UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

1199SEIU NATIONAL BENEFIT FUND, 1199SEIU GREATER NEW YORK BENEFIT FUND, 1199SEIU NATIONAL BENEFIT FUND FOR HOME CARE WORKERS, AND 1199SEIU LICENSED PRACTICAL NURSES WELFARE FUND, on behalf of themselves and others similarly situated

Plaintiffs,

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., AND BOEHRINGER INGELHEIM INTERNATIONAL GMBH

Defendants.

Case No.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

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I. INTRODUCTION

1. More than thirty-four million Americans live with potentially life-threatening chronic lung disease, including asthma and chronic obstructive pulmonary disease (COPD). Asthma is a long-term disease characterized by inflammation and muscle tightening around the airways, making it harder to breathe. COPD is an obstructive lung disease that over time makes breathing difficult. While asthma and COPD have no cure, certain drugs, including inhalers, can help asthma and COPD patients manage their disease and lead healthier, more active lives.

2. These inhaler treatments have been available for decades. Two such drugs—Combivent Respimat (for COPD) and Spiriva Respimat (for COPD and asthma)—are the only inhalation sprays for their active ingredients (ipratropium-albuterol and tiotropium) available in the United States. The Food and Drug Administration (FDA) approved Combivent Respimat in 2011 and Spiriva Respimat in 2014. Today, both sprays remain widely used.

3. In exchange for developing these drugs, Boehringer Ingelheim Pharmaceuticals, Inc. received patents (which were then assigned to Boehringer Ingelheim International Gmbh (collectively, "Boehringer")) that allowed them to earn over $45 billion in profits. But the patents on the underlying active ingredients expired in 2020 conferring a monopoly on the drugs. Both drugs should therefore now be available to the millions of Americans who suffer from asthma and COPD in a lower-cost generic format. Instead, to this day only Boehringer produces and sells Combivent Respimat and Spiriva Respimat, continuing to earn billions in profts *after the expiration of the patents referencing the drugs' active ingredients*.

4. Boehringer's monopoly on ipratropium-albuterol and tiotropium inhalation sprays defies a U.S. regulatory scheme designed to promote generic entry on the expiration or invalidation of patents. Federal laws attempt to "balance two competing interests: [p]romoting competition between 'brand-name' or innovator drugs' and 'generic' drugs, and encouraging research and innovation."[1] In order to incentivize and reward innovation, the U.S. patent system permits drug companies to sell new medications on the market and bars other manufacturers from making generic versions for a set period of time. Once the drug patent expires, generics are allowed on the market, nearly always selling for less than the brand-name drug.

5. The availability of generics has tangible, cost and life-saving effects on patients and health insurers. From 2014 to 2019, for instance, one in eight Americans lost a loved one because they could not afford the cost of their medication.[2] That figure is double for people of color.

6. Furthermore, the people most likely to suffer from asthma and COPD are those least likely to be able to afford inhalers. Those living in poor and underserved communities are exposed to allergens and pollutants at higher rates, increasing their likelihood of developing asthma and COPD.[3] In the United States, Native Americans (12%) and Black Americans

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[1] Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676, 37676 (June 18, 2003) (to be codified 21 C.F.R. 314).

[2] Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, Gallup (Nov. 12, 2019), https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx.

[3] Letter from Sen. Bernard Sanders et al., to Emma Walmsley, CEO, GSK at 3 (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-GSK.pdf.

(10.9%) have the highest rates of asthma.[4] Black children are nearly eight times more likely to die from asthma. People living in rural areas—with higher smoking rates and half as many per capita health providers and specialists—are far more likely to develop COPD, suffer complications, and die from the disease. And yet, Americans everywhere pay exorbitant prices for medications needed to prevent these outcomes. Here, Boehringer charges as much as $500 (and more than $600 after retail markups) per month for inhaler products that sometimes cost ten times less in Germany, Japan, Canada, France, and the U.K.[5]

7. To protect this prize, Boehringer manipulated the U.S. patent and drug approval system to unlawfully exclude generic competitors, monopolize the markets for Combivent Respimat and Spiriva Respimat, and extract monopoly profits from drugs that should have been available in generic form years ago. Specifically, Boehringer listed non-drug patents in the FDA's register of "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), adopted the Respimat inhaler device for the specific purpose of foreclosing generic competition on the active ingredients of Combivent (product hopping), and engaged in sham litigation against a potential entrant based on Orange book listings it knew to be wrongful.

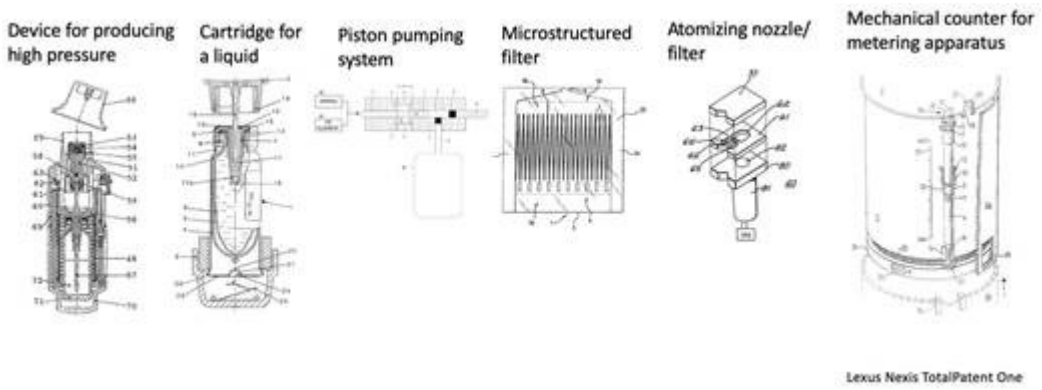
8. Listing a patent in the Orange Book gives drug companies like Boehringer a powerful tool—the ability to trigger an automatic, thirty-month stay of approval of a generic

[4] *Current Asthma Demographics*, Am. Lung Ass'n (last updated July 6, 2020), https://www.lung.org/research/trends-in-lung-disease/asthma-trends-brief/current-demographics.
[5] Letter from Sen. Bernie Sanders et al., to Hubertus von Baumbach, Chairman Bd. Dirs., Boehringer Ingelheim International GmbH., Re: Improper Orange Book-Listed Patents for Atrovent HFA, Combivent Respimat, Spiriva, and Spiriva Respimat (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Boehringer-Ingelheim.pdf.

competitor drug. Because improper Orange Book listings can effectively block competition, Congress and the FDA have strictly limited the types of patents that can be listed in the Orange Book—only "drug substance," "drug product," and "method of use" patents qualify.

9. Notwithstanding the clear language of the statute, Boehringer knowingly and willfully listed twenty-five device-only patents in the Orange Book as covering Combivent Respimat. Boehringer then listed nineteen of these patents again as covering Spiriva Respimat. In other words, it listed nineteen device-only patents twice. While most of those patents' exclusivities have finally expired, Boehringer still lists six unexpired device-only patents in the Orange Book as covering both Combivent Respimat and Spiriva Respimat "drug products" – in other words, it lists these six patents twice.

Figure 1: Boehringer's Unexpired Device-Only Patents[6]



10. Boehringer knew that listing these device-only patents in the Orange Book would break the law. Federal law states that a manufacturer may only list a "patent that claims the drug

[6] William B. Feldman, *The High Costs of Asthma Medications in the US* 12 (2024), https://bwhsevereasthmacme.org/wp-content/uploads/2024/03/7-Feldman-Pharmacoeconomics-of-Asthma-Medications.pdf.

or a method of using the drug that is the subject of the [new drug application]."[7] Indeed, the FDA in 2003 *rejected* the view that "integral devices," such as "*metered dose inhalers*," that do not claim a drug product "should be submitted and listed."[8] Boehringer, however, decided to chance it, declaring "under penalty of perjury" that its device-only patents nevertheless qualified.[9]

11. Worse yet, it continues to list the patents despite the fact that regulators have explicitly advised Boehringer that it has abused the regulatory process. In September 2023, the Federal Trade Commission (FTC) issued a Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book.[10] In that statement, the FTC explained the difference between permissible and impermissible Orange Book listings, and why improper listing of patents in the Orange Book "may harm competitive conditions in pharmaceutical markets" and "constitute illegal monopolization." The FTC urged drug manufacturers to "immediately remove any patents that fail to meet listing requirements" and warned that false certifications of compliance with Orange Book regulations "may constitute a potential criminal violation for the submission of false statements."[11] Its statement highlighted judicial decisions, including the First Circuit's *In re Lantus Direct Purchaser Antitrust Litigation*, 950 F.3d 1, 7 (1st Cir. 2020). *Lantus* found that a manufacturer improperly listed a device patent covering an

[7] 21 § C.F.R. § 314.53(b)(1).
[8] Patent Submission and Listing Requirements, 68 Fed. Reg. at 36680 (emphasis added).
[9] *See id.* at 36686; *see also* 21 C.F.R. § 314.53(c)(1)(ii); *see also infra* Section IV.A.3.
[10] FTC, *Statement Concerning Brand Drugs Manufacturers' Improper Listing of Patents in the Orange Book* 1 (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.
[11] *Id.* at 3, 5-6 (emphasis added).

injector pen drive mechanism in the Orange Book because the patent did not claim the drug ingredient or a method of using it.[12]

12. Last November, the FTC sent a warning letter directly to Boehringer about the six device-only patents, specified above, improperly listed in the Orange Book as covering the Combivent Respimat and Spiriva Respimat drug products.[13] The FTC wrote, "This letter is to inform you that we believe certain patents have been improperly or inaccurately listed in the Orange Book with regard to Boehringer Ingelheim Pharmaceuticals, Inc. products . . . ."[14] The FTC further reasoned that "patents improperly listed in the Orange Book may delay lower-cost generic drug competition" and that "[e]ven brief delays in generic competition can reduce patient access to more affordable alternatives and increase costs across the entire health care system."[15]

13. Other drug makers, including GlaxoSmithKline PLC ("GSK"), heeded the FTC's admonishment. GSK withdrew four of five challenged Orange Book listings related to three of its asthma inhalers. Boehringer did not. As a result, the U.S. Senate Committee on Health, Education, Labor, and Pensions, led by Senators Bernard Sanders (Chairman), Tammy Baldwin, Ben Ray Lujan, and Edward J. Markey, initiated "an investigation into Boehringer Ingelheim's inhaler products and the company's extensive efforts to keep prices high for patients."[16]

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[12] *Id*. at 6 n.31.
[13] Letter from Rahul Roa, Dep. Dir., FTC, to Gen. Counsel, Boehringer Ingelheim Pharms., Re: Improper Orange Book-Listed Patents for Atrovent HFA, Combivent Respimat, Spiriva, and Spiriva Respimat (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/boehringer-ingelheim-orange-book.pdf.
[14] *Id*. at 1.
[15] *Id*. at 2 (emphasis added).
[16] *See* Sanders et al., *supra* note 5, at 1 (emphasis added).

14. This lawsuit is brought by jointly administered health and welfare funds Plaintiffs 1199SEIU National Benefit Fund, 1199SEIU Greater New York Benefit Fund, 1199SEIU National Benefit Fund for Home Care Workers, and 1199SEIU Licensed Practical Nurses Welfare Fund (collectively, "the 1199SEIU Benefit Funds" or "Plaintiffs"). The 1199SEIU Benefit Funds seek justice on behalf of themselves and all others similarly situated who paid for Combivent Respimat and Spiriva Respimat at monopoly prices long after Boehringer's drug patents expired and a generic drugs should have entered the markets.

15. Specifically, Plaintiffs seek injunctive relief to open the markets and damages for purchases and reimbursements of Combivent Respimat and Spiriva Respimat by Plaintiffs and other end-payors since February 23, 2020, and August 23, 2020, respectively—when, but for Boehringer's unlawful scheme, the markets for Combivent Respimat and Spiriva Respimat would have been open to competition.

II. PARTIES

16. Plaintiffs 1199SEIU National Benefit Fund, 1199SEIU Greater New York Benefit Fund, 1199SEIU National Benefit Fund for Home Care Workers, and 1199SEIU Licensed Practical Nurses Welfare Fund are jointly administered health and welfare funds. Among the largest labor-management funds in the country, the 1199SEIU Benefit Funds provide comprehensive health and welfare benefits to 400,000 working and retired healthcare industry workers and their families, who reside in numerous locations in the United States. The 1199SEIU Benefit Funds indirectly purchased and paid, not for resale, for some or all of the purchase price for Combivent Respimat and Spiriva Respimat in numerous jurisdictions during

the Class Period. As a result, the 1199SEIU Benefit Funds were injured in their business or property by reason of the violations of law alleged herein. When a generic version of a prescription drug is available, 1199SEIU Benefit Funds' members—and 1199SEIU Benefit Funds—typically purchase and/or provide reimbursement for the generic version. The 1199SEIU Benefit Funds expect that they will purchase and/or provide reimbursement for Combivent Respimat, Spiriva Respimat, and generic ipratropium-albuterol and tiotropium inhalation sprays (to the extent they are available) in the future. Consequently, the 1199SEIU Benefit Funds will continue to be injured unless the defendants are enjoined from their unlawful conduct as alleged herein.

17. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 900 Ridgebury Road in Ridgefield, Connecticut 06877. Boehringer Ingelheim Pharmaceuticals, Inc. is a U.S. subsidiary of Boehringer Ingelheim International GmbH and the largest U.S. subsidiary of Boehringer Ingelheim Corporation. Boehringer Ingelheim Pharmaceuticals, Inc. manufactures and sells Combivent Respimat and Spiriva Respimat. Boehringer Ingelheim Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 021747 for Combivent Respimat (ipratropium and albuterol) and NDA No. 021936 for Spiriva Respimat (tiotropium bromide).

18. Defendant Boehringer Ingelheim International GmbH is a German private limited liability company with its principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany. It is one of the largest pharmaceutical companies in the world and the parent company of Boehringer Ingelheim Pharmaceuticals, Inc. Boehringer Ingelheim Pharmaceuticals, Inc.

assigned Boehringer Ingelheim International GmbH the following six patents for Combivent Respimat and Spiriva Respimat that are at issue in this complaint: US 7284474 ('474) entitled "Piston Pumping System," US 7896264 ('264) entitled "Micro-Structured Nozzle w/Filter," US 7837235 ('235) entitled "Device for Clamping Fluid," US 7396341 ('341) entitled "Blocking Device," US 9027967 ('967) entitled "Device for Clamping a Fluidic Component," and US 8733341 ('3,341) entitled "Atomizer w/Nozzle." In addition, Boehringer Ingelheim International Gmbh is the registered trademark holder of RESPIMAT®, COMBIVENT®, and SPIRIVA® which are used by Boehringer Ingelheim Pharmaceuticals, Inc. in the marketing and sales of Combivent Respimat and Spiriva Respimat. .The marketing of Combivent Respimat and Spiriva Respimat in the U.S. contribute to a substantial portion of Boehringer Ingelheim International GmbH's global sales revenue.

III. JURISDICTION AND VENUE

19. Subject matter jurisdiction: This Court has jurisdiction over this case pursuant to Title 28, Section 1332(d) and the Class Action Fairness Act of 2005 ("CAFA"), Title 28, Section 1711, *et seq*. This case is a class action, the amount in contrary exceeds $5 million, and plaintiffs are citizens of a different state than Boehringer. Additionally, this Court has subject matter jurisdiction over plaintiffs' claim for injunctive relief pursuant to Sections 4 and 16 of the Clayton Act, Title 15, Sections 15 and 26. This Court also has subject matter jurisdiction under Title 28, sections 1331 (federal question) and 1337(a) (antitrust). Finally, this Court has supplemental jurisdiction over the state law claims under Title 28, Section 1367.

20. Venue: Venue is appropriate in this district under Title 28, Section 1391. Boehringer Ingelheim Pharmaceuticals, Inc. is headquartered in Connecticut and a substantial part of the events or omissions giving rise to these claims occurred here. Venue is also proper in this district under Title 15, Sections 15(a) and 22. During the Class Period (defined below), Boehringer transacted business, were found, or had agents in this district and a substantial portion of the affected interstate trade and commerce described below has been carried out in this district.

21. Personal jurisdiction: This Court has personal jurisdiction over Boehringer. Boehringer Ingelheim Pharmaceuticals, Inc. is headquartered in this district, purposefully directed its business activity toward this jurisdiction, and had substantial contacts with this jurisdiction. Plaintiffs' claims for relief arise from and relate to illegal acts committed by Boehringer Ingelheim Pharmaceuticals, Inc. within this jurisdiction, and Boehringer Ingelheim International GmbH's intellectual property is used by Boehringer Ingelheim Pharmaceuticals, Inc. to further illegal acts within this jurisdiction. Further, personal jurisdiction exists based on the contacts with the United States of both defendants, and venue is proper under the Clayton Act. Plaintiffs also paid unlawful overcharges for Combivent Respimat and Spiriva Respimat within this jurisdiction.

IV. BACKGROUND ON DRUG PATENT PROCEDURES AND PRACTICES

22. Federal drug laws "reflect an attempt to balance two competing interests: [p]romoting competition between 'brand-name' or 'innovator drugs' and 'generic' drugs, and

encouraging research and innovation."[17] In service of this goal, Congress in 1984 enacted the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act.[18]

23. Federal patent law and the Hatch-Waxman Act provide exclusivity periods to incentivize brand drug makers to innovate and develop new drugs.[19] At the same time, the Hatch-Waxman Act streamlines the generic drug approval process and incentivize generic manufacturers to come to market.[20] The entry of generic drugs into the market produces enormous cost savings to patients and health insurers.[21] However, due to the threat of lost profits, brand drug manufacturers—such as Boehringer—have used numerous techniques to unlawfully extend their patent exclusivity, including by wrongfully listing device-only patents in the FDA's Orange Book, product hopping, and engaging in sham litigation.[22]

A. The Regulatory Process for New Drugs

1. The New Drug Approval Process

24. The federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-392,[23] requires brand drug manufacturers that wish to sell a new drug product to file with the FDA a New Drug Application ("NDA").[24] An NDA may be submitted pursuant to Section 505(b)(1) or Section 505(b)(2) of the FDCA.

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[17] Patent Submission and Listing Requirements, 68 Fed. Reg. at 37676.
[18] Pub. L. No. 98-417, 98 Stat. 1585 (1984).
[19] *See* Section IV. A, below.
[20] *See* Section IV. B. 2, below.
[21] *See* Section IV. B. 3, below.
[22] *See* Section IV. C, below.
[23] 21 C.F.R. § 310.3 (h)(1-4).
[24] 21 U.S.C. § 355(a).

25. Section 505(b)(1). An NDA submitted under Section 505(b)(1) must include submission of specific data concerning the safety and effectiveness of the drug.[25] This typically includes data gathered during animal studies and human clinical trials.[26]

26. The application must also identify any patents that protect the proposed new drug. Specifically, it must include:

> The patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacturer, use, or sale of the drug, and that – (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval is sought or has been granted in the application.[27]

27. Section 505(b)(2). An NDA may be submitted under Section 505(b)(2) if the new brand drug has the same active ingredient as an already-approved drug, but in a different dosage, route of administration, or rate of or mechanism of delivery.[28] Because the new brand drug will include a previously-approved active ingredient (called the reference listed drug), the 505(b)(2) NDA may rely on the reference listed drug's data, including the reference listed drug's studies and trials.[29] The applicant need only create a bridge between what is already known about the previously approved drug and the new drug product.

28. Under the Hatch-Waxman Act, brand drug companies receive periods of "regulatory exclusivity" to protect intellectual property rights and encourage innovation via new

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[25] 21 U.S.C. § 355(b)(1)(A)(i), (viii).
[26] 21 U.S.C. § 355(c).
[27] 21 U.S.C. § 355(b)(1)(A)(viii).
[28] 21 U.S.C. § 355(b)(2).
[29] *Id.*; *see also* 21 C.F.R. § 314(3) (defining 505(b)(2) application and reference listed drug).

drug development.[30] A newly patented brand-name drug that incorporates an active ingredient previously approved by the FDA (also known as a 505(b)(2) drug) may receive a New Product ("NP") exclusivity period of three years. However, a new drug for which none of the active ingredients have been approved by the FDA (also known as a 505(b)(1) drug) may receive a five-year New Chemical Entity ("NCE") period of exclusivity. These are in addition to any periods of exclusivity based on the patent itself, which typically run for twenty years from the initial patent application.

2. New Drug Patents Are Listed in the Orange Book.

29. The Hatch-Waxman Act and FDA regulations require publication of brand manufacturers' drug patent information in the Orange Book, so that would-be competitors understand the scope of the drug's ostensible patent protection.[31] Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance.[32]

30. The short time frame for providing such listings is intended to help generic drug manufacturers "assess the intellectual property assertions related to an NDA holder's product that could potentially block entry of their proposed follow-on drug product or generic drug product."[33] Therefore, in the event that an NDA holder later "determines that a patent or patent claim no longer meets the requirements for listing in the Orange Book," the NDA holder is

[30] Cong. Rsch. Serv., *The Role of Patents and Regulatory Exclusivities in Drug Pricing* (Jan. 30, 2024), https://crsreports.congress.gov/product/pdf/R/R46679.
[31] 21 U.S.C. §§ 355(b)(1)(A)(viii), (c)(2); 21 C.F.R. § 314.53(b)(1).
[32] 21 C.F.R. § 314.53(c)(1)(ii).
[33] Listing of Patent Information in the Orange Book, 85 Fed. Reg. 33169-01, 33172 (June 1, 2020).

"required to promptly notify the FDA to amend the patent information or withdraw the patent or patent information."[34]

3. Process for Listing Patents in the Orange Book

31. First, when a brand drug manufacturer submits an NDA, it includes all patents claiming the proposed new drug itself or method of use.[35] These patents represent the universe of patents that apply to the drug and could conceivably—even if wrongfully—be listed in the Orange Book.

32. Second, brand manufacturers are also required to complete FDA Form 3542 (the "Patent Listing Form") when submitting a patent for listing in the Orange Book.[36] The Patent Listing Form requires companies to identify a patent's number, issue and expiration date, the proprietary name of the approved drug, active ingredients in, and dosage forms, strengths, and route of administration of the approved drug product for which the patent information is being submitted. Thus, the form provides public information about the patents so that would-be generic competitors have notice of existing patent exclusivity periods.

33. Third, the Form asks a series of questions to aid the NDA holder in determining whether the patent should be listed in the Orange Book. Questions 2.1, 3.1, and 4.1 are designed to separate drug patents from device-only patents that are not properly listed in the Orange Book.

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[34] 21 C.F.R. § 314.53(f)(2)(i) (2016).
[35] *Id.* at § 314.53(b).
[36] Patent Submission and Listing Requirements, 68 Fed. Reg. at 36705; *see also* 21 C.F.R. § 314.53(c)(1)(ii).

34. Question 2.1 asks whether the patent "claim[s] the drug substance that is the active ingredient in the drug product that is described in the approved application."[37] Question 3.1 asks whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."[38] And Question 4.1 asks whether the patent "claim[s] one or more methods of using the approved drug product."[39] If the answer to any of these questions is "no," then the "FDA will not list the patent in the Orange Book."[40]

35. The Patent Listing Form also requires the brand manufacturer to attest to the truth of the information submitted. The FDA Patent Listing Form's mandatory declaration includes the following language: [41]

> The undersigned *declares that this is an accurate and complete submission of patent information* for the NDA or supplement approved under Section 505 of the Federal Food, Drug and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 C.F.R. 314.53. *I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.*
>
> Warning: *a willfully and knowingly false statement is a criminal offense* under 18 U.S.C. 1001.

[37] Patent Submission and Listing Requirements, 68 Fed. Reg. at 36705; *see also* 21 C.F.R. § 314.53(c)(2).
[38] *Id*.
[39] *Id*.
[40] *Id*.
[41] *Id*. (emphasis added); *see also* 21 C.F.R. § 314.53(c)(2)(Q).

