UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

MASSACHUSETTS LABORERS' HEALTH & WELFARE FUND, on behalf of itself and others similarly situated,

Plaintiffs,

v.

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

Defendants.

Civ. No. 1:24-cv-10565

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT
AND DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

I. INTRODUCTION

1. The federal drug laws strike a careful balance between rewarding Adrugmakers for innovation and ensuring public access to medication at reasonable prices. To incentivize innovation, brand-name drugmakers receive a period of patent exclusivity during which they can—and do—charge astronomical prices for life-saving medications. Immediately after that exclusivity period ends, however, the drug laws allow affordable generic products to enter the market.

2. While generic products save billions of dollars a year for patients, health plans, and other entities that pay for prescription medication, they are a threat to brand-name drugmakers' thirst for profits. Once a generic drug enters the market, it quickly erodes brand-name sales and, in turn, profits. As a result, some brand-name drugmakers seek to unlawfully prolong their period of patent exclusivity through a variety of anticompetitive and deceptive tactics.

3. The defendants in this action, Boehringer Ingelheim Pharmaceuticals, Inc. and its parent company, Boehringer Ingelheim International GmbH, have hatched and executed a scheme—the Respimat Orange Book scheme—to unlawfully thwart generic competition in multiple markets—including those for Combivent Respimat and its generic equivalents, and Spiriva Respimat and its generic equivalents.

4. Combivent Respimat and Spiriva Respimat are both drug-device combinations. Combivent Respimat is a combination of two medicines: ipratropium bromide (an anticholinergic) and albuterol sulfate (a beta$_2$-adrenergic agonist). It is approved for the treatment of chronic obstructive pulmonary disease (or COPD) that

is inadequately controlled by albuterol alone. Spiriva Respimat, which contains an anticholinergic called tiotropium bromide, is approved as a once-daily maintenance treatment for the symptoms of COPD, and as a maintenance treatment for asthma in patients over five years old.

5. Today, Boehringer (defined below) sells both medicines in its proprietary inhaler, the Respimat. But that was not always the case. Both products are tweaks to older products on which Boehringer has already enjoyed many years of monopoly profits at a rate of billions of dollars a year. For half a century, Boehringer has sold products containing ipratropium bromide. For almost thirty years, it has sold a product combining ipratropium bromide and albuterol sulfate, called Combivent. And for nearly twenty years, Boehringer enjoyed monopoly profits over a tiotropium bromide product called Spiriva—for a long time the company's best-selling product which only finally faced generic competition this year.

6. But Boehringer was not satisfied with its astounding profits on Combivent, Spiriva, and its other related products. So, in the early 2000s, it developed a new "soft mist" inhaler as a guise to seek approval for a new product, and thwart the generic competition it knew was approaching.

7. Boehringer's older products were all sold in a standard "metered dose" inhaler—a common design used by dozens of drug companies to dispense hundreds of other respiratory drug products. Several such inhalers are available in the public domain, and so once a generic drugmaker developed its own version of the medication inside of Boehringer's Combivent and Spiriva, the U.S. Food and Drug

Administration (FDA) approval of generic drug competition would not be far behind. For Boehringer, this would not do.

8. Boehringer designed an inhaler that looks different—and in which the medication cannister is seated differently. Whereas most standard inhalers have an L-shaped design, which holds the cannister of medication upright during administration, the Respimat device was designed so that the medication cannister was held horizontally while dispensing the drug. This was not a difference intended to confer some medical benefit on patients.

9. The purpose of the Respimat device's different design was its patentability. Boehringer obtained patents claiming this Respimat device—none of which validly claimed the drug substances ipratropium bromide, tiotropium bromide, or albuterol sulfate or the drug products in Combivent Respimat and Spiriva Respimat—and then used those patents to block generic competitors from eroding its multi-billion dollar sales on its Combivent and Spiriva franchises.

10. Brand-name drugmakers are required to truthfully and accurately identify to the FDA any patents which "claim[] the drug" in its product. Patents which claim the drug—meaning the active ingredient is contained within the patent's claims—must be listed. Patents which do not claim the drug (or a method of using a drug) must not be listed. The patents the brand company identifies are then listed in the FDA's compendium of products and their related patents, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the Orange Book.

11. Listing a patent in the Orange Book has important implications on competition. A drugmaker seeking to introduce an affordable generic version of an expensive brand-name drug, like Combivent Respimat or Spiriva Respimat, must either await the expiration of all listed patents, or else certify to the FDA that it believes the patents are invalid or not infringed by the proposed generic drug. A long list of patents in the Orange Book may deter a generic company from even beginning the drug development process at all. But even if a generic applicant opts to challenge the patents, the mere fact of the patent listings may delay generic competition. The brand-name drugmaker may—if certain conditions are satisfied—sue its would-be competitor before the generic product even comes to market. A timely lawsuit automatically delays approval of any generic products for two and a half years.

12. This regulatory process is intended to help speed generic products to market—the Orange Book listing requirements are meant to give a generic company notice of what intellectual property interests it must design around in order to bring affordable medications to market; the pre-marketing lawsuit process and two-and-a-half year delay is intended to facilitate resolution of intellectual property disputes without a risk to the generic competitor of ruinous monetary damages.

13. Boehringer has hijacked this pro-generic legal and regulatory framework, and repurposed it to delay generic competition.

14. By the time the FDA approved Combivent Respimat, any patents over ipratropium bromide or albuterol sulfate (or the combination of ipratropium bromide and albuterol sulfate) had long since expired. Boehringer should have faced robust

generic competition for Combivent Respimat in or around February 2020. When the FDA approved Spiriva Respimat, Boehringer had only a few remaining patents that claimed the drug tiotropium bromide—and those expired in 2020.

15. So Boehringer hatched and executed a scheme to protect its billions in profits from its COPD franchises. It improperly submitted twenty-three patents to the FDA for listing in the Orange Book as claiming Combivent Respimat, Spiriva Respimat, or both. Six of those patents remain listed today. Those patents are:

- U.S. Patent No. 7,284,474;
- U.S. Patent No. 7,396,341;
- U.S. Patent No. 7,837,235;
- U.S. Patent No. 7,896,264;
- U.S. Patent No. 8,733,341; and
- U.S. Patent No. 9,027,967.

All of these patents claim an inhaler device or a mechanical component of that device. One claims a piston-pumping system. One a means of stopping the flow of gas past a spring-actuated output drive. Two a fluidic clamp. A high-pressure nozzle. And an atomizer. Not one of these patents claims tiotropium bromide, ipratropium bromide, or albuterol sulfate in any valid claim. None of them, therefore, could lawfully be listed in the Orange Book.

16. That did not stop Boehringer. It caused the patents to be listed, pretending that it had a lawful monopoly over the drug substances in Combivent Respimat and Spiriva Respimat until 2030, even though lawful patent protection over those drugs has long ago expired. Then, when a would-be competitor sought FDA

approval to make affordable generic versions of Combivent Respimat and Spiriva Respimat, Boehringer leveraged its improper listings to sue its would-be competitor in June of 2023, which may delay any generic competition until December 2025, if not longer, absent prompt intervention from the Court. And, to protect its anticompetitive Orange-Book-listing scheme, Boehringer falsely recertified its listings for the six currently listed patents when the Federal Trade Commission (FTC) disputed the listings.

17. Affordable generic versions of Combivent Respimat and Spiriva Respimat should have been available at least as early as 2020, shortly after the last patent that claimed the drug products in Combivent Respimat and Spiriva Respimat expired. Entities like the plaintiff, who pay for prescription medications on behalf of patients, should have been able to pay for affordable generic versions of Boehringer's inhaler products, rather than Boehringer's expensive brand-name versions.

18. But as a result of Boehringer's wrongful Orange-Book-listing scheme, there is, to this day, no affordable generic versions of either Combivent Respimat or Spiriva Respimat. Payors must continue to pay for expensive brand-name products, instead of affordable generic products that should have been available years ago. This has caused payors, including the plaintiff, to suffer many millions, if not billions, of dollars in overcharges over the past three years.

19. This suit seeks to remedy those overcharges.

II. PARTIES

20. The plaintiff, Massachusetts Laborers' Health & Welfare Fund (Massachusetts Laborers or the Fund) is an "employee welfare benefit plan" within

the meaning of § 3(3) of ERISA, § 1002(3). It provides health, dental, and prescription benefits and life insurance, accident insurance, and accident and sickness benefits to participants. The Massachusetts Laborers' administers the Fund at 1400 District Avenue, Burlington, Massachusetts, within this judicial district. During the class periods, as defined below, Massachusetts Laborers purchased, paid, and/or provided reimbursement for some or all of the purchase price of Combivent Respimat and Spiriva Respimat for the personal and/or household use of its members (i.e., not for resale) from pharmacies in multiple states, including Massachusetts, New Hampshire, Maine, Rhode Island, and New Jersey.

21. The defendant, Boehringer Ingelheim International GmbH ("BI International") is a limited liability company organized and existing under German law, with a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany. BI International is the assignee of the following patents: U.S. Patent No. 7,284,474; U.S. Patent No. 7,896,264; U.S. Patent No. 7,396,341; U.S. Patent No. 9,027,967; U.S. Patent No. 7,837,235; and U.S. Patent No. 8,733,341.

22. The defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation organized under the laws of Delaware, and headquartered at 900 Ridgebury Road, Ridgefield, Connecticut. It is a subsidiary of BI International. BIPI is the owner of two New Drug Applications (NDA) filed with and approved by the FDA: NDA No. 021747, for Combivent Respimat, and NDA No. 021936, for Spiriva Respimat.

23. Collectively, BI International and BIPI are referred to as "Boehringer." They are both plaintiffs in two lawsuits against would-be generic competitors: *Boehringer Ingelheim Pharmaceuticals, Inc. v. Anobri Pharmaceuticals US, LLC*, No. 23-cv-3530 (D.N.J., filed June 29, 2023) and *Boehringer Ingelheim Pharmaceuticals, Inc. v. Anobri Pharmaceuticals US, LLC*, No. 23-cv-3531 (D.N.J., filed June 29, 2023).

III. JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d) because this is a qualifying class action, as defined in § 1332(d)(1)(B); the amount in controversy stretches into the hundreds of millions, if not billions, of dollars and thus exceeds the $5 million jurisdictional threshold set forth in § 1332(d)(2); at least one plaintiff is a citizen of a different state than the defendants, and the classes (comprised of citizens of states and U.S. territories) have brought suit against a foreign entity, BI International. Thus, this class action meets the criteria under both subsections (A) and (C) of § 1332(d)(2).

25. This Court also has subject matter jurisdiction under 28 U.S.C. §§ 1331 (federal question), 1337(a) (antitrust), and 15 U.S.C. § 15 (antitrust).

26. The defendants transact business within this district; they transact their affairs and carry out interstate trade and commerce, in substantial part, in this district; and/or they have an agent and/or can be found in this district. Venue and personal jurisdiction are therefore appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22.

27. Venue is also appropriate within this district under 28 U.S.C. § 1391 because the defendants transacted business within this district and the interstate trade and commerce, hereinafter described, is carried out in substantial part in this district, and a substantial part of the events giving rise to the plaintiff's claims occurred in this district.

28. This Court also has personal jurisdiction over the defendants because the plaintiff paid for Combivent Respimat and Spiriva Respimat in this district.

IV. INDUSTRY BACKGROUND

29. Branded drug companies can obtain valid patents over their prescription drug products. These patents provide limited protection from generic competition by other drug companies for a fixed period—often called an exclusivity period—set by Congress. Being able to protect truly novel products with patents encourages innovation and the development of new medications.

30. Patents provide a form of exclusivity for drug products. A valid, enforceable patent may exclude others from making the patented invention (provided that the would-be competitor's product actually infringes the patent, and provided that the brand-name drugmaker has standing to sue). Usually, the scope of protection provided by a patent expires when the patent expires. However, in the drug context, there is a narrow exception.

31. To spur drug companies to ensure their drugs are safe and effective for use in children, the FDA may grant an additional six month "exclusivity" for a drug for which a brand drugmaker has studied its safety and efficacy in children. For example, if a patent claiming a drug product were set to expire on January 1, and the

drug's sponsor studied the effect of the drug product on children, its lawful exclusivity period would extend to July 1.

32. There is another type of exclusivity: regulatory exclusivity. Regulatory exclusivities are intended to reward companies for bringing new products to market.[1] If a brand-name drugmaker creates a truly new product—a product in which none of the active ingredients have been approved by the FDA before, the company is entitled to a five-year "New Chemical Entity" (or NCE) period of exclusivity.[2] Otherwise,[3] a brand-name drug that incorporates an active ingredient previously approved by the FDA can receive an "NP" exclusivity of just three years. Unlike the pediatric exclusivity, these exclusivities run concurrently to any patent exclusivities.

33. These regulatory exclusivities are intended to represent the longest lawful monopoly a brand-name drugmaker may hold over its product, absent any patent protection.

34. During an exclusivity period, brand-name drugmakers can demand very high prices for medications that cost relatively little to manufacture. Because patent protection or FDA regulatory exclusivities prevent other companies from making a competing generic version of the medication, purchasers, payors, and the public must pay those very high prices.

[1] *See* 21 U.S.C. §§ 355(c)(3)(E), 355(j)(5)(F).

[2] 21 CFR 314.108.

[3] There are other more rarely invoked exclusivities, such as the Orphan Drug Exclusivity, not relevant here.

35. Once a brand drug company's period of exclusivity expires, though, the company can no longer lawfully block generic competition. Other drug companies seeking to market generic versions of the drug—identical versions of the drug that are just as safe and effective, yet far less expensive—can enter the market. Generic drugs have saved the public more than $2.6 trillion over the past decade.

36. The federal drug laws balance these competing interests: rewarding and incentivizing genuine innovation by brand-name drugmakers while ensuring the earliest possible availability of more affordable generic drugs.

37. They accomplish this, in part, by requiring brand-name drugmakers to submit to the FDA information about patents that claim (i) a drug's active ingredient, (ii) a drug product that includes the active ingredient, or (iii) a method of using the drug. The FDA publishes this information in a ministerial capacity, without scrutiny, in the Orange Book, so that generic companies seeking to come to market know which patents might stand in their way.[4]

38. A would-be generic competitor must notify the brand-name drugmaker if it seeks to market a generic version of a brand-name drug before the expiration of an Orange Book listed patent for the brand drug. If the brand-name drugmaker has an objectively reasonable and good-faith basis to believe that the competitor's product would infringe a valid, enforceable drug patent, it can sue. By suing, the brand-name drugmaker can delay approval of the competing product for two and a half years.

[4] *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) ("[The FDA] . . . administers the Hatch-Waxman Amendments in a ministerial fashion simply following the intent of the parties that list patents.").

39. But unscrupulous drug companies can (and do) game the system by submitting false or misleading patent information to the FDA's Orange Book—for example, by representing that a patent claims the drug when it does not. This forces a would-be competitor to give the brand company advance notice of competition; enables the brand company to sue; triggers an automatic two-and-a-half-year delay in generic competition; and provides the opportunity for the brand-name drugmaker to settle the suit in a way that delays competition even more.

40. Boehringer is just this sort of unscrupulous company.

A. The federal drug laws speed generic drug availability by (i) allowing generic drugmakers to file abbreviated drug applications and (ii) streamlining patent disputes.

41. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*. governs the manufacture, sale, and marketing of prescription drugs in the U.S.

42. Before any drug may be sold in the United States, it must first be approved by the FDA. There are three types of drug applications for FDA approval—two for brand-name drugs and one for generics.

43. A manufacturer seeking to market and sell a new brand drug must submit a New Drug Application, or NDA.[5] Typically, an NDA is submitted pursuant to § 505(b)(1) of the FDCA and must include specific and extensive data concerning the safety and effectiveness of the drug.[6]

[5] 21 U.S.C. § 355(b)(1).

[6] *Id.*

44. Sometimes, an application may be submitted under § 505(b)(2) if the proposed product has the same active ingredient as an already-approved product (called the reference product), but in a different amount, dose, or form. A brand-name drugmaker that files a § 505(b)(2) NDA may rely on some of the reference product's data rather than repeating.[7]

1. In the Hatch-Waxman Amendments, Congress created a streamlined, abbreviated approval process for generic drugs.

45. Until 1984, all drugmakers had to submit voluminous NDAs with costly and time-consuming clinical studies before they could market or sell any drug—brand name *or* generic. Because would-be generic companies intended to make their drugs available at an affordable price, clinical studies were almost always cost prohibitive. And even those companies able to shoulder that cost faced potentially ruinous liability: if their product infringed just one of the brand-name drugmaker's patents, the brand company could sue once they launched, exposing the company to astronomical litigation costs and the possibility of significant monetary damages.

46. Because of these risks, generic companies just waited until they were certain they could no longer be sued before even beginning to try to develop a much-needed generic drug. As a result, in 1983, 65% of brand-name drugs with no patent protection had no generic competition, and only 19% of non-antibiotics prescriptions were filled with generic drugs.

[7] 21 U.S.C. § 355(b)(2).

47. In 1984, Congress tried to address this problem by enacting the Drug Price Competition and Patent Term Restoration Act,[8] known as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments created a simplified pathway to approval for generic drugs.

48. Rather than requiring expensive, time-consuming clinical trials for generic drugs, the Hatch-Waxman Amendments allow a generic drug company to file an Abbreviated New Drug Application, or ANDA. In an ANDA, a generic company can establish that its product is bioequivalent to the brand-name drug (the reference-listed drug). "Bioequivalent" means that the generic drug contains the same active ingredient(s) in the same amount, administered in the same form, at the same strength; and is absorbed into the body in the same way, at the same rate, and to the same extent as the brand-name drug. A bioequivalent generic drug has the same clinical effect as its brand-name counterpart and allows the ANDA applicant to rely on the NDA's clinical studies to prove its own drug safe and effective.

49. Drugs that are bioequivalent are also therapeutically equivalent, meaning that one may be substituted for the other. The FDA has a term for this: generic drugs that are bioequivalent to brand-name drugs are "AB-rated" to the brand-name drug.

50. Every state has adopted laws that require or permit pharmacies to substitute affordable AB-rated generic equivalents for brand-name prescriptions.

[8] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

51. As a result, when an AB-rated generic drug enters the market, prices decline rapidly and sales shift quickly to the generic product. Often 80% of the market shifts to generic sales within six months after generic entry. Within a year, generic drugs capture 90% of sales, and the price drops to just 15% of the branded price.

52. To ensure that this brand-to-generic switch happens as soon as possible, the Hatch-Waxman Amendments introduced a second innovation: a streamlined process for resolving disputes over Orange Book-listed patents.

2. The Hatch Waxman Amendments streamlined patent dispute resolution.

53. The drug laws provide a way for generic companies to challenge weak or invalid drug patents without risking damages if the patents are upheld.

i. The plain language of the Hatch-Waxman Amendments limits Orange Book listings to patents that claim the drug or a method of using the drug for which the applicant submitted the application.

54. From 1983 until 2019, the FDCA required NDA applicants to submit the following to the FDA:

> the patent number and the expiration date of any patent which *claims the drug for which the applicant submitted the application* or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[9]

55. In this provision, Congress imposed a two-part listing test; brand-name drugmakers must submit only those patents that satisfy both prongs.

[9] 21 U.S.C. § 355(b)(1) (2019) (emphasis added).

56. First, the universe of patents that Congress contemplated in this provision is narrow. Not only must the patent claim a drug (or a method of using a drug), it must also claim the drug or a method of using the drug for which the brand drug company submitted its NDA. And it is not enough for a patent to just mention a drug for which an NDA holder submitted its NDA: it must "claim" that drug.

57. "Claim" has a specific meaning in patent law. A patent's "claim" is "the portion of the patent document that defines the scope of the patentee's rights."[10] It is found in "specific, formal language recited at the conclusion of a patent 'specification,' which is the required written description of an invention . . . in a patent or patent application."

58. A mere reference to the drug for which a brand-name drugmaker submitted its application that appears elsewhere in a patent, such as the abstract or specification, is not enough to list a patent in the Orange Book. The reference to the drug for which a brand-name drugmaker submitted its NDA must appear in the claims. A patent that does not mention, much less claim, a drug cannot lawfully be submitted to the FDA for listing in the Orange Book.[11]

59. Second, the patent must reasonably be capable of being asserted against a would-be competitor seeking to make the drug. The brand-name drugmaker must not submit a patent that is invalid or otherwise unenforceable. A patent may be invalid for a number of reasons: the claimed invention may be obvious, and thus

[10] *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

[11] *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 7 (1st Cir. 2020).

invalid, for example. It may be anticipated by prior inventions. Or it could fail to adequately and concretely describe an invention so as to enable a person of ordinary skill in the art to practice the invention.

60. If a patent fails to satisfy one of the statutory listing test's two criteria, a brand-name drugmaker must not submit it for listing in the Orange Book.

61. A brand-name drugmaker may obtain additional patents after NDA approval. If those patents satisfy the two-part statutory listing test, the brand-name drugmaker must submit the patents' information to the FDA once they issue.[12]

ii. The FDA's implementing regulations limit drug patents to those that claim the drug substance or a drug product containing the drug substance.

62. In October 1994, the FDA issued a new regulation, 21 C.F.R. § 314.53, implementing Congress' two-part statutory listing test. There are three key provisions in those initial implementing regulations.

63. **First, a brand drug company cannot submit a patent unless it claims a drug substance, drug product, or method of using a drug substance or drug product**. The regulations explained which patents "claim[] the drug" within the meaning of the statute: "*drug substance* (active ingredient) patents, *drug product* (formulation and composition) patents, and method-of-use patents."[13]

64. The FDA reiterated what was clear from the plain language of the statute: only patents that claim the drug for which an NDA was filed may be

[12] 21 U.S.C. § 355(c)(2) (2019).

[13] 21 C.F.R. § 314.53(b)(1) (2009) (emphasis added).

submitted. The final rule declared that "[f]or patents that claim the drug substance, the applicant shall submit information *only* on those patents that claim the drug substance *that is the subject of the pending or approved application* or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application."[14]

65. **Second, the regulations obligate a drugmaker to identify the type of patent it is submitting**. Section 314.53(c)(1) sets forth the patent information that an NDA holder must submit to the FDA including: (i) the patent number and the date on which the patent will expire; (ii) the type of patent, i.e., "[d]rug substance (active ingredient), drug product (formulation or composition), and method-of-use"; and (iii) the name of the patent owner or owners.[15] During the rulemaking process, the FDA rejected commenters' efforts to eliminate this requirement.[16]

66. **Third, brand-name drugmakers must submit a declaration that the submitted patent is properly listable**. To ensure that brand-name drugmakers truthfully submitted only patents permitted by the statute's plain language and the explanatory text of § 314.53(b), the FDA's regulations required that any patent submission be accompanied by a signed declaration:

[14] *Id.* (emphasis added)

[15] 21 C.F.R. § 314.53(c)(2).

[16] *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) (explaining that "[t]he requirement . . . that applicants provide information on the type of patent and the name of the patent owner or authorized representative is consistent with the purpose of section 505(b)(1) [i.e., § 355(b)(1)] of the act").

> The undersigned declares that Patent No. ____ covers the formulation, composition, and/or method of use of (*name of drug product*). This product is (*currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act*) [or] (*the subject of this application for which approval is being sought*): _____.[17]

67. Several industry commenters tried to deter the FDA from implementing these safeguards against untruthful patent submissions. For example, one suggested deleting the language requiring a brand-name drug company to swear that a patent claimed the drug substance, drug product, or method of use "and replacing it with a general certification that the patents listed by the applicant contain claims with respect to which the applicant could reasonably assert a claim of infringement against a person engaged in the unlicensed manufacture, use, or sale of the drug for which the application was submitted."[18]

68. The FDA rejected the comment, noting that the statute's plain text imposed the limitation that the submitted patent must "claim[] the drug" or a method of using the drug, not just that the patent may be asserted. This, the agency said, coupled with the fact that the "FDA lacks patent law expertise" warranted a two-part certification that tracked the two-part statutory listing test.[19]

69. Other commenters suggested that the FDA, not drugmakers, should evaluate whether a submitted patent meets the statutory listing test.[20] The FDA rejected these comments, too. It explained that the "FDA does not have the expertise

---

[17] 21 C.F.R. § 314.53(c)(2).

[18] 59 Fed. Reg. at 50343.

[19] *Id.* at 50343–44.

[20] *See id.* at 50343, 50345.

to review patent information" and "its scarce resources" would be better utilized in reviewing applications rather than reviewing patent claims.[21] And it explained that "the declaration requirements under § 314.53(c), as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted."[22]

70. Section 314.53 went into effect on November 2, 1994.

iii. In 2003, the FDA amended its Orange-Book-listing regulations in response to improper listings.

71. On June 18, 2003, the FDA amended § 314.53 of its regulations "to help ensure that NDA applicants submit only appropriate patents,"[23] and to prevent brand-name drugmakers from "submitting patents that do not meet the statutory and regulatory requirements."[24]

72. The FDA did not change the key provisions of its rules: it reiterated that the statute imposed a two-part test requiring applicants to submit only a "patent that claims the drug or a method of using the drug that is the subject of the new drug application . . . *and* with respect to which a claim of patent infringement could reasonably be asserted" against a would-be competitor.[25]

---

[21] *Id.* at 50343.

[22] *Id.* at 50345.

[23] Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676.

[24] *Id.* at 36683.

[25] *Id.* at 36703.

73. There are four key clarifying provisions in the new rule and the FDA's accompanying commentary.

74. **First, the FDA removed any ambiguity as to what it meant for a patent to claim the "drug product."** The new rule provided a very clear explanation of how an NDA holder could determine whether a patent "claims the drug" within the meaning of the statute: Read the FDA's regulations.

