BW, McWilliams JM. *Reduced Cost Sharing and Medication Management Services for COPD: A Randomized Clinical Trial*. JAMA INTERNAL MEDICINE, Jul. 2024, https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2821705.

[76] *See* Kesselheim AS, Avorn J, Sarpatwari A. *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, JAMA, 2016, Volume 316, Issue 8, 858–871, https://jamanetwork.com/journals/jama/article-abstract/2545691; Rome BN, Egilman AC, Kellelheim AS, *Trends in Prescription Drug Launch Prices, 2008-2021*, JAMA, 2022, Volume 327, Issue 21, 2145–2147, https://jamanetwork.com/journals/jama/fullarticle/2792986; Feldman WB, Rome BN, Raimond VC, *Estimating Rebates and Other Discounts Received by Medicare Part D*, JAMA HEALTH FORUM, June 2021, Volume 2, Issue 6, e210626. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2780805; Feldman WB, Gagne JJ, Kesselheim AS. *Trends in Medicare Part D Inhaler Spending: 2012-2018*, ANNALS OF THE AMERICAN THORACIC SOCIETY, Volume 18, Issue 3, 545–547, https://www.atsjournals.org/doi/10.1513/AnnalsATS.202008-1082RL.

magnitude of reduction. For example, the presence of just one generic manufacturer tends to lower prices by approximately 10%, while the presence of 5 generic competitors lowers prices by 50% and 8 generic manufacturers by 70%.[77] Thus, even though ProAir HFA faces competition now from 2 generic competitors, greater price reductions would be expected if more competitors entered. However, these competitors, like Amneal, may be deterred or delayed from entering the market because of ongoing patents listed in the Orange Book. These patents are harming patients by increasing the costs of market entry for generic firms, which in turn lead to fewer competitors and higher prices.[78]

The decision in *Teva vs. Amneal* could have far-reaching impact for other classes of drugs.

Although inhalers have historically been one of the largest markets for drug-device combinations, manufacturers have listed device-only patents on a range of

[77] Dave CV, Hartzema A, Kesselheim AS, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, THE NEW ENGLAND JOURNAL OF MEDICINE, Dec. 2017, Volume 377, Issue 26, 2597–2598, https://www.nejm.org/doi/full/10.1056/NEJMc1711899.

[78] Conrad R, Lutter R. *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, U.S. Food & Drug Administration, https://www.fda.gov/media/133509/download; Nguyen NX, Sheingold SH, Tarazi W, Bosworth A. *Medicare Part D: Competition and Prices in Generic Drug Markets 2007- 2018*, Issue Brief No. HP-2021-01, Office of the Assistant Secretary for Planning and Evaluation, U.S. Dept. of Health and Human Services, Jan. 19, 2021, https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/198346/medicare-part-d-generic-comp.pdf.

other products. Prominent examples include insulin injector pens and glucagon-like peptide-1 receptor agonists like Ozempic/Wegovy (semaglutide) for diabetes and weight loss. Improper listings of device-only patents have also been found on a wide range of products.

Insulin Injector Pens. These products were listed in the Orange Book until 2020, when they were removed as the FDA began regulating them as biologics. Of the 33 drug-device combination insulin products approved from 1986-2019, 63% of all patents listed in the Orange Book were on the delivery devices. Twenty-two products had last-to-expire patents that were on the delivery devices, of which 17 (77%) made no mention of insulin. These device-only patents making no mention of insulin extended the duration of market protection by a median of 4.3 years beyond other patents. There were 67 unique device patents on insulin products in the cohort, and 85% made no mention of insulin in their claims.

Glucagon-like peptide-1 receptor. In a study of GLP-1 receptor agonists approved by the FDA from 2005 to 2021, more than half of all patents listed in the Orange Book were on the delivery devices of these products.[79] The median duration of expected market protection on GLP-1 receptor agonists was 18 years. Manufacturers listed a total of 107 patents on the delivery devices of these products, and not a single

[79] Alhiary R, Kesselheim AS, Gabriele S, Beall RF, Tu SS, Feldman WB. *Patents and Regulatory Exclusivities on GLP-1 Receptor Agonists*, JAMA, July 2023, Volume 330, Issue 7, 650–657, https://jamanetwork.com/journals/jama/article-abstract/2808050.

one mentioned the active ingredients in the products on which the patents were listed.[80] Removal of these device patents from the Orange Book would have reduced the median number of patents per product from 20.5 to 6.