36. The FDA then publishes a list of those patents in the publicly available Orange Book.[42] Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that claim the brand drug.[43]

4. Congress and the FDA Strictly Limit the Types of Patents Listed in the Orange Book.

37. Listing a patent in the Orange Book can be enormously valuable; the listing gives brand manufacturers the power to trigger an automatic delay of FDA approval of competing generic products for thirty months regardless of whether the patent is valid or infringed and *regardless of whether the patent was lawfully listed in the Orange Book*. Given the potential for abuse, Congress and the FDA impose strict limits on the types of patents listed in the Orange Book. A patent may be listed in the Orange Book if it claims an active drug ingredient or a method of using it. Other patents, such as those merely claiming a device that may be used with some active ingredients, may *not*. Congress and the FDA have enforced this limitation on several different occasions.

38. 1989 FDA Proposed Rule re Types of Patents to be Listed. In 1989, the FDA issued a proposed rule to implement the Hatch-Waxman Act, including proposed regulations detailing the types of patents the FDA regarded as covered by the requirements in Sections 505(b)(1) and 505(b)(2) of the FDCA. The FDA proposed that to comply with these sections,

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[42] U.S. Dep't Health & Human Servs. et al., *Orange Book Questions and Answers Guidance for Industry* 11 (July 2022), https://www.fda.gov/media/160167/download#:~:text=Following%20the%20submission%20of%20a,reflected%20in%20the%20Orange%20Book.

[43] 21 C.F.R. § 314.53(c)(2)(ii).

"NDA applicants would be required to submit information on drug (ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents."[44]

39. 1994 FDA Regulation re Process Patents. In 1994, the FDA finalized the regulations governing certain patent and exclusivity provisions of the Hatch-Waxman Act and reiterated that information on process patents (i.e., patents on manufacturing processes or methods) should *not* be submitted to the FDA for inclusion in the Orange Book.[45]

40. 2002 FDA Proposed Rule re Requirements for Orange Book Listings. In 2002, the FDA proposed a rule in response to: (1) disputes over whether certain listed patents met the regulatory requirements for listing in the Orange Book and (2) a request from the FTC to issue a regulation or guidance clarifying whether an NDA holder can list various types of patents in the Orange Book.[46] The proposed rule addressed: (1) the types of patents that may and may not be listed, including certain patents that claim method of use; (2) the patent certification statement that NDA applicants must submit as part of an NDA or a supplement to an NDA; and (3) the thirty-month stay of approval for a 505(b)(2) application or an abbreviated new drug application ("ANDA") set out in the Hatch-Waxman Act.[47]

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[44] *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28918 (proposed July 10, 1989) (to be codified at 21 C.F.R. pts. 10, 310, 314, 320).
[45] *See* Abbreviated New Drug Application Regulations, 59 Fed. Reg. 50338, 50363 (Oct. 3, 1994) (to be codified at 21 C.F.R. § 314) (stating that patents for manufacturing process should *not* be submitted).
[46] *See* Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays, 67 Fed. Reg. 65448, 65449 (proposed Oct. 24, 2022) (to be codified at 21 C.F.R. § 314).
[47] *See* §§ 505(c)(3)(c) and 505(j)(5)(B)(iii) of the FDCA.

41. 2003 FDA Finalized Rules re Patent Listing Requirements. In June 2003, the FDA issued its final rule on patent listing requirements to incorporate the above proposals, prohibiting submission of patents claiming packaging, intermediates, or metabolites.[48] The FDA clarified that NDA holders may submit only a "patent that claims the drug or a method of using the drug that is the subject of the NDA."[49] The patent must also be one "to which a claim of patent infringement could reasonably be asserted."[50] It stated, "[P]atents claiming packaging . . . must not be submitted for listing."[51] "Such packaging and containers are distinct from the drug product and thus fall outside of the requirements for patent submission."[52]

42. The FDA considered whether "integral devices," such as "metered dose inhalers," that fail to claim a drug product "should be submitted and listed" in 2003.[53] It explained that they should *not*:

> [W]e have clarified the rule to ensure that if the patent claims the drug product as defined in § 314.3, the patent must be submitted for listing.
>
> Section 314.3 defines a "drug product" as "* * * a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." The appendix in the Orange Book lists current dosage forms for approved drug products. The list includes metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems. **The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product**.[54]

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[48] *See* Patent Submission and Listing Requirements, 68 Fed. Reg. at 36677.
[49] Patent Submission and Listing Requirements, 68 Fed. Reg. at 36697.
[50] *Id*. at 36703.
[51] *Id*. at 36692.
[52] *Id*. at 36680.
[53] *Id*.
[54] *Id*. (emphasis added); *see also* 21 C.F.R. § 314.3 (defining "drug substance" as "an active ingredient that is intended to furnish pharmacological activity or other direct effect").

43. 2003 Hatch-Waxman Act. In 2003, Congress permitted generic manufacturers that are sued for infringement to bring a counterclaim seeking to remove the Orange Book listing.[55] This reflected Congress's developing understanding of the potential for abuse of the Orange Book.

44. 2021 Orange Book Transparency Act. In 2021, Congress passed the Orange Book Transparency Act, P.L. 116-290 (Jan. 5, 2021), to address a trend in branded drug manufacturers' submission of patents "for the purpose of blocking generic competition."[56]

45. The Orange Book Transparency Act amended the FDCA's listing provisions to require the FDA to list and publish each drug exclusivity period that has not concluded, and reiterated that *only* drug substance, drug product, and method of use patents should be submitted to the Orange Book. Specifically, it required submission and listing of:

> (vii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that
>
> (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition); or
>
> (II) claims a method of using such drug for which approval is sought or has been granted in the application.[57]

[55] *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I); *see also* Hatch-Waxman Act, Pub. L. 98-417, 98 Stat. 1585 (1984).
[56] H.R. Rep. No. 116-47 (2019).
[57] *See* § 505(b)(1)(A)(vii) of the FDCA (21 U.S.C. § 355 (b)(1)(A)(viii)); *see also* 21 C.F.R. § 314.53.

46. The listing provisions confirmed that information on patents that do not meet these requirements are prohibited.[58] Thus, a patent that does not even mention a drug's active ingredient or a method of using that drug's ingredient in any of the patent's claims clearly may not be submitted for the Orange Book.[59] A patent that merely mentions the drug's active ingredient in the specification and fails to include the active ingredient as a limitation in the claim likewise may not be submitted for listing in the Orange Book.[60]

47. It is incumbent on brand manufacturers, not the FDA, to ensure that Orange Book listings satisfy the law. The FDA performs only a "ministerial" act in listing the patents identified by the brand manufacturer in the Orange Book.

B. The Entry of Generic Drugs Into the Market

48. When the exclusivity period for a brand drug's active ingredients expires, generic competitors may enter the market with lower-cost generic substitutes. The Hatch-Waxman Act created a streamlined process for approving generic drugs for entry into the market. Additionally, it grants the first generic entrant the exclusive right to sell a generic version (alongside the brand drug) for 180 days. This further incentivizes generic entry. The resulting

[58] *Id.* § 505(c)(2) of the FDCA and 21 C.F.R. § 314.53.
[59] *Id.*
[60] *See* 21 C.F.R. § 314.53(b) ("For patents that claim a drug product, the applicant must **submit information only on those patents that claim the drug product**, as is defined in [21 C.F.R § 314.3]." (emphasis added)); *see also id.* ("For patents that claim the drug substance, the applicant must **submit information only on those patents that claim the drug substance** that is the subject of the pending or approved NDA or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending NDA." (emphasis added)).

competition tends to dramatically reduce drug prices, saving health insurers and patients billions upon billions of dollars across the market.

1. The Generic Drug Approval Process

49. A generic drug must be equivalent to the brand-name medicine in dosage, safety, effectiveness, strength, stability, and quality, as well as the method of administration.[61] Like newly developed drugs, all generic drugs must receive approval from the FDA before being sold in the United States.

50. Pre-Hatch-Waxman Approval Process. Prior to the Hatch-Waxman Act, to come to market, the costs and risks of becoming a generic competitor often outweighed the benefits, particularly because generics sell for a fraction of the price of brand name drugs and generate much smaller profits. But prior to Hatch-Waxman, *all* drug makers, including generic drug manufacturers, had to submit full NDAs before marketing a drug based on extensive and costly animal studies and human clinical trials. As a result, very few generic drugs had come to market prior to the Hatch-Waxman Act.[62]

51. Hatch-Waxman Streamlined Generic Application Process. The Hatch-Waxman Act created Section 505(j)—a simplified, less expensive process by which generic drug

[61] FDA, *Generic Drug Facts* (last updated Nov. 1, 2021), https://www.fda.gov/drugs/generic-drugs/generic-drug-facts#:~:text=Generic%20medicines%20work%20the%20same%20as%20brand%2Dname%20medicines&text=A%20generic%20medicine%20is%20required,as%20their%20brand%2Dname%20counterparts.

[62] *See* Gary Owens, *Seizing the Opportunity*, 1 Am. Health Drug Benefits 3, 52-55 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4115321/#R1 ("In 1984, only about 18.6% of all prescriptions in the United States were filled with generic medications.").

manufacturers may seek approval of a new generic drug. Instead of submitting a full NDA, generic drug manufacturers may now submit an ANDA which requires only a showing that a proposed generic drug is bioequivalent to the reference listed drug.

52. A bioequivalent shares the same method of administration, dosage, form and rate of absorption, and effects as the reference listed drug.[63] After establishing bioequivalence, the FDA permits the ANDA applicant to rely on the reference listed drug's clinical studies and trials for safety and efficacy data.[64]

53. For ANDA approval of a drug-device combination, like an inhaler, the FDA applies a few additional requirements. A drug-device ANDA must include submission of in vitro and in vivo studies, in addition to "human studies." These three studies demonstrate that patients can use the generic product as intended.

54. Orange Book Certification and Infringement Actions. As part of the Hatch-Waxman Act, would-be generic manufacturers also must follow certain procedures with respect to the Orange Book. During the ANDA application process, a generic manufacturer must include in its submission a certification addressing all of the brand drug's patents that have been listed in the Orange Book. An ANDA applicant must certify one of the following:

(I) No patent has been listed in the Orange Book.

(II) The listed patent has expired.

(III) The generic manufacturer will not market its competing product until after the patent's expiration.

[63] 21 U.S.C. § 355(j)(2); 21 C.F.R. § 320.
[64] 21 U.S.C. § 355(j).

(IV) The listed patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic product.[65]

55. Paragraph I, II, and III certifications do not threaten a current or valid patent. However, because Paragraph IV certification challenges the validity or enforceability of an NDA holder's patent, the ANDA applicant must provide the NDA holder with notice of it.[66]

56. In turn, the Hatch-Waxman Act deems a Paragraph IV certification as an act of infringement, which gives a brand manufacturer the right to immediately sue the generic manufacturer within forty-five days of receiving Paragraph IV notice—even *before* the generic drug enters the market.[67] However, a brand manufacturer can only sue for infringement if the patent at-issue is validly listed in the Orange Book.[68]

57. If an infringement action is filed within forty-five days of notice, FDA approval to market the generic drug is automatically postponed for thirty months.[69] The thirty-month stay remains in place until the patent expires or the ANDA applicant succeeds in the infringement action.[70]

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[65] *Id.* at § 355(h)(2)(A)(vii).
[66] *Id.* at § 355(h)(2)(B).
[67] Pub. L. 98-417, 98 Stat. at 1589 ("If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received.").
[68] There is no right to file an infringement suit in response to a Paragraph IV certification if the infringement suit would be objectively baseless. *See, e.g.*, *Fed. Trade Comm'n v. AbbVie Inc.,* 976 F.3d 327, 361 (3d Cir. 2020) ("[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.").
[69] 21 U.S.C. § 355(j)(5)(B)(iii).
[70] *Id.*

2. Congress Incentivizes Generic Manufacturers to Bring Generic Drugs to Market.

58. Congress created an incentive for generic drug makers to submit Paragraph IV certifications. The first to do so may receive the exclusive right to sell a generic version for 180 days.[71] During this period, the FDA is prohibited from approving other generic manufacturers' ANDAs. The only competition the first filer faces during this period is the brand manufacturer who, under its own NDA, may sell or license its own generic product (known as an "authorized generic").[72]

59. The 180-day exclusivity offers a strong incentive because during this time a first generic can capture a durable market share advantage. One study found that the first generic entrant has a market share advantage of 80% over the second generic entrant, and 225% over the third entrant over a three-year period of analysis.[73] These results imply that the size of the early mover advantage (first-filer) grows with lead time-in-market.[74] Thus, the 180-day exclusivity

[71] *See* Federal Food, Drug, and Cosmetic Act, Pub. L. 110-85, 121 Stat. 823 (2007) §§ 505(j)(5)(B)(iv)(I), 505(j)(5)(B)(iv)(aa)-(cc), and 505(j)(5)(D)(iii).
[72] *See* Ernst Berndt et al., *The Generic Drug User Fee Amendments: an Economic Perspective*, 5 J. Law Biosci. 103-141 (2018), https://pubmed.ncbi.nlm.nih.gov/29707218/; *see also* Natalie Peelish, *Antirust and Authorized Generics: a New Predation Analysis*, 72 Stan. L. Rev. 791 (2020) ("When a brand manufacturer launches an authorized generic at the beginning of the first-filer generic's exclusivity period, price competition begins much sooner.").
[73] Yu Yu & Saching Gupta, *Pioneering Advantage in Generic Drug Competition*, 8 Int. J. of Pharm. & Healthcare Mktg 1750 (2014), https://www.emerald.com/insight/content/doi/10.1108/IJPHM-11-2013-0063/full/html.
[74] *Id.*

period awarded to the first generic manufacturer leads to a first-filer market share advantage of 173%.[75]

3. The Entry of Generic Drugs Benefits Insurers and Consumers.

60. When generic drugs enter the market, insurers and consumers benefit. Generic competition with brand drugs enables consumers, health and welfare funds, and other insurers to: (a) purchase generic versions of the drug at substantially lower prices than the brand; and/or (b) purchase the branded drug at a slightly reduced price.[76]

61. Formulary Laws Favor Generic Substitution. Since the passage of the Hatch-Waxman Act, every state has adopted substitution laws that either require or permit pharmacies to substitute bioequivalent generics for brand drug prescriptions (unless the prescribing physician has specifically ordered otherwise).[77] Some states have even implemented "positive formulary" laws that identify generics that may be substituted.[78]

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[75] The early mover's exclusivity advantage grows as lead time-in-market increases. Thus, the share ratio grows by exp(0.05*T) if the first generic entrant has T months in market before entry of the second generic drug." In the data, Yu (2014) assumes entry after one month: exp(-0.59 + 0.05*1)/exp(-2*0.59) = 1.90 (90% market share advantage). The equation exp(0.05*T) shows that the advantage of being the first generic drug in the market increases exponentially with time (T) before other competitors arrive. For example, with a 6-month lead, the advantage is calculated as exp(-0.59*(0.05*6))/exp(-2*0.59) = 2.726 (172.6% market share advantage).

[76] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission.

[77] Alison Masson & Robert L. Steiner, FTC, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* 1 (1985), https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf.

[78] Other states have "negative formulary" laws which identify generics that cannot be substituted.

Figure 2. State Drug-Substitution Laws That Support Generic Substitution[79]

Type of Law	States and Territories
***Mandatory/permissive substitution*:** States generally either permit or mandate that the pharmacist substitute a generic version of a prescribed drug if all prescription requirements are met.	*Mandatory*: FL, KY, MA, MN, MS, NJ, NY, PA, PR, RI, WA, WV. *Permissive*: AL, AK, AZ, AR, CA, CO, CT, DE, DC, GA, GU, HI, ID, IA, KS, LA, ME, MD, MO, MT, NE, NH, NM, NC, ND, OH, OR, SC, SD, TN, TX, UT, VT, VA, WI, WY.
***State drug formulary*:** Some states provide a positive (drugs are equivalent and interchangeable) or a negative (drugs are not equivalent and not interchangeable) formulary to guide appropriate substitution.	*Positive*: DE, DC, FL, HI, IL, MA, NE, NV, NH, NJ, NY, TN, UT, VA, WI. *Negative*: AR, KY, MN, MO, NC.
***Cost savings requirement*:** Most states require that the drug dispensed be less or no more expensive than the drug prescribed and that some of the cost savings be passed on to the purchaser.	*Less or no more expensive*: AK, AR, CA, DC, GA, GU, HI, ID, IL, KS, KY, ME, MD, MA, MS, MO, NV, NH, NJ, NY, NC, ND, OH, OR, PA, PR, RI, TN, TX, VT, VA, WI, WY. *Requirement not mentioned*: AL, AZ, LA, ME, PR, SC, SD, UT.

62. Substitution laws and other institutional features of pharmaceutical distribution and use create an economic dynamic in which the launch of bioequivalent generics results both in rapid price decline and rapid sales shift from brand to generic purchasing.[80]

63. Generic Drugs Gain Market Share. Experience and economic research show that the first generic manufacturer to enter the market prices its product below the price of its branded

[79] Jesse C. Vivian, *Generic-Substitution Laws*, 33 U.S. Pharm. 30 (2008), https://www.uspharmacist.com/article/generic-substitution-laws.
[80] *See* Berndt, *The Generic Drug User*, *supra* note 72.

counterpart in order to compete.[81] Thus, the first generic manufacturer almost always captures a large share of sales from the branded form of the drug.[82] Within the first six months of market entry, generics generally seize approximately 80% of the market.[83] Consequently, there is a reduction in average price paid for a prescription for the same drug.[84] In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry.

64. Sizeable Cost Savings Due to Generic Substitution. Because generic versions of a corresponding branded drug product are clinically identical commodities that cannot be differentiated, the primary basis for generic competition is price. A 2022 FDA study found that generic drug approvals in 2018, 2019, and 2020, resulted in savings of $17.8 billion, $24.8 billion, and $10.7 billion, respectively, based on sales generated in the twelve months following an approval.[85] Yearly variation depended on the number of generics approved for high revenue

[81] FDA, *Generic Competition and Drug Prices* (2005), http://wayback.archive-it.org/7993/20190914072411/https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices ("On average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer.").
[82] Ryan Conrad et al., *Estimating Cost Savings From New Generic Drug Approvals in 2018, 2019, and 2020*, at 4 (2022) ("Price and market share can vary widely among competing producers of the same drug product. For example, a brand drug may be priced ten-times that of a generic equivalent, yet the generic may hold ninety percent of the market share.").
[83] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* 66-68 (Aug. 2011), 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.
[84] *Id.*
[85] *See* Conrad, *Estimating Cost Savings, supra* note 82. "Savings" are calculated by subtracting sales revenue prior to an ANDA approval by "current" sales revenue (i.e., sales revenue for the unique drug product following a generic approval). These figures account for all generic approvals in these years where sales revenue data is available.

products, which typically result in larger savings.[86] The first approval of a generic for a branded drug, in particular, generates outsized savings.[87] First-generics represented about 12% of the products with generic approvals but resulted in approximately 29% of the savings from 2018 to 2020.[88] COPD treatments, like the at-issue drugs, are exactly the type of high revenue products for which first-generics generate substantial savings. For instance, the first-generic approval of Advair HFA (fluticasone propionate and salmeterol xinafoate), a COPD maintenance treatment, in 2019 resulted in savings of $1.35 billion in just twelve months.[89] A study of invoice prices from a 2019 FDA report shows that generics are at least 31% less expensive than their brand name counterparts when there is a single generic competitor.[90]

65. As a result, healthcare insurers and patients have saved billions of dollars due to the entry of generic drug competitors. The Association for Accessible Medicines Report on U.S. Generic and Biosimilar Medicines Savings estimates that generics and biosimilars have "saved $373 billion in 2021, and more than $2.6 trillion in the last decade."[91]

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[86] *Id.*
[87] *Id.* First generic approvals are those where no other generic existed in the market previously. For example, in 2018, there were 810 ANDAs approved by the FDA. Of these, sales data for 755 ANDAs representing 413 unique drug products are available (meaning that, on average, there is more than one ANDA approved per unique drug in a given year). Of these 413 unique products, 42 products had a first-generic ANDA approval.
[88] *Id.*
[89] *Id.*
[90] Ryan Conrad & Randall Lutter, FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* 2 (Dec. 2019), https://www.fda.gov/media/133509/download.
[91] *See* Ass'n for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* (Sept. 2022), https://accessiblemeds.org/resources/blog/2022-savings-report#:~:text=Because%20tens%20of%20millions%20of%20Americans%20entrust%20their,more%20than%20%242.6%20trillion%20in%20the%20last%20decade.

C. Brand Manufacturers Manipulate the Patent System to Unlawfully Prolong Patent Exclusivity.

66. Because brand manufacturers stand to lose hundreds of millions or billions of dollars in profits when faced with generic competition, they often manipulate the patent and regulatory systems to extend their monopolies. These tactics include improperly listing device-only patents in the Orange Book, product hopping, and bringing sham patent litigation. Brand manufacturers, including Boehringer, have used these tactics to delay or prevent altogether generic inhaler competition.

1. Brand Manufacturers Manipulate the Orange Book by Unlawfully Listing Device-Only Patents.

67. The FDA serves only a ministerial role in maintaining the Orange Book. It accepts and publishes whatever the brand submits. Therefore, brand manufacturers can, and frequently do, list patents that do not satisfy the requirements of the FDCA.

68. As relevant here, brand manufacturers, and inhaler manufacturers in particular, list device-only patents in the Orange Book—ignoring the law, regulations, and judicial decisions discussed above. The FDA approved fifty-three brand-name inhalers from 1986 through 2020.[92] Across the fifty-three brand inhalers approved during this period, thirty-nine of the brand inhalers improperly listed 137 device-only patents in the Orange Book—77% of which failed to mention any relevant connection with the drug product itself.[93] Twenty-four of the 137

[92] During this period, the FDA approved a total of 62 inhalers—only 9 of which were generics. William B. Feldman et al., *Patenting Strategies on Inhaler Delivery Devices*, Chest (Feb. 2023), https://pubmed.ncbi.nlm.nih.gov/36842533.
[93] *Id*.

device-only patents listed in the Orange Book belonged toBoehringer on its Respimat drug products.[94] Boehringer's device-only patents, its improper listing of those patents in the Orange Book, and its failure to respond to FTC and Congressional warnings by delisting those patents are discussed further in Section V.D., below.

69. Brand manufacturers *should not* submit device-only patents for listing, but some, like Boehringer, continue to do so in order to help themselves to the automatic thirty-month stay triggered by a Paragraph IV certification, thereby preventing generic competitors from entering the market.

70. Would-Be Generic Competitors Must Litigate Improper Orange Book Listings. As a result, generic makers have repeatedly resorted to the judicial system to address improper Orange Book listings. Multiple courts have recognized that improper Orange Book listings violate the antitrust laws. *See, e.g.*, *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d at 6-7, 15 (finding improper listing of component device patent may support Section 2 Sherman Act claim); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 315 (D.R.I. 2019) (ruling "sham Orange Book listing claim" under Section 2 of the Sherman Act may proceed to trial); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 531 (D.N.J. 2004) ("[T]here exists no regulatory scheme [for Orange Book listings] so extensive as to supplant antitrust laws.").

71. For example, courts have found that a "patent must be one for which infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the

[94] William B. Feldman et al., *Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020*, 41 Health Affairs 787, 790 (2022).

manufacture, use, or sale of the drug." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 641 F. Supp. 3d 85, 89 (D. Del. 2022), *aff'd*, 60 F.4th 1373 (Fed. Cir. 2023). A combination patent that does not provide protection over a standalone drug substance would not be infringed by a generic manufacturer when manufacturing that standalone drug—and therefore should not be listed in the Orange Book. *See United Food & Com. Workers Loc. 1776 v. Takeda Pharm. Co.*, 11 F.4th 118, 131 (2d Cir. 2021) (discussing combination patents in the context of drug patent infringement).