75. Under § 314.53, "[f]or patents that claim a drug product, the [NDA holder] shall submit information *only* on those patents that claim a drug product, *as is defined in § 314.3*, that is described in the pending or approved application."[26]

76. Section 314.3 provides the definitions that apply to Part 314 of the FDA's regulations, including the Orange Book listing regulations in § 314.53.[27]

77. It defines "drug substance" as "an active ingredient that is intended to furnish pharmacological activity or other direct effect . . . ."[28]

78. It defines "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, *that contains a drug substance*, generally, but not necessarily, in association with one or more other ingredients."[29]

79. The definition of drug product incorporates the defined term "drug substance." Putting the two definitions together, then, the FDA defines "drug product" as:

---

[26] *Id.* at 36704.

[27] 21 C.F.R. § 314.1.

[28] 21 C.F.R. § 314.3.

[29] *Id.*

> a finished dosage form, e.g., tablet, capsule, or solution, that contains ["an active ingredient that is intended to furnish pharmacological activity or other direct effect"], generally, but not necessarily, in association with one or more other ingredients.[30]

80. The FDA, therefore, made it clear: only those patents that claim the drug substance, either on its own or in combination with other ingredients, may be submitted for listing in the Orange Book.

81. A patent which claims some aspect of an approved drug *in combination with* the drug substance may be listed. But a patent that claims that aspect alone, and *not in combination* with the active ingredient, must *not* be listed.[31]

82. For example, a patent that claims only an *in*active ingredient does not meet the definition of a drug product patent and must not be submitted to the Orange Book. But a patent that claims the inactive ingredient in combination with the drug's active ingredient could qualify as a "drug product" patent.

83. Likewise, a patent that claims only a controlled-release tablet coating must not be listed submitted for listing in the Orange Book. But a patent that claims the drug coating in combination with the drug's active ingredient would be a "drug product" patent which should be submitted for listing in the Orange Book.

84. And a patent that claims only a device used to deliver the active ingredient (such as an autoinjector, an injector pen, or an inhaler) must not be

[30] *Id.*

[31] *Lantus*, 950 F.3d at 7.

submitted for listing in the Orange Book. Only if the patent claimed the device *in combination with the active ingredient* could the patent lawfully be submitted.[32]

85. **Second, the FDA's existing rules made clear that patents claiming a molecule other than the active ingredient must not be submitted**. In its 2003 rulemaking, the FDA addressed the industry's uncertainty as to whether patents should be submitted for listing if they claimed a polymorphic form of an active ingredient.[33]

86. Some commenters urged the FDA to get even more specific about what patents must not be submitted. This included a comment suggesting that the FDA impose "[s]pecific exclusions" of other categories of patents, such as "patents for forms of the active ingredient not marketed, such as acids, freebases, salts, and isomers."[34]

87. The FDA declined to make this change—but not because patents claiming an acid, freebase, salt, or isomer of an active ingredient were listable. The agency "believe[d] the patent information requested" (i.e., the requirement that the NDA holder identify whether the patent claimed the drug for which it submitted its NDA) "is sufficient to ensure only eligible patents are submitted for listing."[35]

---

[32] 68 Fed. Reg. 36676 at 36680.

[33] *Id.* at 36678. Polymorphs are substances with the same chemical composition, but different physical structures. For example, diamond and graphite are polymorphs: they contain identical substances, arranged into different crystalline forms. Substances with different chemical compositions are not polymorphs. For example, Beclomethasone is not a polymorph of beclomethasone dipropionate.

[34] *Id.* at 36685.

[35] *Id.* at 36687. The FDA also noted that listing some exclusions could lead to confusion "over whether the examples are all-inclusive or whether other types of patents were excluded as well." *Id.*

88. **Third, the FDA *rejected* suggestions that device patents should be listed in the Orange Book**. The FDA confirmed in its rulemaking that "patents claiming packaging . . . must not be submitted for listing" in the Orange Book,[36] because "[s]uch packaging and containers are distinct from the drug product and thus fall outside of the requirements for patent submission."[37]

89. Nevertheless, some commenters argued that "integral" devices such as "metered dose inhalers" "should be submitted and listed."[38] The FDA said no, politely. It explained:

> [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.*[39]

90. The FDA made clear: the relevant question is whether a patent claims "a finished dosage form . . . that contains a drug substance," not whether it claims some "integral" aspect of the drug product. It *rejected* the idea that it was enough for a patent to claim just a device, even if that device was "integral" to using the drug.

---

[36] 68 Fed. Reg. at 36680.

[37] *Id.*

[38] *Id.*

[39] *Id.* (emphasis added).

91. **Fourth, the FDA strengthened brand-name drug companies' obligation to submit only truthful, accurate information**. The FDA updated the declaration brand-name companies are required to make when submitting a patent for listing. It did so by providing a standardized form for patent submissions, called the FDA Form 3542 (the "Patent Listing Form").[40]

92. The Patent Listing Form requires companies to identify a patent by the patent number, issue and expiration dates, and owner, then asks a series of questions to guide the NDA holder in determining whether the patent is listable.

93. Question 2.1 asks whether the patent "claim[s] the drug substance that is the active ingredient in the drug product described in the approved NDA or supplement." If the NDA holder answers "no," the form warns, the "FDA will not list the patent in the Orange Book as claiming the drug substance[.]"

94. Question 3.1 asks whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*"; if the NDA holder answers "no," the "FDA will not list the patent in the Orange Book as claiming the drug product[.]"

95. And Question 4.1 asks whether the patent "claim[s] one or more methods of using the approved drug product." If the answer is "no," then the "FDA will not list the patent in the Orange Book as claiming the method of use[.]"[41]

96. The FDA reiterated in its rulemaking that its "patent listing role remains ministerial."[42] In reviewing the Patent Listing Form, the FDA does not

[40] *Id.* at 36710–12.

[41] *Id.* at 36711–12.

[42] *Id.* at 36683.

ensure that a brand-name drugmaker's answers are truthful; it merely ensures that the company has provided answers that, *if accurate*, would entitle the company to list the patent in the Orange Book.

97. Instead, the agency strengthened the language of the declaration that the brand-name drugmaker's representative must sign to ensure compliance:

> 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.[43]

iv. The FDA's process for handling patent listing disputes relies on honesty and self-policing by manufacturers.

98. The FDA's Orange Book listing regulations allow anyone to dispute the accuracy or relevance of a listed patent, although the FDA's role in this process, like that of its patent listing role, remains ministerial and relies entirely on the veracity of the patent holder. There is no mechanism for the FDA itself to dispute patent listings.

99. Section 314.53(f)(1) provides that any person who disputes the accuracy or relevance of a patent listed in the Orange Book may submit to the FDA a written "314.53(f) Patent Listing Dispute" that describes the specific grounds for

[43] *Id.* at 36712.

disagreement with the listing so that the FDA sends the text of the dispute to the patent holder "without review or redaction."[44]

100. The patent holder then has 30 days from receipt of the dispute to either re-certify the propriety of the listing (under the same provisions it used to submit the original listing), or to withdraw or amend the patent listing.[45] The FDA defers to the patent holder's chosen course of conduct and does not take any unilateral action: "Unless the NDA holder withdraws or amends its patent information in response to the patent listing dispute, the Agency will not change the patent information in the Orange Book."[46]

v. Despite the plain language of the FDCA and the FDA's regulations, brand-name drugmakers continue to seek ways to list device-only patents.

101. Even after the FDA clarified in 2003 that device-only patents could not be submitted to the Orange Book, brand-name drugmakers kept trying to convince the FDA to allow them to submit for listing patents that claimed a device, not a drug.

102. The FDA provides a number of ways for companies to seek changes to existing regulations. One is a citizen petition directed at requesting changes to how a specific drug or class of drugs is treated by the FDA.[47] Another is a request for an advisory opinion.[48] Both types of petitions constitute requests to *change* what the

[44] 21 C.F.R. § 314.53(f)(1) (emphasis added).

[45] 21 C.F.R. § 314.53(f)(1)(i).

[46] 21 C.F.R. § 314.53(f)(1)(i)(A).

[47] 21 C.F.R. § 10.30.

[48] 21 C.F.R. § 10.85.

drug laws and regulations permit or require: sponsors do not (in good faith) ask the FDA to enact a policy it has already enacted.[49]

103. Between 2005 and 2012, four brand-name drugmakers—AstraZeneca (AZ), GlaxoSmithKline (GSK), Novo Nordisk, and Forrest Labs., Inc. (Forrest)—submitted advisory opinion petitions to the FDA concerning the listability of device patents.

104. Each petitioner acknowledged that the FDA could have expressly required the listing of "integral" device patents but did not. And each recognized that "[t]he key factor is whether the patent being submitted claims the finished dosage form of the approved drug product" as defined in 21 C.F.R. § 314.3.

105. Most of the petitioners acknowledged that FDA draft guidance concerning combination products—one concerning nasal aerosol sprays and one concerning inhalers—defined a "drug product" *not* as just the device alone, but as the formulation "together" with the device "collectively."

106. Each admitted that the regulations do not permit brand-name drugmakers to list patents claiming just a device alone:

- **GSK**: "FDA *has yet to be explicit* on the question of whether the listing requirement applies to patents that . . . do not claim the drug substance . . . in conjunction with the drug delivery device[.]"[50]

[49] Some drugmakers do to delay competition. Because the FDA defers approving an ANDA until it has resolved all petitions affecting that application, brand-name drugmakers have exploited the petitioning process to thwart competition. Some petitions provide no scientific basis for the changes requested. Very few—just 3 out of 42—citizens petitions presented any data or analysis that would support a change in the FDA's rules or policies. Instead, most were intended primarily to delay the approval of competing drug products, not to raise"valid scientific issues.

[50] GSK later informed the FDA that it would list its device patents anyway, "regardless of whether the approved drug substance is specifically mentioned in the claims of such patents."

- **AZ First Petition**: "FDA *has not . . . directly addressed* whether patents directed to . . . inhalers . . . that do not recite the approved active ingredient or formulation should be listed in the Orange Book."

- **AZ Second Petition**: "*FDA has not directly addressed the question* [of] whether the listing requirement applies to patents [that] disclose but do not claim, or neither disclose nor claim, the active ingredient or formulation of the approved drug product."

- **Forest**: "[G]uidance regarding compliance with the listing requirement is not clear when the patent claims a drug delivery device integral to the administration of the active ingredient but does not recite the active ingredient. . . . *[N]either the rules nor past guidance from the FDA address the issue . . . explicitly*[.]"

- **Novo**: "FDA's distinction between pre-filled drug delivery systems and product packaging *remains unclear* . . . ."

107. In other words, each petitioner acknowledged that there was no concrete regulatory imperative to list a patent claiming a device alone.

108. And each petitioner implicitly admitted the true reason for their requests: the desire to delay competition. None of them was express about it, but each noted (favorably) that listing device-only patents would enable a brand company to sue a would-be competitor and trigger an automatic 30-month delay of competition.

109. In sum, the brand-name drugmakers (a) acknowledged the FDA had already rejected suggestions that device-only patents be listed in the Orange Book; (b) admitted that the FDA had admonished that the "key factor" was whether a patent met § 314.3's definition of a drug product; (c) admitted that the "drug product" for a combination patent was the formulation "together" with the device "collectively"; (d) conceded that the regulations did not require listing device-only patents; and (e) betrayed their intent to leverage device patents to delay competition.

110. None of the petitioners offered an interpretation of the existing rules that would permit listing device-only patents; instead, they each argued the FDA should change its rules. None provided any reasoned basis for this change beyond than their desire to leverage those patents to delay competition. But the fact that the brand-name drugmakers wanted to bottleneck competition with device patents does not mean the law or the regulations permitted them to do so. Nor does that desire make it reasonable to violate the FDA's clear regulations.

111. The FDA—having already addressed the issue—did not grant any of these petitions. In fact, it declined to respond "due to the need to address other Agency priorities." The FDA is a resource-, budget-, and time-constrained agency. It does not divert resources from drug approvals to address issues squarely governed by existing rules—particularly on patent-law issues, on which the FDA lacks expertise.

vi. In 2020, Congress cracked down on continued listing abuse.

112. In 2019, the Orange Book Transparency Act was introduced in the U.S. House of Representatives. A House Committee report cited, among the reasons for the bill, the fact that "some branded drug manufacturers . . . are submitting patents . . . for the purpose of blocking generic competition."[51]

113. On January 5, 2021, it became law. It amended the FDCA's listing provision to reiterate that *only* drug substance, drug product, and method-of-use patents should be submitted to the Orange Book. It required submission of:

[51] *Orange Book Transparency Act of 2019*, H.R. 116-47.

> (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) patent; or
> >
> > (II) claims a method of using such drug for which approval is sought or has been granted in the application.[52]

vii. The statutory and regulatory rules for Orange Book listings provide a very simple rule.

114. These straightforward statutory and regulatory limitations on what patents may be listed as drug product or drug substance patents can be distilled to a very simple two-part rule.

115. First, a patent can only be listed if it "claims the drug for which the applicant submitted the application or . . . a method of using such drug." That means:

- If a patent does not mention, let alone claim, the drug's active ingredient (or a method of using that drug's ingredient), then it must not be submitted for listing.
- If a patent merely mentions the drug's active ingredient in the specification, but does not include the active ingredient as a limitation in a claim, then it must not be submitted.
- If a patent claims an active ingredient for a drug other than the one that is the subject of the brand-name drugmaker's NDA, then it must not be submitted.

[52] Pub. L. 116-290 (Jan. 5, 2021).

116. Second, if a patent passes the first step of this test, the patent must be one that "could reasonably be asserted" against a would-be competitor. A brand-name drugmaker must not submit a patent that it knows or reasonably should know is invalid or unenforceable, because an invalid or unenforceable patent cannot be asserted against a would-be competitor.

117. If a patent does not pass both criteria under the listing test, it must not be listed in the Orange Book.

118. Boehringer broke this simple rule dozens of times.

3. The Hatch-Waxman Amendments require would-be generic companies to address each Orange-Book-listed patent.

119. The notice provided by brand-name drugmakers to would-be competitors by submitting patents to the Orange Book is not a one-way street. In exchange, the Hatch-Waxman Amendments require would-be competitors to notify the brand-name drugmaker of any patents it believes are invalid or not infringed.

120. For each patent listed in the Orange Book, a would-be generic competitor must include in its ANDA one of four certifications:

> (I) No patents have been listed in the Orange Book;
>
> (II) Any listed patents have expired;
>
> (III) The would-be competitor will wait for a patent's expiration before marketing its competing product; or
>
> (IV) A listed patent "is invalid or will not be infringed by the manufacture, use, or sale" of the competitor's product.[53]

[53] 21 U.S.C. § 355(j)(2)(A)(vii).

121. If an ANDA applicant makes a certification under one of the first two paragraphs, then no patent will delay generic competition. At the other extreme, a certification under the third paragraph (known as a "paragraph III certification") means the generic applicant will have to wait until the relevant patent has expired.

122. The fourth option, known as a "paragraph IV certification," provides a middle ground—a means to speed generic entry even when patents are listed in the Orange Book. A generic competitor must notify the brand-name drugmaker of any paragraph IV certifications it makes in its ANDA and provide a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."[54] This serves "to give notice, if necessary, to the patent holder so that any legal disputes regarding the scope of the patent and the possibility of infringement can be resolved as quickly as possible."[55]

123. For method-of-use patents, there is a fifth option: a would-be competitor can file what is known as a "section viii carveout" statement. Under Section 505(j)(2)(A)(viii) of the FDCA, a would-be generic competitor can submit a statement averring that it will not market the drug for one or more methods of use claimed by a listed patent:

> [I]f with respect to the listed drug referred to in [section 505(j)(2)(A)(i)] information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this

[54] *See* 21 U.S.C. § 355(j)(1)(B)(iv)(II).

[55] *Torpharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 71 (D.D.C. 2003).

> subsection, [the ANDA must contain] a statement that the method of use patent does not claim such a use.[56]

If an ANDA applicant files a section viii statement, the patent claiming the protected method of use cannot bar approval of the ANDA.

4. Hatch-Waxman patent certifications may lead to litigation.

124. Often a generic company that provides a brand-name drugmaker with a paragraph IV notification will make an Offer of Confidential Access, allowing the brand-name drugmaker to review portions of the ANDA to assess infringement.

125. Filing an ANDA may provoke litigation. Congress provided an incentive to generic companies to bear this litigation burden. The first generic drug maker to file a substantially complete ANDA containing a paragraph IV certification is eligible for 180 days of marketing exclusivity when it launches.[57]

126. This first generic drugmaker is referred to as the "first-filer," and the exclusivity it is eligible for is called the first-filer's six-month or 180-day exclusivity. "Exclusivity," however, is a bit of a misnomer. The FDCA prohibits the FDA from approving other *ANDAs* during that 180-day period, but a brand-name drugmaker may sell or license a generic product, called an "authorized generic," under its NDA.

127. If a first-filer certifies that it will wait until all Orange-Book-listed patents expire, it does not get the six-month exclusivity. That is, the exclusivity is

[56] 21 U.S.C. § 355(j)(2)(A)(viii).

[57] 21 U.S.C. § 355(j)(5)(B)(iv)(I).

intended to serve as an incentive to try to bring generic drugs to market *before* all Orange-Book-listed patents expire.

128. But a generic drug company cannot race to be the first-filer and then sit on its exclusivity, bottlenecking the market indefinitely. The FDCA provides ways in which a first-filer may forfeit exclusivity. For example, a first-filer forfeits its exclusivity if it fails to launch its product within 75 days after the later of either (i) ANDA approval or (ii) a court decision finding, or a settlement admitting, that the patents blocking the first-filer from market entry are invalid or not infringed.[58]

129. A 180-day exclusivity is incredibly valuable to a generic applicant: automatic substitution laws and the fact that no other ANDAs may be approved during that time allows the first-filer to reap substantial profits. As the Supreme Court has recognized, "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first-filer.[59]

5. If a brand-name drugmaker has a reasonable, good-faith basis to believe it has standing, and that its patents are valid and would be infringed, it may sue.

130. When Congress enacted the Hatch-Waxman Amendments, it also amended the patent laws to facilitate resolution of disputes as to whether a proposed ANDA product infringes a valid, enforceable patent listed in the Orange Book.

[58] *Id.* § 355(j)(5)(D)(i)(I).

[59] *FTC v. Actavis*, 570 U.S. 136, 144 (2013) (quoting *Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)

131. Section 271 of Title 35 of the United States Code enumerates what constitutes patent infringement. Ordinarily, a patent holder must wait until a competitor "makes, uses, offers to sell, or sells" an infringing product before suing.[60]

132. There is a special exception for generic drugs contained in § 271(e)(2)(A): filing an ANDA containing a paragraph IV certification to one or more Orange-Book-listed patents constitutes "technical" patent infringement and provides the brand company standing to sue.[61] This exception applies only where an ANDA is for a "*drug claimed in a patent* or the use of which is claimed in a patent."[62]

133. If a brand-name drugmaker with a reasonable and good-faith belief that an ANDA product infringes one or more valid and properly listed patents sues within forty-five days of receiving a paragraph IV notification, the Hatch-Waxman Act imposes an automatic stay preventing the FDA from granting final approval to the ANDA until (a) the passage of 30 months or (b) a court decision finding that the patent is invalid or not infringed by the ANDA product, whichever happens sooner.[63] A section viii carveout, however, does not trigger this mechanism, and cannot delay ANDA approval or the generic competition that follows.

134. If an ANDA is ready for approval before one of those conditions occurs, the FDA may grant "tentative approval." Tentative approval is warranted when an

---

[60] 35 U.S.C. § 271(a).

[61] *See* 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (§ 271(e)(2) creates a "highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification").

[62] 35 U.S.C. § 271(e)(2)(A).

[63] 21 U.S.C. § 355(j)(5)(B)(iii). This is sometimes referred to as "Hatch-Waxman litigation."

application satisfies all scientific and procedural conditions to final approval, but the FDA may not grant final approval due to the 30-month litigation stay.[64]

B. Brand-name drugmakers can enforce patents that are not listed in the Orange Book.

135. Until Congress enacted the Hatch-Waxman Amendments, there was no streamlined patent resolution process: there was no Orange Book, no paragraph IV certification process, and no ability for brand-name drugmakers to sue before a competitor launched the product. Instead, brand-name drugmakers could sue a competitor when that competitor launched its allegedly infringing generic product.

136. This is how brand-name drugmakers defended their intellectual property for years. And it is how every owner of every other type of intellectual property—from blenders to computers, from automobiles to medical devices—protects non-drug-substance inventions.

137. The Hatch-Waxman Amendments created a special procedure specifically for patents claiming a drug substance, a drug product containing a drug substance, or a method of using a drug substance or product. It did not eliminate the right of a brand-name drugmaker to defend inventions *other* than a drug substance, drug product, or method-of-use through ordinary patent-law principles. A brand-name drugmaker seeking to defend a device patent, therefore, may still sue once a competitor launches a product that it believes infringes that device patent.

[64] *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB); 21 C.F.R. § 314.107(b)(3)(v).

C. Generic-drug availability translates into substantial savings for payors and patients.

138. When only a brand-name drug is available in the market, the cost of the medicine is very high. But that cost shrinks as generic drugs become available.

139. The launch of even one generic version of a drug translates to substantial savings. The first manufacturer to launch a generic version of a drug prices its product slightly below the price of the brand-name counterpart. State substitution laws requiring or permitting substitution of an AB-rated generic drug for a brand-name drug lead to a rapid shift in the market away from the brand-name drug and to the generic drug, even though there is only a slight discount on price.

140. According to the FTC and FDA, the greatest price reduction occurs when a second generic competitor enters the market. Because the brand-name drugmaker rarely drops its price to match the first-filer's price, the first-filer does not face price competition while it is alone in the market. When a second competitor enters, the generic companies compete on price. This drives generic prices down significantly: the second generic launch results in a price reduction of approximately 50%.

141. As more generic drugs enter the market, the price reduction can reach 85% or more. Typically, in a fully "genericized" market, prices are close to marginal manufacturing costs.

D. Brand companies seeking to unlawfully prolong their monopoly have developed ways to abuse the Hatch-Waxman system and leveraged them to delay affordable generic drugs.

142. For as long as Congress has sought to speed the availability of affordable generic medications, brand-name drugmakers have frustrated those efforts.

1. Wrongful Orange Book listings

143. One such tactic deployed by brand-name drug companies to exploit the Hatch-Waxman framework and delay competition is with wrongful Orange Book listings.

144. In creating the streamlined patent resolution process outlined above, the FDA struck a careful balance. Brand-name drugmakers benefit from asserting their intellectual property before a competing generic drug is launched and having two-and-a-half years to resolve good-faith patent disputes. Generic companies benefit from having a resource to identify drug patents that may block their drug product and a means of addressing disputes without risking damages.

145. But this trade-off comes with risks. Orange Book listing makes every patent a potential source of delay of generic competition, because listing a patent gives the brand-name drugmaker near-automatic injunctive relief, regardless of the merits of any infringement claims.

146. Brand-name drugmakers have weaponized this process. Listing a patent in the Orange Book that does not satisfy the two-part statutory listing test forces would-be competitors to make a certification to the patent (even though the patent does not belong in the Orange Book and should require no such certification). If the generic company makes a paragraph IV certification, the brand-name drugmaker gets to sue and trigger an automatic two-and-a-half-year delay in competition.

147. In other words, a brand-name drugmaker that improperly lists patents in the Orange Book can trigger an unjustified two-and-a-half-year delay in

competition. That is two-and-a-half years of additional monopoly profits gained by submitting to the Orange Book a patent that does not satisfy the two-part listing test.

2. Sham litigation

148. Hatch-Waxman confers standing on a brand-name drugmaker to sue after receiving a paragraph IV notice from a would-be generic competitor. But that standing does not carry with it the right to file a frivolous suit.

149. It is incumbent upon litigants not to bring cases or make arguments that they know are meritless, or that they are pressing in bad faith. This includes brand-name drugmakers: they may not bring sham litigation.

150. Litigation is a sham if a reasonable person standing in the plaintiff's shoes would not expect there is a basis to file the suit, and the suit was brought to thwart competition. In the context of Hatch-Waxman litigation, this means that an infringement suit is a sham if no reasonable brand-name drugmaker would reasonably expect there was a basis for bringing a Hatch-Waxman action, yet the NDA holder brought the suit anyway for the purpose of delaying generic competition.

151. Some brand-name drugmakers do just that. Brand-name drugmakers know they cannot access the automatic two-and-a-half-year delay in generic approval unless they sue. And so some sue, regardless of the objective merit of that suit, just to delay competition.

152. There are at least two ways in which a Hatch-Waxman litigation may be objectively baseless.

153. First, Hatch-Waxman litigation may be a sham if a brand-name drugmaker sues over a patent that a reasonable drugmaker knows or should know is (a) invalid or unenforceable, or (b) not infringed by the would-be competitor's product.

154. Second, Hatch-Waxman litigation may be a sham if the brand-name drugmaker sues over a patent that a reasonable drugmaker would have or should have known was improperly listed in the Orange Book. Only patents which "claim[] a drug" may be listed in the Orange Book.[65] And the patent-law provisions creating the Hatch-Waxman litigation right of action apply only to patents claiming "a drug."[66]

155. If a brand-name drugmaker brings a suit over a patent that a reasonable company would know was (a) invalid, unenforceable, or not infringed by a competitor, or (b) improperly listed in the Orange Book—and if its motivation for doing so was to delay or frustrate competition—then the litigation is a sham.

V. FACTUAL BACKGROUND

A. The cost of inhaled drug products, like Combivent Respimat and Spiriva Respimat, represent a significant health concern.