Impact on a wide range of products. In preliminary work looking at all delivery device patents in the Orange Book (not yet published), the Amici professors of law and medicine have found device-only patents not only on inhalers and injector pens (insulin and GLP-1s) but on a wide range of products. These include transdermal patches, intranasal drugs, and birth control devices. The precedent set in *Teva v. Amneal* could have far-reaching consequences for pharmaceuticals in the US. Indeed, 40% of the top-selling drugs in Medicare Part D in 2022 (the last year with available data) were drug-device combinations.[81]

IV. CONCLUSION

Brand name drug manufacturers are leveraging the patent system to extend monopoly power in ways that were never originally intended by Congress. The patent system plays an important role in promoting innovation and compensating drug firms for investment in research and development. However, patents are meant to provide *limited* monopoly power for a fixed period of time. Once patents expire, robust

[80] Alhiary R, Gabriele S, Kesselheim AS, Tu SS, Feldman WB, *Delivery Device Patents on GLP-1 Receptor Agonists*, JAMA, Feb. 2024, Volume 331, Number 9, 794–796, https://jamanetwork.com/journals/jama/fullarticle/2814942.

[81] Center for Medicare & Medicaid Services, *Medicare Part D Spending by Drug*, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.

competition can result in lower prices, increasing access to therapies and delivering better health outcomes for patients. Patients with asthma and COPD rely on inhalers to control their symptoms. Yet, these products remain expensive, in part because brand-name manufacturers have obtained numerous patents on inhalers, including on their delivery devices.

V. SIGNATORIES[82]

William B. Feldman, M.D., D.Phil., M.P.H.,
Harvard Medical School

Aaron S. Kesselheim, M.D., J.D., M.P.H.,
Harvard Medical School

S. Sean Tu, J.D., Ph.D.,
West Virginia University College of Law

Jerry Avorn, MD, Professor of Medicine,
Harvard Medical School

Reed F. Beall, PhD, Associate Professor,
University of Calgary's Cumming School of Medicine

Robyn T. Cohen MD, MPH, Associate Professor of Pediatrics,
Boston University Chobanian and Avedesian School of Medicine

Ravi Gupta, MD, MSHP, Assistant Professor,
Johns Hopkins University School of Medicine

Thomas R. Radomski, MD, MS,
Associate Professor of Medicine and Clinical and Translational Science, University of Pittsburgh

Reshma Ramachandran, MD, MPP, MHS, Assistant Professor of Medicine,
Yale University School of Medicine

Rita F. Redberg, MD, MSc, Professor of Medicine,
University of California, San Francisco

Benjamin N. Rome, MD, MPH, Assistant Professor of Medicine,
Harvard Medical School

[82] Institutions for identification purposes only. All participants sign in their individual capacities.

Joseph Ross, MD, MHS, Professor of Medicine and of Public Health,
Yale University School of Medicine

S. Christy Sadreameli, MD, MHS, Assistant Professor of Pediatrics,
The Johns Hopkins University School of Medicine

Olivier J. Wouters, PhD, Assistant Professor of Health Policy, London School of Economics and Political Science

Dated: September 11, 2024

Respectfully Submitted,

/s/ Kristen A. Johnson
Kristen A. Johnson
Lauriane Williams
HAGENS BERMAN SOBOL SHAPIRO LLP
One Faneuil Hall Square, 5th Floor
Boston, MA 02109
Telephone: 617-482-3700
Facsimile: 617-482-3003
kristenj@hbsslaw.com
laurianew@hbsslaw.com

CERTIFICATE OF SERVICE

I hereby certify that, on September 11, 2024, I electronically filed the foregoing motion to amend the caption with the Clerk of the Court for the U.S. Court of Appeals for the Federal Circuit using the CM/ECF system. All participants are registered CM/ECF users and will be served by the appellate CM/ECF system.

Dated: September 11, 2024

/s/ Kristen A. Johnson
Kristen A. Johnson

FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 24-1936

Short Case Caption: Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

☑ the filing has been prepared using a proportionally-spaced typeface and includes 6,181 words.

☐ the filing has been prepared using a monospaced typeface and includes _____ lines of text.

☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 09/11/2024

Signature: /s/ Kristen A. Johnson

Name: Kristen A. Johnson