72. Additionally, the Supreme Court held that the patent must claim "the drug for which the [brand] submitted the NDA or . . . a method of using such a drug" in order to be listed in the Orange Book. *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). "A patent claim that fails to explicitly include the drug actually makes *neither* type of claim on the drug." *United Food*, 11 F.4th at 134-35; *see also In re Lantus*, 950 F.3d at 8 (holding that a patent "does not claim [the drug], nor even a method of using" if the patent "does not . . . mention" the NDA drug). Therefore, a patent that does not reference the NDA drug should not be listed in the Orang Book.

73. The FTC Challenges Improper Orange Book Listings. Unlike the FDA, the FTC has the statutory authority to monitor and act on improper Orange Book listings.[95] In 2023, the FTC employed new strategies to increase drug competition by identifying Orange Book

[95] *See* Federal Trade Commission Act, 15 U.S.C. § 5 (creating a cause of action for "unfair methods of competition" and "unfair or deceptive acts or practices in or affecting commerce" that, under the Act, may only be brought by the FTC).

manipulation and warning brand manufacturers of the FTC's readiness to take legal action against those companies that fail to correct improper listings.

74. The FTC held a Listening Session which concluded with a unanimous vote to issue a Policy Statement on unlawful listings of device-only patents on or about September 14, 2023.[96] Following its September 14, 2023 statement, the FTC challenged more than 100 patents held by manufacturers of brand-name asthma inhalers, epinephrine autoinjectors, and other drug products "as improperly or inaccurately listed" in the Orange Book.[97] The Commission then issued notice letters to ten drug manufacturers "identify[ing] specific patents that FTC contends are improperly listed for specific asthma and other inhaler devices," among other products.[98]

2. Brand Drug Manufacturers Employ Product Hopping to Suppress Competition.

75. To delay competition, a brand manufacturer also may make minor, non-therapeutic changes to a brand drug that is nearing the end of its exclusivity period. This can destroy or impair the market for the original formulation, and thereby frustrate would-be generic competition and bypass state automatic substitution laws. A brand drug manufacturer, for example, may change the container or device that a drug is packaged in, but make no material change affecting treatment to the drug itself. Known as a "product hop," this tactic can be accomplished through a "soft switch" or a "hard switch." A "soft switch" happens when the

[96] FTC, *Statement*, *supra* note 10, at 1.
[97] *See* Press Release, FTC, FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book (Nov. 7, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book.
[98] *Id.*

manufacturer keeps the original drug on the market after introducing a reformulated version. Physicians are then encouraged to write prescriptions for the new formulation. A "hard switch" refers to a practice in which the manufacturer withdraws the original formulation from the market altogether. If successful, new generics based on the old formulation will not be automatically substituted for the new version by doctors and pharmacists. The generic may have to start all over by abandoning its ANDA for the old formulation and filing one for the new formulation, essentially re-starting the regulatory approval process.

76. Brand inhaler manufacturers may employ a variation of this tactic by "device hopping"—meaning the manufacturer develops a new device for the same active ingredient but claims new device patents. Would-be competitors must develop new generic drug-device combinations rather than the drug alone. In the past fifty years, brand inhaler manufacturers created nineteen new inhaler devices and received a median of 28.1 years of protection between the sale of their original products and their follow-on products—significantly longer than the typical twenty years of protection resulting from the filing of the patent application on the underlying drug compound.[99] The drugs delivered in these inhaler devices—including Combivent Respimat—have been the same since the 1980s.

77. Product hops by brand drug manufacturers lead to increase costs to U.S. patients and payors such as Plaintiffs. A report looking at just five examples of product hopping in the last twenty years—for the brand drugs Prilosec, TriCor, Suboxone, Doryx, and Namenda—estimates that these five product hops cost health insurers and consumers an additional $4.7

[99] *Id.*

billion *annually*.[100] "[W]hen [product hopping] coerces consumers and impedes competition," it violates the antitrust laws.[101]

3. Brand Manufacturers Bring Sham Litigation to Suppress Competition.

78. Brand manufacturers often bring sham Hatch-Waxman litigation for the sole purpose of triggering the automatic thirty-month stay for ANDA filers. Litigation is a sham when a reasonable drug manufacturer would know that the patents at issue are invalid, unenforceable, not infringed by the ANDA filer's product, or improperly listed in the Orange Book. Sham patent litigation violates the antitrust laws.

79. In sum, the combination of improper Orange Book listing, device hopping, and threatened or actual sham litigation have earned brand inhaler manufacturers billions of dollars in profits. From 2000 to 2021, the FDA approved thirty-nine brand name inhalers. Only eighteen patents claiming the drugs' active ingredient are listed, while 239 patents claiming something else, such as devices, were listed in the Orange Book in connection with these inhalers. And during this time, manufacturers raked in $178.1 billion in profits on inhalers.

[100] Alex Brill, *The Cost of Brand Drug Product Hopping* 2 (Sept. 2020), https://www.optum.com/content/dam/optum3/optum/en/resources/PDFs/3505955-thought-leadership-cost-of-product-hopping-sept2020.pdf.

[101] *See New York v. Actavis*, 787 F.3d 638, 652 (2d Cir. 2015) ("Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition.").

Boehringer earned the second highest revenue amongst inhaler brand drug manufacturers through the sale of Spiriva Respimat—making the company $30.5 billion.[102]

80. Of the $178.1 billion paid to brand manufacturers, $110.3 billion (62%) came *after* the inhalers' drug patents expired but while the device patents remained active, meaning brand manufacturers earned far more revenue on inhalers at a time when generics *could have* entered the market but-for the remaining device-only patents.[103]

V. FACTUAL ALLEGATIONS

A. Inhalers Are Critical to Treatment of Asthma and Chronic Obstructive Pulmonary Disease That Affect Millions of Americans.

81. Asthma and chronic obstructive pulmonary disease are chronic, potentially fatal diseases that affect millions of Americans. Today, approximately one in every thirteen Americans have asthma, and COPD is almost as prevalent.[104] Each day, just in the United States, asthma and COPD kill 10 and 390 people respectively.[105] COPD is the sixth-leading cause of death in the United States.[106]

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[102] William B. Feldman et al., *Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021*, 329 JAMA 87-89 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9857605/.
[103] *Id*.
[104] *What Is COPD?*, Nat'l Heart, Lung & Blood Inst. (last updated Oct. 25, 2023), https://www.nhlbi.nih.gov/health/copd#:~:text=In%20the%20United%20States%2C%20COPD, Control%20and%20Prevention%20(CDC).
[105] *Asthma Facts and Figures*, Asthma & Allergy Found. of Am. (last updated Sept. 2023), https://aafa.org/asthma/asthma-facts/.
[106] *COPD Trends Brief: Mortality*, Am. Lung Assoc., https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-mortality#:~:text=Select...-,Leading%20Causes,19%2C%20accidents%2C%20and%20stroke.

82. Since the 1950s, doctors have prescribed FDA-approved inhalers for the treatment of COPD and asthma. For drug manufacturers, that means that inhalers are big business. For instance, from 2014 to 2018, Medicare spent a total of $50.5 billion on inhalers over the course of four years generally through Medicare Part D for some 85 million beneficiaries.[107] Over that same period, inhaler use increased by 130%. Medicare's expenditures for inhalers are expected to increase even more in the future.

83. As described in Section V.B. below, very few inhaler device innovations have been developed over the last sixty years. By contrast, costs for inhaler treatments have *increased* in the United States even though inhaler treatments have become relatively cheap in much of the world.

84. Inhalers used to treat asthma and COPD can either be relievers (also known as rescue inhalers) or maintenance inhalers for daily use, such as Boehringer's Combivent Respimat and Spiriva Respimat. Boehringer's Respimat drug products remain the only inhalation sprays on the market containing their active ingredients. Further, there are no direct substitutes for either Respimat product, and indirect or economic substitutes cannot reasonably be used in place of either Combivent Respimat or Spiriva Respimat due to the active ingredients' unique effects. Those active ingredients have been available in pharmaceuticals for decades. In fact, the same active ingredients were sold in Boehringer's older Combivent and Spiriva Handihaler drug products. *See* Section V.C., below.

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[107] Akesh Thomas et al., *Trends in Inhaler Prescriptions and Associated Cost In the United States From 2014 to 2018: An Analysis From the Medicare Part D Database*, Cureus (2021), https://doi.org/10.7759/cureus.13498.

85. Boehringer obtained FDA approval of its Combivent Respimat and Spiriva Respimat and employed unlawful tactics to stifle generic competition and maintain its monopoly. Namely, Boehringer manipulated the patent and Orange Book system to extend periods of exclusivity for its inhaler treatments. As further described in Subsection V.D., Boehringer achieved multi-decade exclusivity for Combivent Respimat and Spiriva Respimat through (1) product hopping; (2) improper listing of dozens of patents in the Orange Book; and (3) filing sham infringement actions against would-be generic competitors.

B. Evolution of the Inhaler Device

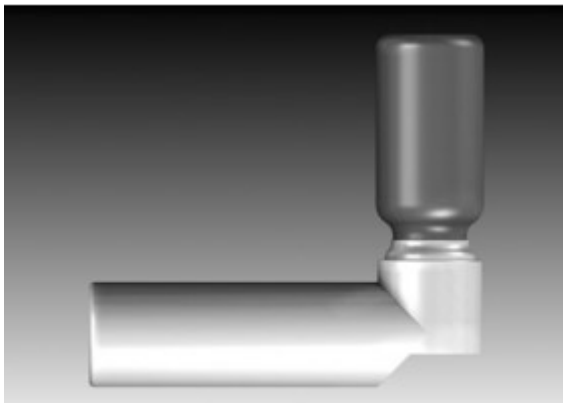
86. Inhaler treatments are not new. For decades, people with asthma and COPD have relied on some form of prescription inhalers to manage their diseases. Therapeutic aerosol delivery devices were used in early civilizations, but the FDA approved the first modern inhaler a half-century ago. In recent years, environmental concerns led to a change in formulation for all FDA-approved inhaler treatments, but the active ingredients remain similar to those used in the first modern inhalers. Yet despite the lack of innovation in such active ingredients, in the 2000s and early 2010s, the number of new inhaler patents reached more than one per year.

87. Modern Inhalers. Modern inhalers (pressurized metered-dose inhalers, "pMDI") have been around since 1956.[108] George L. Maison, a pharmacologist, invented the first pMDI after his thirteen-year-old asthmatic daughter asked, "Daddy, why can't they put my asthma

[108] *See* Grahma Compton, *A Brief History of Inhaled Asthma Therapy Over the Last Fifty Years*, 15 Nature 326, 327 (2006), https://www.nature.com/articles/pcrj2006092.pdf.

medicine in a spray-can like they do hair spray?"[109] As president of Riker Laboratories, Inc. (now "3 M Drug Delivery Systems"), Maison used technology from aerosol hairspray devices to develop (and patent) a metering valve capable of delivering precise amounts of atomized liquid.[110] The pMDIs used the energy of compressed propellants, holding the drug (or drugs) they are designed to deliver in solution or suspended in propellants (or a mixture of propellants and co-solvents).[111]

Figure 3. Drawing of the first pMDI, Medihaler Iso, which consisted of a plastic-coated glass vial crimped to a 50 mcl metering valve, the formulation, and the plastic mouthpiece adapter.[112]

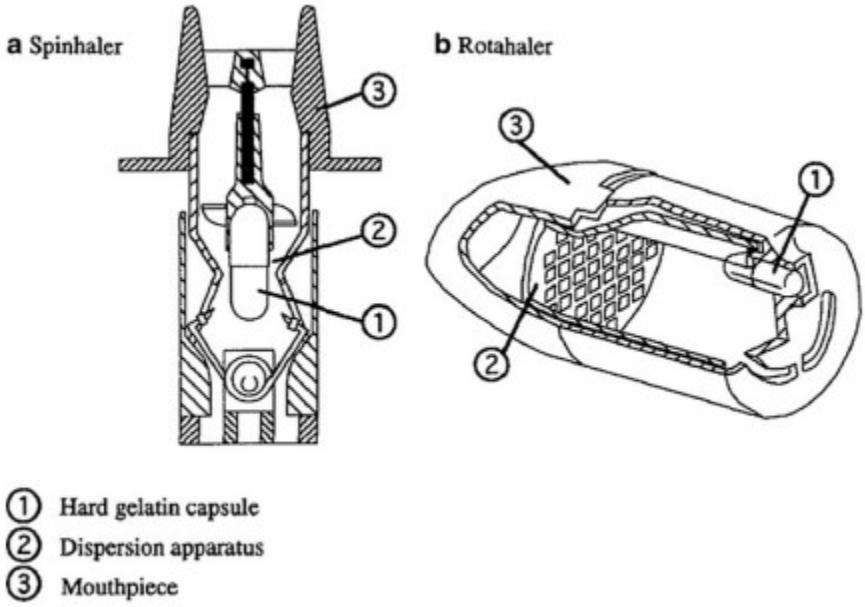


88. Dry-Powder Inhalers. pMDIs evolved to deliver medication to the lungs in the form of dry powder: "dry-powder inhalers" or DPIs. DPIs hold the medication either in a capsule for manual loading or within the inhaler itself. Once loaded or actuated, the patient puts

[109] Stephen W. Stein & Charles G. Thiel, *The History of Therapeutic Aerosols: A Chronological Review*, 30 J. Aerosol Med. & Pulmonary Drug Delivery 20 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278812/pdf/jamp.2016.1297.pdf.
[110] *Id*.
[111] Anne Haaije de Boer & Kyrre Thalberg, *Metered Dose Inhalers (MDI), in* Inhaled Medicines 65-97 (Stravros Kassinos, et al. ed., 2021).
[112] *See* Stein & Thiel, *History of Therapeutic Aerosols, supra* note 109.

the mouthpiece of the inhaler into their mouth and takes a sharp, deep inhalation (ensuring that the medication reaches the lower parts of the lungs).[113]

Figure 4. Schematic drawing of two early DPIs.[114]



89. Environmental Concerns. In the mid-1980s, environmental concerns grew over the inert nature of chlorofluorocarbon ("CFC") propellants used in MDIs.[115] The Montreal Protocol, signed in 1987, called for the elimination of CFC propellants by January 1996.[116] Although the ban exempted MDIs until medically acceptable alternatives became available, the

[113] *Id.*
[114] *See* Stein & Thiel, *History of Therapeutic Aerosols, supra* note 109.
[115] *Id.*
[116] U.S. Dep't of State, *The Montreal Protocol on Substances that Deplete the Ozone Layer* (1988), https://www.state.gov/key-topics-office-of-environmental-quality-and-transboundary-issues/the-montreal-protocol-on-substances-that-deplete-the-ozone-layer/#:~:text=The%20Montreal%20Protocol%2C%20finalized%20in,%2C%20fire%20extinguishers%2C%20and%20aerosols.

pharmaceutical industry raced to develop alternatives.[117] By 2010, the FDA created a timeline to phase out the last CFC-based MDI on the U.S. market.[118]

90. Non-CFC-Based Inhalers. Most brands addressed the CFC issue by simply swapping in a new propellant: hydrofluoroalkane (HFA).[119] The last albuterol CFC inhalers were sold in December 2013, and the traditional L-shaped inhaler nevertheless remains in widespread use.

91. Boehringer's Respimat Inhaler. Boehringer developed a compact, non-CFC-based aqueous delivery device, or "soft mist inhaler" ("SMI") in the early 2000s, which it named the "Respimat Inhalation Spray System" ("Respimat").[120] Respimat was approved in Germany in 2004 and in the United States in 2011.[121] Respimat has a reservoir containing up to 120 doses of formulation. Before dosing, the patient twists the base of the device that meters out a dose and compresses a spring, which then serves as the energy source to deliver the formulation. When the patient inhales, they press a button that releases the spring and forces the formulation through a complex nozzle configuration to generate a breathable aerosol. Multiple products have

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[117] FDA, *Phase-Out of CFC Metered-Dose Inhalers Containing Flunisolide, Triamcinolone, Metaproterenol, Pirbuterol, Albuterol and Ipratropium in Combination, Cromolyn and Nedocromil – Questions and Answers* (updated Oct. 29, 2015), https://www.fda.gov/drugs/information-drug-class/phase-out-cfc-metered-dose-inhalers-containing-flunisolide-triamcinolone-metaproterenol-pirbuterol-0.
[118] *Id*.
[119] FDA, *Transition From CFC Propelled Albuterol Inhalers to HFA Propelled Albuterol Inhalers: Questions and Answers* (Dec. 31, 2008), https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/transition-cfc-propelled-albuterol-inhalers-hfa-propelled-albuterol-inhalers-questions-and-answers.
[120] *See* Stein & Thiel, *History of Therapeutic Aerosols*, *supra* note 109.
[121] *Id.*

been approved using Respimat. These products include Spiriva Respimat (tiotropium), Combivent Respimat (ipratropium and albuterol), Striverdi Respimat (olodaterol), and Stiolto Respimat (tiotropium and olodaterol).[122]

Figure 5. A picture of a Respimat inhaler.[123]

[122] *Id.*
[123] *Id.*

C. Boehringer's Inhaler Drug Products

92. The Respimat products did not represent innovative new treatments. Rather, Boehringer dressed up and sold *old* drugs in a *new* package.[124]

1. Active Ingredients in Combivent Respimat and Spiriva Respimat

93. Combivent Respimat contains two active ingredients—albuterol sulfate ("albuterol") and ipratropium bromide ("ipratropium"). Spiriva Respimat delivers tiotropium bromide ("tiotropium"). These active ingredients are bronchodilators, or a type of medication that makes breathing easier by relaxing the muscles in the lungs and widening the airways. Each active ingredient has been used effectively for the treatment of COPD and/or asthma.

94. Albuterol. Albuterol, also known as salbutamol, was first approved by the FDA in 1981 for treating acute and severe respiratory conditions caused by asthma and COPD, such as bronchitis (swelling of the air passages leading to the lungs), and emphysema (damage to air sacs in the lungs).[125] The albuterol compound patent (U.S. Patent No. 3,644,353) was issued in 1972 and expired in 1989—thirty-five years ago.[126]

95. Ipratropium. Boehringer obtained FDA approval of ipratropium in 1986 for use in a pMDI called Atrovent.[127] Ipratropium treats symptoms of COPD, such as wheezing, shortness of breath, coughing, and chest tightness. Boehringer's patent for the ipratropium

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[124] Further description of Combivent Respimat and Spiriva Respimat are discussed in Section V.C.2.
[125] *See* Stein & Thiel, *History of Therapeutic Aerosols*, *supra* note 109.
[126] K. V. Blake et al, *Evaluation of a Generic Albuterol Metered-Dose Inhaler: Importance of Priming the MDI*, 68 Ann. of Allergy 169-174 (1992), https://pubmed.ncbi.nlm.nih.gov/1739192/.
[127] *See* Stein & Thiel, *History of Therapeutic Aerosols*, *supra* note 109.

compound (U.S. Patent No. 3,681,500) was issued in 1972, and the patent expired in 1989.[128] However, Boehringer received a patent term extension until 1991 under Title 35, section 156.[129]

96. Combivent. Albuterol and Ipratropium Combined. Boehringer developed a drug consisting of both albuterol and ipratropium, and in 1997, obtained a patent for an aerosolized formulation of the compound (Patent No. 5,603,918), which it would market as "Combivent." The FDA approved Boehringer's NDA for Combivent on October 24, 1996. Since the patents on both ipratropium and albuterol had expired long before, Combivent obtained only a three-year exclusivity period. That exclusivity expired on October 24, 1999 – nearly *twenty-five years ago*.[130]

97. Although the Montreal Protocol called for the elimination of all CFC products, it carved out an essential use exception for CFC-based inhalers.[131] Under this exception, the FDA granted Combivent an essential-use designation through December 31, 2013.[132] The essential-use designation exetended Boerhinger's marketing and sale of CFC-based Combivent (ending in

[128] U.S. Patent No. 3,681,500 (issued Aug. 1, 1972).
[129] *Id.*
[130] Letter from Renata Albrecht, Dir., FDA Ctr. Drug Evaluation & Rsch., to Michelle A. McGuinness, VP, Veloxis Pharms. 43-44 (Jan. 12, 2015), https://www.thefdalawblog.com/wp-content/uploads/archives/docs/ENVARSUS%20XR%20-%20FDA%20Letter%20Decision%201-2015.pdf.
[131] *See* EPA, *Exemptions for Essential Uses of Chlorofluorocarbons for Metered-Dose Inhalers* (updated Feb. 21, 2024), https://www.epa.gov/ods-phaseout/exemptions-essential-uses-chlorofluorocarbons-metered-dose-inhalers.
[132] FDA, *Phase-Out of CFC Metered-Dose Inhalers Containing Flunisolide, Triamcinolone, Metaproterenol, Pirbuterol, Albuterol and Ipratropium in Combination, Cromolyn and Nedocromil – Questions and Answers* (updated Oct. 29, 2015), https://www.fda.gov/drugs/information-drug-class/phase-out-cfc-metered-dose-inhalers-containing-flunisolide-triamcinolone-metaproterenol-pirbuterol-0.

2013). Generics could not enter the market because an ANDA for a CFC-formulated drug would not be approved under the FDA's CFC ban.

98. Tiotropium. Boehringer patented tiotropium in 1997 (U.S. Patent No. 5,610,163). The '163 patent expired in 2012—twelve years ago.[133] In 2004, the FDA approved tiotropium for use in Boehringer's dry-powder inhaler, Spiriva Handihaler. In 2007, Boehringer obtained a patent (U.S. Patent No. RE39820) for tiotropium bromide monohydrate used in the tiotropium inhalation spray. That patent expired January 30, 2018—six years ago.[134]

2. Drug Delivery of the Active Ingredients in Spiriva and Combivent

99. Boehringer sold the same active ingredients in its Combivent metered-dose inhaler and Spiriva Handihaler drugs before Combivent Respimat and Spiriva Respimat entered the market. As previously discussed in Section V.B, environmental concerns regarding CFCs required a simple switch to non-CFC propellants. Boehringer, however, seized the opportunity afforded by the CFC ban to design, essentially, a new package for the same active ingredients in its Combivent drug solely to preserve its monopoly. Likewise, Boehringer kept the original Spiriva ingredients used in its Spiriva Handihaler while only changing the delivery form from dry powder to aerosolized spray.

[133] Clinical Trials Arena, *Spiriva – Treatment for Chronic Obstructive Pulmonary Disease*, Clinical Trials Arena (Apr. 3, 2012), https://www.clinicaltrialsarena.com/projects/spiriva-treatment-for-chronic-obstructive-pulmonary-disease/?cf-view.

[134] Jon W. Dudas, Certificate Extending Patent Term Under 35 U.S.C. § 156 (Spiriva HandiHaler (tiotropium bromide inhalation powder) (U.S.P.T.O. Sept. 4, 2007), https://www.uspto.gov/sites/default/files/web/offices/pac/dapp/opla/term/certs/re39820.pdf.

100. Combivent Respimat. Combivent Respimat—the Combivent drug delivered in the Respimat device—is a short-acting, daily inhaled medicine taken four times a day. Each dose lasts approximately six to eight hours. On October 7, 2011, the FDA approved Combivent Respimat, and it became available by prescription in the United States on or around September 18, 2012. Boehringer of course had, since 1996, previously marketed the combination of albuterol and ipratropium in its Combivent product. As a result, Boehringer received only a three-year regulatory exclusivity for Combivent Respimat, which expired on October 7, 2014, *ten years ago*.

101. Spiriva Respimat. Spiriva Respimat—the Spiriva drug delivered through the Respimat device—is a long acting, daily inhaled prescription medication taken once daily. The FDA approved Spiriva Respimat on September 24, 2014, and it became available by prescription on or around January 21, 2015.[135] Similar to the Combivent Respimat drug, Boehringer previously marketed, and continues to market, tiotropium in its Spiriva Handihaler (a dry powder inhaler).[136] As a result, Boehringer received only a three-year regulatory exclusivity for Spiriva Respimat due the change in the tiotropium formulation, which expired on September 24, 2017, *seven years ago*.[137]

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[135] *See* Press Release, Boehringer Ingelheim Announces FDA Approval of Spiriva Respimat (tiotropium bromide) Inhalation Spray for the maintenance of COPD (Sept. 25, 2014), https://www.boehringer-ingelheim.com/us/fda-approves-spirivar-respimatr-tiotropium-bromide-bi-us.