156. Asthma and COPD—the diseases Combivent Respimat and Spiriva Respimat are designed to treat—are chronic diseases that make it difficult or impossible to breathe. Asthma is one of the most common respiratory diseases in the country and the most common chronic disease among children. About one in every 13 Americans have it. COPD is almost as prevalent, though it is concentrated among adults. Both diseases can be fatal: asthma kills about 10 people every day, while

[65] 21 U.S.C. § 355(b)(1).

[66] 35 U.S.C. § 271(e)(2).

COPD kills about 390 people every day and is the sixth-leading cause of death in the United States.

157. Inhalers are a mainstay of asthma and COPD treatment. The invention of inhalers dates to the founding of this country. The first inhaler, called the "Mudge Inhaler," was commercialized in 1778 (though there are records of therapeutic inhalation methods dating back to ancient Egypt). The dry powder inhaler was invented in Boston in 1852. And the first metered-dose inhaler was invented in 1956, after a young asthmatic girl asked "Daddy, why can't they put my asthma medicine in a spray-can like they do hair spray?"

158. Despite being old technology that dispense old drugs, the patenting of inhalers has been an aggressive focus of the pharmaceutical industry over the past three decades. Where there had been less than 10 total patents for dry-powder inhalers or metered dose inhalers between 1973 and 1990, the number of new inhaler patents in the United States exploded in the 2000s and early 2010s, reaching more than 60 per year. Boehringer itself owns dozens of patents claiming inhalers or components of inhalers.

159. This explosion of patented inhalers represents opportunism by the brand-name drug industry in the face of two regulatory requirements. The first was the FDA's mandate, in 2003, that any *new* metered dose inhaler devices must have a dose counter or dose indicator. Despite the fact that the FDA expressly stated that this requirement was *not* "intended for manufacturers of already marketed MDI drug products," many brand-name drug-makers—Boehringer included—scrambled to

patent dose counters for their existing inhaler products. Why? Because, as the FDA had stated, any generic version of a brand-name inhaler product with a dose counter must also have a dose counter. By patenting their dose-counters, brand-name drug companies knew they could prevent competition to their inhaled medications—even those for which lawful patent protection over the drug substance itself expired decades ago. Suddenly, in the mid-2000s, asthma and COPD patients who had been able to count on affordable generic versions of their inhaled medications were in for sticker shock at the pharmacy counter, when they were forced to suddenly begin buying expensive brand-name inhalers once more.

160. A second blow to asthma and COPD patients' wallets came in the early 2010s. For decades, drug companies had used chlorofluorocarbons (or CFCs) as an aerosolizing agent in metered dose inhalers. An international treaty, the Montreal Protocol signed in 1987, banned the use of CFC propellants. For most industries, CFCs had to be eliminated by 1996. But the treaty included an exception for metered dose inhalers, until medically acceptable alternatives were available. In the United States, drug companies took their sweet time. But in April 2010, the FDA issued a final rule, requiring any drug products still containing CFCs—including some of Boehringer's products—to "phase out," and be discontinued.[67] Once again, the brand-name pharmaceutical industry saw the FDA's regulatory action, intended to improve

[67] FDA, *Phase-Out of CFC Metered-Dose Inhalers Containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and medocromil – Questions and Answers*, https://www.fda.gov/drugs/information-drug-class/phase-out-cfc-metered-dose-inhalers-containing-flunisolide-triamcinolone-metaproterenol-pirbuterol-0#1.WhatactionisFDAtakingtoday (last visited Nov. 20, 2023).

patient (and ecological) safety, as an opportunity for a money-grab. Drugmakers raced to patent formulations and uses of promising replacement propellants—most notably hydrofluoroalkanes (HFAs). Nearly 1,000 patents have been issued for the use of HFAs in metered dose inhalers. Boehringer holds at least 60.

161. The end result of all these device hops and improper device patents is that inhaler manufacturers enjoy unconscionably long exclusivity periods, far in excess of what the FDA ever envisioned. For example, GSK filed its first fluticasone inhaler patent (Flovent) in 1981 and has patents on follow-on devices extending through 2030, or *49 years* after the first filing with no gaps between products. Uninterrupted patents also run continuously for 46 years on GSK's fluticasone-salmeterol inhalers and Teva's Branded beclomethasone dipropionate inhalers. Boehringer's Combivent inhaler patents run for 34 years, stretching from its original approval in 1996 until the last-to-expire patent on the CFC-free version in 2030. Strikingly, the majority of profits earned by these inhaler manufacturers occur *after* the drug product patents have expired but when secondary patents are active—62% of profits earned between 2000-2021, or $110.8 billion—turning on its head the FDA's incentive to promote drug innovation through patent protections.

162. The impact of these artificially extended patent exclusivities is borne by the consumers, who must pay more out-of-pocket—whether in the form of higher co-pays, deductibles, or insurance premiums. Even worse, the financial burden imposed on families by higher out-of-pocket medication costs is known to increase stress and

fear, and induces cost-related nonadherence—a problem that affects nearly one-third of adults with chronic health conditions.

163. When faced with the burden of overly expensive medication, people are forced to make dangerous choices like taking smaller doses, skipping doses, delaying refills, and borrowing medicines from others. Cost-saving nonadherence is higher in the United States than any other economically developed country, worsening health status and causing more frequent asthma and COPD exacerbations as well as unnecessary hospitalizations. A recent report from the Centers for Disease Control and Prevention (CDC) found that nearly nine million adults in the United States are not taking their medication as prescribed because of the high cost of medications.

164. The extremely high cost of prescription inhalers has been recognized as a public health concern in the United States for years—particularly with respect to patients with chronic respiratory diseases like COPD and asthma. The fearsome burden these overpriced medications place on consumers is reflected as well in government spending: between 2014-2018, Medicare spent about 50.5 billion dollars on prescribed inhalers, an increase of 128% expenditure over those four years.

165. It is worth noting that this is a uniquely American phenomenon—in other countries, where manufacturers like Boehringer cannot get away with its unlawful patent listing scheme, the cost of these life-saving medications is a fraction of the price paid by U.S. citizens. For example, Spiriva Respimat costs about $600 in the United States, while its list price ranges from $21 to $54 in Germany, France, Japan, Canada, and the United Kingdom. In all those countries, Boehringer

continues to successfully market and profit from these medications, without price-gouging consumers.

166. Patenting inhaler devices, and then selling them in combination with drug substances over which lawful patent has, or is about to, expire, does not just ensure that brand companies can sue would-be competitors. It also makes it harder for generic companies to come to market. A study examining inhaler patents from 1986–2020 found that in all those years, only one of 53 branded inhalers faced successful interchangeable generic competition prior to the expiration of its patent exclusivities—Teva's ProAir HFA (albuterol)—which still enjoyed a remarkable 27-year run of patent protection. And even though it was ultimately successful, it still took the generic manufacturer Perrigo over 8 years to achieve successful market entry in 2020, after it first settled with Teva in 2012.

B. For years, Boehringer Ingelheim sold two legacy COPD treatments: Combivent and Spiriva in generic inhalers.

1. Boehringer obtained the rights to an inhaler designed to be different from other inhalers ubiquitous in the market—for the sake of being different.

167. Most inhalers look similar and function in a similar fashion. The public is likely familiar with the standard, L-shaped inhaler that most inhaled medicines come in:

There is nothing about this inhaler design that makes it ill-suited for any particular aerosolized medication: it is or has been commonly used with albuterol, ipratropium, tiotropium, beclomethasone, and other inhaled medications.

168. As described below, Boehringer contentedly sold its two legacy COPD treatments, Spiriva and Combivent, in these generic "L shaped" inhalers for many years—inhaler designs that are readily available in the public domain. But as expiration of its patent protection over its legacy Spiriva and Combivent products approached, Boehringer sensed the end of its astronomical profits in the areas of COPD and asthma treatment.

169. Rather than cede its profits to generic competition, Boehringer developed the Respimat inhaler device in 2004. It was described as a "compact aqueous delivery system" but it was essentially the same old mutton dressed as lamb—it delivered the same drugs, although it looked different because the medication canister was oriented horizontally, rather than vertically:

170. This device-switch strategy was an intentional effort to stretch patent exclusivity for much longer than Boehringer could lawfully claim for its legacy drugs.

171. Boehringer's Respimat inhaler device represents a distinction without a difference when it comes to patient outcomes. While manufacturers try to justify device changes by claiming that some patients may benefit from one type of inhaler over another (based on factors including inspiratory force, dexterity, and others), treatment guidelines tend not to favor any particular device type so long as clinicians counsel their patients on proper use and patients are comfortable using the prescribed device. And, while drug manufacturers may assert that their device changes are intended to improve adherence or drug administration, there has been no improvements with inhaler efficacy or compliance over the last 40 years, despite countless design changes. In the end, these inhaler switches and maneuvers serve only one end—to prolong manufacturers' monopoly profits.

2. The drug substances in Combivent Respimat are old drug substances.

172. The drug product in Combivent Respimat is a combination of two active ingredients: ipratropium bromide and albuterol sulfate. Both are old drugs. Albuterol sulfate was patented in 1972; its patents have long since expired. Ipratropium bromide was introduced as a treatment for COPD two years later in 1974; its original patents, too, have long since expired.

173. Boehringer first introduced a drug product containing ipratropium bromide, called Atrovent, in 1986. Atrovent was covered by one patent, U.S. Patent No. 3,681,500, which claimed the drug substance ipratropium bromide. That patent expired in August 1991, and Atrovent's New Chemical Entity exclusivity expired in December 1991. But in the meantime, Boehringer enjoyed a lucrative exclusivity during which no generic versions of the drug were available.

174. In the mid-1990s, as Boehringer watched generic competition erode its high profits on Atrovent, it introduced a second ipratropium-bromide-containing product, Combivent. In 1996, the FDA approved Combivent as a combination of ipratropium bromide and albuterol in a standard inhaler. Because the patent on ipratropium bromide had expired, and because the patent on albuterol had long since expired, Boehringer could not list any patents in the Orange Book. A regulatory exclusivity protected Combivent from competition, but only until October 24, 1999. Soon thereafter, Boehringer faced several generic competitors.

3. In the early 2010s, Boehringer used the requirement to remove CFCs from its inhalation products as an excuse to launch the Combivent Respimat.

175. In April 2010, the FDA announced that it had finalized a rule phasing out seven different inhaler products that contained chlorofluorocarbons, or CFCs, because CFCs are harmful to the environment. Under that rule, Boehringer could no longer sell its original Combivent formulation after December 31, 2013.

176. Undaunted in its quest to maintain monopoly profits, Boehringer reformulated its Combivent product, replacing CFCs with HFAs. Boehringer was not alone in shifting from CFCs to HFAs—many inhaler manufacturers did the same in the face of the FDA's mandate to stop using CFCs.

177. But Boehringer took it a step further. It changed the inhaler sold with its Combivent product from a standard inhaler to a new inhaler variant, called the Respimat. It submitted NDA No. 21747 to the FDA for a "new" product, called the Combivent Respimat. Combivent Respimat comprised a mixture of ipratropium bromide and albuterol in a metered dose inhaler.

178. The FDA approved Combivent Respimat on October 7, 2011. Because Combivent Respimat did not contain a new chemical entity, Boehringer received only a three-year regulatory exclusivity, which expired on October 7, 2014.

179. On December 31, 2013, Boehringer discontinued selling its original Combivent product, as required by the FDA's regulations.

180. The change from Combivent's legacy inhaler to the Respimat inhaler was not necessary to accommodate the shift from a CFC-containing product to an HFA-containing product.

181. Nor was it particularly helpful for patients. The original Combivent product required patients to take two 2 inhalations 4 times a day (and no more than 12 puffs a day); while Combivent Respimat required 1 inhalation 4 times a day (and not more than 6 puffs a day). This created confusion and safety issues for patients, as physicians continued to submit prescriptions to pharmacies with instructions to take two puffs instead of one. And it created billing problems for pharmacies as a 4-puff a day dosing regimen would last 30 days, whereas a 6-puff a day regimen lasted only 20, so patients sometimes struggled to receive timely refills of this medication they needed in order to be able just to breathe.

182. But that did not matter to Boehringer. As will become clear below, Boehringer made the change to the Respimat inhaler because it held several patents claiming that inhaler. It intended to use those patents to delay competition; and to protect its monopoly profits.

4. The FDA approved Spiriva Respimat in 2014; it was not a new drug substance, even then.

183. As with Combivent Respimat, Spiriva Respimat was not an innovative new drug. Instead, it was a tweak from an earlier product, called Spiriva.

184. In January 2004, the FDA approved Boehringer's application to make Spiriva, which was the drug substance tiotropium bromide provided with a standard inhaler. Spiriva was, and remains, one of Boehringer's top products. In 2015, Spiriva was the best-selling product, generating net sales of over $3.9 billion. In 2017, Spiriva was globally the most prescribed medication for long-term treatment of COPD. Boehringer filled up the Orange Book entry for its original Spiriva product with a

dozen patents—several of which do not claim the drug tiotropium bromide—extending its purported monopoly over that product through 2026 (or 2030, if you count its latest-expiring improperly listed patent).[68] Boehringer enjoyed almost 20 years of monopoly over its Spiriva product: it did not face generic competition until June 2023, when Lupin launched a generic version of Spiriva.

185. Unsatisfied with its success with Spiriva, or its improper patent thicket, Boehringer sought ways to extend its astronomical profits at the expense of COPD sufferers. In November 2007, it submitted to the FDA NDA No. 21936, seeking to make, market, and sell Spiriva's active ingredient, tiotropium bromide, in its Respimat metered dose inhaler as a treatment for COPD. The FDA approved Boehringer's Spiriva Respimat application on September 24, 2014. Because Spiriva Respimat did not contain a new chemical entity, the FDA granted Boehringer only a three-year regulatory exclusivity, which expired on September 24, 2017.

186. As with Boehringer's switch from Combivent to Combivent Respimat, there was no medical or scientific justification for Boehringer to suddenly change the inhaler in which it sold Spiriva. And as with the Combivent to Combivent Respimat shift, the change in inhaler device could cause problems for patients. But, once again, changing from a standard inhaler to a Respimat inhaler allowed Boehringer to improperly stuff the Orange Book with sixteen device patents.

[68] Boehringer listed its latest-expiring patent that includes tiotropium bromide in its claims as a "drug product" patent, although it is actually a method of use patent: it claims a method of using an inhaler to administer tiotropium bromide. *See* U.S. Patent No. 8,022,082. Listing this patent as a drug product patent, rather than a method-of-use patent, ensured that it would (and will) be more difficult for generic drugmakers to design around, because it prevented generic drugmakers from submitting a section viii carveout to this patent. 21 U.S.C. § 355(j)(2)(A)(viii).

C. Upon introducing the Respimat inhaler with its Combivent and Spiriva drug products, Boehringer improperly submitted inhaler device patents for listing in the Orange Book.

1. Boehringer improperly submitted 23 device patents to the Orange Book as claiming Combivent Respimat.

187. Every patent listed for Combivent Respimat was a device patent; only 2 of the 25 patents that have ever been listed actually referenced the drug combination of ipratropium bromide and albuterol sulfate in a claim. Boehringer submitted both of those patents immediately upon Combivent Respimat's approval in October 2011.

188. First, Boehringer submitted a device patent, U.S. Patent No. 6,988,496 (the '496 patent), entitled "Cartridge for a liquid," to the FDA for listing in the Orange Book. That patent issued on January 24, 2006, and expired February 23, 2020. This patent seems to have intended to claim the drug product in Combivent: dependent claim 36 reads:

> A cartridge according to claim 34 for a medical liquid wherein the medical liquid contains one or more of the active substances Berotect (Fenoterol hydrobromide); 1-(3,5-dihydroxy-phenyl)-2-[[1-(4-hydroxy-benzyl)-ethyl]-amino]-ethanol hydrobromide), Atrovent (Ipratropium bromide), Berodual (combination of Fenoterol hydrobromide and Ipratropium bromide), Salbutamol, *Salbutomal sulphate Combivent*, Oxivent (Oxitropium bromide), Ba 679 (Tiotropium bromide), BEA 2108 (di-(2-thienyl)-glycolic acid tropenol ester), Flunisolid, Budesonid and Beclomethasone.

"Salbutamol sulphate Combivent" does not correspond with any known drug: salbutamol is another name for albuterol, but there is already albuterol contained within Combivent. To the extent that this is a typographical error, Boehringer could

have, but does not appear to have, requested the U.S. Patent and Trademark Office (PTO) to issue a certificate of correction to ameliorate this ambiguity.

189. Second, Boehringer submitted another device patent, U.S. Patent No. 7,104,470 (the '470 patent), entitled "Device for producing high pressure in a fluid in miniature." Its principal independent claim was for a replaceable cartridge for an atomizable liquid. Dependent claim 3 of that patent read:

> The replaceable unit of claim 1, wherein said storage container comprises a pharmaceutically acceptable solution of a medicament selected from the group consisting of berotec, berodual, flunisolide, Atrovent, salbutamol, budesonide, combivent, tiotropium, oxivent, and suitable peptides.

190. That patent issued September 12, 2006, and expired October 4, 2016.

i. Boehringer wrongfully caused the '084 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

191. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 5,405,084 (the '084 patent), entitled "Nozzle assembly for preventing back-flow."

192. The '084 patent issued on April 11, 1995, and contains 16 claims: 3 independent claims and 13 dependent claims.

193. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

194. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '084 patent.

195. The ’084 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

196. Boehringer submitted the ’084 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the ’084 patent Patent Listing Form by answering “yes” to Question 3.1—whether the patent “claim[s] the approved drug product *as defined in 21 CFR 314.3*.”

197. Because the ’084 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer’s response to question 3.1 was false.

198. Because Boehringer’s answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the ’084 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

199. Because Boehringer wrongfully submitted the ’084 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

200. The ’084 patent, if valid and enforceable, expired April 11, 2012.

ii. Boehringer wrongfully caused the ’143 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

201. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 5,472,143 (the ’143 patent), entitled “Atomising nozzle and filter and spray generation device.”

202. The ’143 patent issued on December 5, 1995, and contains 44 claims: 2 independent claims and 42 dependent claims.

203. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

204. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '143 patent.

205. The '143 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

206. Boehringer submitted the '143 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '143 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

207. Because the '143 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

208. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '143 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

209. Because Boehringer wrongfully submitted the '143 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

210. The '143 patent, if valid and enforceable, expired September 29, 2013.

iii. Boehringer wrongfully caused the '944 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

211. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 5,497,944 (the '944 patent), entitled "Atomising devices and methods."

212. The '944 patent issued on March 12, 1996, and contains 76 claims: 11 independent claims and 65 dependent claims.

213. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

214. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '944 patent.

215. The '944 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

216. Boehringer submitted the '944 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '944 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

217. Because the '944 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

218. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '944 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

219. Because Boehringer wrongfully submitted the '944 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

220. The '944 patent, if valid and enforceable, expired March 12, 2013.

iv. Boehringer wrongfully caused the '271 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

221. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 5,662,271 (the '271 patent), entitled "Atomizing devices and methods."

222. The '271 patent issued on September 2, 1997, and contains 49 claims: 6 independent claims and 43 dependent claims.

223. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

224. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '271 patent.

225. The '271 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

226. Boehringer submitted the '271 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '271 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

227. Because the ’271 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer’s response to question 3.1 was false.

228. Because Boehringer’s answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the ’271 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

229. Because Boehringer wrongfully submitted the ’271 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

230. The ’271 patent, if valid and enforceable, expired September 2, 2014.

v. Boehringer wrongfully caused the ’851 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

231. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 5,911,851 (the ’851 patent), entitled “Atomizing nozzle and filter and spray generating device.”

232. The ’851 patent issued on June 15, 1999, and contains 21 claims: 3 independent claims and 18 dependent claims.

233. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

234. In fact, the words “ipratropium bromide” and “albuterol” do not appear anywhere in the ’851 patent.

235. The ’851 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

236. Boehringer submitted the '851 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '851 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

237. Because the '851 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

238. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '851 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

239. Because Boehringer wrongfully submitted the '851 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

240. The '851 patent, if valid and enforceable, expired September 29, 2013.

vi. Boehringer wrongfully caused the '416 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

241. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 5,964,416 (the '416 patent), entitled "Device for producing high pressure in a fluid in miniature."

242. The '416 patent issued on October 12, 1999, and contains 22 claims: 3 independent claims and 19 dependent claims.

243. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

244. The words "ipratropium bromide" do not appear anywhere in the '416 patent. "Salbutamol" (another name for albuterol) and Combivent are mentioned in the patent's specifications, but not in the patent's claims.

245. The '416 patent does not claim an ipratropium bromide and albuterol sulfate combination product.

246. Boehringer submitted the '416 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '416 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

247. Because the '416 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

248. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '416 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

249. Because Boehringer wrongfully submitted the '416 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

250. The '416 patent, if valid and enforceable, expired October 4, 2016.

vii. Boehringer wrongfully caused the '676 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

251. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 6,007,676 (the '676 patent), entitled "Atomizing nozzle and filter and spray generating device."

252. The '676 patent issued on December 28, 1999, and contains 32 claims: 5 independent claims and 27 dependent claims.

253. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

254. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '676 patent.

255. The '676 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

256. Boehringer submitted the '676 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '676 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

257. Because the '676 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

258. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '676 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

259. Because Boehringer wrongfully submitted the '676 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

260. The '676 patent, if valid and enforceable, expired September 29, 2013.

viii. Boehringer wrongfully caused the '054 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

261. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 6,149,054 (the '054 patent), entitled "Mechanical counter for a metering apparatus."

262. The '054 patent issued on November 21, 2000, and contains 29 claims: 3 independent claims and 26 dependent claims.

263. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

264. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '054 patent.

265. The '054 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

266. Boehringer submitted the '054 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '054 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

267. Because the '054 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

268. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '054 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

269. Because Boehringer wrongfully submitted the '054 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

270. The '054 patent, if valid and enforceable, expired December 19, 2016.

ix. Boehringer wrongfully caused the '442 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

271. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 6,176,442 (the '442 patent), entitled "Device for mounting a component exposed to a pressurized fluid."

272. The '442 patent issued on January 23, 2001, and contains 17 claims: 1 independent claim and 16 dependent claims.

273. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '442 patent.

274. The '442 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

275. Boehringer submitted the '442 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '442 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

276. Because the '442 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

277. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '442 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

278. Because Boehringer wrongfully submitted the '442 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

279. The '442 patent, if valid and enforceable, expired October 4, 2016.

x. Boehringer wrongfully caused the '795 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

280. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 6,453,795 (the '795 patent), entitled "Locking mechanism for a spring-actuated device."

281. The '795 patent issued on September 24, 2002, and contains 7 claims: 1 independent claim and 6 dependent claims.

282. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

283. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '795 patent.

284. The '795 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

285. Boehringer submitted the '795 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '795 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

286. Because the '795 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

287. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '795 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

288. Because Boehringer wrongfully submitted the '795 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

289. The '795 patent, if valid and enforceable, expired December 5, 2016.

xi. Boehringer wrongfully caused the '362 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

290. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 6,503,362 (the '362 patent), entitled "Atomizing nozzle an filter and spray generating device."

291. The ’362 patent issued on January 7, 2003, and contains 20 claims: 1 independent claim and 19 dependent claims.

292. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

293. In fact, the words “ipratropium bromide” and “albuterol” do not appear anywhere in the ’362 patent.

294. The ’362 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

295. Boehringer submitted the ’362 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the ’362 patent Patent Listing Form by answering “yes” to Question 3.1—whether the patent “claim[s] the approved drug product *as defined in 21 CFR 314.3*.”

296. Because the ’362 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer’s response to question 3.1 was false.

297. Because Boehringer’s answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the ’362 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

298. Because Boehringer wrongfully submitted the ’362 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

299. The ’362 patent, if valid and enforceable, expired September 29, 2013.

xii. Boehringer wrongfully caused the '124 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

300. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 6,726,124 (the '124 patent), entitled "Device for producing high pressure in a fluid in miniature."

301. The '124 patent issued on April 27, 2004, and contains 7 claims: 3 independent claims and 4 dependent claims.

302. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

303. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '124 patent. Salbutamol and Combivent are mentioned in the patent's specification, but not in the patent's claims.

304. The '124 patent does not claim an ipratropium bromide and albuterol sulfate combination product.

305. Boehringer submitted the '124 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '124 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

306. Because the '124 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

307. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '124 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

308. Because Boehringer wrongfully submitted the '124 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

309. The '124 patent, if valid and enforceable, expired October 4, 2016.

xiii. Boehringer wrongfully caused the '413 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

310. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 6,846,413 (the '413 patent), entitled "Microstructured filter."

311. The '413 patent issued on January 25, 2005, and contains 25 claims: 2 independent claims and 23 dependent claims.

312. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

313. In fact, the words "ipratropium bromide" do not appear anywhere in the '413 patent. "Salbutarnol"[69] and "Combivent" are referenced in the patent's specification, but not in the patent's claims.

314. The '413 patent does not claim an ipratropium bromide and albuterol sulfate combination product.

[69] Given salbutarnol is not a drug, this is likely a typo and intended to be salbutamol, which is another name for albuterol.

315. Boehringer submitted the '413 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '413 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

316. Because the '413 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

317. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '413 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

318. Because Boehringer wrongfully submitted the '413 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

319. The '413 patent, if valid and enforceable, expired August 28, 2018.

xiv. Boehringer wrongfully caused the '042 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

320. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 6,977,042 (the '042 patent), entitled "Microstructured filter."

321. The '042 patent issued on December 20, 2005, and contains 27 claims: 2 independent claims and 25 dependent claims.

322. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

323. In fact, the words "ipratropium bromide" do not appear anywhere in the '042 patent. "Salbutamol" and "Combivent" appear in the patent's specification, but not in its claims.