[136] In 2004, the FDA approved Boehringer's original Spiriva product, tiotropium delivered in a generic inhaler device. This patent, U.S. Patent No. RE39820, expired January 30, 2018.

[137] Boehringer requested 3 years of exclusivity for its Spiriva Respimat drug product. *See* Ctr. Drug Evaluation & Rsch., *Patent Labeling Review – Spiriva Respimat (NDA 21-936)* at 3 (Aug.

D. Manipulation of the Patent and Orange Book System to Maximize Profit

102. Because Combivent Respimat and Spiriva Respimat did not represent real innovations, they received limited regulatory exclusivity as detailed above. And the underlying medications had long fallen out of patent. Thus, to protect its monopoly profits, Boehringer engaged in several multi-decade schemes that manipulated United States patent and drug laws to prevent and deter generic competition for Spiriva and Combivent.

103. First, when its Combivent patents neared the end of its essential-use designation, Boehringer engaged in product hopping—a strategy used by brand drug companies to prevent generic competition by shifting patients from a brand drug product to a reformulation of the drug that has longer exclusivity.[138] Boehringer repackaged its old drug (Combivent) in a new inhaler device (Respimat), and then used patents on the device to block generic competition. *See* Section V.D.1., below.

104. Second, Boehringer improperly listed dozens of these device-only patents in the Orange Book. These listings purported to extend Boehringer's monopoly through 2030. But for the device-only patents, generics could have received FDA approval and entered the market as early as 2020—when the last properly listed patent expired. *See* Section V.D.2, below.

105. Third, from 2023 to 2024, when a viable generic drug maker applied for approval to manufacture and market generic versions of Combivent Respimat and Spiriva Respimat, Boehringer brought baseless patent infringement suits against the generic drug maker. These

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28, 2014), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/021936Orig1s000OtherR.pdf.

[138] *See supra* Section IV.C. regarding product hopping.

suits were baseless because they relied on its improper listing of device-only patents in the Orange Book. *See* Section V.D.3., below.

1. Boehringer Engaged in Product Hopping to Extend Its Monopoly.

106. Boehringer manipulated the patent system to maximize its profit for Combivent Respimat through a tactic known as "product hopping." Specifically, it shifted the Combivent drug, which did not therapeutically change, to the new Respimat device.

107. Boehringer possessed a patent for an aerosolized formulation of ipratropium and albuterol, and sought FDA approval of these drugs delivered in an inhaler device. On or about October 24, 1996, the FDA approved Boehringer's NDA, No. 020291, for the Combivent drug.[139] This patent was set to expire in 1999.[140] In anticipation of Combivent's exclusivity expiration and the FDA's impending ban on CFCs, Boehringer repackaged (or "hopped") Combivent in a new device, the Respimat inhaler.

108. Although Boehringer made no changes to the drug product itself, it sought approval for a new drug-device combination product called "Combivent Respimat" in October 2008.[141] On October 7, 2011, the FDA approved the "new" product, Boehringer introduced Combivent Respimat on the market, and shortly thereafter Boehringer discontinued the original Combivent. This shift from the legacy inhaler to the Respimat inhaler was not necessary for

[139] Letter from Renata Albrecht, Dir., FDA Ctr. Drug Evaluation & Rsch., to Michelle A. McGuinness, VP, Veloxis Pharms. 43-44 (Jan. 12, 2015), https://www.thefdalawblog.com/wp-content/uploads/archives/docs/ENVARSUS%20XR%20-%20FDA%20Letter%20Decision%201-2015.pdf.
[140] *Id.*
[141] FDA, Approval Letter for Combivent Respimat (NDA 021747) (Oct. 7, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021747s000ltr.pdf.

compliance with the FDA's ban on CFCs, afforded no functional benefit to patients, and was primarily motivated to protect Boehringer's monopoly.

2. Boehringer Improperly Listed Device-Only Patents in the Orange Book.

109. To maintain its monopoly profits for Combivent Respimat and Spiriva Respimat, Boehringer manipulated the Orange Book system that was originally designed to *encourage* generic competitors to enter the market. Specifically, Boehringer illegally listed device-only patents in the FDA's Orange Book.[142] This practice discouraged would-be generics from entering the market and helped Boehringer to an automatic, thirty-month stay against generic manufacturers who apply for approval to bring off-patent Combivent and Spiriva drugs to market.

110. Device-Only Patents for Combivent Respimat. Combivent Respimat patents first appeared in the Orange Book in 2011. Boehringer's Combivent franchise (comprising of the original Combivent product and Combivent Respimat) is a particularly notorious example of over-extending exclusivity using inhaler devices: it claims thirty-four years of patent protection, from the approval of original Combivent in 1996 until the last-to-expire patent listed under Combivent Respimat in 2030.

111. Of Boehringer's twenty-five patents listed, only three make any reference to the drug combination of ipratropium bromide and albuterol sulfate: the "Cartridge for a liquid"

[142] As described in Section IV.C., the FDA and courts have emphasized that listing device-only patents is unlawful. Boehringer knew or should have reasonably known that listing its device-only patents violated FDA regulations, required the company to commit perjury in submitting the Patent Listing Form, and exposed itself to antitrust liability.

patent (U.S. Patent No. 6,988,496), "Cartridge for a liquid" patent (U.S. Patent No. 7,802,568), and "Device for producing high pressure in a fluid in miniature" patent (U.S. Patent No. 7,104,470), expiring February 23, 2020, and October 4, 2016 respectively.[143] The table below identifies Boehringer's twenty-five wrongfully listed patents—of which the six device-only patents are bolded.

Patent No.	**Invention**	**Expiration Date**
5405084	Nozzle Assembly for Preventing Back-Flow	April 11, 2012
5472143	Atomizing Nozzle and Filter and Spray Generation Device	Sept. 29, 2013
5497944	Atomizing Devices and Methods	March 12, 2013
5662271	Atomizing Devices and Methods	Sept. 24, 2014
5911851	Atomizing Nozzle and Filter and Spray Generating Device	Sept. 29, 2013
5964416	Device for Producing High Pressure in a Fluid in Miniature	Oct. 4, 2016
6007676	Atomizing Nozzle and Filter and Spray Generating Device	Sept. 29, 2013
6149054	Mechanical Counter for a Metering Apparatus	Dec. 19, 2016
6176442	Device for Mounting a Component Exposed to a Pressurized Fluid	Oct. 4, 2016
6453795	Locking Mechanism for a Spring-Actuated Device	Dec. 5, 2016
6503362	Atomizing Nozzle and Filter and Spray Generating Device	Sept. 29, 2013
6726124	Device for Producing High Pressure in a Fluid in Miniature	Oct. 4, 2016
7104470	Device for Producing High Pressure in a Fluid in a Miniature	Oct. 4, 2016
6846413	Microstructured Filter	Aug. 28, 2018
6977042	Microstructured Filter	Aug. 28, 2018
7246615	Atomizing Nozzle and Filter and Spray Generating Device	May 31, 2016
6988496	Cartridge for a Liquid	Feb. 23, 2020
7802568	Cartridge for a Liquid	Feb. 23, 2020

[143] *See* NFS Listing Matrix.

7988001	Container Provided With a Pressure Equalization Opening	Aug. 22, 2022
7284474	**Piston Pumping System**	**Aug. 26, 2024**
7396341	**Blocking Device**	**Oct. 10, 2026**
7837235	**Device for Clamping Fluid**	**Mar. 13, 2028**
7896264	**Micro-Structured Nozzle w/Filter**	**May 26, 2025**
8733341	**Atomizer w/Nozzle**	**Oct. 16, 2030**
9027967	**Device for Clamping Fluid**	**Mar. 31, 2027**

112. Device-Only Patents for Spiriva Respimat. For Spiriva Respimat, in 2014, Boehringer listed the same six unexpired device-only patents that it listed for Combivent Respimat, along with thirteen others.[144] Boehringer achieved an additional six-months of protection for each patent by obtaining Pediatric Exclusivity. Of the nineteen patents Boehringer listed for Spiriva Respimat, only four—the '470 patent (expired Oct. 4, 2016), Reissued Patent 39,820 (expired Jan. 30, 2018), the '496 patent (expired Feb. 23, 2020), and the '568 patent (expired Feb. 23, 2020)—reference a drug compound. The other fifteen patents claim only device parts. The six unexpired device-only patents for Spiriva Respimat are listed below,

Patent No.	Invention	Expiration Date
7284474	Piston Pumping System	Aug. 26, 2024
7284474*		Feb. 26, 2025
7396341	Blocking Device	Oct. 10, 2026
7396341*		Apr. 10, 2027
7837235	Device for Clamping Fluid	Mar. 13, 2028
7837235*		Sept. 13, 2028
7896264	Micro-Structured Nozzle w/Filter	May 26, 2025
7896264*		Nov. 26, 2025
8733341	Atomizer w/Nozzle	Oct. 16, 2030
8733341*		Apr. 16, 2031
9027967	Device for Clamping Fluid	Mar. 31, 2027

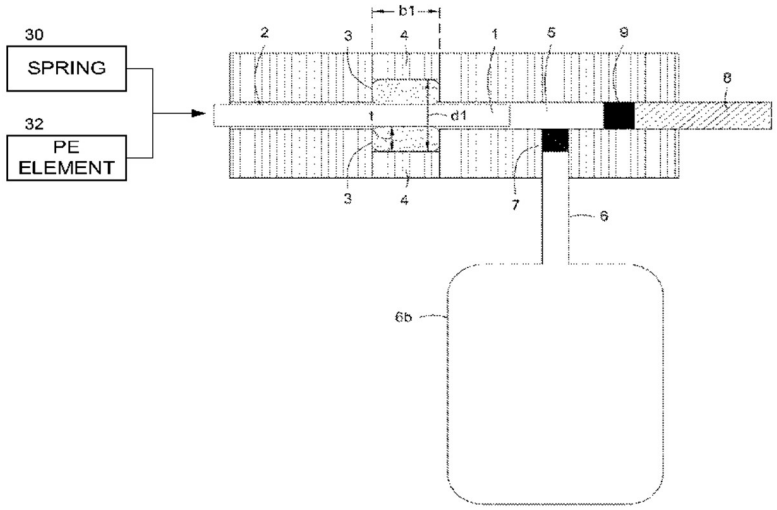
[144] The '3,341 and '967 patents were submitted for listing in connection with Combivent Respimat and Spiriva Respimat in August 2015.

9027967*		Oct. 1, 2027

The asterisks in the chart denote pediatric exclusivity Boehringer obtained for each unexpired patent.

113. Boehringer's Unexpired Device-Only Patents. As of the date of this complaint, there remain six unexpired patents listed under Combivent Respimat and Spiriva Respimat in the Orange Book. The following six patents are all device-only patents on components of the Respimat inhaler, not the drugs it delivers.

114. **Unexpired Device-Only Patent 1:** U.S. Patent No. 7,284,474 (the '474 patent) claims a piston-pumping system with an "O-ring" seal. It expires in August of 2024.[145]



[145] *Piston-pumping system having O-ring seal properties*, Google Patents, https://patents.google.com/patent/US7284474B2/en.

115. **Unexpired Device-Only Patent 2:** U.S. Patent No. 7,396,341 (the '341 patent) claims a "locking-stressing-mechanism" designed to block a device after some permitted period of use (or number of "puffs") has elapsed. It expires in October 2026.[146]

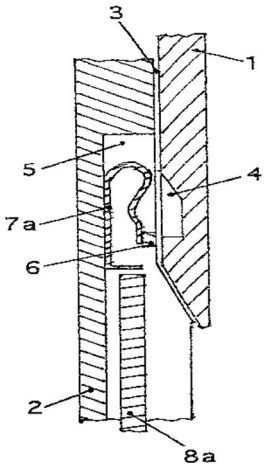


Fig. 1

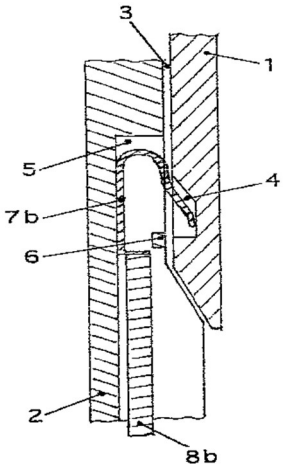
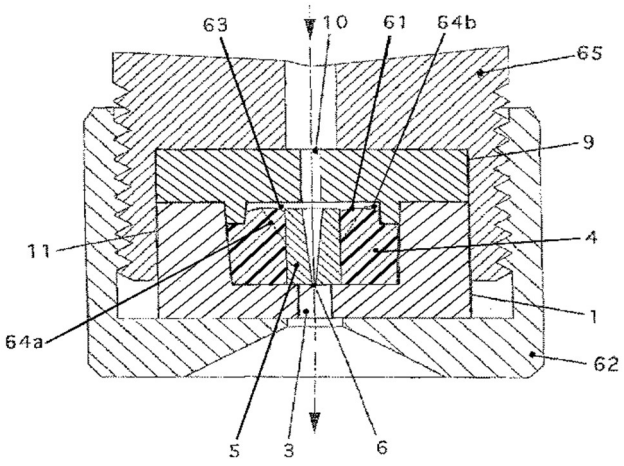


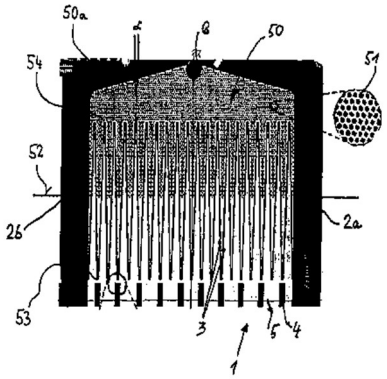
Fig. 2

116. **Unexpired Device-Only Patent 3:** U.S. Patent No. 7,837,235 ('235 patent) claims a liquid clamping device and expires in March 2028.[147]

[146] *Blocking device for a locking stressing mechanism having a spring-actuated output drive device*, Google Patents, https://patents.google.com/patent/US7396341B2/en.
[147] *Device for clamping a fluidic component*, Google Patents, https://patents.google.com/patent/US7837235B2/en?oq=7837235.

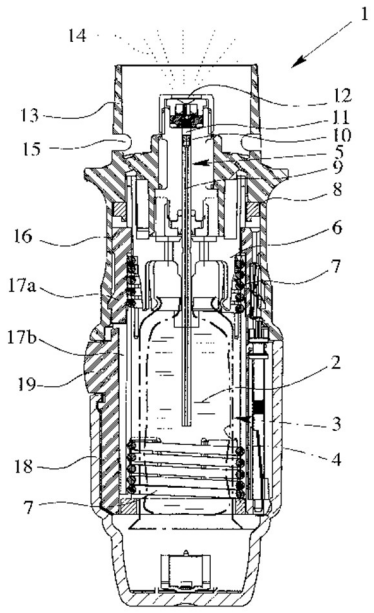


117. **Unexpired Device-Only Patent 4:** U.S. Patent No. 7,896,264 (the ’264 patent) claims a nozzle for producing high pressure and expires in May 2025.[148]

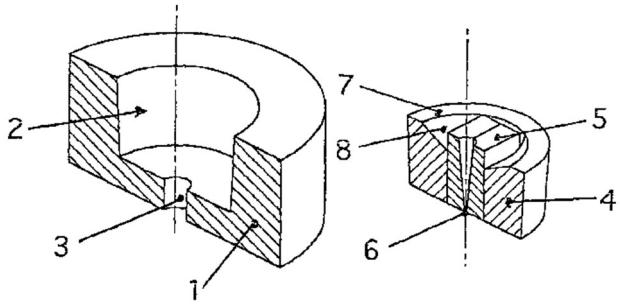


118. **Unexpired Device-Only Patent 5:** U.S. Patent No. 8,733,341 (the ’3,341 patent) claims an atomizer device with a filter and expires in June 2030.[149]

[148] *Microstructured high pressure nozzle with built-in filter function*, Google Patents, https://patents.google.com/patent/US7896264B2/en?oq=7896264.
[149] *Atomizer and method of atomizing fluid with a nozzle rinsing mechanism*, Google Patents, https://patents.google.com/patent/US8733341B2/en?oq=8733341.



119. **Unexpired Device-Only Patent 6:** U.S. Patent No. 9,027,967 (the '967 patent) claims a liquid clamping device and expires in March 2027.[150]



120. None of the six device patents includes any claims for ipratropium or albuterol for Combivent Respimat *or* tiotropium for Spiriva Respimat.

[150] *Device for clamping a fluidic component*, Google Patents, https://patents.google.com/patent/US9027967B2/en?oq=9027967.

121. Not only did Boehringer wrongfully list device-only patents in the Orange Book, Boehringer affirmatively misrepresented the patents it listed as drug product patents. In connection with the listing of all six of these patents, Boehringer was required to submit FDA Form 3542. On each form, Boehringer represented to the FDA that the patent "claim[ed] the approved drug product [Combivent Respimat (or Spiriva Respimat)] as defined in 21 CFR 314.3." This representation was false and misleading. In fact, none of these patents claim the active ingredients in Combivent Respimat (ipratropium-albuterol), or Spiriva Respimat (tiotropium). They are solely device patents. Therefore, they cannot and do not claim any drug product and are not listable in the Orange Book.

122. FTC Notified Boehringer That Its Combivent Respimat and Spiriva Respimat Device Patents Are Improperly Listed. Boehringer's monopolistic conduct has not gone unnoticed by federal agencies. In September 2023, Boehringer received a warning from the FTC that its improper device-only listings for Combivent Respimat and Spiriva Respimat violate federal laws and regulations. Rather than addressing its improperly listed patents, Boehringer ignored the FTC warning letter and maintains both its improper listings and sham litigation against Anobri.

123. FTC's Warning Letter to Boehringer. As discussed in Section IV.C., the FTC sent warning letters directly to ten brand manufacturers that the agency identified as having improperly listed device-only patents in the Orange Book in November 2023. Having listed over a dozen device-only patents of which six of those remain unexpired for Combivent Respimat and

Spiriva Respimat, Boehringer was among the ten drug manufacturers who received an FTC warning letter.[151]

124. In its letter, **the Commission indicated that it "believe[s] certain patents have been improperly or inaccurately listed in the Orange Book with regard to Boehringer Ingelheim Pharmaceuticals, Inc. products**." According to the FTC's letter, six unexpired patents listed under Combivent Respimat (ipratropium-albuterol) and Spiriva Respimat (tiotropium)—the '474 patent, the '341 patent, the '235 patent, the '264 patent, the '3,341 patent, and the '967 patent—were all improperly listed. The FTC "availed [itself]" of the FDA's process for disputing a patent listing. Under that process, Boehringer had thirty days, until December 7, 2023, to either remove its improper listings, or once again (falsely) certify, under penalty of perjury, that the patents belong in the Orange Book. The FTC warned Boehringer: "We have opted to use the FDA's regulatory dispute process to address the improper listings, but we retain the right to take any further action in the public interest," including suing Boehringer for violations of the antitrust laws.[152]

125. Other Manufacturers De-Listed. Other manufacturers having received warning letters from the FTC engaged in the dispute process in good faith, leading them to remove improperly listed patents from the Orange Book. For example, GlaxoSmithKline PLC agreed to

[151] *See* FTC, *Improper Orange Book-Listed Patents for Atrovent HFA, Combivent Respimat, Spiriva, and Spiriva Respimat* (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/boehringer-ingelheim-orange-book.pdf. The FDA notified Boehringer of its receipt of the FTC's patent disputes on or about November 16, 2023.
[152] *Id*.

withdraw four of the five listings challenged by the FTC, related to three of its asthma inhalers – Advair, Flovent and Ventolin.[153]

126. Boehringer Refused to De-List. Rather than heed the FTC's admonishment, on December 15, 2023, Boehringer responded to the FDA's notice, and no changes were made to their (wrongfully) listed patents in the Orange Book. Boehringer instead *resubmitted* to the FDA Patent Listing forms – two for each of the '474, '6,341, '235, '264, '3,341, and '967 patents. In each of those resubmitted Patent Listing Forms, Boehringer once again made a certification, under penalty of perjury, that the information in the Patent Listing Forms "complies with the requirements of" 21 C.F.R. § 314.54.

127. Senate Investigation. After failing to delist improperly listed patents from the Orange Book, the United States Senate Committee on Health, Education, Labor and Pensions ("HELP") launched an investigation into the price of asthma inhalers. The Committee sent letters to the four biggest manufacturers of inhalers sold in the United States, including Boehringer, in January 2024.[154] In its letter to Boehringer, the Committee accused Boehringer of knowingly gaming the system to prevent generics from entering the market by continuously

[153] *See* Zachary Brennan, *GSK and Others Delist Orange Book Patents After FTC Targets Protections on Inhalers and Epinephrine Injectors*, Endpoints News (Feb. 16, 2024), https://endpts.com/gsk-and-others-delist-orange-book-patents-after-ftc-targets-protections-on-inhalers-and-epinephrine-injectors/#:~:text=GSK%20agreed%20to%20delist%2012,Califf%2C%20which%20outlined%20the%20changes.

[154] Press Release, Sen. Tammy Baldwin, Senator Baldwin, Colleagues Launch Investigation into Pharmaceutical Companies' High Price of Asthma Inhalers (Jan. 8, 2024), https://www.baldwin.senate.gov/news/press-releases/senators-baldwin-colleagues-launch-investigation-into-pharmaceutical-companies-high-price-of-asthma-inhalers.

repackaging the same drugs in Combivent on the eve of patent expiration, and falsely certifying its device patent listings to the FDA.

128. The HELP Committee requested documents and information on Boehringer's internal efforts to ensure their inhalers do not face competition, including its patent listing strategies.

129. To date, Boehringer has not removed its improperly listed device-only patents from the Orange Book.

3. Boehringer Engaged in Sham Patent Litigation to Prevent a Generic Manufacturer from Entering the Market.

130. Boehringer's misconduct did not end after improperly obtaining decades of patent exclusivity for its Respimat products. Rather, when a would-be generic competitor, Anobri Pharmaceuticals U.S., LLC ("Anobri"), developed generic versions of Combivent Respimat and Spiriva Respimat, Boehringer doubled down on its improper listings. It engaged in sham litigation against this would-be competitor thereby triggering the automatic thirty-month stay afforded by its wrongful Orange Book listings.

131. Prior to 2023, no generic drug manufacturer had challenged Boehringer's device-only Combivent Respimat and Spiriva Respimat Orange Book Listings. In March 2023, Anobri became the first to submit ANDAs for a generic version of either drug.

132. Anobri's Paragraph IV Certification for Generic Spiriva Respimat. On March 7, 2023, Anobri submitted ANDA No. 216581 for the first generic Spiriva Respimat. The ANDA included Paragraph IV certifications challenging the '474 patent as not infringed; the '264 patent as not infringed; the '6,341 patent as not infringed; the '967 patent as invalid; the '235 patent as

invalid; and the '3,341 patent as not infringed. Thereafter, on or about May 18, 2023, Anobri provided Boehringer with notice of the Paragraph IV certifications.

133. Anobri's Paragraph IV Certification for Generic Combivent Respimat. On March 30, 2023, Anobri also submitted ANDA No. 216580 for approval of the first generic version of Combivent Respimat. The ANDA included Paragraph IV certifications challenging the '474 patent as not infringed; the '264 patent as not infringed; the '6,341 patent as not infringed; the '967 patent as invalid; the '235 patent as invalid; and the '3,341 patent as not infringed. Thereafter, on or about May 18, 2023, Anobri mailed Boehringer a notice letter regarding the Paragraph IV certifications.

134. Boehringer Files Sham Litigation. On June 29, 2023, Boehringer filed two infringement suits against Anobri in the District of New Jersey: *Boehringer Ingelheim Pharms., Inc. v. Anobri Pharms. US, LLC*, No. 23-cv-3530 (D.N.J.) (the "Spiriva Respimat infringement action"), and *Boehringer Ingelheim Pharms., Inc. v. Anobri Pharms. US, LLC*, No. 23-cv-03531 (D.N.J.) (the "Combivent Respimat infringement action").