324. The '042 patent does not claim an ipratropium bromide and albuterol sulfate combination product.

325. Boehringer submitted the '042 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '042 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

326. Because the '042 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

327. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '042 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

328. Because Boehringer wrongfully submitted the '042 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

329. The '042 patent, if valid and enforceable, expired August 28, 2018.

xv. Boehringer wrongfully caused the '615 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

330. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 7,246,615 (the '615 patent), entitled "Atomising nozzle and filter and spray generating device."

331. The '615 patent issued on July 24, 2007, and contains 20 claims: 1 independent claim and 19 dependent claims.

332. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

333. In fact, the words "ipratropium bromide" and "albuterol sulfate" do not appear anywhere in the '615 patent.

334. The '615 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

335. Boehringer submitted the '615 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '615 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

336. Because the '615 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

337. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '615 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

338. Because Boehringer wrongfully submitted the '615 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

339. The '615 patent, if valid and enforceable, expired May 31, 2016.

xvi. Boehringer wrongfully caused the '474 patent to be listed in the Orange Book as a Combivent Respimat drug product patent, where it remains improperly listed today.

340. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 7,284,474 (the '474 patent), entitled "Piston-pumping system having o-ring seal properties."

341. The '474 patent issued on October 23, 2007, and contains 17 claims: 1 independent claim and 16 dependent claims.

342. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

343. In fact, the words "ipratropium bromide" and "albuterol sulfate" do not appear anywhere in the '474 patent.

344. The '474 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

345. Boehringer submitted the '474 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '474 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

346. Because the '474 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

347. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '474 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

348. Because Boehringer wrongfully submitted the '474 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

349. The '474 patent, if valid and enforceable, expires August 26, 2024.

xvii. Boehringer wrongfully caused the '6,341 patent to be listed in the Orange Book as a Combivent Respimat drug product patent, where it remains improperly listed today.

350. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 7,396,341 (the '6,341 patent), entitled "Blocking device for a locking stressing mechanism having a spring-actuated output drive device."

351. The '6,341 patent issued on July 8, 2008, and contains 11 claims: 1 independent claim and 10 dependent claims.

352. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

353. "Salbutamol (or albuterol)," "ipratropium bromide," and "Combivent" are mentioned in the patent's specification, but not in the patent's claims.

354. The ’6,341 patent does not claim an ipratropium bromide and albuterol sulfate combination product.

355. Boehringer submitted the ’6,341 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the ’6,341 patent Patent Listing Form by answering “yes” to Question 3.1—whether the patent “claim[s] the approved drug product *as defined in 21 CFR 314.3*.”

356. Because the ’6,341 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer’s response to question 3.1 was false.

357. Because Boehringer’s answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the ’6,341 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

358. Because Boehringer wrongfully submitted the ’6,341 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

359. The ’6,341 patent, if valid and enforceable, expires October 10, 2026.

xviii. Boehringer wrongfully caused the ’568 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

360. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 7,802,568 (the ’568 patent), entitled “Cartridge for a liquid.”

361. The ’568 patent issued on September 28, 2010, and contains 8 claims: 2 independent claims and 6 dependent claims.

362. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

363. "Salbutamol" and Combivent are mentioned in the patent's specifications, but not in the patent's claims.

364. The '568 patent does not claim an ipratropium bromide and albuterol sulfate combination product.

365. Boehringer submitted the '568 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '568 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

366. Because the '568 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

367. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '568 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

368. Because Boehringer wrongfully submitted the '568 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

369. The '568 patent, if valid and enforceable, expired February 23, 2020.

xix. Boehringer wrongfully caused the '235 patent to be listed in the Orange Book as a Combivent Respimat drug product patent, where it remains improperly listed today.

370. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 7,837,235 (the '235 patent), entitled "Device for clamping a fluidic component."

371. The '235 patent issued on November 23, 2010, and contains 9 claims: 1 independent claim and 8 dependent claims.

372. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

373. "Salbutamol (or albuterol)," "ipratropium bromide," and "combivent" are mentioned in the patent's specifications, but not in the patent's claims.

374. The '235 patent does not claim an ipratropium bromide and albuterol sulfate combination product.

375. Boehringer submitted the '235 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '235 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

376. Because the '235 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

377. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '235 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

378. Because Boehringer wrongfully submitted the '235 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

379. The '235 patent, if valid and enforceable, expires March 13, 2028.

xx. Boehringer wrongfully caused the '264 patent to be listed in the Orange Book as a Combivent Respimat drug product patent, where it remains improperly listed today.

380. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 7,896,264 (the '264 patent), entitled "Microstructured high pressure nozzle with built-in filter function."

381. The '264 patent issued on March 1, 2011, and contains 37 claims: 1 independent claim and 36 dependent claims.

382. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

383. "Combivent (ipratropium bromide plus salbutamol)" is referenced in the patent's specification, but not in the patent's claims.

384. The '264 patent does not claim an ipratropium bromide and albuterol sulfate combination product.

385. Boehringer submitted the '264 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as

such in the '264 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

386. Because the '264 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

387. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '264 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

388. Because Boehringer wrongfully submitted the '264 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

389. The '264 patent, if valid and enforceable, expires May 26, 2025.

xxi. Boehringer wrongfully caused the '001 patent to be listed in the Orange Book as a Combivent Respimat drug product patent.

390. In October 2011, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 7,988,001 (the '001 patent), entitled "Container provided with a pressure equalization opening."

391. The '001 patent issued on August 2, 2011, and contains 2 independent claims.

392. Neither claim recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

393. In fact, the words "ipratropium bromide" and "albuterol" do not appear anywhere in the '001 patent.

394. The ’001 patent does not mention, let alone claim, an ipratropium bromide and albuterol sulfate combination product.

395. Boehringer submitted the ’001 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the ’001 patent Patent Listing Form by answering “yes” to Question 3.1—whether the patent “claim[s] the approved drug product *as defined in 21 CFR 314.3*.”

396. Because the ’001 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer’s response to question 3.1 was false.

397. Because Boehringer’s answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the ’001 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

398. Because Boehringer wrongfully submitted the ’001 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

399. The ’001 patent, if valid and enforceable, expired August 22, 2022.

xxii. Boehringer wrongfully caused the ’3,341 patent to be listed in the Orange Book as a Combivent Respimat drug product patent, where it remains improperly listed today.

400. In August 2015, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 8,733,341 (the ’3,341 patent), entitled “Atomizer and method of atomizing fluid with a nozzle rinsing mechanism.”

401. The '3,341 patent issued on May 27, 2014, and contains 16 claims: 2 independent claims and 14 dependent claims.

402. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

403. "Ipratropium salts" and "albuterol" are mentioned in the patent's specification, but not in the patent's claims.

404. To the extent that Boehringer may point to dependent claims 8 or 10 as claiming Combivent Respimat, those claims are invalid, for at least four reasons.

a. Claims 8 and 10 of the '3,341 patent are invalid for failure to satisfy § 112(a)'s enablement requirement.

405. Both claim 8 and claim 10 are invalid under 35 U.S.C. § 112. Each describes a variation of the atomizer defined in claim 1 by reference to various categories, or genera (the plural of genus), of potential compounds, spelled out in the patent's specification. These claims, known as "genus" claims, fail to satisfy the patent laws' requirement for an adequate written specification because they do not enable a person having ordinary skill in the art—the patent-law equivalent of the hypothetical reasonable person—to practice the full scope of the claims' inventions without undue experimentation.

406. The '3,341 patent's specification lists examples of each category of compound that may fill the empty atomizer described in claim 1. For example, the specification reads:

> The compounds used as betamimetics are preferably compounds selected from among albuterol, arformoterol, bambuterol, bitolterol, broxaterol, carbuterol, clenbuterol,

fenoterol, formoterol, hexoprenaline, ibuterol, isoetharine, isoprenaline, levosalbutamol, mabuterol, meluadrine, metaproterenol, orciprenaline, pirbuterol, procaterol, reproterol, rimiterol, ritodrine, salmefamol, salmeterol, soterenol, sulphonterol, terbutaline, tiaramide, tolubuterol, zinterol, CHF-1035, HOKU-81, KUL-1248 and

3-(4-{6-[2-hydroxy-2-(4-hydroxy-3-hydroxymethyl-phenyl)-ethylamino]-hexyloxy}-butyl)-benzyl-sulphonamide

5-[2-(5,6-diethyl-indan-2-ylamino)-1-hydroxy-ethyl]-8-hydroxy-1H-quinolin-2-one

4-hydroxy-7-[2-{[2-{[3-(2-phenylethoxy)propyl]sulphonyl}ethyl]-amino}ethyl]-2(3H)-benzothiazolone

1-(2-fluoro-4-hydroxyphenyl)-2-[4-(1-benzimidazolyl)-2-methyl-2-butylamino]ethanol

1-[3-(4-methoxybenzyl-amino)-4-hydroxyphenyl]-2-[4-(1-benzimidazolyl)-2-methyl-2-butylamino]ethanol

1-[2H-5-hydroxy-3-oxo-4H-1,4-benzoxazin-8-yl]-2-[3-(4-N,N-dimethylaminophenyl)-2-methyl-2-propylamino]ethanol

1-[2H-5-hydroxy-3-oxo-4H-1,4-benzoxazin-8-yl]-2-[3-(4-methoxyphenyl)-2-methyl-2-propylamino]ethanol

1-[2H-5-hydroxy-3-oxo-4H-1,4-benzoxazin-8-yl]-2-[3-(4-n-butyloxyphenyl)-2-methyl-2-propylamino]ethanol

1-[2H-5-hydroxy-3-oxo-4H-1,4-benzoxazin-8-yl]-2-{4-[3-(4-methoxyphenyl)-1,2,4-triazol-3-yl]-2-methyl-2-butylamino}ethanol

5-hydroxy-8-(1-hydroxy-2-isopropylaminobutyl)-2H-1,4-benzoxazin-3-(4H)-one

1-(4-amino-3-chloro-5-trifluoromethylphenyl)-2-tert.-butylamino)ethanol

6-hydroxy-8-{1-hydroxy-2-[2-(4-methoxy-phenyl)-1,1-dimethyl-ethylamino]-ethyl}-4H-benzo[1,4]oxazin-3-one

6-hydroxy-8-{1-hydroxy-2-[2-(ethyl 4-phenoxy-acetate)-1,1-dimethyl-ethylamino]-ethyl}-4H-benzo[1,4]oxazin-3-one

6-hydroxy-8-{1-hydroxy-2-[2-(4-phenoxy-acetic acid)-1,1-dimethyl-ethylamino]-ethyl}-4H-benzo[1,4]oxazin-3-one

8-{2-[1,1-dimethyl-2-(2,4,6-trimethylphenyl)-ethylamino]-1-hydroxy-ethyl}-6-hydroxy-4H-benzo[1,4]oxazin-3-one

6-hydroxy-8-{1-hydroxy-2-[2-(4-hydroxy-phenyl)-1,1-dimethyl-ethylamino]-ethyl}-4H-benzo[1,4]oxazin-3-one

6-hydroxy-8-{1-hydroxy-2-[2-(4-isopropyl-phenyl)-1.1 dimethyl-ethylamino]-ethyl}-4H-benzo[1,4]oxazin-3-one

8-{2-[2-(4-ethyl-phenyl)-1,1-dimethyl-ethylamino]-1-hydroxy-ethyl}-6-hydroxy-4H-benzo[1,4]oxazin-3-one

8-{2-[2-(4-ethoxy-phenyl)-1,1-dimethyl-ethylamino]-1-hydroxy-ethyl}-6-hydroxy-4H-benzo[1,4]oxazin-3-one

4-(4-{2-[2-hydroxy-2-(6-hydroxy-3-oxo-3,4-dihydro-2H-benzo[1,4]oxazin-8-yl)-ethylamino]-2-methyl-propyl}-phenoxy)-butyric acid

8-{2-[2-(3,4-difluoro-phenyl)-1,1-dimethyl-ethylamino]-1-hydroxy-ethyl}-6-hydroxy-4H-benzo[1,4]oxazin-3-one

1-(4-ethoxy-carbonylamino-3-cyano-5-fluorophenyl)-2-(tert-butylamino)ethanol

2-hydroxy-5-(1-hydroxy-2-{2-[4-(2-hydroxy-2-phenyl-ethylamino)-phenyl]-ethylamino}-ethyl)-benzaldehyde

N-[2-hydroxy-5-(1-hydroxy-2-{2-[4-(2-hydroxy-2-phenyl-ethylamino)-phenyl]-ethylamino}-ethyl)-phenyl]-formamide

8-hydroxy-5-(1-hydroxy-2-{2-[4-(6-methoxy-biphenyl-3-ylamino)-phenyl]-ethylamino}-ethyl)-1H-quinolin-2-one

8-hydroxy-5-[1-hydroxy-2-(6-phenethylamino-hexylamino)-ethyl]-1H-quinolin-2-one

5-[2-(2-{4-[4-(2-amino-2-methyl-propoxy)-phenylamino]-phenyl}-ethylamino)-1-hydroxy-ethyl]-8-hydroxy-1H-quinolin-2-one

> [3-(4-{6-[2-hydroxy-2-(4-hydroxy-3-hydroxymethyl-phenyl)-ethylamino]-hexyloxy}-butyl)-5-methyl-phenyl]-urea
>
> 4-(2-{6-[2-(2,6-dichloro-benzyloxy)-ethoxy]-hexylamino}-1-hydroxy-ethyl)-2-hydroxymethyl-phenol
>
> 3-(4-{6-[2-hydroxy-2-(4-hydroxy-3-hydroxymethyl-phenyl)-ethylamino]-hexyloxy}-butyl)-benzylsulphonamide
>
> 3-(3-{7-[2-hydroxy-2-(4-hydroxy-3-hydroxymethyl-phenyl)-ethylamino]-heptyloxy}-propyl)-benzylsulphonamide
>
> 4-(2-{6-[4-(3-cyclopentanesulphonyl-phenyl)-butoxy]-hexylamino}-1-hydroxy-ethyl)-2-hydroxymethyl-phenol
>
> N-adamantan-2-yl-2-(3-{2-[2-hydroxy-2-(4-hydroxy-3-hydroxymethyl-phenyl)-ethylamino]-propyl}-phenyl)-acetamide
>
> optionally in the form of the racemates, enantiomers, diastereomers thereof and optionally in the form of the pharmacologically acceptable acid addition salts, solvates or hydrates thereof. According to the invention the acid addition salts of the betamimetics are preferably selected from among the hydrochloride, hydrobromide, hydriodide, hydrosulphate, hydrophosphate, hydromethane-sulphonate, hydronitrate, hydromaleate, hydroacetate, hydrocitrate, hydrofumarate, hydrotartrate, hydroxalate, hydrosuccinate, hydrobenzoate and hydro-p-toluenesulphonate.

This describes 1,072 different varieties of betamimetic salts (67 different molecules, each with 16 different possible salts), *plus* all of their racemates, enantiomers, [and] diastereomers," *plus* all solvates" and "hydrates" thereof. Upon information and belief, the number of potential betamimetics described in this passage of the specification could far exceed 5,000 different compounds.

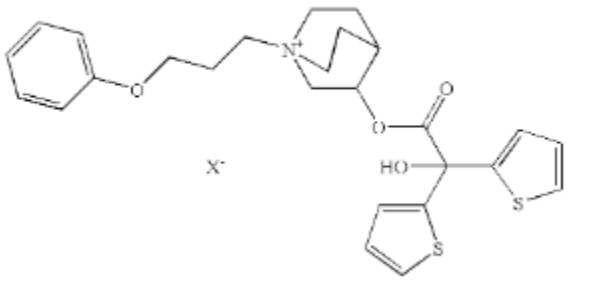
407. And as for anticholinergics, the specification suggests:

> The anticholinergics used are preferably compounds selected from among the tiotropium salts, preferably the

bromide salt, oxitropium salts, preferably the bromide salt, flutropium salts, preferably the bromide salt, ipratropium salts, preferably the bromide salt, glycopyrronium salts, preferably the bromide salt, trospium salts, preferably the chloride salt, tolterodine. In the above-mentioned salts the cations are the pharmacologically active constituents. As anions the above-mentioned salts may preferably contain the chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate or p-toluenesulphonate, while chloride, bromide, iodide, sulphate, methanesulphonate or p-toluenesulphonate are preferred as counter-ions. Of all the salts the chlorides, bromides, iodides and methanesulphonates are particularly preferred.

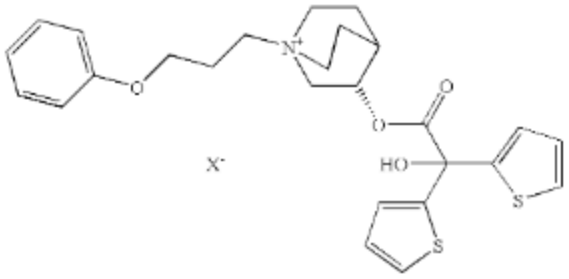
Other preferred anticholinergics are selected from among the salts of formula AC-1

AC-1



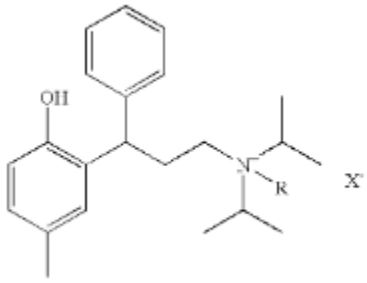
wherein X– denotes an anion with a single negative charge, preferably an anion selected from among the fluoride, chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate and p-toluenesulphonate, preferably an anion with a single negative charge, particularly preferably an anion selected from among the fluoride, chloride, bromide, methanesulphonate and p-toluenesulphonate, particularly preferably bromide, optionally in the form of the racemates, enantiomers or hydrates thereof. Of particular importance are those pharmaceutical combinations which contain the enantiomers of formula AC-1-en

AC-1-en



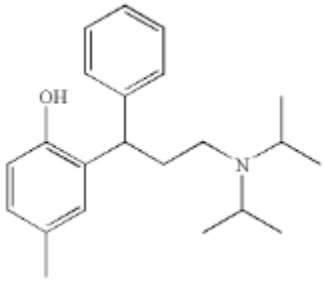
wherein X− may have the above-mentioned meanings. Other preferred anticholinergics are selected from the salts of formula AC-2

AC-2



wherein R denotes either methyl or ethyl and wherein X− may have the above-mentioned meanings. In an alternative embodiment the compound of formula AC-2 may also be present in the form of the free base AC-2-base.

AC-2-base



Other specified compounds are:

tropenol 2,2-diphenylpropionate methobromide,

scopine 2,2-diphenylpropionate methobromide,

scopine 2-fluoro-2,2-diphenylacetate methobromide,

tropenol 2-fluoro-2,2-diphenylacetate methobromide;

tropenol 3,3′,4,4′-tetrafluorobenzilate methobromide,

scopine 3,3′,4,4′-tetrafluorobenzilate methobromide,

tropenol 4,4′-difluorobenzilate methobromide,

scopine 4,4′-difluorobenzilate methobromide,

tropenol 3,3′-difluorobenzilate methobromide,

scopine 3,3′-difluorobenzilate methobromide;

tropenol 9-hydroxy-fluorene-9-carboxylate methobromide;

tropenol 9-fluoro-fluorene-9-carboxylate methobromide;

scopine 9-hydroxy-fluorene-9-carboxylate methobromide;

scopine 9-fluoro-fluorene-9-carboxylate methobromide;

tropenol 9-methyl-fluorene-9-carboxylate methobromide;

scopine 9-methyl-fluorene-9-carboxylate methobromide;

cyclopropyltropine benzilate methobromide;

cyclopropyltropine 2,2-diphenylpropionate methobromide;

cyclopropyltropine 9-hydroxy-xanthene-9-carboxylate methobromide;

cyclopropyltropine 9-methyl-fluorene-9-carboxylate methobromide;

cyclopropyltropine 9-methyl-xanthene-9-carboxylate methobromide;

cyclopropyltropine 9-hydroxy-fluorene-9-carboxylate methobromide;

cyclopropyltropine methyl 4,4′-difluorobenzilate methobromide.

Tropenol 9-hydroxy-xanthene-9-carboxylate methobromide;

> scopine 9-hydroxy-xanthene-9-carboxylate methobromide;
>
> tropenol 9-methyl-xanthene-9-carboxylate methobromide;
>
> scopine 9-methyl-xanthene-9-carboxylate methobromide;
>
> tropenol 9-ethyl-xanthene-9-carboxylate methobromide;
>
> tropenol 9-difluoromethyl-xanthene-9-carboxylate methobromide;
>
> scopine 9-hydroxymethyl-xanthene-9-carboxylate methobromide,
>
> The above-mentioned compounds may also be used as salts within the scope of the pre-sent invention, wherein instead of the methobromide the salts metho-X are used, wherein X may have the meanings given hereinbefore for X−.

This passage concretely describes 592 anticholinergic salts, but *also* purports to encompass as-yet undiscovered compounds *and* all of their salts. Conservatively, this amounts to at least another 85 compounds. In total, then, that is nearly 700 anticholinergic candidates.

408. The specification also refers to 22 different corticosteroids, 39 known and unknown PDE-4 inhibitors, 12 LTD-4 antagonists, 98 EGFR-inhibitors, 11 dopamine agonists, and 22 H1-antihistamines. But it also purports to sweep within the definition of each class of molecule (*e.g.*, corticosteroid, PDE-4 inhibitor, LTD-4 antagonist, EGFR-inhibitor, dopamine agonist, and H1-antihistamines), every single salt, solvate, or hydrate of every single "racemate, enantiomer, [and] diastereomer" of every listed molecule.

409. In total, therefore, the '3,341 patents' specification purports to sweep thousands, if not tens of thousands, of molecules—some of which have yet to be

discovered within the scope of the genus claims in Claims 8 and 10 of the '3,341 patent.

410. But there is more. Claims 8 and 10 both refer to "any combination of each of the foregoing" molecules. The specification purports to encompass "double or triple combinations" of these molecules within the fluid contained in the described atomizer. That would extend the reach of the genus claims to trillions of drug products.

411. This is not an exaggeration. To understand the astonishing scope of what Boehringer purports to claim, suppose the patent claimed *only* betamimetics, anticholinergics, and combinations of betamimetics and anticholinergics. Assume there are only 2 racemates of each enumerated molecule (there aren't), 2 enantiomers of each (there aren't), and 2 diastereomers of each (once again, there aren't). And assume there are only 2 kinds of solvates and 2 kinds of hydrates for each (there aren't). That would mean that the term "betamimetic," as used in the '3,341 patent's specification and claims 8 and 10 would encompass 10,720 different compounds. The term "anticholinergic" would encompass up to 5,632 different compounds (some of which have not even been discovered yet. If the patents' claims encompass all double and triple combinations, then Claims 8 and 10 would encompass 16,352 different individual compounds, 267,371,552 combinations of two compounds, and almost 4.4 *trillion* combinations of three compounds. If a person of ordinary skill in the art were to test one such molecule or combination an hour, every hour of the day without

breaking to eat, sleep, shower, use the bathroom, or watch Netflix, it would take that person *499 million years* to exhaust the possible combinations.

412. That is *just* combinations of betamimetics and anticholinergics (and *just* two racemates, two enantiomers, two diastereomers, two solvates, and two hydrates of each). The total number of possible combinations would reach *many* orders of magnitude higher when the other classes of compounds (corticosteroids, PDE-4 inhibitors, LTD-4 antagonists, EGFR-inhibitors, dopamine agonists, and H1-antihistamines), as well as the full scope of all racemates, enantiomers, and diastereomers, as well as all hydrates and solvates, are included.

413. And, at the end of the day, the thousands of included compounds enumerated in the '3,341 patents' specification are just the "preferred" examples of the various genera included in Claims 8 and 10. There could well be an astronomical number of additional, apparently non-preferred, compounds.

414. As the Federal Circuit has explained, a claim that encompasses a "potentially enormous" number of possible species within a genus fails for non-enablement.[70]

b. Claims 8 and 10 of the '3,341 patent also fail § 112's requirement for a written description.

415. A patent is invalid for failing to meet the requirement for a written specification when claims not presented in the original patent application were amended or added during prosecution.[71] The sufficiency of the written description is

[70] *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

[71] *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991).

judged as of the time the application is filed: "[the] original disclosure serves to limit the permissible breadth of [the] later-drafted claims."[72] Consider this analogy:

> The inventor files a patent application claiming "a stainless steel rake having a hard-wood handle." The specification discloses numerous species of hardwood, including beech, hickory, maple, oak, and walnut. It also explains how to make and use the rake. While the application is pending at the USPTO, the inventor seeks to amend the application by adding a genus claim that recites "a stainless steel rake having a wooden handle." Note that this claim comprises a larger genus because "wood" is broader than "hardwood." Enablement isn't an issue because rake-making is a predictable technology. But unfortunately for the inventor, the specification only describes and exemplifies hardwoods.[73]

416. In the '3,341 patent the specification (both upon initial submission and in final form) only describes the use of the atomizer with single compounds of combinations of two compounds:

> In the compounds mentioned below, W is a pharmacologically active substance and is selected (for example) from among the betamimetics, anticholinergics, corticosteroids, PDE4-inhibitors, LTD4-antagonists, EGFR-inhibitors, dopamine agonists, H1-antihistamines, PAF-antagonists and PI3-kinase inhibitors. Moreover, double or triple combinations of W may be combined and used in the device according to the invention. Combinations of W might be, for example:
>
> > W denotes a betamimetic, combined with an anticholinergic, corticosteroid, PDE4-inhibitor, EGFR-inhibitor or LTD4-antagonist,

[72] *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998).

[73] Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 Harvard J.L. & Tech. 1, 19 (2021).

> W denotes an anticholinergic, combined with a betamimetic, corticosteroid, PDE4-inhibitor, EGFR-inhibitor or LTD4-antagonist,
>
> W denotes a corticosteroid, combined with a PDE4-inhibitor, EGFR-inhibitor or LTD4-antagonist
>
> W denotes a PDE4-inhibitor, combined with an EGFR-inhibitor or LTD4-antagonist
>
> W denotes an EGFR-inhibitor, combined with an LTD4-antagonist.

The patent provides no guidance, at all, as to how to select the contemplated "triple" combinations. Just as "wood" is broader than the hardwoods listed in the rake example above, "double or triple combinations" is broader than the double combinations described in the '3,341 patent's specification as initially drafted.

417. The intent of the inventors to broaden the scope of the claimed invention can be seen in their unprompted amendments to the draft claims that would become Claims 8 and 10. As initially drafted in an international patent application and submitted to the PTO, the predecessor to Claim 8, submitted to the PTO with the rest of the initial application on November 5, 2008, read:

> Atomiser according to one of the preceding claims, characterize in that the atomizer (1) contains an inhalable formulation or a medicament in the form of a fluid (2), selected from among in particular the anticholinergics, betamimetics, steroids, phosphodiesterase IV-inhibitors, LTD-4 antagonists and EGFRE-kinase-inhibitors, antiallergics, ergot alkaloid derivatives, triptans, CGRP-antagonists, phosphodiesterase-V-inhibitors, and *combinations of such active substances, e.g. betamimetics plus anticholinergics or betamimetics plus antiallergics*.

418. The inventors then submitted an unsolicited (e.g., not in response to any PTO action) set of amended claims "to clarify the claimed subject matter." The revision to Claim 8's predecessor read:

> Atomiser according to ~~one of the preceding claims~~ Claim 1, characterized in that the atomizer (1) contains an inhalable formulation or a medicament in the form of a fluid (2), selected from ~~among in particular the~~ anticholinergics, betamimetics, steroids, phosphodiesterase IV-inhibitors, LTD-4 antagonists and EGFRE-kinase-inhibitors, antiallergics, ergot alkaloid derivatives, triptans, CGRP-antagonists, phosphodiesterase-V-inhibitors, and ~~combinations of such active substances, e.g. betamimetics plus anticholinergics or betamimetics plus antiallergics~~ any combination of each of the foregoing.

419. The same changes were made to the draft claim that would become claim 10.

420. The inventors falsely claimed to the PTO that "[n]o new matter [was] added by this amendment." But these changes broadened the scope of the purportedly claimed invention in two ways. First, it removed language suggesting that a combination would be two compounds: "e.g., betamimetics plus anticholinergics or betamimetics plus antiallergics." It replaced it with language vague enough to encompass combinations of three compounds. Second, it removed a reference to the compounds being "active substances"—removing the limitation on the claim that the substances actually confer some kind of medical benefit. Removing that limitation vastly, vastly expanded the number of potential compounds and combinations that Boehringer could sweep within the scope of its genus claims. Claims 8 and 10 are, accordingly, invalid for failure to conform to the written description requirement found in 35 U.S.C. § 112.

c. Claims 8 and 10 of the '3,341 patent are invalid under the on-sale bar.

421. Even if the genus claims are not invalid for non-enablement and lack of a written specification, Claims 8 and 10 of the '3,341 patent are additionally invalid under the on-sale bar. When the '3,341 patent's inventors amended their claims in November 2008, they also amended the specification "to include International Application No. PCT/EP2007003322, filed April 16, 2007."

422. An invention cannot be patented if it has been for sale or otherwise available to the public for over one year prior to the patent filing.[74] So, if Boehringer had sold a Respimat inhaler containing a combination of compounds, as described in its application, prior to April 16, 2006, then the invention described in the '3,341 patent is unpatentable, and any such claims are invalid.

423. Boehringer did sell a Respimat product falling within the scope of the claims before April 16, 2006. It first sold a Respimat inhaler containing a combination of a betamimetic (fenoterol) and an anticholinergic (ipratropium bromide) in Europe as early as 2004. Accordingly, (at least) claims 8 and 10 of the '3,341 patent are invalid under § 102's on-sale bar.

d. Claims 8 and 10 of the '3,341 patent are invalid as obvious.

424. A purported invention that would be obvious to a person of ordinary skill in the art is not patentable. If a patent issues with a claim over something that is obvious, that claim is invalid.

[74] 35 U.S.C. § 102.

425. Even if the genus claims were valid, and even if Boehringer had not sold a claimed product more than a year before submitting the application leading to the '3,341 patent, Claims 8 and 10 would be invalid as obvious.

426. It would have been obvious to a person of ordinary skill in the art to fill the empty atomizer described in the '3,341 patent with most, if not all, of the genera listed in Claims 8 and 10. There were already products on the market that combined anticholinergics with inhalers (for example, Boehringer's own Atrovent and Spiriva products). There were already products on the market that combined anticholinergics and betamimetics with an inhaler (like Combivent). The '3,341 patent just describes a new type of inhaler: it would have been obvious to any person of ordinary skill in the art.

427. The statutory Orange Book listing test imposes two conditions that must be satisfied for a patent to be listed; not only must it claim the drug, but it must be a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[75] An invalid patent claim cannot "reasonably be asserted" against a would-be infringer.

[75] 21 U.S.C. § 355(b)(1) (2019).

e. Boehringer submitted the '3,341 patent for listing in the Orange Book, even though it met neither prong of the statutory Orange Book listing test.

428. In sum, then, the '3,341 patent does not claim an ipratropium bromide and albuterol sulfate combination product in any valid, enforceable claim. Because the '3,341 patent does not claim an ipratropium bromide and albuterol sulfate combination product in any valid, enforceable claim, Boehringer should not have submitted it for patent listing.

429. Nevertheless, Boehringer submitted the '3,341 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '3,341 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

430. Because the '3,341 patent does not validly claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

431. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '3,341 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

432. Because Boehringer wrongfully submitted the '3,341 patent to the FDA, it wrongfully caused that patent—a patent that does not validly claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

433. The '3,341 patent, if valid and enforceable, expires June 7, 2030.

xxiii. Boehringer wrongfully caused the '967 patent to be listed in the Orange Book as a Combivent Respimat drug product patent, where it remains improperly listed today.

434. In August 2015, Boehringer submitted to the FDA a Patent Listing Form for U.S. Patent No. 9,027,967 (the '967 patent), entitled "Device for clamping a fluidic component."

435. The '967 patent issued on May 12, 2015, and contains 11 claims: 2 independent claims and 9 dependent claims.

436. None of those claims recite the Respimat inhaler device in combination with ipratropium bromide and albuterol sulfate.

437. "Combivent," "ipratropium bromide," and "salbutamol (or albuterol)" are referenced in the patent's specifications, but not in the patent's claims.

438. The '967 patent does not claim an ipratropium bromide and albuterol sulfate combination product.

439. Boehringer submitted the '967 patent as a drug product patent claiming the drug product Combivent Respimat. That means that Boehringer identified it as such in the '967 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

440. Because the '967 patent does not claim a combination of ipratropium bromide and albuterol sulfate, it does not claim the drug product Combivent Respimat. Therefore, Boehringer's response to question 3.1 was false.

441. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '967 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

442. Because Boehringer wrongfully submitted the '967 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Combivent Respimat—to be listed in the Orange Book under Combivent Respimat.

443. The '967 patent, if valid and enforceable, expires March 31, 2027.

2. Boehringer improperly submitted 16 device patents to the Orange Book as claiming Spiriva Respimat.

444. Only three of the nineteen patents that have ever been listed for Spiriva Respimat referenced tiotropium bromide in the claims. Boehringer submitted all three of those patents immediately upon Spiriva Respimat's approval in October 2014.

445. First, Boehringer submitted the '470 patent.

446. Second, Boehringer submitted the '496 patent. Because Boehringer tested the use of Spiriva Respimat in children, the FDA granted Boehringer a pediatric exclusivity extension on each of its listed patents in February 2017. So the protection conferred by the '496 patent expired August 23, 2020.

447. And third, Boehringer submitted U.S. Reissued Patent No. RE39,820 (the '820 patent), entitled *Esters of thienyl carboxylic acids and amino alcohols and their quaternization products*. That patent issued on September 4, 2007, and expired January 30, 2018, with a pediatric exclusivity extending to July 30, 2018.

i. Boehringer wrongfully caused the '416 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

448. Upon Spiriva Respimat's approval in October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '416 patent with respect to Spiriva Respimat, just has it had for Combivent Respimat three years earlier.

449. None of the '416 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

450. The patents' specification mentions tiotropium bromide, but its claims do not.

451. The '416 patent does not claim a tiotropium drug product.

452. Boehringer submitted the '416 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '416 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

453. Because the '416 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

454. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '416 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

455. Because Boehringer wrongfully submitted the '416 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

ii. Boehringer wrongfully caused the '054 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

456. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '054 patent with respect to Spiriva Respimat.

457. None of the '054 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

458. In fact, the words "tiotropium bromide" do not appear anywhere in the '054 patent.

459. The '054 patent does not claim a tiotropium drug product.

460. Boehringer submitted the '054 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '054 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

461. Because the '054 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

462. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '054 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

463. Because Boehringer wrongfully submitted the '054 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

iii. Boehringer wrongfully caused the '442 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

464. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '442 patent with respect to Spiriva Respimat.

465. None of the '442 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

466. In fact, the words "tiotropium bromide" do not appear anywhere in the '442 patent.

467. The '442 patent does not claim a tiotropium drug product.

468. Boehringer submitted the '442 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '442 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

469. Because the '442 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

470. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '442 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

471. Because Boehringer wrongfully submitted the '442 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

472. When Boehringer initially submitted its '442 Patent Listing Form, the patent number that appeared in the Orange Book was U.S. Patent No. 6,176,422. It is unknown whether this error was due to the information Boehringer submitted or a transcription error by the FDA. However, it was corrected in or before January 2016, when the 36th Edition of the Orange Book published. To correct the mislisting, Boehringer had to submit a second Patent Listing Form for the '442 patent—meaning Boehringer falsely certified for a second time that the '442 patent claimed the Spiriva Respimat drug product, when it does not.

iv. Boehringer wrongfully caused the '795 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

473. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '795 patent with respect to Spiriva Respimat.

474. None of the '795 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

475. In fact, the words "tiotropium bromide" do not appear anywhere in the '795 patent.

476. The '795 patent does not claim a tiotropium drug product.

477. Boehringer submitted the '795 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '795 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

478. Because the '795 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

479. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '795 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

480. Because Boehringer wrongfully submitted the '795 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

v. Boehringer wrongfully caused the '124 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

481. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '124 patent with respect to Spiriva Respimat, just as it had for Combivent Respimat three years earlier.

482. None of the '124 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

483. "Tiotropium bromide" is referenced in the patent's specification, but not in the patent's claims.

484. The '124 patent does not claim a tiotropium drug product.

485. Boehringer submitted the '124 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '124 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

486. Because the '124 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

487. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '124 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

488. Because Boehringer wrongfully submitted the '124 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

vi. Boehringer wrongfully caused the '413 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

489. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '413 patent with respect to Spiriva Respimat.

490. None of the '413 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

491. In fact, the words "tiotropium bromide" do not appear anywhere in the '413 patent.

492. The patent's specification references "Ba 679" which appears to be the designation tiotropium bromide was given during development. There are no references to Ba 679 in the patent's claims.

493. The '413 patent does not claim a tiotropium drug product.

494. Boehringer submitted the '413 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such

in the '413 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

495. Because the '413 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

496. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '413 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

497. Because Boehringer wrongfully submitted the '413 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

vii. Boehringer wrongfully caused the '042 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

498. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '042 patent with respect to Spiriva Respimat.

499. None of the '042 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

500. In fact, the words "tiotropium bromide" do not appear anywhere in the '042 patent.

501. "Ba 679" is referenced in the patent's specification, but not in the patent's claims.

502. The '042 patent does not claim a tiotropium drug product.

503. Boehringer submitted the '042 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '042 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

504. Because the '042 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

505. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '042 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

506. Because Boehringer wrongfully submitted the '042 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

viii. Boehringer wrongfully caused the '615 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

507. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '615 patent with respect to Spiriva Respimat.

508. None of the '615 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

509. In fact, the words "tiotropium bromide" do not appear anywhere in the '615 patent.

510. The '615 patent does not claim a tiotropium drug product.

511. Boehringer submitted the '615 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '615 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

512. Because the '615 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

513. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '615 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

514. Because Boehringer wrongfully submitted the '615 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

ix. Boehringer wrongfully caused the '474 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

515. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '474 patent with respect to Spiriva Respimat.

516. None of the '474 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

517. In fact, the words "tiotropium bromide" do not appear anywhere in the '474 patent.

518. The '474 patent does not claim a tiotropium drug product.

519. Boehringer submitted the '474 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '474 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

520. Because the '474 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

521. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '474 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

522. Because Boehringer wrongfully submitted the '474 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

x. Boehringer wrongfully caused the '6,341 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

523. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '6,341 patent with respect to Spiriva Respimat, just has it had for Combivent Respimat three years earlier.

524. None of the '6,341 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

525. While the patent's specification mentions tiotropium bromide, none of the references to those substances appear in the patent's claims.

526. The '6,341 patent does not claim a tiotropium drug product.

527. Boehringer submitted the '6,341 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '6,341 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

528. Because the '6,341 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

529. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '6,341 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

530. Because Boehringer wrongfully submitted the '6,341 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

xi. Boehringer wrongfully caused the '568 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

531. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the '568 patent with respect to Spiriva Respimat, just has it had for Combivent Respimat three years earlier.

532. None of the '568 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

533. While the patent's specification mentions tiotropium bromide, none of the references to those substances appear in the patent's claims.

534. The ’568 patent does not claim a tiotropium drug product.

535. Boehringer submitted the ’568 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the ’568 patent Patent Listing Form by answering “yes” to Question 3.1—whether the patent “claim[s] the approved drug product *as defined in 21 CFR 314.3*.”

536. Because the ’568 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer’s response to question 3.1 was false.

537. Because Boehringer’s answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the ’568 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

538. Because Boehringer wrongfully submitted the ’568 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

xii. Boehringer wrongfully caused the ’235 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

539. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the ’235 patent with respect to Spiriva Respimat, just has it had for Combivent Respimat three years earlier.

540. None of the ’235 patent’s claims recite the Respimat inhaler device in combination with tiotropium bromide.

541. While the patent’s specification mentions tiotropium bromide, none of the references to those substances appear in the patent’s claims.

542. The ’235 patent does not claim a tiotropium drug product.

543. Boehringer submitted the ’235 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the ’235 patent Patent Listing Form by answering “yes” to Question 3.1—whether the patent “claim[s] the approved drug product *as defined in 21 CFR 314.3*.”

544. Because the ’235 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer’s response to question 3.1 was false.

545. Because Boehringer’s answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the ’235 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

546. Because Boehringer wrongfully submitted the ’235 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

xiii. Boehringer wrongfully caused the ’264 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

547. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the ’264 patent with respect to Spiriva Respimat, just has it had for Combivent Respimat three years earlier.

548. None of the ’264 patent’s claims recite the Respimat inhaler device in combination with tiotropium bromide.

549. While the patent’s specification mentions tiotropium bromide, none of the references to those substances appear in the patent’s claims.

550. The ’264 patent does not claim a tiotropium drug product.

551. Boehringer submitted the ’264 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the ’264 patent Patent Listing Form by answering “yes” to Question 3.1—whether the patent “claim[s] the approved drug product *as defined in 21 CFR 314.3*.”

552. Because the ’264 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer’s response to question 3.1 was false.

553. Because Boehringer’s answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the ’264 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

554. Because Boehringer wrongfully submitted the ’264 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

xiv. Boehringer wrongfully caused the ’001 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

555. In October 2014, Boehringer submitted to the FDA a Patent Listing Form for the ’001 patent with respect to Spiriva Respimat, just has it had for Combivent Respimat three years earlier.

556. None of the ’001 patent’s claims recite the Respimat inhaler device in combination with tiotropium bromide.

557. In fact, the words “tiotropium bromide” do not appear anywhere in the ’001 patent.

558. The ’001 patent does not claim a tiotropium drug product.

559. Boehringer submitted the ’001 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the ’001 patent Patent Listing Form by answering “yes” to Question 3.1—whether the patent “claim[s] the approved drug product *as defined in 21 CFR 314.3*.”

560. Because the ’001 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer’s response to question 3.1 was false.

561. Because Boehringer’s answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the ’001 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

562. Because Boehringer wrongfully submitted the ’001 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

xv. Boehringer wrongfully caused the ’3,341 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

563. In August 2015, Boehringer submitted to the FDA a Patent Listing Form for the ’3,341 patent with respect to Spiriva Respimat, just has it did for Combivent Respimat.

564. None of the ’3,341 patent’s claims recite the Respimat inhaler device in combination with tiotropium bromide.

565. While the patent’s specification mentions tiotropium salts, none of the references to those substances appear in the patent’s claims.

566. Claims 8 and 10 of the '3,341 patent are invalid for the reasons described above.[76]

567. The '3,341 patent does not validly claim a tiotropium drug product.

568. Boehringer submitted the '3,341 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '3,341 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

569. Because the '3,341 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

570. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '3,341 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

571. Because Boehringer wrongfully submitted the '3,341 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

[76] *See supra* Section V.C.1.xxii.

xvi. Boehringer wrongfully caused the '967 patent to be listed in the Orange Book as a Spiriva Respimat drug product patent.

572. In August 2015, Boehringer submitted to the FDA a Patent Listing Form for the '967 patent with respect to Spiriva Respimat, just has it did for Combivent Respimat.

573. None of the '967 patent's claims recite the Respimat inhaler device in combination with tiotropium bromide.

574. While the patent's specification mentions tiotropium bromide, none of the references to those substances appear in the patent's claims.

575. The '967 patent does not claim a tiotropium drug product.

576. Boehringer submitted the '967 patent as a drug product patent claiming the drug product Spiriva Respimat. That means that Boehringer identified it as such in the '967 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

577. Because the '967 patent does not claim tiotropium bromide, it does not claim the drug product Spiriva Respimat. Therefore, Boehringer's response to question 3.1 was false.

578. Because Boehringer's answer to Question 3.1 was false, the certification, made under penalty of perjury, that the information in the '967 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

579. Because Boehringer wrongfully submitted the '967 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product Spiriva Respimat—to be listed in the Orange Book under Spiriva Respimat.

D. Boehringer has wrongfully submitted patents for listing in the Orange Book under Combivent Respimat and Spiriva Respimat more than four dozen times.

580. In total, since 2011, Boehringer has certified on *52 separate occasions* that a Respimat device patent was properly listed in the Orange Book as claiming either Combivent Respimat or Spiriva Respimat.

581. This includes 23 patent certifications for the initial submission of device patents listed under Combivent Respimat, 16 patent certifications for the initial submission of device patents listed under Spiriva Respimat, 1 additional patent certification to correct the '442 patent number listed under Spiriva Respimat, 6 certifications for patents listed under Combivent Respimat in response to the FTC's patent disputes, and 6 certifications for patents listed under Spiriva Respimat in response to the FTC's patent disputes.

582. Each of these 52 certifications was made under penalties of perjury.

583. Each of these 52 certifications were false.

584. By making these false certifications, Boehringer unlawfully caused device patents to be wrongfully listed in the Orange Book as drug patents, and thwarted the FTC's initial challenge to those improper listings.

E. The FTC and Congress are now investigating Boehringer's unlawful patent listings.

585. Boehringer's patent protection for its Combivent franchise (comprising the original Combivent product and Combivent Respimat) is a particularly notorious example of over-extending an exclusivity using inhaler devices: it claims 34 years of

patent protection, from the approval of Combivent in 1996 until the last-to-expire patent listed under Combivent Respimat in 2030.

586. Since the FDA first issued its Orange-Book-listing regulations in 1997, it has been clear that patents with claims that do not include a drug's active ingredient must not be listed. Since the First Circuit's *Lantus* decision 2020, it has been clear that improperly listing patents in the Orange Book can lead to antitrust liability. But neither of these unequivocal admonishments have deterred brand companies—Boehringer included—from improperly and unlawfully listing device patents in the Orange Book.

587. So, on September 20, 2023, the FTC issued a policy statement entitled *Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book*. In that statement, the FTC advised that the Commission intended to use its authority to protect competition in order to address improper Orange Book listings.

588. The FTC explained that:

> certain manufacturers have submitted patents for listing in the Orange Book that claim neither the reference listed drug nor a method of using it. When brand drug manufacturers abuse the regulatory processes set up by Congress to promote generic drug competition, the result may be to increase the cost of and reduce access to prescription drugs.

589. The Commission warned that "[t]he improper listing of patents in the Orange Book may . . . constitute illegal monopolization."

590. The FTC issued its policy statement to "put market participants on notice that the FTC intends to scrutinize improper Orange Book listings to determine whether these constitute unfair methods of competition . . . ."

591. On November 7, 2023, the FTC sent a warning letter to Boehringer to inform the company that the Commission "believe[s] certain patents have been improperly or inaccurately listed in the Orange Book with regard to Boehringer Ingelheim Pharmaceuticals, Inc. products." The FTC "availed [itself]" of the FDAs 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 competition laws.

592. Among the patent listings identified as illegal by the FTC were the listings of the '474, '6,341, '235, '264, '3,341, and '967 patents under both Combivent Respimat and Spiriva Respimat.

593. The FDA notified BIPI of its receipt of the FTC's patent disputes on or about November 16, 2023.

594. BIPI was not the only manufacturer to receive a warning letter from the FTC and notification of a listing dispute from the FDA. Some other manufacturers heeded the FTC's admonishment and 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 withdraw four of the five listings challenged by the FTC, related to three of its asthma inhalers—Advair, Flovent and Ventolin.

595. But not Boehringer. On December 15, 2023, BIPI responded to the FDA's notice, and no Orange Book changes were made as a result of BIPI's response.

596. This means that BIPI recertified to the FDA each of its patent listings identified as improper by the FTC. It 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, BIPI 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. § 314.53. Those certifications are false.

597. The FTC is not the only government entity scrutinizing Boehringer's Orange Book listings. In January 2024, 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. The letter to Boehringer accused the company of knowingly gaming the system to prevent generics from entering the market by continuously repackaging the same drugs in Combivent on the eve of patent expiration, and falsely certifying its device patent listings to the FDA.

598. 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. To date, Boehringer has not publicly responded to the investigation or the document requests.

F. Boehringer brought sham litigations against its would-be competitor, suing even though it knew, or should have known, that it lacked standing to do so.

599. Although Boehringer deliberately designed its Respimat inhaler to thwart generic competition, at least one would-be competitor has emerged.

1. In March 2023, a would-be competitor, Anobri, filed ANDAs for generic Combivent Respimat and generic Spiriva Respimat.

600. In March 2023, Anobri Pharmaceuticals US, LLC (along with its parent company, Shanghai Anovent Pharmaceutical Co., Ltd. and one of Shanghai Anovent's other subsidiaries, Nanchang Anovent Pharmaceutical Co., Ltd.) submitted two ANDAs to the FDA: one for a generic version of Spiriva Respimat and one for a generic version of Combivent Respimat.

601. On March 7, 2023, Anobri filed the first ANDA seeking to make, market, and sell an affordable generic version of Spiriva Respimat. In its application, Anobri made a paragraph IV certification to the patents Boehringer had wrongfully listed in the Orange Book as claiming Spiriva Respimat.

602. On March 30, 2023, Anobri submitted the first ANDA seeking to make, market, and sell an affordable generic version of Combivent Respimat. In its application, Anobri made a paragraph IV certification to the patents Boehringer had wrongfully listed in the Orange Book under Combivent Respimat.

603. Anobri notified Boehringer of its Spiriva Respimat and Combivent Respimat paragraph IV certifications by two letters received by Boehringer received on or about May 18, 2023.

604. These and other ANDAs would have been filed sooner but for Boehringer's wrongful Orange Book patent listings, which misrepresented the length of its exclusivity period and the extent of patent protection for the product.

2. Boehringer sued Anobri over its ANDAs in two separate, but equally sham, lawsuits.

605. On June 29, 2023, Boehringer sued Anobri in the United States District Court for the District of New Jersey alleging that Anobri's proposed Spiriva Respimat ANDA infringed all of the patents then listed in the Orange Book as (wrongfully) claiming Spiriva Respimat: the '474 patent, the '264 patent, the '6,341 patent, the '967 patent, the '235 patent, and the '3,341 patent.

606. On the same day and in the same court, Boehringer filed a second suit against Anobri, alleging that Anobri's proposed Combivent Respimat ANDA infringed the same patents: the '474 patent, the '264 patent, the '6,341 patent, the '967 patent, the '235 patent, and the '3,341 patent.[77] Again, these are all of the patents then listed in the Orange Book as claiming Combivent Respimat.

607. In both cases, Anobri has answered the complaint and asserted counterclaims, arguing that each of Boehringer's claims of the patents were invalid. Boehringer answered Anobri's counterclaims.

[77] Boehringer also filed complaints in the District Court for the District of Delaware, but voluntarily dismissed when Anobri consented to jurisdiction in New Jersey.

3. Boehringer lacked standing to pursue either lawsuit.

608. Boehringer should have never brought either lawsuit: no reasonable pharmaceutical company in Boehringer's position would have expected to succeed.

609. None of the patents over which Boehringer sued Anobri in the *Spiriva Respimat* case "claim[ed] the drug" Spiriva Respimat or its active ingredient, tiotropium bromide.

610. Because none of the patents claimed the drug product Spiriva Respimat or the drug substance tiotropium bromide, none should have been listed in the Orange Book in the first place. Because none should have been listed in the Orange Book, Anobri should not have been forced to file paragraph IV certifications to any of the patents in the Orange Book. Instead, Anobri should have been entitled to make a Paragraph I certification. And because Anobri should not have been forced to file paragraph IV certifications, Boehringer should have had no ability to sue Anobri until after Anobri began selling its generic Spiriva Respimat product.