135. In the Spiriva Respimat infringement action, Boehringer alleges Anobri's proposed Spiriva Respimat ANDA infringed all six patents listed in the Orange book as claiming Spiriva Respimat.[155] In the Combivent Respimat infringement action, Boehringer alleges

[155] Pl.'s Compl. at 11-26, *Boehringer Ingelheim Pharms., Inc. v Anobri Pharms. US, LLC*, No. 2:23-cv-03530 (D.N.J. June, 29, 2023), ECF No. 1.

Anobri's proposed Combivent Respimat ANDA infringed those same six patents that are listed in the Orange Book but as claiming Combivent Respimat.[156]

136. Anobri filed an amended answer and counterclaim in each infringement action, asserting that the '967 and '235 patents are invalid while the '6,341, '3,341, '474, and '264 patents will not be infringed.[157]

137. On December 12, 2023, the Combivent Respimat and Spiriva Respimat infringement actions were consolidated in one proceeding under Civil Action No. 23-3530.

138. Boehringer claims that Anobri's generic Spiriva Respimat and Combivent Respimat products infringe Patents '474 (Piston-Pumping System Having O-Ring Seal Properties), '264 (Microstructured High Pressure Nozzle with Built-In Filter), '6,341 (Blocking Device for a Locking Mechanism Having a Spring-Actuated Output Drive Device), '967 (Device for Clamping a Fluidic Component), '235 (Device for Clamping a Fluidic Component), and '3,341 (Atomizer and Method of Atomizing Fluid with Nozzle Rinsing Mechanism)—all of which remain unexpired. However, none of the patents claim (or reference) either brand drug's active ingredients, but all are listed as "drug products" in connection with Spiriva Respimat and Combivent Respimat. Boehringer improperly listed these patents for Combivent Respimat and Spiriva Respimat and therefore has no legal basis for legal action against Anobri, and

[156] Pl.'s Compl. at 11-26, *Boehringer Ingelheim Pharms., Inc. v. Anobri Pharms. US, LLC*, No. 2:23-cv-03531 (D.N.J. June 29, 2023), ECF No. 1.
[157] Def.'s Am. Answer to Pl.'s Countercl. at 16-18, *Boehringer Ingelheim Pharms., Inc. v Anobri Pharms. US, LLC,* 2:23-cv-03531 (D.N.J. Oct. 16, 2023), ECF No 22.

correspondingly no basis to force a thirty-month delay of FDA approval of Anobri's generic equivalents.

VI. CLASS ACTION ALLEGATIONS

139. Combivent Respimat Damages Class. The 1199SEIU Benefit Funds bring this action on behalf of themselves and a class of indirect Combivent Respimat purchasers under Federal Rule of Civil Procedure 23(b)(3) seeking damages pursuant to the antitrust, unfair competition, and consumer protection laws of the states listed below (the "End-Payor Damages Jurisdictions")[158]:

> All persons and entities in the End-Payor Damages Jurisdictions who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Combivent Respimat and/or generic versions of the same, other than for resale, from February 23, 2020, through the present (the "Combivent Respimat Class Period").
>
> This class excludes: (a) Boehringer, its officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (c) all persons or entities who purchased Combivent Respimat for purposes of resale or directly from Boehringer; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any "flat co-pay" consumers whose purchases of Combivent Respimat were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price; (f) pharmacy benefit managers; and (g) any judges or justices involved in this action and any members of their immediate families.

[158] The "End-Payor Damages Jurisdictions" consist of: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennesse, Utah, Vermont, Virginia, West Virginia, and Wisconsin.

140. Spiriva Respimat Damages Class. The 1199SEIU Benefit Funds brings this action on behalf of themselves and a class of indirect Spiriva Respimat purchasers under Federal Rule of Civil Procedure 23(b)(3) seeking damages pursuant to the antitrust, unfair competition, and consumer protection laws of the End-Payor Damages Jurisdictions:

> All persons and entities in the End-Payor Damages Jurisdictions who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Spiriva Respimat and/or generic versions of the same, other than for resale, from August 23, 2020, through the present (the "Class Period").
>
> This class excludes: (a) Boehringer, its officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (c) all persons or entities who purchased Spiriva Respimat for purposes of resale or directly from Boehringer; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any "flat co-pay" consumers whose purchases of Spiriva Respimat were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price; (f) pharmacy benefit managers; and (g) any judges or justices involved in this action and any members of their immediate families.

141. The Combivent Respimat Damages Class and Spiriva Respimat Damages Class are referred to herein as the "Damages Classes."

142. Combivent Respimat Nationwide Equitable Relief Class. The 1199SEIU Benefit Funds brings this action on behalf of themselves and as a class of indirect Combivent Respimat purchasers under Federal Rule of Civil Procedure 23(b)(2), seeking injunctive relief, disgorgement, and restitution pursuant to the Clayton and Sherman Acts and under the laws of all States and of the District of Columbia, Puerto Rico and the U.S. Virgin Islands:

> All persons and entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Combivent Respimat and/or generic versions of the same, other than for

resale, from February 23, 2020, through the present (the "Combivent Respimat Class Period").

This class excludes: (a) Boehringer, its officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (c) all persons or entities who purchased Combivent Respimat for purposes of resale or directly from Boehringer; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any "flat co-pay" consumers whose purchases of Combivent Respimat were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price; (f) pharmacy benefit managers; and (g) any judges or justices involved in this action and any members of their immediate families.

143. Spiriva Respimat Nationwide Equitable Relief Class. The 1199SEIU Benefit Funds bring this action on behalf of themselves and as a class of indirect Spiriva Respimat purchasers under Federal Rule of Civil Procedure 23(b)(2), seeking injunctive relief, disgorgement, and restitution pursuant to the Clayton and Sherman Acts and under the laws of all States and of the District of Columbia, Puerto Rico and the U.S. Virgin Islands:

All persons and entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Spiriva Respimat and/or generic versions of the same, other than for resale, from August 23, 2020, through the present (the "Class Period").

This class excludes: (a) Boehringer, its officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (c) all persons or entities who purchased Spiriva Respimat for purposes of resale or directly from Boehringer; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any "flat co-pay" consumers whose purchases of Spiriva Respimat were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price; (f) pharmacy benefit managers; and (g) any judges or justices involved in this action and any members of their immediate families.

144. The Combivent Respimat Nationwide Equitable Relief Class and Spiriva Respimat Nationwide Equitable Relief Class are referred to herein as the "Nationwide Equitable Relief Classes."

145. The Combivent Respimat Damages Class, Spiriva Respimat Damages Class, Combivent Respimat Nationwide Equitable Relief Class, and Spiriva Respimat Nationwide Equitable Relief Class are referred to herein as the "Classes."

146. Numerosity. While the 1199SEIU Benefit Funds do not know the exact number of the members of the Classes, the 1199SEIU Benefit Funds believe there are at least thousands of members in each Class.

147. Commonality. Common questions of law and fact exist as to all members of the Classes. This is particularly true given the nature of Boehringer's scheme, which did not vary at all Class member to Class member but applied equally to all Class members, thereby making appropriate relief with respect to the Classes as a whole. Such questions of law and fact common to the Classes include, but are not limited to:

a. whether Boehringer willfully obtained and/or maintained monopoly power over Combivent Respimat or Spiriva Respimat and their generic equivalents;

b. whether Boehringer improperly listed device-only patents in the Orange Book, thereby claiming the drug products of Combivent Respimat or Spiriva Respimat;

c. whether Boehringer unlawfully delayed or prevented generic manufacturers of Combivent Respimat or Spiriva Respimat equivalents from entering the market in the United States;

d. whether the law requires definition of a relevant market when direct proof of monopoly power is available, and if so the definition of the relevant market;

e. whether Boehringer's activities as alleged herein have substantially affected interstate commerce;

f. the effect of Boehringer's alleged conduct on the prices of Combivent Respimat or Spiriva Respimat or generic equivalents sold in the United States during the Class Period;

g. whether, and if so to what extent, Boehringer's conduct caused antitrust injury (*i.e.*, overcharges) to the 1199SEIU Benefit Funds and Class Members;

h. the appropriate injunctive and related equitable relief; and

i. the appropriate class-wide measure of damages.

148. The questions of law and fact common to the members of the Classes predominate over any questions affecting only individual members.

149. Typicality. The 1199SEIU Benefit Funds' claims are typical of the claims of Class members. The 1199SEIU Benefit Funds and all members of the Classes are similarly affected by Boehringer's wrongful conduct in that they (1) paid artificially inflated prices for Combivent Respimat or Spiriva Respimat purchased indirectly from Boehringer and (2) were deprived of earlier and more robust competition from less-expensive generic versions of Combivent Respimat or Spiriva Respimat as a result of Boehringer's wrongful conduct. The 1199SEIU Benefit Funds' claims arise out of the same common course of conduct giving rise to the claims of the other members of the Classes.

150. Adequacy. The 1199SEIU Benefit Funds will fairly and adequately protect the interests of the Classes. The 1199SEIU Benefit Funds are members of each Class, and the 1199SEIU Benefit Funds' interests are coincident with, and not antagonistic to, those of the other

members of the Classes. Additionally, the 1199SEIU Benefit Funds are represented by counsel who are competent and experienced in the prosecution of antitrust and class action litigation.

151. Superiority. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of evidence, effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

152. The prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Boehringer.

VII. MARKET POWER AND RELEVANT MARKET

153. The relevant geographic market is the United States.

154. The relevant product markets are: (1) the market for ipratropium-albuterol inhalation spray (Combivent Respimat and would-be AB-rated generics); and (2) the market for tiotropium inhalation spray (Spiriva Respimat and would-be AB-rated generics).

155. Boehringer's unlawful schemes allowed Boehringer to wrongfully acquire, maintain, and exploit its monopoly power over both markets.

156. Without judicial intervention, Boehringer will maintain and exploit its monopoly power over both markets—forcing the 1199SEIU Benefit Funds and others similarly situated to continue paying supracompetitive prices due to Boehringer's exclusionary conduct.

A. The Market for Ipratropium-Albuterol Inhalation Spray

157. The market for ipratropium-albuterol inhalation spray is a relevant antitrust market. Direct evidence shows that (a) but for Boehringer's conduct, generic versions of Combivent Respimat would have entered the market at substantially lower prices than branded Combivent Respimat; and (b) Boehringer never lowered Combivent Respimat prices in response to the pricing of any other inhaled medication product.

158. Combivent Respimat is the only inhalation spray version of ipratropium-albuterol available for sale in the United States.[159] Boehringer is therefore the only manufacturer and seller of ipratropium-albuterol inhalation sprays in the United States. In other words, at all relevant times, Boehringer's share of the relevant market was and remains 100%.

159. Branded drugs like Combivent Respimat are differentiated based on features and benefits (including medical indications, duration of relief, frequency of use, and convenience), and not only based upon price. In part because health insurers typically bear much of the cost of prescriptions, doctors and patients are generally price-insensitive when prescribing and purchasing prescription drugs like Combivent Respimat. And generic substitution laws in almost

[159] FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*, (current as of Apr. 17, 2024), https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm (active ingredient: Ipratropium bromide; Albuterol Sulfate).

every state prevent pharmacists from filling a prescription with a drug that is not an AB-rated equivalent of the prescribed drugs.

160. Combivent Respimat is not reasonably interchangeable with any products apart from AB-rated generic versions of Combivent Respimat. The attributes of Combivent Respimat significantly differentiate it from other treatments for COPD. Even drugs within its same therapeutic class do not constrain the price of Combivent Respimat. The FDA does not regard Combivent Respimat and other COPD treatments as interchangeable. Accordingly, a small but significant, non-transitory price increase to the price of Combivent Respimat would not have caused a significant loss of sales.

161. Drugs Within the Same Class as Combivent Respimat Are Not in the Relevant Market. The active ingredients in ipratropium-albuterol inhalation sprays belong to a medication group known as "Short Acting Combinations." Medications in this group combine two types of ingredients: one that relaxes muscles in the airways quickly ("short-acting muscarinic antagonist," "SAMA"), and another that acts rapidly to increase airflow to the lungs ("short-acting beta agonist," "SABA").[160] These medications are termed "short-acting" because they only stay in the body for a short time.

162. DuoNeb. The only other medication falling within the "short acting combination" family is DuoNeb (now discontinued) and its four generic equivalents.[161] DuoNeb is a type of

[160] *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 832-34 (Laurence Brunton et al. eds., 2018).
[161] *See* FDA, *Orange Book, supra* note 159, Albuterol Sulfate; Ipratropium Bromide.

medication with the same active ingredients contained in Combivent Respimat.[162] However, the drug solution can only be used in conjunction with a nebulizer device. With that device, patients must sit by their nebulizer machines and use a mouthpiece. The medicine enters the patient's lungs while taking slow, deep breaths for up to 10 to 15 minutes.[163] By comparison, Combivent Respimat delivers a slow mist that must be inhaled for *only ten seconds*.[164] The nebulizer also requires electricity and compressed gas to run properly while a spray inhaler does not. Due to difficulties with portability, nebulizers are primarily used at home and in hospital settings.[165] Ipratropium-albuterol inhalation spray, in other words, is easier to handle and travel with than the nebulizer device since it is smaller, requires less time for the medication to be administered, and does not require electricity.

163. Additionally, the fact that Boehringer is able to charge—with all rebates and discounts applied—in excess of $489 (as it now does in 2024) when a ninety-day supply of generic DuoNeb costs only $27 shows that Boehringer does not compete with generic DuoNeb.[166] Based on the foregoing, neither DuoNeb nor its generic equivalents are substitutes for ipratropium-albuterol inhalation spray.

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[162] DuoNeb was first approved by the FDA in March 2001. As of the date of this complaint, DuoNeb has been discontinued and replaced by four ANDAs claiming the ipratropium – albuterol combined therapy.

[163] *COPD – How to use a Nebulizer?*, Mount Sinai, https://www.mountsinai.org/health-library/selfcare-instructions/copd-how-to-use-a-nebulizer.

[164] *Combivent Respimat: How it works,* Boehringer Ingelheim Pharms, https://patient.boehringer-ingelheim.com/us/combivent/about/how-it-works.

[165] Sean McCarthy et al., *Future Trends in Nebulized Therapies for Pulmonary Disease*, 10 J. Pers. Med. 37 (2020), https://pubmed.ncbi.nlm.nih.gov/32397615/.

[166] *See DuoNeb Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-

164. Rescue Inhalers. Additionally, rescue inhalers are not substitutes for Combivent Respimat. Rescue inhalers are medications designed for immediate relief of asthma symptoms. They work by quickly relaxing the muscles around the airways, making it easier to breathe during an asthma attack. Because rescue inhalers only provide short-term relief for asthma, they are not substitutes for Combivent Respimat, which used daily helps maintain control of respiratory symptoms over a prolonged period.[167]

165. Individual Drug Compounds. Although its ingredients—ipratropium and albuterol—are available individually, they are not substitutes for Combivent Respimat. These two active ingredients combined provide better treatment than either active ingredient alone because the combination is more effective at improving pulmonary function than albuterol alone.[168] For example, a study analyzing the differences in outcomes between patients using the combination therapy and patients only using albuterol found that the combination of ipratropium and albuterol was 26 to 28% more effective than albuterol alone as measured by mean peak response to the drug.[169]

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guide/duoneb#:~:text=A%20generic%20version%20of%20DuoNeb,from%20%2426.61%20for%2090%20milliliters; *see also* FDA, Orange Book, *supra* note 159.

[167] *Asthma and COPD: Basic Mechanisms and Clinical Management* 123-125 (Peter J. Barnes et al. eds., 2009).

[168] The COMBIVENT Inhalation Sol. Study Grp., *Routine Nebulized Ipratropium and Albuterol Together Are Better Than Either Alone in COPD*, 112 Chest J. 1514-21 (1997), https://doijournal.chestnet.org/10.1378/chest.112.6.1514article/S0012-3692(15)47358-1/abstract.

[169] Sammy Campbell, *For COPD a Combination of Ipratropium Bromide and Albuterol Sulfate Is More Effective Than Albuterol Base*, 159 Arch. Intern. Med. 156-160 (1999), https://doi.org/10.1001/archinte.159.2.156jamanetwork.com/journals/jamainternalmedicine/fullarticle/414245.

166. Furthermore, Combivent Respimat is considered an "add-on" therapy: Combivent Respimat is prescribed for patients with COPD on a regular aerosol bronchodilator (i.e., ipratropium or albuterol by themselves) who continue to show evidence of bronchospasm and who require a second bronchodilator.[170] In other words, Combivent Respimat is *only prescribed if symptoms* of COPD *persist even with use of other available inhalers* for the single drugs ipratropium or albuterol. Additionally, it is designed to be *used in conjunction with monotherapy inhalers* (i.e., inhalers containing a single active ingredient). This means that a consumer could not substitute ipratropium and albuterol, by themselves, for Combivent Respimat.

167. In sum, Combivent Respimat does not exhibit significant, positive cross-elasticities of demand with respect to the price of any other inhaled medication product. For that reason, only the market entry of competing generic ipratropium-albuterol inhalation spray products would render Boehringer unable to profitably maintain its prices for Combivent Respimat without losing substantial sales. Boehringer thus needed to control only Combivent Respimat and its generic equivalents, and no other products, in order to maintain supracompetitive Combivent Respimat prices profitably without losing substantial sales.

B. The Market for Tiotropium Inhalation Spray

168. A relevant antitrust market is the market for tiotropium inhalation spray. Direct evidence shows that (a) but for Boehringer's conduct, generic versions of Spiriva Respimat would have entered the market at substantially lower prices than branded Spiriva Respimat; and

[170] *Combivent Respimat: How it works,* Boehringer Ingelheim Pharms, https://patient.boehringer-ingelheim.com/us/combivent/about/how-it-works.

(b) Boehringer never lowered Spiriva Respimat prices in response to the pricing of any other inhaled medication product.

169. Spiriva Respimat is the only tiotropium inhalation spray available for sale in the United States.[171] Boehringer is the only manufacturer and seller of tiotropium inhalation sprays in the United States. In other words, at all relevant times, Boehringer's share of the relevant market was and remains 100%.

170. Branded drugs like Spiriva Respimat are differentiated based on features and benefits (including medical indications, duration of relief, frequency of use, and convenience), and not only based upon price. In part because health insurers typically bear much of the cost of prescriptions, doctors and patients are generally price-insensitive when prescribing and purchasing prescription drugs like Spiriva Respimat. And generic substitution laws in almost every state prevent pharmacists from filling a prescription with a drug that is not an AB-rated equivalent of the prescribed drugs.

171. Spiriva Respimat is not reasonably interchangeable with any product apart from AB-rated generic version of Spiriva Respimat. The attributes of Spiriva Respimat significantly differentiate it from other treatments for asthma and COPD. Even drugs within its same therapeutic class do not constrain the price of Spiriva Respimat. The FDA does not regard Spiriva Respimat and other COPD treatments as interchangeable. Accordingly, a small but significant, non-transitory price increase to the price of Spiriva Respimat would not have caused a significant loss of sales.

[171] FDA, *Orange Book*, *supra* note 159, active ingredient: Tiotropium Bromide.

172. Drugs Within the Same Class as Spiriva Respimat Are Not in the Relevant Market. Spiriva Respimat belongs to the long-acting muscarinic antagonist ("LAMA") family of medications. Drugs in this family work by relaxing the muscles around the airways in the lungs to keep them open for up to 24 hours, thereby easing breathing and managing symptoms consistently.[172] No other drug in this family is a substitute as Spiriva Respimat alone is approved to treat patients aged six years and above.

173. HandiHaler and LupinHaler. Spiriva HandiHaler and its generic version (LupinHaler), the dry powder form of tiotropium, cannot be substituted with Spiriva Respimat.[173] They differ from Spiriva Respimat in method and ease of use, reason for use, and age of user.

174. *First*, the HandiHaler and LupinHaler use a dry powder inhaler, which requires forceful inhalation that can be challenging for some patients with severe COPD. A study analyzing patient preferences of dry powder tiotropium versus tiotropium inhalation spray found that after the first survey, 17.5% of patients preferred the HandiHaler and 45.6% preferred the Respimat. In a second survey, performed two to three years later, the number of patients who preferred the Respimat had increased to 79.5%.[174]

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[172] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease*, Global Initiative for Chronic Obstructive Lung Disease (2024), https://goldcopd.org/2024-gold-report/.

[173] Peter Calverley et al., *Tiotropium Respimat versus HandiHaler: Comparison of Bronchodilator Efficacy of Various Doses in Clinical Trials*, 33 Advances in Therapy 786-793 (2016), https://doi.org/10.1007/s12325-016-0322-9.

[174] Soichiro Hanada et al., *Questionnaire on Switching from the Tiotropium HandiHaler to the Respimat Inhaler in Patients with Chronic Obstructive Pulmonary Disease: Changes in Handling and Preferences Immediately and Several Years After the Switch,* 6 Intl. J. Chronic Obstructive Pulmonary Disease 69-77 (2015), https://pubmed.ncbi.nlm.nih.gov/25609941/.

175. *Second*, dry powder tiotropium and tiotropium inhalation spray differ in terms of their medical indications. HandiHaler and LupinHaler are used for the long-term, once daily maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema, and for reducing COPD exacerbations. On the other hand, while Spiriva Respimat is also approved for the long-term, once-daily maintenance treatment of bronchospasm associated with COPD, it *cannot* be used to treat bronchitis and emphysema. Spiriva Respimat *can*, however, be used for the long-term once-daily maintenance treatment of asthma in patients six years old and older.[175]

176. *Third*, the fact that the dry powder form of tiotropium bromide cannot substitute for Spiriva Respimat is demonstrated by the fact that the generic version of the HandiHaler (the LupinHaler) came to market in 2023 and has not resulted in lower Spiriva Respimat prices or significantly reduced Spiriva Respimat sales. The imperviousness of Spiriva Respimat prices to the entry of generic LupinHaler confirms Boehringer's continued market power over the relevant tiotropium inhalation spray market.

177. Incruse Ellipta and Tudorza Pressair. Nor are other dry powder inhalers like Incruse Ellipta (umeclidinium bromide) and Tudorza Pressair (aclidinium bromide) substitutes for Spiriva Respimat. Incruse Ellipta and Tudorza Pressair differ from Spiriva Respimat in their

[175] Magellan Rx Management, *COPD Agents Therapeutic Class Review (TCR)*, Tex. Health & Hum. Servs. (July 13, 2021), https://www.hhs.texas.gov/sites/default/files/documents/apr-2023-durb-agenda-item3n.pdf; Dept. Health & Human Servs. et al., *Pediatric Postmarketing Pharmacovigilance Review* (2018), https://www.fda.gov/files/advisory%20committees/published/spiriva-pediatric-postmarketing-pharmacovigilance-review.pdf.

method and ease of use. Both require the forceful inhalation that can be challenging for some patients with severe COPD.

178. Lonhala Magnair and Yupelri Neb. Nebulizers such as Lonhala Magnair (glycopyrrolate) and Yupelri Neb (revefenacin) are not substitutes for Spiriva Respimat. They lack portability, require longer setup, and administration times—all of which can be impractical for patients needing on-the-go treatment. Those limitations likewise prevent other nebulizers from being a substitute.