611. The same holds true for Combivent Respimat. None of the patents over which Boehringer sued Anobri in the *Combivent Respimat* case "claim[ed] the drug" Combivent Respimat or either of its active ingredients, ipratropium bromide or albuterol sulfate.

612. Because none of the patents claimed the drug product Combivent Respimat or the drug substances ipratropium bromide or albuterol, none should have been listed in the Orange Book in the first place. Because none should have been listed in the Orange Book, Anobri should not have been forced to file paragraph IV certifications to any of them. Instead, Anobri should have been entitled to make a

Paragraph I certification. And because Anobri should not have been forced to file paragraph IV certifications, Boehringer should have had no ability to sue Anobri until after Anobri began selling its generic Combivent Respimat product.

4. A reasonable brand-name drugmaker in Boehringer's position would have had no objectively reasonable expectation of succeeding on the merits of a suit for which it lacked standing.

613. A reasonable drug company in Boehringer's position would have known they did not have standing to sue Anobri for infringing Boehringer's device patents. That is because Boehringer's standing is founded on having listed its device patents in the Orange Book—listings that a reasonable brand-name drug company in Boehringer's position would have known were improper.

614. Standing to sue for patent infringement "derives from the Patent Act, which provides that '[a] patentee shall have remedy by civil action for infringement of his patent."[78] Generally, a patentee lacks standing to sue until a competitor "makes, uses, offers to sell, or sells" an infringing product.[79]

615. Section 271(e)(2) of the Patent Act creates a narrow exception allowing a brand-name drugmaker to sue a would-be competitor if it submits an ANDA containing a paragraph IV certification "for a drug claimed in a patent."[80]

---

[78] *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1376–77 (Fed. Cir. 2000) (quoting 35 U.S.C. § 281).

[79] 35 U.S.C. § 271(a).

[80] 35 U.S.C. § 271(e)(2).

616. The standing provision imports the same limitation in the Orange Book listing statute: the patent must claim a *drug*.[81] A brand-name drugmaker cannot sue unless its would-be competitor files a paragraph IV certification. Prior to a launch, a brand-name drugmaker cannot sue a would-be competitor over patents in the Orange Book. [82]

617. Anobri had not yet entered the market and sold any generic Spiriva Respimat or Combivent Respimat, so Boehringer could not claim standing to sue for infringement under Section 271(a). Boehringer could not invoke Section 271(e)(2)'s limited exception, because that applies only to patents that claim a drug that are properly listed in the Orange Book.

618. To "claim[] the drug," a patent must claim the drug substance (the active ingredient) or a drug formulation (a chemical composition that includes the active ingredient).[83] As the First Circuit stated in *Lantus* , a patent that does not claim the active ingredient, either alone or in combination with other elements of the drug product "does not fit the bill."[84]

619. None of the patents over which Boehringer sued Anobri claim Combivent Respimat or Spiriva Respimat's active ingredients, ipratropium bromide,

[81] *Compare* 35 U.S.C. § 271(e)(2) *with* 21 U.S.C. § 335(b)(1).

[82] *Abbott Labs. v. Zenith Labs., Inc.*, No. 94-cv-6792, 1995 WL 117984, at *12 (N.D. Ill. Mar. 16, 1995) (brand company that did not list patent in Orange Book cannot sue pursuant to § 271(e)(2)(A)).

[83] 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b)(1) (citing 21 C.F.R. § 314.3).

[84] 950 F.3d at 10.

albuterol sulfate, and tiotropium bromide.[85] Therefore, Boehringer could not lawfully list any of the patents in the Orange Book.

620. To the extent that Boehringer may argue that it had a basis, at the outset of the suits, to believe it could assert its device patents in a pre-sale Hatch-Waxman suit against Anobri, a reasonable company in Boehringer's position could not have held that belief later than November 7, 2023, when Boehringer received the FTC's warning letter.

5. A reasonable company in Boehringer's position would have known that Claims 8 and 10 of the '3,341 patent were invalid.

621. A reasonable brand-name pharmaceutical company in Boehringer's position would have known that Claims 8 and 10 of the '3,341 patent were invalid for non-enablement, failure to meet the written description requirements of § 112, violation of § 102's on-sale bar, and obviousness.

622. It is not enough that a patent "claim[] the product" in order to be listable: that is a necessary but not sufficient condition for listing. To satisfy the two-part statutory listing requirement, the patent must also be one "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."[86] A patent that is invalid—which the patent owner knows or should know is invalid—cannot "reasonably be asserted" in a patent infringement suit.

[85] Boehringer does not even specify which claims of the patents were infringed.

[86] 21 U.S.C. § 355(b)(1).

623. Since Claims 8 and 10 are invalid for several reasons, a reasonable brand-name drug company in Boehringer's position would have known that those claims could not have been asserted against a would-be competitor. In other words, this is another reason why Boehringer lacked standing to assert the '3,341 patent in a pre-sale Hatch-Waxman lawsuit. Accordingly, Boehringer's infringement allegations as to Claims 8 and 10 of the '3,341 patent are objectively meritless.

624. The fact that the claims of the patent which arguably could (if valid) claim the drug products Combivent Respimat and Spiriva Respimat are invalid also renders Boehringer's allegations of infringement as to those patents substantively objectively meritless. A reasonable company in Boehringer's position would have known that, and could not have filed suit in good faith. This is yet another reason why Boehringer's lawsuits are shams.

6. Boehringer's baseless lawsuits were motivated by a desire to delay competition for Combivent Respimat and Spiriva Respimat.

625. A litigation is a sham where, as here, (1) the lawsuit is objectively baseless, and (2) the lawsuit is subjectively motivated by a desire to frustrate competition.[87]

626. When, as is the case here, "a litigant institutes a proceeding knowing, or under circumstances in which he should know, that he lacks standing, the proceeding is baseless."[88] A reasonable drug company in Boehringer's position should

[87] *E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).

[88] *Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27*, 855 F. Supp. 2d 476, 489 (D. Md. 2012); *see In re Burlington N., Inc.*, 822 F.2d 518, 530 (5th Cir. 1987) (refusing to

have known, based on the FDA's 2003 regulations and the FDA's accompanying commentary and explanation, that the Spiriva Respimat and Combivent Respimat patents should not have been listed in the Orange Book—and that, therefore, that Boehringer lacked standing to sue Anobri.

627. To the extent that Boehringer might assert—as other drug companies unsuccessfully have—that the regulations were unclear, any such uncertainty was resolved no later than February 2020, when the First Circuit released its *Lantus* decision. As of that time, a reasonable company in Boehringer's position would have known that all of the patents were improperly listed, and thus it lacked standing. A reasonable, law-abiding drug company in Boehringer's position never would have listed any of the patents in the first place; and if they did, they would have removed them from the Orange Book no later than February 2020.

628. But Boehringer did not sue Anobri in a good faith effort to protect valid and valuable intellectual property. Instead, Boehringer sued to prevent generic competition.

629. Boehringer's lawsuits against Anobri were plainly motivated by a desire to delay competition. A litigant may not use litigation "as an anticompetitive weapon."[89] That's what Boehringer did.

allow defendant to escape liability for sham petitioning where defendants' "interest in a controversy is not sufficient to confer standing").

[89] *Prof. Real Estate Invs., Inc. v. Columbia Pics. Indus., Inc.*, 508 U.S. 49, 61 (1993) (quoting *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991)).

VI. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO THE PLAINTIFF AND THE CLASSES

630. Boehringer's wrongful conduct as described in this complaint, constituted an unlawful anticompetitive scheme—the Respimat Orange-Book-listing scheme—to thwart competition in the markets for not one, but two drugs.

631. Boehringer's Respimat Orange-Book-listing scheme has proved lucrative for the company. It has sold approximately $6.5 billion of Spiriva Respimat since February 2020. It has sold more than $3 billion in Combivent Respimat since August 2020. This is billions of dollars more in sales that Boehringer could have made if it had not engaged in its scheme to impair competition. Generic entry would have driven prices down and eroded Boehringer's market share. If Boehringer had not stuffed the Orange Book with unlistable device patents, a generic company would have been able to file an ANDA even earlier than Anobri did, resulting in earlier price decreases and erosion.

632. Boehringer's anticompetitive scheme impaired and delayed the sale of affordable generic versions of Spiriva Respimat and Combivent Respimat in the United States, freeing Boehringer to sell Spiriva Respimat and Combivent Respimat at artificially high prices.

633. But for Boehringer's anticompetitive conduct, at least one generic manufacturer would have entered the marketplace and competed with Boehringer's brand-name Spiriva Respimat and Combivent Respimat products much sooner.

634. For Combivent Respimat, the last lawfully listed patent expired in February 2020. That means that, but for Boehringer's improper Orange Book listings,

Combivent Respimat should have faced robust generic competition starting in or around February 2020. Because there would have been no listed patents, and therefore no paragraph IV requirements, there would have been rigorous competition and rapid commoditization of the market almost as soon as that regulatory exclusivity expired.

635. Combivent Respimat would have faced several generic competitors very quickly: ipratropium bromide and albuterol sulfate are both old drugs, which multiple generic companies have been able to synthesize and obtain approval for over the years.

636. For Spiriva Respimat, the last lawfully listed patent expired in February 2020, with a pediatric exclusivity that expired in August 2020. So, but for Boehringer's improper Orange Book listings, Spiriva Respimat should have faced a generic competitor in or around August 2020, with more generic competitors entering the marketplace six months later.

637. Had Boehringer not executed its unlawful Respimat patent listing scheme, at least one generic competitor would have been prepared to launch a generic version of Spiriva Respimat in 2020. In May 2018, Lupin, Inc., filed an ANDA seeking FDA approval to make, market and sell a generic version of Boehringer's original Spiriva product. The only difference between Spiriva and Spiriva Respimat is the inhaler with which it is co-packaged. So, but for the patents protecting the Respimat inhaler, Lupin would have been able and incentivized to submit an ANDA for Spiriva Respimat as well.

638. Consequently, but for Boehringer's anticompetitive conduct, the plaintiff and other members of the classes would have been able to (a) purchase generic Spiriva Respimat and Combivent Respimat instead of Boehringer's expensive Spiriva Respimat and Combivent Respimat products for some or all their (i) tiotropium bromide and (ii) ipratropium bromide and albuterol HFA needs; and (b) paid a lower price for their (i) tiotropium bromide and (ii) ipratropium bromide and albuterol HFA needs.

639. Had Boehringer not engaged in anticompetitive conduct, the market would have embraced generic versions of Spiriva Respimat and Combivent Respimat—which are just as safe and effective as Spiriva Respimat and Combivent Respimat at a fraction of the price. Because of state substitution laws, generic Spiriva Respimat and generic Combivent Respimat would have captured 90% of the (i) tiotropium bromide and (ii) ipratropium bromide and albuterol HFA markets, respectively, and ushered in substantial cost savings to the plaintiff and members of the classes. As a result of Boehringer's anticompetitive scheme, however, generic competition for Spiriva Respimat and Combivent Respimat have been thwarted.

640. During the relevant period, the plaintiff and other purchasers paid for substantial amounts of Spiriva Respimat and Combivent Respimat; the prices the plaintiff and other third-party payors paid for prescriptions of these products was substantially greater than the prices they would have paid but for the unlawful conduct alleged herein.

641. As a result, the plaintiff and other third-party payors have incurred substantial losses, the exact amount of which will be the subject of proof at trial.

VII. MARKET POWER AND MARKET DEFINITION

642. Through its wrongful Orange-Book-listing scheme, Boehringer wrongfully acquired, locked in, and exploited monopoly power two markets: (i) the Combivent Respimat Relevant Market and (ii) the Spiriva Respimat Relevant Market. At all relevant times, it had the power to raise or maintain the price of Spiriva Respimat and Combivent Respimat to supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

A. The Combivent Respimat Relevant Market.

643. To the extent the plaintiff may be required to plead and prove Boehringer's monopoly power by defining a relevant product market, the plaintiff alleges that the relevant antitrust market is the ipratropium bromide- albuterol sulfate HFA inhalation spray market (consisting of Combivent Respimat and its AB-rated generics).

644. Until in or around 2013, there were other products on the market that contained the combination of ipratropium bromide and albuterol—notably Combivent and its generic equivalents, and DuoNeb, a product made by Mylan Specialty LP. But these other COPD treatments were not equivalent to one another, nor were they equivalent to Combivent Respimat. Combivent contained CFCs, while Combivent Respimat did not; and DuoNeb came in a solution form, as compared to Combivent Respimat's aerosolized form.

645. Because neither Combivent nor DuoNeb is equivalent to Combivent Respimat, neither could be automatically substituted for a prescription for Combivent Respimat at the pharmacy counter.

646. Because it lacked an equivalent in the market, a small, but significant, non-transitory increase in the price of Combivent Respimat would not have caused a significant loss of sales.

647. Combivent Respimat does not exhibit significant, positive cross-elasticity of demand with respect to the price of any other COPD treatment, other than those containing a combination of ipratropium bromide and albuterol sulfate HFA in an aerosolized form.

648. Boehringer needed only to control Combivent Respimat and its generic equivalents, and no other products, in order to maintain Combivent Respimat's supra-competitive prices profitably without losing substantial sales. The only market event that would render Boehringer unable to profitably maintain supra-competitive prices would be the entry of a generic aerosolized ipratropium bromide and albuterol sulfate HFA product.

649. Boehringer sold Combivent Respimat at prices well above marginal costs, and in excess of competitive prices; as a result, it enjoyed high profit margins with the price more than 60% higher than the cost of production.

650. Boehringer has had, and has exercised, the power to exclude competition to Combivent Respimat.

651. Boehringer enjoyed, at all relevant times, high barriers to entry with respect to Combivent Respimat.

652. There is direct evidence of Boehringer's market power and the anticompetitive effects of its scheme sufficient to show Boehringer's ability to control the price of, and exclude competition for, Combivent Respimat, without the need to define the relevant antitrust market.

653. The direct evidence includes: (a) the fact that competing ipratropium bromide and albuterol sulfate HFA producers would have entered the market at a substantial discount to the price of Combivent Respimat, but for Boehringer's anticompetitive conduct; and (b) the gross margin on Combivent Respimat were, at all times, substantial enough to show market power.

654. The United States, its territories, and the District of Columbia constitute the relevant geographic market.

655. Boehringer's share in the relevant market was 100% at all relevant times, continuing today.

B. The Spiriva Respimat Relevant Market.

656. To the extent the plaintiff may be required to plead and prove Boehringer's monopoly power by defining a relevant product market, the plaintiff alleges that the relevant antitrust market is the tiotropium inhalation spray market (consisting of Spiriva Respimat and its AB-rated generics).

657. There are other products on the market that contain tiotropium bromide—notably Stiolto Respimat. But these other COPD treatments were not equivalent to one another, nor were they equivalent to Spiriva Respimat. Stiolto

Respimat, for example, contains not just tiotropium bromide but also olodaterol hydrochloride.

658. Because Stiolto Respimat is not equivalent to Spiriva Respimat, it could not be automatically substituted for a prescription for Spiriva Respimat at the pharmacy counter.

659. Because it lacked an equivalent in the market, a small, but significant, non-transitory increase in the price of Spiriva Respimat would not have caused a significant loss of sales.

660. Spiriva Respimat does not exhibit significant, positive cross-elasticity of demand with respect to the price of any other COPD treatment, other than those containing tiotropium bromide.

661. Boehringer needed only to control Spiriva Respimat and its generic equivalents, and no other products, in order to maintain Spiriva Respimat's supra-competitive prices profitably without losing substantial sales. The only market event that would render Boehringer unable to profitably maintain supra-competitive prices would be the entry of a generic tiotropium bromide.

662. Boehringer sold Spiriva Respimat at prices well above marginal costs, and in excess of competitive prices; as a result, it enjoyed high profit margins with the price more than 60% higher than the cost of production.

663. Boehringer has had, and has exercised, the power to exclude competition to Spiriva Respimat.

664. Boehringer enjoyed, at all relevant times, high barriers to entry with respect to Spiriva Respimat.

665. There is direct evidence of Boehringer's market power and the anticompetitive effects of its scheme sufficient to show Boehringer's ability to control the price of, and exclude competition for, Spiriva Respimat, without the need to define the relevant antitrust market.

666. The direct evidence includes: (a) the fact that competing tiotropium bromide producers would have entered the market at a substantial discount to the price of Spiriva Respimat, but for Boehringer's anticompetitive conduct; and (b) the gross margin on Spiriva Respimat were, at all times, substantial enough to show market power.

667. The United States, its territories, and the District of Columbia constitute the relevant geographic market.

668. Boehringer's share in the relevant market was 100% at all relevant times, continuing today.

VIII. MARKET EFFECTS

669. Boehringer willfully and unlawfully maintained its market power in both the Spiriva Respimat Relevant Market and Combivent Respimat Relevant Market by engaging in an overarching scheme to exclude competition. Boehringer designed this scheme to delay competition on the merits, for the anticompetitive purpose of thwarting, or at least delaying, competition against its Combivent Respimat and Spiriva Respimat franchises. As a result of the scheme, Boehringer

was able to maintain supracompetitive prices for Combivent Respimat and Spiriva Respimat.

670. Boehringer's overarching anticompetitive scheme to delay competition in both the Combivent Respimat and Spiriva Respimat markets consisted of (1) submitting two dozen different device patents in the Orange Book as claiming Combivent Respimat and/or Spiriva Respimat; (2) falsely certifying, under penalty of perjury, that those patents claim a "drug product," as that term is defined by the FDA; and (3) leveraging those improper patent listings to delay generic competition through sham litigations.

671. These acts, in combination and individually, were undertaken to serve Boehringer's anticompetitive aims.

672. Boehringer's acts and practices described in this complaint had the purpose and effect of unreasonably restraining competition and injuring competition by preventing competition for Boehringer's Spiriva Respimat and Combivent Respimat franchises. They allowed Boehringer to wrongfully maintain its monopoly and exclude competition in the Spiriva Respimat market and Combivent Respimat market. This harmed the plaintiff and other members of the classes.

673. Boehringer's conduct has delayed competition unlawfully, and wrongfully enabled Boehringer to sell its Spiriva Respimat and Combivent Respimat products without competition from more affordable generic versions of the drugs. But for Boehringer's illegal conduct, one or more generic competitors would have entered the Spiriva Respimat market and/or Combivent Respimat market sooner.

674. For example (but without limitation), had Boehringer not engaged in the unlawful conduct described in this complaint, (a) an affordable generic tiotropium bromide product would have entered the Spiriva Respimat market in or around August 2020, when the patents claiming tiotropium bromide expired and (b) an affordable generic ipratropium bromide and albuterol sulfate HFA product would have become available in or around February 2020, when the last valid patent for Combivent Respimat expired. The plaintiff and other members of the classes would have paid for fewer prescriptions of expensive brand-name Combivent Respimat and Spiriva Respimat, and instead benefitted from the availability of lower-cost generic versions of those drugs.

675. Boehringer's illegal scheme to foreclose competition to its Combivent Respimat and Spiriva Respimat franchises from equivalent generic products caused the plaintiff and all members of the classes to pay more than they would have for prescriptions of Combivent Respimat and Spiriva Respimat franchise products absent the illegal conduct.

676. When a generic drug enters a previously monopolized market, they are priced below the cost of their brand-name counterparts. As more generic drugs enter the market, the price drops even further; and the price of the brand-name drug may drop slightly to try to keep some of its sales from being eroded by its new generic competitors. State substitution laws drive prescription dispensing to these less expensive generic products, for which the plaintiff and members of the classes pay

less to reimburse prescriptions. Therefore, brand-name drugmakers have a financial interest in delaying the onset of generic competition.

677. Boehringer's unlawful conduct deprived the plaintiff and members of the classes of the benefits of competition that the state and federal antitrust laws are designed to protect.

IX. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

678. During the relevant time period, Boehringer sold, and will continue to sell, Combivent Respimat and Spiriva Respimat across state lines.

679. During the relevant time period, the plaintiff and members of the classes paid for substantial amounts of Combivent Respimat and Spiriva Respimat at supracompetitive prices. They will begin to pay for substantial amounts of generic Combivent Respimat and Spiriva Respimat from Anobri and any other subsequent generic competitors once the anticompetitive effects of Boehringer's conduct cease.

680. As a result of Boehringer's illegal conduct, as described in this complaint, the plaintiff and members of the classes were compelled to pay, did pay, and will continue to pay, artificially inflated prices to reimburse prescriptions of Combivent Respimat and Spiriva Respimat.

681. During the relevant time period, Boehringer effected its overarching anticompetitive scheme, as described in this complaint, using the United States mail, interstate carriers, interstate and foreign travel, and interstate and foreign wire commerce.

X. CLASS ACTION ALLEGATIONS

682. The plaintiff brings this action on behalf of itself and all others similarly situated under Federal Rule of Civil Procedure 23(a) and 23(b)(3) in two classes:

> **The Combivent Respimat Class.** All persons or entities in the United States, its territories, and the District of Columbia who purchased or paid for Combivent Respimat, and/or AB-rated generic equivalents of Combivent Respimat from a source other than (i) the defendants or any of their subsidiaries; or (ii) any manufacturer of an AB-rated generic equivalent of Combivent Respimat or any of its subsidiaries at any time between February 23, 2020 (or the date on which generic Combivent Respimat would have otherwise become available in the absence of Boehringer's anticompetitive conduct) and the date on which the anticompetitive effects of Boehringer's conduct ceases.

And

> **The Spiriva Respimat Class.** All persons or entities in the United States, its territories, and the District of Columbia who purchased or paid for Spiriva Respimat, and/or AB-rated generic equivalents of Spiriva Respimat from a source other than (i) the defendants or any of their subsidiaries; or (ii) any manufacturer of an AB-rated generic equivalent of Spiriva Respimat or any of its subsidiaries at any time between August 24, 2020 (or the date on which generic Spiriva Respimat otherwise would have become available in the absence of Boehringer's anticompetitive conduct) and the date on which the anticompetitive effects of Boehringer's conduct ceases.

683. Excluded from both classes are the defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

684. Members of each class are so numerous that joinder is impracticable. The plaintiff believes that there are thousands of members in each class.[90]

685. The plaintiff's claims are typical of the claims of the members of each class. The plaintiff and all members of the classes were damaged by the same wrongful conduct of Boehringer, i.e., they paid artificially inflated prices for (i) ipratropium bromide and albuterol and (ii) tiotropium bromide products, including Combivent Respimat and Spiriva Respimat, and were deprived of earlier and more robust competition from more affordable generic versions of Combivent Respimat and Spiriva Respimat because of Boehringer's wrongful conduct.

686. The plaintiff will fairly and adequately protect and represent the interests of the classes. The interests of the plaintiff are coincident with, and not antagonistic to, those of the classes.

687. The plaintiff is represented by counsel with experience in the prosecution of class-action antitrust litigation, with particular experience with class action antitrust litigation involving pharmaceutical products.

688. Questions of law and fact common to the members of the classes predominate over questions that may affect only individual class members because Boehringer has acted on grounds generally applicable to the classes as a whole, thus making overcharge damages with respect to the classes as a whole appropriate. Such generally applicable conduct is inherent in Boehringer's wrongful conduct.

[90] To the extent discovery may reveal that subclassing would aid in the administrability of the case, the plaintiffs will propose subclassing at the appropriate stage in the litigation.

689. Questions of law and fact common to the Combivent Respimat Class include, without limitation:

- Whether any of Boehringer's Respimat device patents "claim[] the drug"—meaning a combination of ipratropium bromide and albuterol sulfate—in Combivent Respimat;
- Whether Boehringer falsely certified (under penalty of perjury) to the FDA that the Respimat device patents claimed the drug in Combivent Respimat;
- Whether Boehringer's Respimat device patents could be lawfully listed in the Orange Book as claiming Combivent Respimat;
- Whether the listing of Boehringer's Respimat device patents in the Orange Book frustrated competition;
- Whether would-be generic competitors were dissuaded entirely from submitting ANDAs to market affordable generic versions of Combivent Respimat as a result of Boehringer's wrongful listings of the Respimat device patents;
- Whether Boehringer should have delisted its Respimat device patents after the First Circuit admonished the industry that patents which do not claim a drug's active ingredient must not be listed in the Orange Book;
- Whether Boehringer should have relisted its Respimat device patents after the FTC issued a warning letter to Boehringer, and after the FTC notified Boehringer that the FTC sought to have the patents delisted;
- Whether a brand-name drugmaker in Boehringer's position would have known that Boehringer lacked standing to bring Hatch-Waxman litigation over patents that did not claim the drug product Combivent Respimat;
- Whether a reasonable brand-name drugmaker in Boehringer's position would have refrained from suing Anobri for infringement of its Respimat device patents, given the lack of standing;

- Whether Boehringer has any meritorious arguments that Anobri's proposed generic version of Combivent Respimat infringed any valid, enforceable, properly listed patent;

- Whether a reasonable brand-name drugmaker in Boehringer's position would have believed it had any meritorious arguments that Anobri's proposed generic version of Combivent Respimat infringed any valid, enforceable, properly listed patent;

- Whether Boehringer's *Combivent Respimat* litigation against Anobri constituted an abuse of the litigation process because it was intended to block competition, rather than to obtain certainty as to Boehringer's Respimat device patents' invalidity or non-infringement;

- Whether Boehringer's *Combivent Respimat* litigation was intended to frustrate competition;

- Whether Boehringer's conduct with respect to Combivent Respimat constitutes a part of an overarching, anticompetitive scheme to thwart competition for its inhaled COPD treatments;

- Whether Boehringer's Combivent Respimat listings of the Respimat patents and suit over that patent were, individually or collectively, anticompetitive and/or illegal;

- Whether—to the extent Boehringer's conduct is subject to rule-of-reason analysis—there exists any legitimate procompetitive justification for some or all of Boehringer's conduct with respect to its Combivent Respimat product;

- To the extent such justifications exist and are relevant, whether there were less restrictive means of achieving them;

- Whether the Combivent-Respimat-related elements of Boehringer's scheme, in whole or in part, substantially affected interstate commerce;

- Whether Boehringer's scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiff and members of the Combivent Respimat Class;

- Whether, in the absence of Boehringer's anticompetitive conduct, a generic version of Combivent Respimat would have entered the market earlier;
- The date on which such earlier generic entry would have occurred;
- Whether, in the absence of Boehringer's anticompetitive conduct, multiple generic versions of Combivent Respimat would have entered the market;
- The date on which such additional generic entries would have occurred;
- Whether, as a result of Boehringer's anticompetitive conduct, payors were overcharged for prescriptions of inhaled ipratropium bromide and albuterol sulfate HFA;
- Whether Boehringer's anticompetitive conduct was a substantial contributing factor in causing delayed availability of generic Combivent Respimat;
- A reasonable estimate of the delay caused by Boehringer's wrongful conduct; and
- The quantum of overcharges paid by the class in the aggregate.

690. Questions of law and fact common to the Spiriva Respimat Class include, without limitation:

- Whether any of Boehringer's Respimat device patents "claim[] the drug"—meaning either tiotropium bromide—in Spiriva Respimat;
- Whether Boehringer falsely certified (under penalty of perjury) to the FDA that the Respimat device patents claimed the drug in Spiriva Respimat;
- Whether Boehringer's Respimat device patents could be lawfully listed in the Orange Book as claiming Spiriva Respimat;
- Whether the listing of Boehringer's Respimat device patents in the Orange Book frustrated competition;

- Whether would-be generic competitors were dissuaded entirely from submitting ANDAs to market affordable generic versions of Spiriva Respimat as a result of Boehringer's wrongful listings of the Respimat device patents;

- Whether Boehringer should have delisted its Respimat device patents after the First Circuit admonished the industry that patents which do not claim a drug's active ingredient must not be listed in the Orange Book;

- Whether Boehringer should have relisted its Respimat device patents after the FTC issued a warning letter to Boehringer, and after the FTC notified Boehringer that the FTC sought to have the patents delisted;

- Whether a brand-name drugmaker in Boehringer's position would have known that Boehringer lacked standing to bring Hatch-Waxman litigation over patents that did not claim the drug product Spiriva Respimat;

- Whether a reasonable brand-name drugmaker in Boehringer's position would have refrained from suing Anobri for infringement of its Respimat device patents, given the lack of standing;

- Whether Boehringer has any meritorious arguments that Anobri's proposed generic version of Spiriva Respimat infringed any valid, enforceable, properly listed patent;

- Whether a reasonable brand-name drugmaker in Boehringer's position would have believed it had any meritorious arguments that Anobri's proposed generic version of Spiriva Respimat infringed any valid, enforceable, properly listed patent;

- Whether Boehringer's *Spiriva Respimat* litigation against Anobri constituted an abuse of the litigation process because it was intended to block competition, rather than to obtain certainty as to Boehringer's Respimat device patents' invalidity or non-infringement;

- Whether Boehringer's *Spiriva Respimat* litigation was intended to frustrate competition;

- Whether Boehringer's conduct with respect to Spiriva Respimat constitutes a part of an overarching, anticompetitive scheme to thwart competition for its inhaled COPD treatments;

- Whether Boehringer's Spiriva Respimat listings of the Respimat patents and suit over that patent were, individually or collectively, anticompetitive and/or illegal;

- Whether—to the extent Boehringer's conduct is subject to rule-of-reason analysis—there exists any legitimate procompetitive justification for some or all of Boehringer's conduct with respect to its Spiriva Respimat product;

- To the extent such justifications exist and are relevant, whether there were less restrictive means of achieving them;

- Whether the Spiriva-Respimat-related elements of Boehringer's scheme, in whole or in part, substantially affected interstate commerce;

- Whether Boehringer's scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiff and members of the Spiriva Respimat Class;

- Whether, in the absence of Boehringer's anticompetitive conduct, a generic version of Spiriva Respimat would have entered the market earlier;

- The date on which such earlier generic entry would have occurred;

- Whether, in the absence of Boehringer's anticompetitive conduct, multiple generic versions of Spiriva Respimat would have entered the market;

- The date on which such additional generic entries would have occurred;

- Whether, as a result of Boehringer's anticompetitive conduct, payors were overcharged for prescriptions of inhaled tiotropium bromide;

- Whether Boehringer's anticompetitive conduct was a substantial contributing factor in causing delayed availability of generic Spiriva Respimat;
- A reasonable estimate of the delay caused by Boehringer's wrongful conduct; and
- The quantum of overcharges paid by the class in the aggregate.

691. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Class treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that would occur if each action were adjudicated individually. In particular, adjudicating the interests of both classes will greatly aid in the efficiency of adjudicating this controversy, because there are several overlapping questions of fact and law as to Boehringer's anticompetitive conduct with respect to its Respimat Orange-Book-listing scheme, including:

- Whether Boehringer unlawfully maintained monopoly power through its scheme;
- Whether Boehringer unlawfully caused the listing of the '474 patent, which does not "claim the drug" in either Combivent Respimat or Spiriva Respimat, in the Orange Book;
- Whether Boehringer unlawfully caused the listing of the '6,341 patent, which does not "claim the drug" in either Combivent Respimat or Spiriva Respimat, in the Orange Book;
- Whether Boehringer unlawfully caused the listing of the '235 patent, which does not "claim the drug" in either Combivent Respimat or Spiriva Respimat, in the Orange Book;

- Whether Boehringer unlawfully caused the listing of the '264 patent, which does not "claim the drug" in either Combivent Respimat or Spiriva Respimat, in the Orange Book;
- Whether Boehringer unlawfully caused the listing of the '3,341 patent, which does not "claim the drug" in either Combivent Respimat or Spiriva Respimat, in the Orange Book;
- Whether Boehringer unlawfully caused the listing of the '967 patent, which does not "claim the drug" in either Combivent Respimat or Spiriva Respimat, in the Orange Book;
- Whether Boehringer's wrongful Orange Book listings are subject to *per se* antitrust liability, or are assessed under the Rule of Reason;
- Whether Boehringer knew or should have known that the Respimat patents were improperly listed in the Orange Book;
- Whether Boehringer knew or should have known that it lacked standing to sue Anobri over the Respimat patents;
- Whether a reasonable pharmaceutical company in Boehringer's position would have known that it could not have hoped to succeed on the merits of any Hatch-Waxman suit over the Respimat device patents because it lacked standing;
- Whether Boehringer was motivated by a desire to delay competition;
- Whether the elements of Boehringer's overarching scheme were, individually or collectively, anticompetitive;
- Whether Boehringer's scheme, in whole or in part, has substantially affected interstate commerce.

692. The class mechanism will allow injured persons or entities to obtain redress on claims that could not practicably be pursued individually. These

considerations in favor of class treatment substantially outweigh potential difficulties in management of this class action.

693. The plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

A. Claims for relief by the Combivent Respimat Class

FIRST CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme Under State Antitrust Laws
Overarching scheme claim against all defendants

694. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

695. As described above, from October 7, 2011, and continuing to today, Boehringer possessed market power in the market for ipratropium bromide and albuterol sulfate products, including the power to control prices in, prevent prices from falling in, and exclude competitors. No other manufacturer has sold a competing version of ipratropium bromide and albuterol sulfate in the United States.

696. Boehringer willfully and unlawfully maintained its market power in the ipratropium bromide and albuterol sulfate market from February 2020 through the present, by engaging in an overarching anticompetitive scheme to prevent generic versions of its Combivent Respimat products from entering the market. Boehringer obtained this market power through unlawful means, and not as a result of providing a superior product, business acumen, or historical accident.

697. Boehringer knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rate generic versions of Combivent Respimat to maintain is market power. This scheme included:

- Wrongfully causing ineligible device patents to be listed in the Orange Book as Combivent Respimat drug product patents to deter and delay ANDA filers and extend Boehringer's monopoly;
- Asserting its wrongfully listed patents against a would-be competitor in litigation to improperly gain an automatic stay of FDA final approval of Anobri's ANDA filing with the intent to delay generic Combivent Respimat competition; and
- Falsely recertifying ineligible device patents to the FDA to thwart efforts to correct Boehringer's wrongful patent listings through regulatory means.

698. Had Boehringer competed on the merits instead of unlawfully maintaining its monopoly in the market for ipratropium bromide and albuterol sulfate, the plaintiff and the class members would have substituted more lower-priced generic Combivent Respimat for the higher-priced brand-name Combivent Respimat for some or all of their Combivent Respimat requirements, and would have paid substantially lower prices for brand-name Combivent Respimat.

699. The goal, purpose, and effect of Boehringer's overarching anticompetitive scheme was to suppress generic competition for ipratropium bromide and albuterol sulfate, extend its dominance in that market, and maintain Combivent Respimat prices at supracompetitive levels.

700. Boehringer's scheme substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for

Boehringer's actions that outweighs the scheme's harmful effects. Even if there were a conceivable justification that Boehringer could assert, the scheme is and was broader than necessary to achieve such a purpose.

701. But for Boehringer's illegal conduct, generic manufacturers of ipratropium bromide and albuterol sulfate would have been able to fairly compete with Boehringer in a full and timely manner, and the plaintiff and class members, who are third-party payors, would have substituted lower-priced generic ipratropium bromide and albuterol sulfate for some or all of their Combivent Respimat purchases and/or paid lower prices for their branded Combivent Respimat purchases.

702. Through its scheme, Boehringer intentionally, willfully, and wrongfully maintained its market power in violation of the following state laws:[91]

- Ariz. Rev. Stat. § 44-1403 *et seq*., with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Arizona;
- Colo. Rev. Stat. § 6-4-115 *et seq*., with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Colorado;
- Conn. Gen. Stat. Ann. § 35-26 *et seq*., with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Connecticut;
- D.C. Code § 28-4503 *et seq*., with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in the District of Columbia;

[91] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under Mass. Gen. L. ch. 93A, with respect to purchases of Combivent Respimat in Massachusetts, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute.

- Haw. Rev. Stat. § 480 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Hawaii;

- Ill. Comp. Stat. Ann. § 505/1 *et seq.*, and 740 Ill. Comp. Stat. § 10/3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Illinois;

- Iowa Code § 553.4 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Iowa;

- Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Maine;

- Md. Code Ann. Com. Law, § 11-204 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Maryland;

- Mich. Comp. Laws Ann. § 445.771 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Michigan;

- Minn. Stat. § 325d.49 *et seq.*, and Minn. Stat. § 8.31 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Minnesota;

- Miss. Code. Ann. § 75-21-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Mississippi;

- Mont. Code Ann. § 30-14-205 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Montana;

- Neb. Code Ann. § 59-801 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Nebraska;

- Nev. Rev. Stat. Ann. § 598A.210 *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for Combivent

Respimat and its generic equivalents in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. § 356:2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Hampshire;

- N.J. State. Ann. § 56:9-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Jersey;

- N.M. Stat. Ann. § 57-1-2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Mexico;

- N.C. Gen. Stat. § 75-2.1 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in North Carolina;

- N.D. Cent. Code § 51-08.1-01 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in North Dakota;

- Ore. Rev. Stat. § 646.705 *et seq.*, and § 646.725 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Oregon;

- R.I. Gen. Laws § 6-36-4 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Rhode Island;

- S.D. Codified Laws § 37-1-3.2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in South Dakota;

- Utah Code Ann. § 76-10-3104 *et seq.*, with respect to the purchases of Combivent Respimat and its generic equivalents by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Vermont;

- W. Va. Code § 47-18-1 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in West Virginia;

- Wis. Stat. § 133.01 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for Combivent Respimat and its generic equivalents purchased in Wisconsin.

703. As a direct and proximate result of Boehringer's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Boehringer's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their ipratropium bromide and albuterol sulfate products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type that antitrust laws were designed to prevent and remedy, and flows from that which makes Boehringer's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

704. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Boehringer's violations of the above statutes.

705. The plaintiff, through its counsel, have sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Colo. Rev. Stat. § 6-4-116; Conn. Gen. Stat. Ann. §§ 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General

Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Nevada Revised Statute § 598A.210(3); Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

SECOND CLAIM FOR RELIEF
Monopolization Under State Antitrust Laws – Wrongful Combivent Respimat Orange Book Listings
Against all defendants

706. The plaintiff incorporates by reference and re-allege all preceding paragraphs and allegations, as though set forth fully herein.

707. Boehringer willfully and unlawfully maintained its market power in the ipratropium bromide and albuterol sulfate market from February 2020 through the present, by submitting for listing in the Orange Book 23 device patents that did not claim—and in some cases did not even mention—Combivent Respimat's active ingredients, ipratropium bromide and albuterol sulfate, and by failing to withdraw those listings once a federal appeals court unequivocally stated that such listings were improper.

708. Boehringer identified all of the patents that it submitted to the FDA for listing in the Orange Book as claiming a drug product, as defined and required by the FDCA and the FDA's implementing regulations. Each claimed only a device. None of the claims in any of the Combivent Respimat-listed patents claimed that device in combination with Combivent Respimat's active ingredient. Accordingly, none of them claim the "drug product" Combivent Respimat, as that term is defined in 21 C.F.R. § 314.3.

709. For each of the patents Boehringer submitted, it prepared a Patent Listing Form in which its representative swore, under penalty of perjury, that the

patent claimed the drug product Combivent Respimat. Those sworn statements were false.

710. Boehringer's submission of the Combivent Respimat Patent Listing Forms does not constitute petitioning activity protected by the First Amendment, because the submissions trigger the FDA to perform a purely ministerial function.

711. The requirements for patent listings—and the prohibition on listing device-only patents—has been plain from the language of the statute and the FDA's implementing regulations for more than two decades. Boehringer had no objectively reasonable basis to believe that listing patents that did not contain, within their claims, the Combivent Respimat drug substance was required by any concrete factual imperative recognized as legitimate by the FDA.

712. By submitting the Combivent Respimat patents for listing, Boehringer unlawfully gained the power to block competition (thus reducing output and raising prices) because the extensive list of patents dissuaded would-be competitors from submitting an ANDA at all; forced those who persevered and filed an ANDA anyway to make paragraph IV certifications to patents to which they should not have had to so certify; and gave Boehringer the ability to sue would-be competitors and trigger an automatic two and a half year delay in competition.

713. Boehringer obtained this market power through unlawful means, and not as a result of providing a superior product, business acumen, or historical accident.

714. Had Boehringer competed on the merits instead of unlawfully maintaining its monopoly in the market for ipratropium bromide and albuterol sulfate, the plaintiff and the class members would have substituted more lower-priced generic Combivent Respimat for the higher-priced brand-name Combivent Respimat for some or all of their Combivent Respimat requirements, and would have paid substantially lower prices for brand-name Combivent Respimat.

715. The goal, purpose, and effect of Boehringer's wrongful Orange Book listings was to suppress generic competition for ipratropium bromide and albuterol sulfate, extend its dominance in that market, and maintain Combivent Respimat prices at supracompetitive levels.

716. Boehringer's wrongful listings substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for Boehringer's actions that outweighs their harmful effects. Even if there were a conceivable justification that Boehringer could assert, Boehringer's conduct is and was broader than necessary to achieve such a purpose.

717. But for Boehringer's wrongful listings, generic manufacturers of ipratropium bromide and albuterol sulfate would have been able to fairly compete with Boehringer in a full and timely manner, and the plaintiff and class members, who are third-party payors, would have substituted lower-priced generic ipratropium bromide and albuterol sulfate for some or all of their Combivent Respimat purchases and/or paid lower prices for their branded Combivent Respimat purchases.

718. Through its wrongful listings, Boehringer intentionally and wrongfully maintained its market power with respect to Combivent Respimat in violation of the following state laws:[92]

- Ariz. Rev. Stat. § 44-1403 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Arizona;
- Colo. Rev. Stat. § 6-4-115 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Colorado;
- Conn. Gen. Stat. Ann. § 35-26 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Connecticut;
- D.C. Code § 28-4503 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in the District of Columbia;
- Haw. Rev. Stat. § 480 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Hawaii;
- Ill. Comp. Stat. Ann. § 505/1 *et seq.*, and 740 Ill. Comp. Stat. § 10/3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Illinois;
- Iowa Code § 553.4 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Iowa;
- Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Maine;

[92] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under Mass. Gen. L. ch. 93A, with respect to purchases of Combivent Respimat in Massachusetts, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute.

- Md. Code Ann. Com. Law, § 11-204 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Maryland;

- Mich. Comp. Laws Ann. § 445.771 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Michigan;

- Minn. Stat. § 325d.49 *et seq.*, and Minn. Stat. § 8.31 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Minnesota;

- Miss. Code. Ann. § 75-21-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Mississippi;

- Mont. Code Ann. § 30-14-205 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Montana;

- Neb. Code Ann. § 59-801 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Nebraska;

- Nev. Rev. Stat. Ann. § 598A.210 *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for Combivent Respimat and its generic equivalents in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. § 356:2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Hampshire;

- N.J. State. Ann. § 56:9-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Jersey;

- N.M. Stat. Ann. § 57-1-2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Mexico;

- N.C. Gen. Stat. § 75-2.1 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in North Carolina;

- N.D. Cent. Code § 51-08.1-01 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in North Dakota;

- Ore. Rev. Stat. § 646.705 *et seq.*, and § 646.725, *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Oregon;

- R.I. Gen. Laws § 6-36-4 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Rhode Island;

- S.D. Codified Laws § 37-1-3.2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in South Dakota;

- Utah Code Ann. § 76-10-3104 *et seq.*, with respect to the purchases of Combivent Respimat and its generic equivalents by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Vermont;

- W. Va. Code § 47-18-1 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in West Virginia;

- Wis. Stat. § 133.01 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for Combivent Respimat and its generic equivalents purchased in Wisconsin.

719. As a direct and proximate result of Boehringer's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Boehringer's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their ipratropium bromide and

albuterol sulfate products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type that antitrust laws were designed to prevent and remedy, and flows from that which makes Boehringer's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

720. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Boehringer's violations of the above statutes.

721. The plaintiff, through its counsel, has sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Colo. Rev. Stat. § 6-4-116; Conn. Gen. Stat. Ann. §§ 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Nevada Revised Statute § 598A.210(3); Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

THIRD CLAIM FOR RELIEF
Monopolization Under State Antitrust Laws—Sham Litigation
Against all defendants

722. The plaintiff incorporates by reference and re-allege all preceding paragraphs and allegations, as though set forth fully herein.

723. A litigation is a sham if (1) the claims, positions, or arguments advanced are objectively meritless, such that no reasonable brand-name drugmaker in Boehringer's position could reasonably have expected to prevail and (2) the suit is subjectively motivated by an intention to harm competition by using the litigation process as a weapon. In the context of pharmaceutical Hatch-Waxman patent

infringement suits, courts in this District have recognized two ways in which the first part of this test is satisfied.

724. First, a litigation may be objectively unreasonable if a reasonable brand-name drugmaker in Boehringer's position would have known or should have known that the asserted patents could not be adjudicated in a pre-generic launch Hatch-Waxman litigation because they were not properly listable in the Orange Book to begin with.

725. Second, a litigation may be objectively unreasonable if a reasonable brand-name drugmaker in Boehringer's position would not have reasonably expected to succeed in proving that its asserted patents were valid, enforceable, and infringed.

726. As alleged above, Boehringer's lawsuit against Anobri is a sham because a reasonable company in Boehringer's position would have or should have known—especially because of the First Circuit's *Lantus* decision mere months earlier that reaffirmed the plain language of the statutory listing requirements—that the patents it asserted against Anobri should not have been listed in the Orange Book, and that, therefore, it had no standing to sue over those patents until after a generic product launched.

727. Boehringer ignored this because its intent, aim, and goal was to use those litigations to frustrate competition. By simply suing, it triggered automatic thirty-month delays in the approval of Anobri's product.

728. Boehringer's sham litigation substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for

Boehringer's actions that outweighs their harmful effects. Even if there were a conceivable justification that Boehringer could assert, Boehringer conduct is and was broader than necessary to achieve such a purpose.

729. But for Boehringer's sham litigations, generic manufacturers of ipratropium bromide and albuterol sulfate would have been able to fairly compete with Boehringer in a full and timely manner, and the plaintiff and class members, who are third-party payors, would have substituted lower-priced generic ipratropium bromide and albuterol sulfate for some or all of their Combivent Respimat purchases and/or paid lower prices for their branded Combivent Respimat purchases.

730. Through its sham litigation, Boehringer intentionally and wrongfully maintained its market power with respect to Combivent Respimat in violation of the following state laws:[93]

- Ariz. Rev. Stat. § 44-1403 *et seq*., with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Arizona;
- Colo. Rev. Stat. § 6-4-115 *et seq*., with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Colorado;
- Conn. Gen. Stat. Ann. § 35-26 *et seq*., with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Connecticut;
- D.C. Code § 28-4503 *et seq*., with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in the District of Columbia;

[93] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under Mass. Gen. L. ch. 93A, with respect to purchases of Combivent Respimat in Massachusetts, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute.

- Haw. Rev. Stat. § 480 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Hawaii;

- Ill. Comp. Stat. Ann. § 505/1 *et seq.*, and 740 Ill. Comp. Stat. § 10/3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Illinois;

- Iowa Code § 553.4 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Iowa;

- Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Maine;

- Md. Code Ann. Com. Law, § 11-204 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Maryland;

- Mich. Comp. Laws Ann. § 445.771 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Michigan;

- Minn. Stat. § 325d.49 *et seq.*, and Minn. Stat. § 8.31 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Minnesota;

- Miss. Code. Ann. § 75-21-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Mississippi;

- Mont. Code Ann. § 30-14-205 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Montana;

- Neb. Code Ann. § 59-801 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Nebraska;

- Nev. Rev. Stat. Ann. § 598A.210 *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for Combivent

Respimat and its generic equivalents in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. § 356:2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Hampshire;

- N.J. State. Ann. § 56:9-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Jersey;

- N.M. Stat. Ann. § 57-1-2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Mexico;

- N.C. Gen. Stat. § 75-2.1 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in North Carolina;

- N.D. Cent. Code § 51-08.1-01 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in North Dakota;

- Ore. Rev. Stat. § 646.705 *et seq.*, and § 646.725 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Oregon;

- R.I. Gen. Laws § 6-36-4,*et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Rhode Island;

- S.D. Codified Laws § 37-1-3.2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in South Dakota;

- Utah Code Ann. § 76-10-3104 *et seq.*, with respect to the purchases of Combivent Respimat and its generic equivalents by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Vermont;

- W. Va. Code § 47-18-1 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in West Virginia;

- Wis. Stat. § 133.01 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for Combivent Respimat and its generic equivalents purchased in Wisconsin.

731. As a direct and proximate result of Boehringer's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Boehringer's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their ipratropium bromide and albuterol sulfate products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type that antitrust laws were designed to prevent and remedy, and flows from that which makes Boehringer's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

732. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Boehringer's violations of the above statutes.

733. The plaintiff, through its counsel, has sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Colo. Rev. Stat. § 6-4-116; Conn. Gen. Stat. Ann. §§ 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General

Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Nevada Revised Statute § 598A.210(3); Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

FOURTH CLAIM FOR RELIEF
Attempted Monopolization and Monopolistic Scheme Under State Antitrust Laws
Overarching scheme claim against all defendants

734. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

735. As detailed above, Boehringer engaged in restrictive or exclusionary conduct to keep generic versions of Combivent Respimat from entering the market.

736. Boehringer has willingly, knowingly, and with specific intent to do so, attempted to monopolize the Combivent Respimat Relevant Market.

737. Boehringer knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rate generic versions of Combivent Respimat in an attempt to monopolize the relevant market. This scheme included:

- Wrongfully causing ineligible device patents to be listed in the Orange Book as Combivent Respimat drug product patents to extend Boehringer's monopoly from February 2020 until today;
- Asserting its wrongfully listed patents against a would-be competitor in litigation to improperly gain an automatic stay of FDA final approval of Anobri's ANDA filing with the intent to delay generic Combivent Respimat competition; and
- Falsely recertifying ineligible device patents to the FDA to thwart efforts to correct Boehringer's wrongful patent listings through regulatory means.

738. Based on Boehringer's anticompetitive conduct, it has monopoly power, or at a minimum, a dangerous probability of acquiring monopoly power, in the Combivent Respimat Relevant Market.

739. Boehringer's scheme substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for Boehringer's actions that outweighs the scheme's harmful effects. Even if there were a conceivable justification that Boehringer could assert, the scheme is and was broader than necessary to achieve such a purpose.

740. Plaintiff and the class members have sustained injury as a direct and proximate result of Boehringer's unlawful conduct. But for Boehringer's illegal conduct, generic manufacturers of ipratropium bromide and albuterol sulfate would have been able to fairly compete with Boehringer in a full and timely manner, and the plaintiff and class members, who are third-party payors, would have substituted lower-priced generic ipratropium bromide and albuterol sulfate for some or all of their Combivent Respimat purchases and/or paid lower prices for their branded Combivent Respimat purchases.

741. Through its scheme, Boehringer intentionally, willfully, and wrongfully engaged in attempted monopolization in violation of the following state laws:[94]

- Ariz. Rev. Stat. § 44-1403 *et seq*., with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Arizona;

[94] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under Mass. Gen. L. ch. 93A, with respect to purchases of Combivent Respimat in Massachusetts, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute.