179. Ipratropium. Although both tiotropium and ipratropium treat COPD, ipratropium cannot be substituted for tiotropium. First, tiotropium requires fewer doses. Ipratropium, by contrast, has a shorter duration of action and must be taken several times per day; tiotropium need only be taken once per day.[176] Second, overall, tiotropium appears to have more clinical efficacy than ipratropium. A study comparing clinical outcomes of patients using tiotropium with those using ipratropium found that the tiotropium treatment was associated with greater improved lung function, fewer hospital admissions, fewer exacerbations of COPD, and improved quality of life.[177]

180. In sum, Spiriva Respimat does not exhibit significant, positive cross-elasticities of demand with respect to the price of any other inhaled medication product. For that reason, only the market entry of competing, generic tiotropium inhalation spray products would render

[176] Leanne Cheyne et al., *Tiotropium Versus Ipratropium Bromide for Chronic Obstructive Pulmonary Disease* 2, Chochrane Database Systemic Revs. (2015), https://doi.org/10.1002/14651858.CD009552.pub3.
[177] *Id.*

Boehringer unable to profitably maintain its prices for Spiriva Respimat without losing substantial sales. Boehringer thus needed to control only Spiriva Respimat and its generic equivalents, and no other products, in order to maintain supracompetitive Spiriva Respimat prices profitably without losing substantial sales.

VIII. MARKET EFFECTS AND CLASS DAMAGES

181. Boehringer's multi-prong scheme to exclude competition in the ipratropium-albuterol and tiotropium inhalation spray markets—including Boehringer's improper Orange Book listing of device-only patents, use of product hopping for Combivent Respimat, and sham litigation against Anobri—created Boehringer's monopoly power over both markets. As a direct result of Boehringer's unlawful conduct, generic equivalents for Combivent Respimat and Spiriva Respimat have yet to enter the market.

182. But for the conduct alleged above, generic Combivent Respimat would have entered the market as early as February 2020, when the exclusivities associated with U.S. Patent No. 7,802,568 and related patents expired. Likewise, but for the conduct alleged above, generic Spiriva Respimat would have entered the market as early as August 2020, when the exclusivities associated with U.S. Patent No. 7,802,568 and related patents expired.

183. Boehringer's exclusionary conduct has caused and will cause Plaintiffs and the classes to pay more than they would have paid for Respimat, absent that conduct. As discussed in Section IV.B.3, generic versions of branded drugs are typically priced significantly below their corresponding brand drug counterparts, and as more generic manufacturers enter the market, prices for generics predictably decline even further. Drug price competition

consequently enables all brand drug purchasers to buy generic drug counterparts at substantially lower costs.

184. If generic competitors had not been unlawfully prevented from entering the ipratropium-albuterol and tiotropium inhalation spray markets, end-payors like Plaintiffs would have paid less for ipratropium-albuterol and tiotropium inhalation sprays by (a) purchasing and providing reimbursement for AB-rated generic Combivent Respimat and Spiriva Respimat instead of more-expensive branded Respimat products and (b) purchasing and providing reimbursement for branded Respimat products at lower prices.

185. Boehringer's unlawful product deprived Plaintiffs and the classes of the benefits of competition that the antitrust laws were designed to guarantee.

IX. ANTITRUST IMPACT

186. The effect of Boehringer's course of monopolistic conduct was to net Boehringer billions of dollars in revenue at the expense of patients and end-payors, including the 1199SEIU Benefit Funds and others similarly situated.

187. Since the approval and sale of Combivent Respimat and Spiriva Respimat, the 1199SEIU Benefit Funds and others similarly situated purchased substantial amounts of these drugs.

188. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds paid monopoly prices for Combivent Respimat and Spiriva Respimat. Prices for Boehringer's Combivent Respimat and Spiriva Respimat were, and continue to be, substantially higher than the prices they would have paid absent Boehringer's illegal conduct, because: (1) the

price of branded Combivent Respimat and Spiriva Respimat was artificially inflated as a result of Boehringer's unlawful conduct, and (2) the class members were deprived of the opportunity to purchase lower-priced generic versions of Respimat products sooner.

189. As a result, Plaintiffs and class members have sustained substantial losses in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. INTERSTATE AND INTRASTATE COMMERCE

190. Boehringer's efforts to monopolize and restrain competition for Respimat products have substantially affected interstate commerce.

191. At all material times, Boehringer manufactured, marketed, promoted, distributed, and sold substantial amounts of Combivent Respimat and Spiriva Respimat in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

192. At all material times, Boehringer transmitted funds, as well as contracts, invoices, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Respimat products.

193. In furtherance of its efforts to restrain competition in the relevant market, Boehringer employed the U.S. mail and interstate and international phone lines, as well as means of interstate and international travel. Boehringer's activities were within the flow of and have substantially affected interstate commerce.

194. Boehringer's conduct also had substantial intrastate effects in that, among other things, retailers within each state were prevented from offering more affordable generic Respimat products to end-payors inside each respective state. Boehringer's conduct materially deprived the consuming public—including hundreds, if not thousands, of end-payors in each state—of any choice to purchase more affordable generic Respimat products. The continued absence of competition from generic Respimat products directly affects and disrupts commerce within each state.

XI. CONTINUING VIOLATIONS

195. Boehringer engaged in and continues to engage in a course of wrongful conduct, including conduct within the applicable limitations periods. Boehringer's conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Plaintiffs and members of the Damages Classes accordingly can recover for damages sustained during the applicable limitations periods.

CAUSES OF ACTION

COUNT I
For Injunctive Relief Under Section 16 of the Clayton Act for Violation of Section 2 of the Sherman Act: Monopolization
(On Behalf of 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes)

196. Plaintiffs repeat and reallage the facts above.

197. At all relevant times, Boehringer possessed and continues to unlawfully possess monopoly power in the relevant markets for Combivent Respimat (ipratropium-albuterol inhalation spray) and Spiriva Respimat (tiotropium inhalation spray)—the power to control prices, prevent falling prices, and exclude competitors from the relevant markets. During the

relevant time periods, no other manufacturer sold a competing version of any ipratropium-albuterol or tiotropium inhalation spray in the United States.

198. Boehringer willfully and intentionally engaged in an anticompetitive scheme to maintain its monopoly, the components of which either standing alone or in combination (in whole or part) were designed to and in fact have blocked and delayed entry of AB-rated generic versions of Combivent Respimat and Spiriva Respimat. This scheme included improperly listing device-only patents in the Orange Book, engaging in sham litigation against Anobri, and recertifying its device-only patents.

199. Boehringer knew when it submitted device-only patents for listing in the Orange Book that these patents were ineligible for listing because they did not claim a drug under the plain language of the listing statute, the First Circuit's *Lantus* decision, and the FTC's November 2023 warning letter. Boehringer knew that listing device-only patents in the Orange Book would force ANDA applicants to file Paragraph IV certifications that would thereby provide Boehringer the opportunity to file patent infringement suits against those ANDA applicants. Boehringer knew that any lawsuits, however baseless, would trigger an automatic stay of FDA final approval of any pending Paragraph IV-certified ANDA applicant's generic Combivent Respimat or Spiriva Respimat inhalation spray for a period of thirty months—or longer if a court so ordered. Boehringer executed that exact strategy by asserting its ineligible device-only patents against Anobri, a potential generic competitor, in sham litigation after Anobri filed ANDAs for generic versions of both Combivent Respimat and Spiriva Respimat triggering the automatic thirty-month stay.

200. Through its overarching anticompetitive scheme, as alleged extensively above, Boehringer willfully maintained its monopoly power in the relevant markets using restrictive or exclusionary conduct, rather than by means of a superior product, greater business acumen, or historical accident. It thereby injured competition, the 1199SEIU Benefit Funds, and the Nationwide Equitable Relief Classes.

201. By means of this scheme, Boehringer intentionally and wrongfully maintained monopoly power with respect to Combivent Respimat and Spiriva Respimat in violation of Section 2 of the Sherman Act. 15 U.S.C. § 2. As a result of this unlawful maintenance of monopoly power, the 1199SEIU Benefit Funds and members of the Nationwide Equitable Relief Classes paid artificially inflated prices for Combivent Respimat and Spiriva Respimat.

COUNT II
For Injunctive Relief Under Section 16 of the Clayton Act for Violation of Section 2 of the Sherman Act: Attempted Monopolization
(On Behalf of 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes)

202. Plaintiffs repeat and reallage the facts above.

203. Boehringer attempted to monopolize the markets for Combivent Respimat (ipratropium-albuterol inhalation spray) and Spiriva Respimat (tiotropium inhalation spray) in violation of Section 2 of the Sherman Act based on the anticompetitive conduct described herein.

204. Boehringer had a specific intent to monopolize the markets for Combivent Respimat (ipratropium-albuterol inhalation spray) and Spiriva Respimat (tiotropium inhalation spray). As discussed in more detail above, Boehringer specifically engaged in a scheme to improperly list device-only patents in the Orange Book so it could delay entry of generic competitors by engaging in sham litigation against any potential generic competitor that filed an

ANDA, like Anobri. Boehringer designed this scheme to, and in fact did, block and delay entry of AB-rated generic versions of Combivent Respimat and Spiriva Respimat. In doing so, Boehringer attempted to control high prices in the relevant markets and to exclude competition.

205. Through the anticompetitive and exclusionary acts described above, Boehringer achieved a dangerous probability of success of monopolizing the relevant market. Boehringer maintained its 100% market share and significant pricing power over albuterol-ipratropium and tiotropium inhalation sprays in the United States by excluding generic entrants. As a result, Boehringer was able to charge a higher price for Combivent Respimat and Spiriva Respimat.

COUNT III
Violation of State Antitrust Laws:[178] Monopolization and Attempted Monopolization
(On Behalf of 1199SEIU Benefit Funds and the Damages Classes)

206. Plaintiffs repeat and reallage the facts above.

207. At all relevant times, Boehringer possessed and continues to unlawfully possess monopoly power in the relevant markets for Combivent Respimat (ipratropium-albuterol inhalation spray) and Spiriva Respimat (tiotropium inhalation spray)—the power to control prices, prevent falling prices, and exclude competitors from the relevant markets. No other manufacturer sold a competing version of any albuterol-ipratropium or tiotropium inhalation spray in the United States during the relevant time periods.

[178] Plaintiffs allege statutory antitrust violations for the following jurisdictions: Arizona, Colorado, Connecticut, District of Columbia, Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin.

208. Boehringer willfully and intentionally engaged in an anticompetitive scheme to maintain its monopoly, the components of which either standing alone or in combination (in whole or part) were designed to and in fact have blocked and delayed entry of AB-rated generic versions of Combivent Respimat and Spiriva Respimat. This scheme included improperly listing device-only patents in the Orange Book, engaging in sham litigation against Anobri, and recertifying its device-only patents.

209. Boehringer knew when it submitted device-only patents for listing in the Orange Book that these patents were ineligible for listing because they did not claim a drug under the plain language of the listing statute, the First Circuit's *Lantus* decision, and the FTC's November 2023 warning letter. Further, Boehringer knew that listing device-only patents in the Orange Book would force ANDA applicants to file Paragraph IV certifications that would thereby provide Boehringer the opportunity to file patent infringement suits against those ANDA applicants. Boehringer knew that any lawsuits, however baseless, would trigger an automatic stay of FDA final approval of any pending Paragraph IV-certified ANDA applicant's generic Combivent Respimat or Spiriva Respimat product for a period of thirty months—or longer if a court so ordered. Finally, Boehringer executed that exact strategy by asserting its ineligible device-only patents against Anobri, a potential generic competitor, in sham litigation after Anobri filed ANDAs for generic versions of both Combivent Respimat and Spiriva Respimat triggering the automatic thirty-month stay.

210. Through its overarching anticompetitive scheme, as alleged extensively above, Boehringer willfully maintained its monopoly power in the relevant markets using restrictive or

exclusionary conduct, rather than by means of a superior product, greater business acumen, or historical accident. As a result, it injured competition, the 1199SEIU Benefit Funds, and the Damages Classes.

211. The 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business or property by Boehringer's antitrust violations. Their injury consists of having paid higher prices for Combivent Respimat and Spiriva Respimat than they would have paid in the absence of those violations.

212. It was Boehringer's conscious objective to further its dominance in the relevant markets by and through the overarching anticompetitive scheme.

213. There is no valid procompetitive business justification for Boehringer's anticompetitive conduct, and to the extent Boehringer offers one, it is pretextual and not cognizable, and any procompetitive benefits of Boehringer's conduct do not outweigh its anticompetitive harms.

214. By engaging in the foregoing conduct, Boehringer has maintained monopoly power in the relevant markets in violation of the following state laws:

Arizona[179]

215. By reason of the foregoing, Boehringer violated Arizona Revised Statutes, §§ 44-1401, *et seq*. The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price

[179] Plaintiffs' counsel will mail a copy of this class-action complaint to the Attorney General of Arizona and will file proof of that service as required by Arizona Revised Statutes, § 44-1415(A).

competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Arizona; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Arizona; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected Arizona commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of Arizona Revised Statutes, §§ 44-1401, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Arizona Revised Statutes, §§ 44-1401, *et seq.*

Colorado[180]

216. By reason of the foregoing, Boehringer has violated Colorado Revised Statutes, §§ 6-4-105, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Colorado; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Colorado; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU

[180] Plaintiffs' counsel will mail a copy of this class-action complaint to the Attorney General of Colorado as required by Colorado Revised Statutes, §§ 6-4-116.

Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected Colorado commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of Colorado Revised Statutes, §§ 6-4-105, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Colorado Revised Statutes, §§ 6-4-105, *et seq.*

Connecticut[181]

217. By reason of the foregoing, Boehringer has violated Connecticut General Statutes Annotated, §§ 35-27, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Connecticut; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Connecticut; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

[181] Plaintiffs' counsel will mail a copy of this class-action complaint to the Attorney General of Connecticut as required by Connecticut General Statutes § 35-37.

b. During the Class Period, Boehringer's illegal conduct substantially affected Connecticut commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of Connecticut General Statutes Annotated, §§ 35-27, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Connecticut General Statutes Annotated, §§ 35-27, *et seq.* including treble damages and attorney's fees and costs under §35-35.

District of Columbia

218. By reason of the foregoing, Boehringer's has violated District of Columbia Code, §§ 28-4503, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout the District of Columbia; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout the District of Columbia; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected District of Columbia commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of District of Columbia Code, §§ 28-4503, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under District of Columbia Code, §§ 28-4503, *et seq.*

Hawaii

219. By reason of the foregoing, Boehringer violated Hawaii Revised Statutes, §§ 480-9, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Hawaii; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Hawaii; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected Hawaii commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of Hawaii Revised Statutes, §§ 480-9, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Hawaii Revised Statutes, §§ 480-9, *et seq.*

Illinois[182]

220. By reason of the foregoing, Boehringer violated the Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/3, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme in the markets for Combivent Respimat and Spiriva Respimat or generic versions had the following effects:

b. Boehringer's monopolization scheme in the markets for Combivent Respimat and Spiriva Respimat or generic versions had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat was restrained, suppressed, and eliminated throughout Illinois; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Illinois; (3) the 1199SEIU Benefit Funds and members of the Damages Class, including those who resided in Illinois and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in Illinois; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Illinois and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Illinois.

c. During the Class Period, Boehringer's illegal conduct substantially affected Illinois commerce.

d. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

e. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of the Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/3, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek

[182] Plaintiffs' counsel will mail a copy of this class-action complaint to the Attorney General of Illinois as required by 815 Illinois Compiled Statute § 505/10.

all forms of relief available under the Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/3, *et seq.*

Iowa

221. By reason of the foregoing, Boehringer violated Iowa Code §§ 553.5, *et seq*. The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Iowa; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Iowa; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected Iowa commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of Iowa Code §§ 553.5, *et seq*. Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Iowa Code §§ 553.5, *et seq*.

Maine

222. By reason of the foregoing, Boehringer violated 10 Maine Revised Statutes, §§ 1102, *et seq*. The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Maine; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Maine; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected Maine commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of Maine Revised Statutes, 10 M.R.S.A. §§ 1102, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Maine Revised Statutes, 10 M.R.S.A. §§ 1102, *et seq.*

Maryland

223. By reason of the foregoing, Boehringer violated Maryland Complied Laws, §§ 11-204, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Maryland; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Maryland; (3) the 1199SEIU Benefit Funds and members of the Damages Class were deprived of free and open competition; and (4) the 1199SEIU Benefit

Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected Maryland commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of Maryland Complied Laws, §§ 11-204, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Maryland Complied Laws, §§ 11-204, *et seq.*

Massachusetts

224. Unless pre-suit resolution is reached pursuant to pre-suit requirements of Massachusetts law, the 1199SEIU Benefit Funds will amend their complaint to include the following claims under Massachusetts law: By reason of the foregoing, Boehringer violated Massachusetts General Laws, Ch. 93A, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Massachusetts; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Massachusetts; (3) the 1199SEIU Benefit Funds and members of the Damages Class were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected Massachusetts commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of Massachusetts General Laws, Ch. 93A, §§ 11-204, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Massachusetts General Laws, Ch. 93A, *et seq.*

Michigan

225. By reason of the foregoing, Boehringer violated Michigan Compiled Laws, §§ 445.773, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Michigan; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Michigan; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected Michigan commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer's established, maintained, and used a monopoly, or attempted to monopolize in violation of Michigan Compiled Laws, §§ 445.773, *et seq.* Accordingly, the 1199SEIU Benefit

Funds and members of the Damages Classes seek all forms of relief available under Michigan Compiled Laws, §§ 445.773, *et seq.*

Minnesota

226. By reason of the foregoing, Boehringer violated Minnesota Statutes, §§ 325D.52, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Minnesota; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Minnesota; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat.

b. During the Class Period, Boehringer's illegal conduct substantially affected Minnesota commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of Minnesota Statutes, §§ 325D.52, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Minnesota Statutes, §§ 325D.52, *et seq.*

Mississippi

227. By reason of the foregoing, Boehringer violated Mississippi Code, §§ 75-21-3, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price

competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Mississippi; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Mississippi; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Mississippi and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in Mississippi; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Mississippi and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Mississippi.

b. During the Class Period, Boehringer's illegal conduct substantially affected Mississippi commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of the Mississippi Code, §§ 75-21-3, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Mississippi Code §§ 75-21-3, *et seq.*

Nebraska

228. By reason of the foregoing, Boehringer violated Nebraska Revised Statutes, §§ 59-802, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Nebraska; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Nebraska; (3) the 1199SEIU Benefit Funds and members of the Damages Classes,

including those who resided in Nebraska and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in Nebraska; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Nebraska and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Nebraska.

b. During the Class Period, Boehringer's illegal conduct substantially affected Nebraska commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of the Nebraska Revised Statutes, §§ 59-802, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Nebraska Revised Statutes, §§ 59-802, *et seq.*

Nevada[183]

229. By reason of the foregoing, Boehringer violated Nevada Revised Statutes, §§ 598A.060, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Nevada; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Nevada; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Nevada and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were

[183] Plaintiffs' counsel will mail a copy of this class-action complaint to the Attorney General of Nevada as required by Nevada Revised Statute § 598A.210(3).

deprived of free and open competition, including in Nevada; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Nevada and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Nevada.

b. During the Class Period, Boehringer's illegal conduct substantially affected Nevada commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of the Nevada Revised Statutes, §§ 598A.060, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Nevada Revised Statutes, §§ 598A.060, *et seq.*

New Hampshire

230. By reason of the foregoing, Boehringer violated New Hampshire Revised Statutes, §§ 356:3, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout New Hampshire; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout New Hampshire; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in New Hampshire and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in New Hampshire; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in New Hampshire and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by

Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Nevada.

b. During the Class Period, Boehringer's illegal conduct substantially affected New Hampshire commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of New Hampshire Revised Statutes, §§ 356:3, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under New Hampshire Revised Statutes, §§ 356:3, *et seq.*

New Jersey

231. By reason of the foregoing, Boehringer violated New Jersey Statutes, §§ 56:9-4, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout New Jersey; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout New Jersey; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in New Jersey and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in New Jersey; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in New Jersey and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in New Jersey.

b. During the Class Period, Boehringer's illegal conduct substantially affected New Jersey commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of the New Jersey Statutes, §§ 56:9-4, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under New Jersey Statutes, §§ 56:9-4, *et seq.*

New Mexico

232. By reason of the foregoing, Boehringer violated New Mexico Statutes, §§ 57-1-2, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout New Mexico; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout New Mexico; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in New Mexico and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in New Mexico; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in New Jersey and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in New Mexico.

b. During the Class Period, Boehringer's illegal conduct substantially affected New Mexico commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of the New Mexico Statutes, §§ 57-1-2, *et seq.*

Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under New Mexico Statutes, §§ 57-1-12, *et seq.*

North Carolina

233. By reason of the foregoing, Boehringer violated North Carolina General Statutes §§ 75-2.1, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout North Carolina; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout North Carolina; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in North Carolina and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in North Carolina; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in North Carolina and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in North Carolina.

b. During the Class Period, Boehringer's illegal conduct substantially affected North Carolina commerce.

c. As a direct and proximate result of North Carolina unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, North Carolina monopolized or attempted to monopolize in violation of North Carolina General Statutes, §§ 75-2.1, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under North Carolina General Statutes, §§ 75-2.1, *et seq.*

North Dakota

234. By reason of the foregoing, Boehringer violated North Dakota Century Code, §§ 51-08.1-03, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout North Dakota; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout North Dakota; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in North Dakota and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in North Dakota; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in North Dakota and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in North Dakota.

b. During the Class Period, Boehringer's illegal conduct substantially affected North Dakota commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation of North Dakota Century Code, §§ 51-08.1-03, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under North Dakota Century Code, §§ 51-08.1-03, *et seq.*

Oregon

235. By reason of the foregoing, Boehringer violated Oregon Revised Statutes, §§ 646.730, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Oregon; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Oregon; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Oregon and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in Oregon; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Oregon and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Oregon.

b. During the Class Period, Boehringer's illegal conduct substantially affected Oregon commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of the Oregon Revised Statutes, §§ 646.730, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Oregon Revised Statutes, §§ 646.730, *et seq.*

Rhode Island[184]

236. By reason of the foregoing, Boehringer violated Rhode Island General Laws, §§ 6-36-5, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Rhode Island; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Rhode Island; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Rhode Island and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in Rhode Island; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Rhode Island and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Rhode Island.

b. During the Class Period, Boehringer's illegal conduct substantially affected Rhode Island commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of the Rhode Island General Laws, §§ 6-35-5, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Rhode Island General Laws, §§ 6-35-5, *et seq.*

[184] Plaintiffs' counsel will mail a copy of this class-action complaint to the Attorney General of Rhode Island and will file proof of service as required by Rhode Island General Laws § 6-36-21.

South Dakota

237. By reason of the foregoing, South Dakota violated South Dakota Codified Laws §§ 37-1-3.2, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout South Dakota; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout South Dakota; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in South Dakota and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in South Dakota; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in South Dakota and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in South Dakota.

b. During the Class Period, Boehringer's illegal conduct substantially affected South Dakota commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of the South Dakota Codified Laws §§ 37-1-3.2, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under South Dakota Codified Laws §§ 37-1-3.2, *et seq.*

Tennessee

238. By reason of the foregoing, Boehringer violated Tennessee Code §§ 47-25-101, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Tennessee; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Tennessee; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Tennessee and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of full and free competition, including in Tennessee; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Tennessee and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Tennessee.

b. During the Class Period, Boehringer's illegal conduct substantially affected Tennessee commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer's unlawful conduct lessened competition in violation of Tennessee Code §§ 47-25-101 *et seq.*, the 1199SEIU Benefit Funds and the Damages Classes seek all forms of relief available thereunder.

Utah[185]

239. By reason of the foregoing, Boehringer violated Utah Code §§ 76-10-3104, *et seq.*

The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Utah; (2) prices for Combivent Respimat and Spiriva Respimat were raised,

[185] Plaintiffs' counsel will mail a copy of this class-action complaint to the Attorney General of Utah and will file proof of service as required by Utah Code § 76-10-3109.

maintained, and stabilized at artificially high levels throughout Utah; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Utah and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in Utah; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Utah and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Utah.

b. During the Class Period, Boehringer's illegal conduct substantially affected Utah commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer's monopolized or attempted to monopolize in violation of Utah Code §§ 76-10-3104, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Utah Code §§ 76-10-3104, *et seq.*

Vermont

240. By reason of the foregoing, Boehringer violated Vermont Statutes 9 V.S. §§ 2453, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Vermont; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Vermont; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Vermont and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in Vermont; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Vermont and/or purchased Combivent Respimat and

Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Vermont.

b. During the Class Period, Boehringer's illegal conduct substantially affected Vermont commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of Vermont Statutes 9 V.S. §§ 2453, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Vermont Statutes 9 V.S. §§ 2453, *et seq.*

West Virginia

241. By reason of the foregoing, Boehringer violated West Virginia Code, §§ 47-18-1, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout West Virginia; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout West Virginia; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in West Virginia and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in West Virginia; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in West Virginia and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in West Virginia.

b. During the Class Period, Boehringer's illegal conduct substantially affected West Virginia commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer established, maintained, and used a monopoly, or attempted to monopolize in violation West Virginia Code §§ 47-18-1, *et seq.* Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under West Virginia Code §§ 47-18-1, *et seq.*

Wisconsin

242. By reason of the foregoing, Boehringer violated Wisconsin Statutes §§ 133.03, *et seq.* The 1199SEIU Benefit Funds on behalf of the Damages Classes allege as follows:

a. Boehringer's monopolization scheme, in the markets for Combivent Respimat and Spiriva Respimat had the following effects: (1) price competition for Combivent Respimat and Spiriva Respimat or generic versions was restrained, suppressed, and eliminated throughout Wisconsin; (2) prices for Combivent Respimat and Spiriva Respimat were raised, maintained, and stabilized at artificially high levels throughout Wisconsin; (3) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Wisconsin and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer were deprived of free and open competition, including in Wisconsin; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes, including those who resided in Wisconsin and/or purchased Combivent Respimat and Spiriva Respimat that was shipped by Boehringer, paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat, including in Wisconsin.

b. During the Class Period, Boehringer's illegal conduct substantially affected Wisconsin commerce.

c. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured in their business and property and are threatened with further injury.

d. By reason of the foregoing, Boehringer monopolized or attempted to monopolize in violation of Wisconsin Statutes §§ 133.03, *et seq.*

Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all forms of relief available under Wisconsin Statutes §§ 133.03, *et seq.*

COUNT IV
Violation of State Consumer Protection Statutes[186]
(On Behalf of 1199SEIU Benefit Funds and the Damages Classes)

243. Plaintiffs repeat and reallege the facts above.

244. Boehringer engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection and unfair competition statutes listed below.

Arkansas

245. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Arkansas Code Annotated, § 4-88-101, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Arkansas and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential

[186] Plaintiffs bring claims under the following jurisdictions: Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Dakota, Utah, Vermont, and Virginia.

consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Arkansas; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Arkansas; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Classes Period, Boehringer's illegal conduct substantially affected Arkansas commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of Arkansas Code Annotated, § 4-88-101, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

California

246. Boehringer has engaged in unlawful, unfair, or unconscionable, acts or practices in violation of California Business and Professions Code § 17200, *et seq.* During the Class Period, Boehringer manufactured, marketed, sold, or distributed generic Combivent Respimat and Spiriva Respimat in California, and committed and continue to commit acts of unfair competition, as defined by §§ 17200, *et seq.* of the California Business and Professions Code, by

causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain prices at non-competitive and artificially inflated levels. This claim is instituted pursuant to §§ 17203 and 17204 of the California Business and Professions Code, to obtain restitution from Boehringer for acts, as alleged herein, that violated § 17200 of the California Business and Professions Code, commonly known as the Unfair Competition Law. Boehringer's conduct as alleged herein violated § 17200. The acts, omissions, misrepresentations, practices and non-disclosures of Boehringer, as alleged herein, constituted a common, continuous, and continuing course of conduct of unfair competition by means of unfair and unlawful business acts or practices within the meaning of California Business and Professions Code §17200, *et seq.*, including, but not limited to, the following: the violation of Section 2 of the Sherman Act, as set forth above. Boehringer's acts and practices, as described above, whether or not in violation of § 16720, *et seq.* of the California Business and Professions Code, and whether or not concerted or independent acts, are otherwise unfair, unconscionable, or unlawful, and Boehringer's acts or practices are unfair to purchasers of Combivent Respimat and Spiriva Respimat in California within the meaning of § 17200, California Business and Professions Code. The 1199SEIU Benefit Funds and members of the Damages Classes are entitled to full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that have been obtained by Boehringer as a result of such business acts or practices. During the Class Period, Boehringer's illegal conduct substantially affected California commerce and consumers. The illegal conduct alleged herein is continuing and there is no indication that Boehringer will not continue such activity into the future. The unlawful and unfair business

practices of Boehringer, and each of them, as described above, have caused and continue to cause the 1199SEIU Benefit Funds and members of the Damages Classes to pay supracompetitive and artificially inflated prices for Combivent Respimat and Spiriva Respimat. The 1199SEIU Benefit Funds and members of the Damages Classes suffered injury in fact and lost money or property as a result of such unlawful and unfair competition. The conduct of Boehringer as alleged in this Complaint violates § 17200 of the California Business and Professions Code. As alleged in this Complaint, Boehringer has been unjustly enriched as a result of its wrongful conduct and unfair competition. The 1199SEIU Benefit Funds and members of the Damages Classes are accordingly entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by Boehringer as a result of such business practices, pursuant to the California Business and Professions Code, §§17203 and 17204.

Colorado

247. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Colorado Consumer Protection Act, Colorado Rev. Stat. §§ 6-1-101, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Colorado and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the

course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct significantly impacted the public through the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Colorado; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Colorado; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Colorado commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of Colorado Consumer Protection Act, Colorado Rev. Stat. §§ 6-1-101, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Connecticut[187]

248. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Connecticut General Statute §§ 42-110b, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Connecticut and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Connecticut; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Delaware; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct

[187] Plaintiffs' counsel will mail a copy of this class-action complaint to the Attorney General of Connecticut as required by Connecticut General Statute §§ 42-110b.

substantially affected Connecticut commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of Connecticut General Statute §§ 42-110b, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Delaware

249. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Delaware Consumer Fraud Act, 6 Del. Code § 2513, *et seq*. Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Delaware and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Delaware; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels

throughout Delaware; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Delaware commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of Delaware Consumer Fraud Act, 6 Del. Code §§ 2511, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

District of Columbia

250. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of District of Columbia Code §§ 28-3904, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in the District of Columbia and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds

and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalents price competition was restrained, suppressed, and eliminated throughout the District of Columbia; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout the District of Columbia; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected District of Columbia commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of District of Columbia Code § 28-3904, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Florida

251. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.204, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Florida

and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalents price competition was restrained, suppressed, and eliminated throughout Florida; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Florida; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Florida commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.204, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Hawaii

252. Boehringer has engaged in unfair competition or unfair, unconscionable acts or practices in violation of Hawaii Revised Statutes Annotated § 480-2, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Hawaii and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalents price competition was restrained, suppressed, and eliminated throughout Hawaii; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Hawaii; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Hawaii commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are

threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of Hawaii Revised Statutes Annotated §§ 480-2, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Illinois

253. Boehringer has engaged in unfair competition or unfair, unconscionable acts or practices in violation of 815 Illinois Compiled Statutes §§ 505/2, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Illinois and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalents price competition was restrained, suppressed, and eliminated throughout Illinois; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Illinois; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages

Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Illinois commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 Illinois Compiled Statutes §§ 505/2, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Iowa[188]

254. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Iowa Code §§ 714H.3, *et seq.* Boehringer, in a market that includes Massachusetts, knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain, at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Massachusetts and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the

[188] Plaintiffs' counsel will mail a copy of this class-action complaint to the Attorney General of Iowa as required by Iowa Code § 714H.6.

1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalents price competition was restrained, suppressed, and eliminated throughout Massachusetts; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Massachusetts; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Massachusetts commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Iowa Code §§ 714H.3, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Maine

255. Plaintiffs' counsel will mail a written demand for relief to defendants as required by 5 Maine Revised Statues § 213 and will amend their complaint to include the following violation if pre-suit resolution is not achieved: Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of 5 Maine Revised Statues § 207, *et seq.* Boehringer, in a market that includes Maine, knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and

delaying entry of a generic equivalent to maintain, at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Maine and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. The aforementioned conduct on Boehringer's part constituted "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce," in violation of Maine Revised Statues § 207, *et seq*. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalents price competition was restrained, suppressed, and eliminated throughout Maine; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Maine; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Maine commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation

of the Maine Revised Statues § 207, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Massachusetts

256. Plaintiffs' counsel will mail a written demand for relief to defendants as required by Massachusetts Gen. Laws, Ch. 93A, § 9 and will amend their complaint to include the following violation if pre-suit resolution is not achieved: Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Massachusetts Gen. Laws, Ch. 93A, §§ 1, *et seq.* Boehringer was engaged in trade or commerce as defined by G.L. 93A. Boehringer, in a market that includes Massachusetts, knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain, at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Massachusetts and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. The aforementioned conduct on Boehringer's part constituted "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce," in violation of Massachusetts Gen. Laws, Ch. 93A, § 2, 11. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic

equivalents price competition was restrained, suppressed, and eliminated throughout Massachusetts; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Massachusetts; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Massachusetts commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Massachusetts Gen. Laws, Ch. 93A, §§ 1, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Michigan

257. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Michigan Consumer Protection Statute, Mich. Compiled Laws §§ 445.903, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by maintaining at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Michigan and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the

course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalents price competition was restrained, suppressed, and eliminated throughout Michigan; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Michigan; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Michigan commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Michigan Consumer Protection Statute, Mich. Compiled Laws §§ 445.903, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Minnesota

258. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. §§ 325D.43, *et seq.* Boehringer knowingly acted in restraint of trade or commerce

by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Minnesota and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Minnesota; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Minnesota; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Minnesota commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. §§ 325D.43, *et seq.*, and,

accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Mississippi

259. Plaintiffs' counsel will mail a written demand for relief to defendants as required by Mississippi Code § 75-24-15 and will amend their complaint to include the following violation if pre-suit resolution is not achieved: Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Mississippi Code §§ 75-24-5, *et seq.* The 1199SEIU Benefit Funds and members of the Damages Classes purchased generic Combivent Respimat and Spiriva Respimat for personal or family purposes. Boehringer engaged in the conduct described herein in connection with the sale of Mississippi Respimat and Spiriva Respimat in trade or commerce in a market that includes Missouri. Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Mississippi, which conduct constituted unfair practices in that it was unlawful under federal and state law, violated public policy, was unethical, oppressive and unscrupulous, and caused substantial injury to the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer concealed, suppressed, and omitted to disclose material facts to the 1199SEIU Benefit Funds and members of the Damages Classes concerning Boehringer's unlawful activities and artificially inflated prices for Combivent Respimat and Spiriva Respimat. The concealed, suppressed, and omitted facts would have been

important to the 1199SEIU Benefit Funds and members of the Damages Classes as they related to the cost of Combivent Respimat and Spiriva Respimat they purchased—and the generic equivalents they would have purchased at lower cost. Boehringer misrepresented the validity of any basis for extending its Combivent Respimat and Spiriva Respimat monopoly, with Combivent Respimat and Spiriva Respimat priced higher and higher, by making public statements to cause the listing of ineligible device-only patents in the Orange book. Boehringer's statements and conduct concerning the price of Combivent Respimat and Spiriva Respimat were deceptive as they had the tendency or capacity to mislead the 1199SEIU Benefit Funds and members of the Damages Classes to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices established by free and fair market. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Mississippi; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Mississippi; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. The foregoing acts and practices substantially affected Mississippi commerce and consumers and constituted unlawful practices. As a direct and proximate result of the above-described unlawful practices, the 1199SEIU Benefit Funds and members of the Damages Classes suffered ascertainable loss of

money or property. Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under Mississippi Code §§ 75-24-5, *et seq.*

Missouri

260. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. §§ 407.010, *et seq.* The 1199SEIU Benefit Funds and members of the Damages Classes purchased generic Combivent Respimat and Spiriva Respimat for personal or family purposes. Boehringer engaged in the conduct described herein in connection with the sale of Combivent Respimat and Spiriva Respimat in trade or commerce in a market that includes Missouri. Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Missouri, which conduct constituted unfair practices in that it was unlawful under federal and state law, violated public policy, was unethical, oppressive and unscrupulous, and caused substantial injury to the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer concealed, suppressed, and omitted to disclose material facts to the 1199SEIU Benefit Funds and members of the Damages Classes concerning Boehringer's unlawful activities and artificially inflated prices for Combivent Respimat and Spiriva Respimat. The concealed, suppressed, and omitted facts would have been important to the 1199SEIU Benefit Funds and members of the Damages Classes as they related to the cost of Combivent Respimat and Spiriva Respimat they purchased—and the generic

equivalents they would have purchased at lower cost. Boehringer misrepresented the validity of any basis for extending its Combivent Respimat and Spiriva Respimat monopoly, with Combivent Respimat and Spiriva Respimat priced higher and higher, by making public statements to cause the listing of ineligible device-only patents in the Orange book. Boehringer's statements and conduct concerning the price of Combivent Respimat and Spiriva Respimat were deceptive as they had the tendency or capacity to mislead the 1199SEIU Benefit Funds and members of the Damages Classes to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices established by free and fair market. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Missouri; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Missouri; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. The foregoing acts and practices substantially affected Missouri commerce and consumers and constituted unlawful practices in violation of the Missouri Merchandising Practices Act. As a direct and proximate result of the above-described unlawful practices, the 1199SEIU Benefit Funds and members of the Damages Classes suffered ascertainable loss of money or property. Accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under Missouri's Merchandising Practices Act, specifically Mo. Rev. Stat. §§ 407.020, which prohibits

"[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce…", as further interpreted by the Missouri Code of State Regulations, 15 CSR 60-7.010, *et seq.*, 15 CSR 60-8.010, *et seq.*, and 15 CSR 60-9.010, *et seq.*, and Mo. Rev. Stat. § 407.025.

Montana

261. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Montana Unfair Trade Practices and Consumer Protection Act of 1970, Mont. Code, §§ 30-14-103, *et seq.*, and §§ 30-14-201, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Montana and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Montana; (2) Combivent Respimat and Spiriva

Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Montana; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Montana commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Montana Unfair Trade Practices and Consumer Protection Act of 1970, Mont. Code, § 30-14-103, *et seq.*, and § 30-14-201, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Nebraska

262. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. §§ 59-1602, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Nebraska and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the

course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Nebraska; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Nebraska; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected Nebraska commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. §§ 59-16012, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Nevada[189]

263. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0953, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Nevada. Boehringer deliberately failed to disclose material facts to the 1199SEIU Benefit Funds and members of the Damages Classes concerning Boehringer's unlawful activities and artificially inflated prices for Combivent Respimat and Spiriva Respimat. Boehringer's statements and conduct concerning the price of Combivent Respimat and Spiriva Respimat were deceptive as they had the tendency or capacity to mislead the 1199SEIU Benefit Funds and members of the Damages Classes to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices established by a free and fair market. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Nevada; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Nevada; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and

[189] Plaintiffs' counsel will mail a copy of the complaint to the Nevada Attorney General as required by Nevada Revised Statute § 598A.210(3).

members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct had a substantial effect on Nevada commerce and consumers. As a direct and proximate result of Boehringer's violations of law, the 1199SEIU Benefit Funds and members of the Damages Classes suffered an ascertainable loss of money or property as a result of Boehringer's use or employment of unconscionable and deceptive commercial practices as set forth above. That loss was caused by Boehringer's willful and deceptive conduct, as described herein. Boehringer's deception, including its affirmative misrepresentations and omissions concerning the validity of its patents, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices set by a free and fair market. Boehringer's misleading conduct and unconscionable activities constitute violations of Nev. Rev. Stat. §§ 598.0953, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

New Hampshire

264. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the New Hampshire Consumer Protection Act, N.H. Rev. Stat. §§ 358-A:2, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in New Hampshire and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and

members of the Damages Classes. Boehringer engaged in an unfair and deceptive trade practices during the course of its business dealings, which significantly affected the 1199SEIU Benefit Funds and the Classes as actual or potential consumers of the Boehringer's goods and which caused the 1199SEIU Benefit Funds and the Classes to suffer injury. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout New Hampshire; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout New Hampshire; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct substantially affected New Hampshire commerce and consumers. As a direct and proximate result of Boehringer's unlawful conduct, the 1199SEIU Benefit Funds and members of the Damages Classes have been injured and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of the New Hampshire Consumer Protection Act, N.H. Rev. Stat. §§ 358-A:2, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

New Jersey

265. Defendants have engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the New Jersey Consumer Fraud Act, N.J. Statutes

§§ 56:8-1, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in New Jersey. Boehringer deliberately failed to disclose material facts to the 1199SEIU Benefit Funds and members of the Damages Classes concerning Boehringer's unlawful activities and artificially inflated prices for Combivent Respimat and Spiriva Respimat. Boehringer's statements and conduct concerning the price of Combivent Respimat and Spiriva Respimat were deceptive as they had the tendency or capacity to mislead the 1199SEIU Benefit Funds and members of the Damages Classes to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices established by a free and fair market. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout New Jersey; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout New Jersey; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct had a substantial effect on New Jersey commerce and consumers. As a direct and proximate result of Boehringer's violations of law, the 1199SEIU Benefit Funds and members of the Damages Classes suffered an ascertainable loss of money or property as a result of

Boehringer's use or employment of unconscionable and deceptive commercial practices as set forth above. That loss was caused by Boehringer's willful and deceptive conduct, as described herein. Boehringer's deception, including its affirmative misrepresentations and omissions concerning the validity of its patents, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices set by a free and fair market. Boehringer's misleading conduct and unconscionable activities constitute violations of New Jersey Consumer Fraud Act, N.J. Statutes §§ 56:8-1, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

New Mexico

266. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the New Mexico Statute §§ 57-12-3, *et seq.* Boehringer acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to affect, control, and/or maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed or obtained in New Mexico and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. The aforementioned conduct on the part of Boehringer constituted "unconscionable trade practices," in violation of New Mexico Statute § 57-12-3, in that such conduct, *inter alia*, resulted in a gross disparity between the value received by the 1199SEIU Benefit Funds and members of the Damages Classes and the prices paid by them for Combivent Respimat and

Spiriva Respimat as set forth in New Mexico Statute § 57-12-2E. The 1199SEIU Benefit Funds and members of the Damages Classes were not aware that Boehringer had illegally extended its monopoly in the market for Combivent Respimat and Spiriva Respimat or generic equivalent, and were therefore unaware that they were being unfairly and illegally overcharged. Boehringer had the sole power to set that price during the Class Period, and the 1199SEIU Benefit Funds and members of the Damages Classes had no power to negotiate a lower price. Moreover, the 1199SEIU Benefit Funds and members of the Damages Classes lacked any meaningful choice in purchasing Combivent Respimat and Spiriva Respimat or generic equivalent because they were unaware of the unlawful overcharge due to the improperly procured extension of Boehringer's patent protection, and there was no reasonable alternative source of supply through which the 1199SEIU Benefit Funds and members of the Damages Classes could avoid the overcharges. Boehringer's conduct with regard to sales of Combivent Respimat and Spiriva Respimat, including its illegal conspiracy to secretly fix the price of Combivent Respimat and Spiriva Respimat at supracompetitive levels and overcharge consumers, was substantively unconscionable because it was one-sided and unfairly benefited Defendants at the expense of the 1199SEIU Benefit Funds and the public. Boehringer took grossly unfair advantage of the 1199SEIU Benefit Funds and members of the Damages Classes. The suppression of competition that has resulted from Boehringer's scheme has ultimately resulted in unconscionably higher prices for consumers so that there was a gross disparity between the price paid and the value received for Combivent Respimat and Spiriva Respimat. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price

competition was restrained, suppressed, and eliminated throughout New Mexico; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout New Mexico; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct had a substantial effect on New Mexico commerce and consumers. As a direct and proximate result of Boehringer's violations of law, the 1199SEIU Benefit Funds and members of the Damages Classes suffered an ascertainable loss of money or property as a result of Boehringer's use or employment of unconscionable and deceptive commercial practices as set forth above. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of New Mexico Statute §§ 57-12-3, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

New York

267. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of New York General Business Law §§ 349, *et seq.* Boehringer acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to affect, control, or maintain, at artificial and non-competitive levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed or obtained in New York and took efforts to conceal its

conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer made public statements to support those listings that were not in accord with the facts. Boehringer's statements were materially misleading; and Boehringer alone possessed material information that was relevant to consumers, but failed to provide the information. Because of Boehringer's unlawful trade practices in New York, New York Damages Classes members who indirectly purchased Combivent Respimat and Spiriva Respimat were misled to believe that they were paying a fair price for Combivent Respimat and Spiriva Respimat or the price increases for Combivent Respimat and Spiriva Respimat were for valid business reasons; and similarly situated consumers were affected by Boehringer's conduct. Boehringer knew that its unlawful trade practices with respect to Combivent Respimat and Spiriva Respimat would have an impact on New York consumers and not just Boehringer's direct customers. Boehringer knew that their unlawful trade practices with respect to pricing Combivent Respimat and Spiriva Respimat would have a broad impact, causing consumer Classes members who indirectly purchased Combivent Respimat and Spiriva Respimat to be injured by paying more for Combivent Respimat and Spiriva Respimat than they would have paid in the absence of Boehringer's unlawful trade acts and practices. Boehringer's conduct described herein constitutes consumer-oriented deceptive acts or practices within the meaning of New York General Business Law §§ 349, which resulted in consumer injury and broad adverse impact on the public at large, and harmed the public interest of consumers in New York State in an honest marketplace in which economic activity is conducted in a competitive manner. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price

competition was restrained, suppressed, and eliminated throughout New York; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout New York; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer marketed, sold, or distributed Combivent Respimat and Spiriva Respimat in New York, and Boehringer's illegal conduct substantially affected New York commerce and consumers. During the Class Period, Boehringer directly, or indirectly and through affiliates it dominated and controlled, manufactured, sold and/or distributed Combivent Respimat and Spiriva Respimat in New York. The 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available pursuant to New York General Business Law §§ 349(h).

North Carolina

268. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of North Carolina General Statute §§ 75-1.1, *et seq.* Boehringer acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain to affect, control, or maintain at artificial and non-competitive levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed or obtained in North Carolina and took efforts to conceal its conduct from the 1199SEIU Benefit Funds and members of the Damages Classes. Boehringer's recertification of its device-only patents to the FDA was not in accord

with the facts. Boehringer's statements were materially misleading; and Boehringer alone possessed material information that was relevant to consumers, but failed to provide the information. Boehringer's described herein constitutes consumer-oriented deceptive acts or practices within the meaning of North Carolina law, which resulted in consumer injury and broad adverse impact on the public at large, and harmed the public interest of North Carolina consumers in an honest marketplace in which economic activity is conducted in a competitive manner. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout North Carolina; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout North Carolina; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer marketed, sold, or distributed Combivent Respimat and Spiriva Respimat in North Carolina, and Boehringer's illegal conduct substantially affected North Carolina commerce and consumers. During the Class Period, Boehringer directly, or indirectly and through affiliates it dominated and controlled, manufactured, sold, or distributed Combivent Respimat and Spiriva Respimat in North Carolina. The 1199SEIU Benefit Funds and members of the Damages Classes seek actual damages for their injuries caused by these violations in an amount to be determined at trial and are threatened with further injury. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation

of North Carolina General Statute §§ 75-1.1, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

North Dakota

269. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the North Dakota Unlawful Sales or Advertising Practices Statute, North Dakota Century Code §§ 51-15-02, *et seq.* Boehringer acted in restraint of trade or commerce in North Dakota, by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain to affect, control, or maintain at artificial and non-competitive levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in North Dakota. Boehringer's recertification of its device-only patents to the FDA was not in accord with the facts. Boehringer's statements were materially misleading; and Boehringer alone possessed material information that was relevant to consumers, but failed to provide the information. Boehringer misrepresented to all purchasers during the Class Period that Combivent Respimat and Spiriva Respimat prices were competitive and fair. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout North Dakota; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout North Dakota; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for

Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct had a substantial effect on North Dakota commerce and consumers. As a direct and proximate result of Boehringer's violations of law, the 1199SEIU Benefit Funds and members of the Damages Classes suffered an ascertainable loss of money or property as a result of Boehringer's use or employment of unconscionable and deceptive commercial practices as set forth above. Boehringer's deception, including its affirmative misrepresentations and omissions in support of the listings, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices set by a free and fair market. Boehringer's misleading conduct and unconscionable activities constitute violations of North Dakota Century Code §§ 51-15-02, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Rhode Island

270. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Rhode Island Unfair Trade Practice and Consumer Protection Act, R.I. Gen. Laws §§ 6-13.1-2, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain to affect, control, or maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Rhode Island. Boehringer deliberately failed to disclose material facts to the 1199SEIU Benefit Funds and members of the Damages Classes concerning Boehringer's unlawful activities and artificially inflated prices for Combivent

Respimat and Spiriva Respimat. Boehringer's statements and conduct concerning the eligibility of its patents for listing in the Orange book and the price of Combivent Respimat and Spiriva Respimat were deceptive as they had the tendency or capacity to mislead the 1199SEIU Benefit Funds and members of the Damages Classes to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices established by a free and fair market. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Rhode Island; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Rhode Island; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct had a substantial effect on Rhode Island commerce and consumers. As a direct and proximate result of Boehringer's violations of law, the 1199SEIU Benefit Funds and members of the Damages Classes suffered an ascertainable loss of money or property as a result of Boehringer's use or employment of unconscionable and deceptive commercial practices as set forth above. That loss was caused by Boehringer's willful and deceptive conduct, as described herein. Boehringer's deception, including its affirmative misrepresentations and omissions concerning the eligibility of its patents, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices set by a free and fair market. Boehringer's

misleading conduct and unconscionable activities constitute violations of Rhode Island General Laws §§ 6-13.1-2, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

South Dakota

271. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the South Dakota Deceptive Trade Practices and Consumer Protection Statute, S.D. Codified Laws §§ 37-24-6, *et seq.* Boehringer acted in restraint of trade or commerce in South Dakota, by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain to affect, control, or maintain at artificial and non-competitive levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in South Dakota. Boehringer deliberately failed to disclose material facts to the 1199SEIU Benefit Funds and members of the Damages Classes concerning Boehringer's unlawful activities and artificially inflated prices for Combivent Respimat and Spiriva Respimat. Boehringer misrepresented to all purchasers during the Class Period that Combivent Respimat and Spiriva Respimat prices were competitive and fair. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout South Dakota; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout South Dakota; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid

supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. Boehringer's illegal conduct substantially affected South Dakota commerce and consumers. As a direct and proximate result of Boehringer's violations of law, the 1199SEIU Benefit Funds and members of the Damages Classes suffered an ascertainable loss of money or property as a result of Boehringer's willful use or employment of unconscionable and deceptive commercial practices as set forth above. Boehringer's deception, including their affirmative misrepresentations and omissions concerning the price of Combivent Respimat and Spiriva Respimat, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices set by a free and fair market. Boehringer's affirmative misrepresentations and omissions constitute information important to the 1199SEIU Benefit Funds and members of the Damages Classes as they related to the cost of Combivent Respimat and Spiriva Respimat they purchased. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws §§ 37-24-6, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Utah

272. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Utah Consumer Sales Practices Act, Utah Statute §§ 13-11-4, *et seq.* The 1199SEIU Benefit Funds and members of the Damages Classes purchased Combivent Respimat and Spiriva Respimat for personal, family, or household purposes. Boehringer agreed to, and did in fact, act in restraint of trade or commerce in a market

that includes Utah, by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain to affect, control, or maintain at artificial and non-competitive levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Utah. Boehringer deliberately failed to disclose material facts to the 1199SEIU Benefit Funds and members of the Damages Classes concerning Boehringer's unlawful activities and artificially inflated prices for Combivent Respimat and Spiriva Respimat. Boehringer owed a duty to disclose such facts, and considering the relative lack of sophistication of the average, non-business purchaser, Boehringer breached that duty by its silence. Boehringer misrepresented to all purchasers during the Class Period that Combivent Respimat and Spiriva Respimat prices were competitive and fair. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Utah; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Utah; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. Boehringer's illegal conduct substantially affected Utah commerce and consumers. As a direct and proximate result of Boehringer's violations of law, the 1199SEIU Benefit Funds and members of the Damages Classes suffered an ascertainable loss of money or property as a result of Boehringer's use or employment of unconscionable and deceptive commercial practices as set forth above and are threatened with further injury. That loss was

caused by Boehringer's willful and deceptive conduct, as described herein. Boehringer's deception, including its affirmative misrepresentations and omissions concerning the listing of ineligible patents in the Orange book and the price of Combivent Respimat and Spiriva Respimat, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices set by a free and fair market. Boehringer's affirmative misrepresentations and omissions constitute information important to the 1199SEIU Benefit Funds and members of the Damages Classes as they related to the cost of Combivent Respimat and Spiriva Respimat they purchased. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Statute § 13-11-4 *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute and as equity demands.

Vermont

273. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of 9 Vermont Statutes §§ 2453, *et seq.* Boehringer knowingly acted in restraint of trade or commerce by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain to affect, control, or maintain at non-competitive and artificially inflated levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Vermont. Boehringer deliberately failed to disclose material facts to the 1199SEIU Benefit Funds and members of the Damages Classes concerning Boehringer's unlawful activities and artificially inflated prices for Combivent Respimat and Spiriva Respimat. Boehringer's statements and

conduct concerning the price of Combivent Respimat and Spiriva Respimat were deceptive as they had the tendency or capacity to mislead the 1199SEIU Benefit Funds and members of the Damages Classes to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices established by a free and fair market. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Vermont; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Vermont; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. During the Class Period, Boehringer's illegal conduct had a substantial effect on Vermont commerce and consumers. As a direct and proximate result of Boehringer's violations of law, the 1199SEIU Benefit Funds and members of the Damages Classes suffered an ascertainable loss of money or property as a result of Boehringer's use or employment of unconscionable and deceptive commercial practices as set forth above. That loss was caused by Boehringer's willful and deceptive conduct, as described herein. Boehringer's deception, including its affirmative misrepresentations and omissions concerning the validity of its patents, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices set by a free and fair market. Boehringer's misleading conduct and unconscionable activities constitutes unfair competition or unfair or deceptive acts or practices in violation of 9

Vt. Stat. §§ 2453, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

Virginia

274. Boehringer has engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Virginia Consumer Protection Act of 1977, Va. Code §§ 59.1-200, *et seq*. Boehringer acted in restraint of trade or commerce in Virginia, by causing ineligible device-only patents to be listed in the Orange book and delaying entry of a generic equivalent to maintain to affect, control, or maintain at artificial and non-competitive levels, the prices at which Combivent Respimat and Spiriva Respimat was sold, distributed, or obtained in Virginia. Boehringer deliberately failed to disclose material facts to the 1199SEIU Benefit Funds and members of the Damages Classes concerning Boehringer's unlawful activities and artificially inflated prices for Combivent Respimat and Spiriva Respimat. Boehringer misrepresented to all purchasers during the Class Period that Combivent Respimat and Spiriva Respimat prices were competitive and fair. Boehringer's unlawful conduct had the following effects: (1) Combivent Respimat and Spiriva Respimat or generic equivalent price competition was restrained, suppressed, and eliminated throughout Virginia; (2) Combivent Respimat and Spiriva Respimat prices were raised, maintained, and stabilized at artificially high levels throughout Virginia; (3) the 1199SEIU Benefit Funds and members of the Damages Classes were deprived of free and open competition; and (4) the 1199SEIU Benefit Funds and members of the Damages Classes paid supracompetitive, artificially inflated prices for Combivent Respimat and Spiriva Respimat. Boehringer's illegal conduct substantially affected Virginia

commerce and consumers. As a direct and proximate result of Boehringer's violations of law, the 1199SEIU Benefit Funds and members of the Damages Classes suffered an ascertainable loss of money or property as a result of Boehringer's willful use or employment of unconscionable and deceptive commercial practices as set forth above. Boehringer's deception, including their affirmative misrepresentations and omissions concerning listings of its ineligible patents in the Orange book and the price of Combivent Respimat and Spiriva Respimat, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing Combivent Respimat and Spiriva Respimat at prices set by a free and fair market. Boehringer's affirmative misrepresentations and omissions constitute information important to the 1199SEIU Benefit Funds and members of the Damages Classes as they related to the cost of Combivent Respimat and Spiriva Respimat they purchased. Boehringer has engaged in unfair competition or unfair or deceptive acts or practices in violation of Virginia Code §§ 59.1-200, *et seq.*, and, accordingly, the 1199SEIU Benefit Funds and members of the Damages Classes seek all relief available under that statute.

COUNT V
Unjust Enrichment
(On Behalf of 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes)

275. Plaintiffs repeat and reallege the facts above.

276. This claim is pleaded in the alternative to the extent required by law.

277. Boehringer has unlawfully benefited from its sales of Combivent Respimat and Spiriva Respimat because of the unlawful and inequitable acts alleged in this Complaint. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or

reimbursements for Combivent Respimat and Spiriva Respimat at prices that were more than they would have been but for Boehringer's unlawful actions.

278. Boehringer's financial benefits resulting from its unlawful and inequitable acts are traceable to overpayments by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

279. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred upon Boehringer an economic benefit, in the nature of profits resulting from unlawful overcharges, to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

280. Boehringer has been enriched by revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat while the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have been impoverished by the overcharges they paid for Combivent Respimat and Spiriva Respimat imposed through Boehringer's unlawful conduct. Boehringer's enrichment and the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes' impoverishment are connected.

281. There is no justification for Boehringer's retention of, and enrichment from, the benefits it received, which caused impoverishment to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes, because the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes paid supracompetitive prices that inured to Boehringer's benefit, and it would be inequitable for Boehringer to retain any revenue gained from its unlawful overcharges.

282. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes did not interfere with Boehringer's affairs in any manner that conferred these benefits upon Boehringer.

283. The benefits conferred upon Boehringer were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Boehringer's illegal and unfair actions to inflate the prices of Combivent Respimat and Spiriva Respimat.

284. The benefits conferred upon Boehringer are measurable, in that the revenue Boehringer has earned due to its unlawful overcharges of Combivent Respimat and Spiriva Respimat is ascertainable by review of sales records.

285. It would be futile for the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes to seek a remedy from any party with whom they have privity of contract. Boehringer has paid no consideration to any other person for any of the unlawful benefits it received indirectly from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes with respect to Boehringer's sales of Combivent Respimat and Spiriva Respimat.

286. Exhaustion of remedies against the immediate intermediary in the chain of distribution from Plaintiffs and the class indirectly purchased Combivent Respimat and Spiriva Respimat would be futile because the intermediaries are not liable and cannot reasonably be expected to compensate the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

287. The economic benefit of overcharges and monopoly profits derived by Boehringer through charging supracompetitive and artificially inflated prices for Combivent Respimat and Spiriva Respimat is a direct and proximate result of Boehringer's unlawful practices.

288. The financial benefits derived by Boehringer rightfully belong to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes, because the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes paid supracompetitive prices during the Class Period, inuring to the benefit of Boehringer.

289. Under unjust enrichment principles under the laws of all States and of the District of Columbia, Puerto Rico and the U.S. Virgin Islands, it would be inequitable for Boehringer to be permitted to retain any of the overcharges for Combivent Respimat and Spiriva Respimat derived from Boehringer's unlawful, unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

290. Boehringer is aware of and appreciates the benefits bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer consciously accepted the benefits and continues to do so as of the date of this filing.

291. Boehringer should disgorge in a common benefit Funds for the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes all unlawful or inequitable proceeds it received from its sales of Combivent Respimat and Spiriva Respimat.

292. A constructive trust should be imposed upon all unlawful or inequitable sums received by Boehringer traceable to indirect purchases of Combivent Respimat and Spiriva Respimat by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

293. No adequate remedy at law exists for the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

294. Boehringer has been unjustly enriched in violation of the common law of various states, as outlined below

Alabama

295. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Alabama at prices that were more than they would have been but for Boehringer's actions. Boehringer received money from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes as a direct result of the unlawful overcharges, and has retained this money. Boehringer has benefitted at the expense of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes from revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat. It is inequitable for Boehringer to accept and retain the benefits received without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Alaska

296. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Alaska at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Boehringer appreciated the benefits bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer accepted and retained the benefits bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Arizona

297. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Arizona at prices that were more than they would have been but for Boehringer's actions. Boehringer has been enriched by revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have been impoverished by the overcharges for Combivent Respimat and Spiriva Respimat resulting from Boehringer's unlawful conduct. Boehringer's enrichment and the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes' impoverishment are connected. There is no justification for Boehringer's receipt of the benefits causing its enrichment and the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes' impoverishment, because the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes paid supracompetitive prices that inured to Boehringer's benefit, and it would be inequitable for Boehringer to retain any revenue gained from its unlawful overcharges. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have no remedy at law.

Arkansas

298. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Arkansas at prices that were more than they would have been but for Boehringer's actions. Boehringer received money from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes as a direct result of the unlawful overcharges, and has retained this money. Boehringer has paid no consideration to any other person in exchange for this money. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

California

299. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in California at prices that were more than they would have been but for Boehringer's actions. Boehringer has received a benefit from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes as a direct result of the unlawful overcharges. Boehringer retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Colorado

300. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Colorado at prices that were more than they would have been but for Boehringer's actions. Boehringer has

received a benefit from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Boehringer. Boehringer has benefitted at the expense of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Connecticut

301. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Connecticut at prices that were more than they would have been but for Boehringer's actions. Boehringer benefitted in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer has paid no consideration to any other person in exchange for this benefit. Boehringer retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Delaware

302. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Delaware at prices that were more than they would have been but for Boehringer's actions. Boehringer has been enriched by revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes

have been impoverished by the overcharges for Combivent Respimat and Spiriva Respimat resulting from Boehringer's unlawful conduct. Boehringer's enrichment and the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes' impoverishment are connected. There is no justification for Boehringer's receipt of the benefits causing its enrichment, because the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes paid supracompetitive prices that inured to Boehringer's benefit, and it would be inequitable for Boehringer to retain any revenue gained from its unlawful overcharges. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have no remedy at law.

District of Columbia

303. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in the District of Columbia at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable and unjust for Boehringer to retain such benefits.

Florida

304. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Florida at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer appreciated the benefits bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Georgia

305. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Georgia at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Hawaii

306. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Hawaii at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Idaho

307. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Idaho at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer appreciated the benefit conferred upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Illinois

308. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Illinois at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. It is against equity, justice, and good conscience for Boehringer to be permitted to retain the revenue resulting from its unlawful overcharges.

Iowa

309. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Iowa at prices that were more than they would have been but for Boehringer's actions. Boehringer has been enriched by revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat, which revenue resulted from anticompetitive prices paid by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes, which inured to Boehringer's benefit. Boehringer's enrichment has occurred at the expense of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be unjust for

Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Kansas

310. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Kansas at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Kentucky

311. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Kentucky at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Boehringer appreciated the benefit conferred upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Louisiana

312. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Louisiana at prices that were more than they would have been but for Boehringer's actions. Boehringer has been enriched by revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have been impoverished by the overcharges for Combivent Respimat and Spiriva Respimat resulting from Boehringer's unlawful conduct. Boehringer's enrichment and the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes' impoverishment are connected. There is no justification for Boehringer's receipt of the benefits causing its enrichment, because the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes paid supracompetitive prices that inured to Boehringer's benefit, and it would be inequitable for Boehringer to retain any revenue gained from its unlawful overcharges. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have no other remedy at law.

Maine

313. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Maine at

prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer was aware of or appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Maryland

314. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Maryland at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer was aware of or appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Massachusetts

315. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Massachusetts at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer was aware of or appreciated the benefit conferred upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Michigan

316. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Michigan at prices that were more than they would have been but for Boehringer's actions. Boehringer has received a benefit from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Boehringer. Boehringer retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the

circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Minnesota

317. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Minnesota at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer appreciated and knowingly accepted the benefits bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Mississippi

318. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Mississippi at prices that were more than they would have been but for Boehringer's actions. Boehringer received money from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes as a direct result of the unlawful overcharges. Boehringer retained the benefit of overcharges received on the sales of Combivent Respimat and Spiriva Respimat, which in equity and good conscience belong to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes

because of Boehringer's anticompetitive conduct. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Missouri

319. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Missouri at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Montana

320. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Montana at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under

the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Nebraska

321. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Nebraska at prices that were more than they would have been but for Boehringer's actions. Boehringer received money from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes as a direct result of the unlawful overcharges, and has retained this money. Boehringer has paid no consideration to any other person in exchange for this money. In justice and fairness, Boehringer should disgorge such money and remit the overcharged payments back to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Nevada

322. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Nevada at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer in the nature of revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat. Boehringer appreciated the benefits bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes, for which it has paid no consideration to any other person. Under the circumstances, it would be inequitable for

Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

New Hampshire

323. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in New Hampshire at prices that were more than they would have been but for Boehringer's actions. Boehringer has received a benefit from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Boehringer. Under the circumstances, it would be unconscionable for Boehringer to retain such benefits.

New Jersey

324. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in New Jersey at prices that were more than they would have been but for Boehringer's actions. Boehringer has received a benefit from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Boehringer. The benefits conferred upon Boehringer were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer has paid no consideration to any other person for any of the unlawful benefits it received from the 1199SEIU Benefit Funds and the

Nationwide Equitable Relief Classes with respect to Boehringer's sales of Combivent Respimat and Spiriva Respimat. Under the circumstances, it would be unjust for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

New Mexico

325. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in New Mexico at prices that were more than they would have been but for Boehringer's actions. Boehringer has knowingly benefitted at the expense of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes from revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat. To allow Boehringer to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Boehringer's benefit and because Boehringer has paid no consideration to any other person for any of the benefits it received.

New York

326. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in New York at prices that were more than they would have been but for Boehringer's actions. Boehringer has been enriched by revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat, which revenue resulted from anticompetitive prices paid by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes, which inured to Boehringer's

benefit. Boehringer's enrichment has occurred at the expense of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. It is against equity and good conscience for Boehringer to be permitted to retain the revenue resulting from its unlawful overcharges.

North Carolina

327. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in North Carolina at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes did not interfere with Boehringer's affairs in any manner that conferred these benefits upon Boehringer. The benefits conferred upon Boehringer were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. The benefits conferred upon Boehringer are measurable, in that the revenue Boehringer has earned due to unlawful overcharges are ascertainable by review of sales records. Boehringer consciously accepted the benefits conferred upon it.

North Dakota

328. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in North Dakota

at prices that were more than they would have been but for Boehringer's actions. Boehringer has been enriched by revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have been impoverished by the overcharges for Combivent Respimat and Spiriva Respimat resulting from Boehringer's unlawful conduct. Boehringer's enrichment and the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes' impoverishment are connected. There is no justification for Boehringer's receipt of the benefits causing its enrichment, because the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes paid supracompetitive prices that inured to Boehringer's benefit, and it would be inequitable for Boehringer to retain any revenue gained from its unlawful overcharges. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have no remedy at law. Under the circumstances, it would be unjust for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Oklahoma

329. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Oklahoma at prices that were more than they would have been but for Boehringer's actions. Boehringer received money from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes as a direct result of the unlawful overcharges, and has retained this money. Boehringer has paid no consideration to any other person in exchange for this money. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have no remedy at law. It is against equity and

good conscience for Boehringer to be permitted to retain the revenue resulting from its unlawful overcharges.

Oregon

330. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Oregon at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer was aware of the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be unjust for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Pennsylvania

331. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Pennsylvania at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the

Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Puerto Rico

332. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Puerto Rico at prices that were more than they would have been but for Boehringer's actions. Boehringer has been enriched by revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have been impoverished by the overcharges for Combivent Respimat and Spiriva Respimat resulting from Boehringer's unlawful conduct. Boehringer's enrichment and the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes' impoverishment are connected. There is no justification for Boehringer's receipt of the benefits causing its enrichment and the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes' impoverishment, because the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes paid supracompetitive prices that inured to Boehringer's benefit, and it would be inequitable for Boehringer to retain any revenue gained from its unlawful overcharges. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have no remedy at law.

Rhode Island

333. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Rhode Island

at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

South Carolina

334. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in South Carolina at prices that were more than they would have been but for Boehringer's actions. The benefits conferred upon Boehringer were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer realized value from the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

South Dakota

335. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in South Dakota

at prices that were more than they would have been but for Boehringer's actions. Boehringer has received a benefit from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Boehringer. Boehringer was aware of the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable and unjust for Boehringer to retain such benefits without reimbursing the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Tennessee

336. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Tennessee at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. It would be futile for the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes to seek a remedy from any party with whom they have privity of contract. Boehringer has paid no consideration to any other person for any of the

unlawful benefits it received indirectly from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes with respect to Boehringer's sales of Combivent Respimat and Spiriva Respimat. It would be futile for the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes to exhaust all remedies against the entities with which the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have privity of contract because the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes did not purchase Combivent Respimat and Spiriva Respimat directly from Boehringer.

Texas

337. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Texas at prices that were more than they would have been but for Boehringer's actions. Boehringer has received a benefit from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Boehringer. Boehringer was aware of or appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. The circumstances under which Boehringer has retained the benefits bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes are inequitable in that they result from Boehringer's unlawful overcharges for Combivent Respimat and Spiriva Respimat. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have no remedy at law.

Utah

338. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Utah at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer was aware of or appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Vermont

339. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Vermont at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer accepted the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for

Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Virginia

340. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Virginia at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer was aware of the benefit bestowed upon it. Boehringer should reasonably have expected to repay the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. The benefits conferred upon Boehringer were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Boehringer's illegal and unfair actions to inflate the prices of Combivent Respimat and Spiriva Respimat. Boehringer has paid no consideration to any other person for any of the benefits it has received from the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Washington

341. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Washington at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit

upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer was aware of or appreciated the benefit conferred upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

West Virginia

342. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in West Virginia at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer was aware of or appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Wisconsin

343. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Wisconsin at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU

Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

Wyoming

344. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in Wyoming at prices that were more than they would have been but for Boehringer's actions. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have conferred an economic benefit upon Boehringer, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer accepted, used and enjoyed the benefits bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Under the circumstances, it would be inequitable for Boehringer to retain such benefits without compensating the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes.

U.S. Virgin Islands

345. Boehringer unlawfully overcharged the 1199SEIU Benefit Funds, who made purchases of or reimbursements for Combivent Respimat and Spiriva Respimat in the United

States Virgin Islands at prices that were more than they would have been but for Boehringer's actions. Boehringer has been enriched by revenue resulting from unlawful overcharges for Combivent Respimat and Spiriva Respimat, which revenue resulted from anticompetitive prices paid by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes, which inured to Boehringer's benefit. Boehringer's enrichment has occurred at the expense of the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. Boehringer appreciated the benefit bestowed upon it by the 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes. It is against equity and good conscience for Boehringer to be permitted to retain the revenue resulting from its unlawful overcharges. The 1199SEIU Benefit Funds and the Nationwide Equitable Relief Classes have no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, the 1199SEIU Benefit Funds, on behalf of themselves and the Classes, pray that the Court:

346. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Classes, and declare the 1199SEIU Benefit Funds as named representatives of the Classes;

347. Enter judgment against Defendants and in favor of the 1199SEIU Benefit Funds and the Classes;

348. Award the Damages Classes treble damages, plus interest in accordance with law;

349. Award the 1199SEIU Benefit Funds and the Classes their costs of suit, including reasonable attorneys' fees as provided by law;

350. Enter an injunction enjoining Defendants' device-only Orange book listings and enforcement of those patents; and

351. Award such further and additional relief as is necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, the 1199SEIU Benefit Funds, on behalf of themselves and the proposed Classes, demand a trial by jury.

Dated: April 29, 2024

Respectfully submitted,

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