- Colo. Rev. Stat. § 6-4-115 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Colorado;

- Conn. Gen. Stat. Ann. § 35-26 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Connecticut;

- D.C. Code § 28-4503 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in the District of Columbia;

- Haw. Rev. Stat. § 480 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Hawaii;

- Ill. Comp. Stat. Ann. § 505/1 *et seq.*, and 740 Ill. Comp. Stat. § 10/3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Illinois;

- Iowa Code § 553.4 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Iowa;

- Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Maine;

- Md. Code Ann. Com. Law, § 11-204 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Maryland;

- Mich. Comp. Laws Ann. § 445.771 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Michigan;

- Minn. Stat. § 325d.49 *et seq.*, and Minn. Stat. § 8.31 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Minnesota;

- Miss. Code. Ann. § 75-21-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Mississippi;

- Mont. Code Ann. § 30-14-205 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Montana;

- Neb. Code Ann. § 59-801 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Nebraska;

- Nev. Rev. Stat. Ann. § 598A.210 *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for Combivent Respimat and its generic equivalents in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. § 356:2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Hampshire;

- N.J. State. Ann. § 56:9-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Jersey;

- N.M. Stat. Ann. § 57-1-2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in New Mexico;

- N.C. Gen. Stat. § 75-2.1 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in North Carolina;

- N.D. Cent. Code § 51-08.1-01 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in North Dakota;

- Ore. Rev. Stat. § 646.705 *et seq.*, and § 646.725 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Oregon;

- R.I. Gen. Laws § 6-36-4 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Rhode Island;

- S.D. Codified Laws § 37-1-3.2 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in South Dakota;

- Utah Code Ann. § 76-10-3104 *et seq.*, with respect to the purchases of Combivent Respimat and its generic equivalents by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Vermont;

- W. Va. Code § 47-18-1 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in West Virginia;

- Wis. Stat. § 133.01 *et seq.*, with respect to the plaintiff's and class members' purchases of Combivent Respimat and its generic equivalents in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for Combivent Respimat and its generic equivalents purchased in Wisconsin.

742. As a direct and proximate result of Boehringer's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Boehringer's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their ipratropium bromide and albuterol sulfate products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type that antitrust laws were designed to prevent and remedy, and flows from that which makes Boehringer's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

743. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Boehringer's violations of the above statutes.

744. The plaintiff, through its counsel, have sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Colo. Rev. Stat. § 6-4-116; Conn. Gen. Stat. Ann. §§ 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Nevada Revised Statute § 598A.210(3); Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

FIFTH CLAIM FOR RELIEF
Unfair Methods of Competition, and Unfair and Deceptive Acts, in Violation of State Consumer Protection Laws
Overarching scheme claim against all defendants

745. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

746. Boehringer has engaged in unfair competition, and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Boehringer's anticompetitive, deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated generic versions of Combivent Respimat, and were instead forced to pay higher prices.

747. Boehringer's overarching scheme, as alleged in this Complaint and in the First Claim for Relief, violates the following state consumer protection laws:[95]

[95] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under the following statutes, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute: (1) Ind. Code Ann. § 24-5-0.5-1 *et seq*., with respect to purchases of Combivent Respimat in Indiana or

- Alaska Stat. § 45.50.471 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Alaska by class members and/or purchases of ipratropium bromide and Combivent Respimat and its generic equivalents by class members residing in Alaska;

- Ark. Code Ann. § 4-88-107 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Arkansas by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Arkansas;

- Cal. Bus. & Prof. Code § 17200 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in California by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in California. In particular, Boehringer has engaged in an unlawful business practice in violation of Cal. Bus. & Prof. Code § 17200 *et seq*. by violating Cal. Bus. & Prof. Code § 16700, *et seq*. and Cal. Health and Safety Code § 134002;

- Conn. Gen. Stat. § 42-110a *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Connecticut by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Connecticut;

- Del. Code. Ann., tit. 6 § 2511 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Delaware by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Delaware;

- D.C. Code § 28-3901 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in District of Columbia by class members and/or purchases of

by class members residing in Indiana; (2) 5 Me. Rev. Stat. § 207 *et seq*., with respect to purchases of Combivent Respimat in Maine or by class members residing in Maine; (3) Mass. Gen. L. ch. 93A with respect to purchases of Combivent Respimat in Massachusetts or by class members residing in Massachusetts; (4) Miss. Code. § 75-24-1 *et seq*., with respect to purchases of Combivent Respimat in Mississippi or by class members residing in Mississippi; (5) Tex. Bus. & Prof. Code § 17.41 *et seq*., with respect to purchases of Combivent Respimat in Texas or by class members residing in Texas; and (6) Wyo. Stat. Ann. § 40-12-101 *et seq*., with respect to purchases of Combivent Respimat in Wyoming or by class members residing in Wyoming.

Combivent Respimat and its generic equivalents by class members residing in District of Columbia;

- Fla. Stat. § 501.201 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Florida by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Florida;

- Haw. Rev. Stat. § 480 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Hawaii by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. § 505/1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Illinois by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Illinois;

- Iowa Code § 714H.3 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Iowa by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Iowa;

- Md. Code Ann., Com. Law § 13-101 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Maryland by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Maryland;

- Minn. Stat. § 8.31, 325F.67, 325F.68 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Minnesota by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Minnesota;

- Neb. Rev. Stat. § 59-1601 *et seq.*, with respect to purchases of ipratropium bromide and albuterol sulfate products in Nebraska by class members and/or purchases of ipratropium bromide and albuterol sulfate products by class members residing in Nebraska;

- Nev. Rev. Stat. § 598.0903 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Nevada by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Nevada;

- N.H. Rev. Stat. § 358-A:1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New Hampshire by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New Hampshire;

- N.J. Stat. Ann. § 56:8-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New Jersey by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New Jersey;

- N.M. Stat. § 57-12-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New Mexico by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New York by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New York;[96]

- N.C. Gen. Stat. § 75-1.1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in North Carolina by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in North Carolina;

- N.D. Cent. Code. § 51-15-01 *et seq.* with respect to purchases of Combivent Respimat and its generic equivalents in North Dakota by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in North Dakota;

[96] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

- Ohio Rev. Code Ann. § 1345.01 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Ohio by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Ohio;

- Okla. Stat. tit. 15, § 751 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Oklahoma by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Oklahoma;

- S.D. Codified Laws § 37-24-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in South Dakota by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in South Dakota;

- Utah Code Ann. § 13-11-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Utah by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Vermont by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Vermont;

- Va. Stat. Ann. § 59.1-196 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Virginia by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Virginia;

- Wash. Rev. Code § 1986.010 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Washington by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Washington.

748. The plaintiff and members of the class have been injured in their business and property by reason of Boehringer's anticompetitive, unfair,

unconscionable, and/or deceptive acts or practices alleged in this Court. Their injury consists of paying higher prices for ipratropium bromide and albuterol sulfate products than they would have paid in the absence of these violations. This injury is of the type that the state consumer protection statutes were designed to prevent and directly results from Boehringer's unlawful conduct.

749. The plaintiff, through its counsel, have sent or will send letters to the relevant state attorney general as required by Iowa Code § 714H.7.

SIXTH CLAIM FOR RELIEF
Violations of State Consumer Protection Laws—Wrongful Combivent Respimat Orange Book Listings
Against all defendants

750. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

751. Boehringer has engaged in unfair competition, and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Boehringer's anticompetitive, deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated generic versions of Combivent Respimat, and were instead forced to pay higher prices.

752. Boehringer's conduct as alleged in this Complaint and in the Second Claim for Relief violates the following state consumer protection laws:[97]

[97] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under the following statutes,

- Alaska Stat. § 45.50.471 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Alaska by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Alaska;

- Ark. Code Ann. § 4-88-107 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Arkansas by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Arkansas;

- Cal. Bus. & Prof. Code § 17200 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in California by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in California. In particular, Boehringer has engaged in an unlawful business practice in violation of Cal. Bus. & Prof. Code § 17200 *et seq*. by violating Cal. Bus. & Prof. Code § 16700 *et seq*. and Cal. Health and Safety Code § 134002;

- Conn. Gen. Stat. § 42-110a *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Connecticut by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Connecticut;

- Del. Code. Ann., tit. 6 § 2511 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Delaware by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Delaware;

unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute: (1) Ind. Code Ann. § 24-5-0.5-1 *et seq*., with respect to purchases of Combivent Respimat in Indiana or by class members residing in Indiana; (2) 5 Me. Rev. Stat. § 207 *et seq*., with respect to purchases of Combivent Respimat in Maine or by class members residing in Maine; (3) Mass. Gen. L. ch. 93A with respect to purchases of Combivent Respimat in Massachusetts or by class members residing in Massachusetts; (4) Miss. Code. § 75-24-1 *et seq*., with respect to purchases of Combivent Respimat in Mississippi or by class members residing in Mississippi; (5) Tex. Bus. & Prof. Code § 17.41 *et seq*., with respect to purchases of Combivent Respimat in Texas or by class members residing in Texas; and (6) Wyo. Stat. Ann. § 40-12-101 *et seq*., with respect to purchases of Combivent Respimat in Wyoming or by class members residing in Wyoming.

- D.C. Code § 28-3901 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in District of Columbia by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in District of Columbia;

- Fla. Stat. § 501.201 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Florida by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Florida;

- Haw. Rev. Stat. § 480 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Hawaii by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. § 505/1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Illinois by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Illinois;

- Iowa Code § 714H.3 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Iowa by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Iowa;

- Md. Code Ann., Com. Law § 13-101 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Maryland by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Maryland;

- Minn. Stat. § 8.31, 325F.67, 325F.68 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Minnesota by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Minnesota;

- Neb. Rev. Stat. § 59-1601 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Nebraska by class members and/or purchases of Combivent

Respimat and its generic equivalents by class members residing in Nebraska;

- Nev. Rev. Stat. § 598.0903 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Nevada by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Nevada;

- N.H. Rev. Stat. § 358-A:1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New Hampshire by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New Hampshire;

- N.J. Stat. Ann. § 56:8-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New Jersey by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New Jersey;

- N.M. Stat. § 57-12-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New Mexico by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New York by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New York.[98]

- N.C. Gen. Stat. § 75-1.1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in North Carolina by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in North Carolina;

- N.D. Cent. Code. § 51-15-01 *et seq.* with respect to purchases of Combivent Respimat and its generic equivalents in North Dakota by class members and/or

[98] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

purchases of Combivent Respimat and its generic equivalents by class members residing in North Dakota;

- Ohio Rev. Code Ann. § 1345.01 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Ohio by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Ohio;

- Okla. Stat. tit. 15, § 751 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Oklahoma by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Oklahoma;

- S.D. Codified Laws § 37-24-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in South Dakota by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in South Dakota;

- Utah Code Ann. § 13-11-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Utah by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Utah;

- Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Vermont by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Vermont;

- Va. Stat. Ann. § 59.1-196 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Virginia by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Virginia;

- Wash. Rev. Code § 1986.010 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Washington by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Washington.

753. The plaintiff and members of the class have been injured in their business and property by reason of Boehringer's anticompetitive, unfair, unconscionable, and/or deceptive acts or practices alleged. Their injury consists of paying higher prices for ipratropium bromide and albuterol sulfate products than they would have paid in the absence of these violations. This injury is of the type that the state consumer protection statutes were designed to prevent and directly results from Boehringer's unlawful conduct.

754. The plaintiff, through its counsel, has sent or will send letters to the relevant state attorney general as required by Iowa Code § 714H.7.

SEVENTH CLAIM FOR RELIEF
Violations of State Consumer Protection Laws—Sham Litigation
Against all defendants

755. The plaintiff incorporates by reference and re-allege all preceding paragraphs and allegations, as though set forth fully herein.

756. Boehringer has engaged in unfair competition, and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Boehringer's anticompetitive, deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated generic versions of Combivent Respimat, and were instead forced to pay higher prices.

757. Boehringer conduct as alleged in this Complaint and in the Third Claim for Relief violates the following state consumer protection laws:[99]

- Alaska Stat. § 45.50.471 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Alaska by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Alaska;

- Ark. Code Ann. § 4-88-107 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Arkansas by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Arkansas;

- Cal. Bus. & Prof. Code § 17200 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in California by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in California. In particular, Boehringer has engaged in unlawful business practices in violation of Cal. Bus. & Prof. Code § 17200 *et seq*. by violating Cal. Bus. & Prof. Code § 16700 *et seq.*, and Cal. Health and Safety Code § 134002;

- Conn. Gen. Stat. § 42-110a *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Connecticut by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Connecticut;

- Del. Code. Ann., tit. 6 § 2511 *et seq.*, with respect to purchases of Combivent Respimat and its generic

[99] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under the following statutes, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute: (1) Ind. Code Ann. § 24-5-0.5-1 *et seq*., with respect to purchases of Combivent Respimat in Indiana or by class members residing in Indiana; (2) 5 Me. Rev. Stat. § 207 *et seq*., with respect to purchases of Combivent Respimat in Maine or by class members residing in Maine; (3) Mass. Gen. L. ch. 93A with respect to purchases of Combivent Respimat in Massachusetts or by class members residing in Massachusetts; (4) Miss. Code. § 75-24-1 *et seq*., with respect to purchases of Combivent Respimat in Mississippi or by class members residing in Mississippi; (5) Tex. Bus. & Prof. Code § 17.41 *et seq*., with respect to purchases of Combivent Respimat in Texas or by class members residing in Texas; and (6) Wyo. Stat. Ann. § 40-12-101 *et seq*., with respect to purchases of Combivent Respimat in Wyoming or by class members residing in Wyoming.

equivalents in Delaware by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Delaware;

- D.C. Code § 28-3901 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in District of Columbia by class members and/or purchases Combivent Respimat and its generic equivalents by class members residing in District of Columbia;

- Fla. Stat. § 501.201 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Florida by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Florida;

- Haw. Rev. Stat. § 480 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Hawaii by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. § 505/1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Illinois by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Illinois;

- Iowa Code § 714H.3 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Iowa by class members and/or purchases Combivent Respimat and its generic equivalents by class members residing in Iowa;

- Md. Code Ann., Com. Law § 13-101 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Maryland by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Maryland;

- Minn. Stat. § 8.31, 325F.67, 325F.68 *et seq.*, with respect to Combivent Respimat and its generic equivalents in Minnesota by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Minnesota;

- Neb. Rev. Stat. § 59-1601 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Nebraska by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Nebraska;

- Nev. Rev. Stat. § 598.0903 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Nevada by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Nevada;

- N.H. Rev. Stat. § 358-A:1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New Hampshire by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New Hampshire;

- N.J. Stat. Ann. § 56:8-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New Jersey by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New Jersey;

- N.M. Stat. § 57-12-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New Mexico by class members and/or purchases Combivent Respimat and its generic equivalents by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in New York by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in New York;[100]

- N.C. Gen. Stat. § 75-1.1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in North Carolina by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in North Carolina;

[100] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

- N.D. Cent. Code. § 51-15-01 *et seq.* with respect to purchases of Combivent Respimat and its generic equivalents in North Dakota by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in North Dakota;

- Ohio Rev. Code Ann. § 1345.01 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Ohio by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Ohio;

- Okla. Stat. tit. 15, § 751 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Oklahoma by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Oklahoma;

- S.D. Codified Laws § 37-24-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in South Dakota by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in South Dakota;

- Utah Code Ann. § 13-11-1 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Utah by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Vermont by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Vermont;

- Va. Stat. Ann. § 59.1-196 *et seq.*, with respect to purchases of Combivent Respimat and its generic equivalents in Virginia by class members and/or purchases of Combivent Respimat and its generic equivalents by class members residing in Virginia;

- Wash. Rev. Code § 1986.010 *et seq.*, with respect to purchases of ipratropium bromide and albuterol sulfate products in Washington by class members and/or

purchases of ipratropium bromide and albuterol sulfate products by class members residing in Washington.

758. The plaintiff and members of the class have been injured in their business and property by reason of Boehringer's anticompetitive, unfair, unconscionable, and/or deceptive acts or practices alleged in this Court. Their injury consists of paying higher prices for ipratropium bromide and albuterol sulfate products than they would have paid in the absence of these violations. This injury is of the type that the state consumer protection statutes were designed to prevent and directly results from Boehringer's unlawful conduct.

759. The plaintiff, through its counsel, has sent or will send letters to the relevant state attorney general as required by Iowa Code § 714H.7.

B. Claims for relief by the Spiriva Respimat class

EIGHTH CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme Under State Antitrust Laws
Overarching scheme claim against all defendants

760. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

761. As described above, from September 24, 2014, and continuing to today, Boehringer possessed market power in the market for tiotropium bromide products, including the power to control prices in, prevent prices from falling in, and exclude competitors. No other manufacturer has sold a competing version of tiotropium bromide in the United States.

762. Boehringer willfully and unlawfully maintained its market power in the ipratropium bromide and albuterol sulfate market from August 2020 through the

present, by engaging in an overarching anticompetitive scheme to prevent generic versions of its Spiriva Respimat products from entering the market. Boehringer obtained this market power through unlawful means, and not as a result of providing a superior product, business acumen, or historical accident.

763. Boehringer knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rate generic versions of Spiriva Respimat to maintain is market power. This scheme included:

- Wrongfully causing ineligible device patents to be listed in the Orange Book as Spiriva Respimat drug product patents to deter and delay ANDA filers and extend Boehringer's monopoly;
- Asserting its wrongfully listed patents against a would-be competitor in litigation to improperly gain an automatic stay of FDA final approval of Anobri's ANDA filing with the intent to delay generic Spiriva Respimat competition; and
- Falsely recertifying ineligible device patents to the FDA to thwart efforts to correct Boehringer's wrongful patent listings through regulatory means.

764. Had Boehringer competed on the merits instead of unlawfully maintaining its monopoly in the market for tiotropium bromide, the plaintiff and the class members would have substituted more lower-priced generic Spiriva Respimat for the higher-priced brand-name Spiriva Respimat for some or all of their Spiriva Respimat requirements, and would have paid substantially lower prices for brand-name Spiriva Respimat.

765. The goal, purpose, and effect of Boehringer's overarching anticompetitive scheme was to suppress generic competition for tiotropium bromide,

extend its dominance in that market, and maintain Spiriva Respimat prices at supracompetitive levels.

766. Boehringer's scheme substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for Boehringer's actions that outweighs the scheme's harmful effects. Even if there were a conceivable justification that Boehringer could assert, the scheme is and was broader than necessary to achieve such a purpose.

767. But for Boehringer's illegal conduct, generic manufacturers of tiotropium bromide would have been able to fairly compete with Boehringer in a full and timely manner, and the plaintiff and class members, who are third-party payors, would have substituted lower-priced generic tiotropium bromide for some or all of their Spiriva Respimat purchases and/or paid lower prices for their branded Spiriva Respimat purchases.

768. Through its scheme, Boehringer intentionally, willfully, and wrongfully maintained its market power in violation of the following state laws:[101]

- Ariz. Rev. Stat. § 44-1403 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Arizona;
- Colo. Rev. Stat. § 6-4-115 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Colorado;

[101] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under Mass. Gen. L. ch. 93A, with respect to purchases of Spiriva Respimat in Massachusetts, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute.

- Conn. Gen. Stat. Ann. § 35-26 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Connecticut;

- D.C. Code § 28-4503 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in the District of Columbia;

- Haw. Rev. Stat. § 480 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Hawaii;

- Ill. Comp. Stat. Ann. § 505/1 *et seq.*, and 740 Ill. Comp. Stat. § 10/3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Illinois;

- Iowa Code § 553.4 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Iowa;

- Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Maine;

- Md. Code Ann. Com. Law, § 11-204 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Maryland;

- Mich. Comp. Laws Ann. § 445.771 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Michigan;

- Minn. Stat. § 325d.49 *et seq.*, and Minn. Stat. § 8.31 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Minnesota;

- Miss. Code. Ann. § 75-21-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Mississippi;

- Mont. Code Ann. § 30-14-205 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Montana;

- Neb. Code Ann. § 59-801 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Nebraska;

- Nev. Rev. Stat. Ann. § 598A.210 *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for Spiriva Respimat and its generic equivalents in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. § 356:2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Hampshire;

- N.J. State. Ann. § 56:9-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Jersey;

- N.M. Stat. Ann. § 57-1-2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Mexico;

- N.C. Gen. Stat. § 75-2.1,*et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in North Carolina;

- N.D. Cent. Code § 51-08.1-01 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in North Dakota;

- Ore. Rev. Stat. § 646.705 *et seq.*, and § 646.725 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Oregon;

- R.I. Gen. Laws § 6-36-4 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Rhode Island;

- S.D. Codified Laws § 37-1-3.2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in South Dakota;

- Utah Code Ann. § 76-10-3104 *et seq.*, with respect to the purchases of Spiriva Respimat and its generic equivalents by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Vermont;

- W. Va. Code § 47-18-1 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in West Virginia;

- Wis. Stat. § 133.01 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for Spiriva Respimat and its generic equivalents purchased in Wisconsin.

769. As a direct and proximate result of Boehringer's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Boehringer's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their tiotropium bromide products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type that antitrust laws were designed to prevent and remedy, and flows from that which makes Boehringer's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

770. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Boehringer's violations of the above statutes.

771. The plaintiff, through its counsel, have sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Colo. Rev. Stat. § 6-4-116; Conn. Gen. Stat.

Ann. §§ 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Nevada Revised Statute § 598A.210(3); Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

NINTH CLAIM FOR RELIEF
Monopolization Under State Antitrust Laws – Wrongful Spiriva Respimat Orange Book Listings
Against all defendants

772. The plaintiff incorporates by reference and re-allege all preceding paragraphs and allegations, as though set forth fully herein.

773. Boehringer willfully and unlawfully maintained its market power in the ipratropium bromide and albuterol sulfate market from August 2020 through the present, by submitting for listing in the Orange Book 16 patents that did not claim—and in some cases did not even mention—Boehringer's active ingredient, tiotropium bromide, and by failing to withdraw those listings once a federal appeals court unequivocally stated that such listings were improper.

774. Boehringer identified all of the patents that it submitted to the FDA for listing in the Orange Book as claiming a drug product, as defined and required by the FDCA and the FDA's implementing regulations. Each claimed only a device. None of the claims in any of the Spiriva Respimat-listed patents claimed that device in combination with Spiriva Respimat's active ingredient. Accordingly, none of them claim the "drug product" Spiriva Respimat, as that term is defined in 21 C.F.R. § 314.3.

775. For each of the patents Boehringer submitted, it prepared a Patent Listing Form in which its representative swore, under penalty of perjury, that the

patent claimed the drug product Spiriva Respimat. Those sworn statements were false.

776. Boehringer's submission of the Spiriva Respimat Patent Listing Forms does not constitute petitioning activity protected by the First Amendment, because the submissions trigger the FDA to perform a purely ministerial function.

777. The requirements for patent listings—and the prohibition on listing device-only patents—has been plain from the language of the statute and the FDA's implementing regulations for more than two decades. Boehringer had no objectively reasonable basis to believe that listing patents that did not contain, within their claims, the Spiriva Respimat drug substance was required by any concreate factual imperative recognized as legitimate by the FDA.

778. By submitting the Spiriva Respimat patents for listing, Boehringer unlawfully gained the power to block competition (thus reducing output and raising prices) because the extensive list of patents dissuaded would-be competitors from submitting an ANDA at all; forced those who persevered and filed an ANDA anyway to make paragraph IV certifications to patents to which they should not have had to so certify; and gave Boehringer the ability to sue would-be competitors and trigger an automatic two and a half year delay in competition.

779. Boehringer obtained this market power through unlawful means, and not as a result of providing a superior product, business acumen, or historical accident.

780. Had Boehringer competed on the merits instead of unlawfully maintaining its monopoly in the market for ipratropium bromide and albuterol sulfate, the plaintiff and the class members would have substituted more lower-priced generic Spiriva Respimat for the higher-priced brand-name Spiriva Respimat for some or all of their Spiriva Respimat requirements, and would have paid substantially lower prices for brand-name Spiriva Respimat.

781. The goal, purpose, and effect of Boehringer's wrongful Orange Book listings was to suppress generic competition for tiotropium bromide, extend its dominance in that market, and maintain Spiriva Respimat prices at supracompetitive levels.

782. Boehringer's wrongful listings substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for Boehringer's actions that outweighs their harmful effects. Even if there were a conceivable justification that Boehringer could assert, Boehringer's conduct is and was broader than necessary to achieve such a purpose.

783. But for Boehringer's wrongful listings, generic manufacturers of tiotropium bromide would have been able to fairly compete with Boehringer in a full and timely manner, and the plaintiff and class members, who are third-party payors, would have substituted lower-priced generic tiotropium bromide for some or all of their Spiriva Respimat purchases and/or paid lower prices for their branded Spiriva Respimat purchases.

784. Through its wrongful listings, Boehringer intentionally and wrongfully maintained its market power with respect to Spiriva Respimat in violation of the following state laws:[102]

- Ariz. Rev. Stat. § 44-1403 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Arizona;
- Colo. Rev. Stat. § 6-4-115 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Colorado;
- Conn. Gen. Stat. Ann. § 35-26 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Connecticut;
- D.C. Code § 28-4503 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in the District of Columbia;
- Haw. Rev. Stat. § 480 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Hawaii;
- Ill. Comp. Stat. Ann. § 505/1 *et seq.*, and 740 Ill. Comp. Stat. § 10/3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Illinois;
- Iowa Code § 553.4 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Iowa;
- Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Maine;

[102] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under Mass. Gen. L. ch. 93A, with respect to purchases of Spiriva Respimat in Massachusetts, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute.

- Md. Code Ann. Com. Law, § 11-204 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Maryland;

- Mich. Comp. Laws Ann. § 445.771 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Michigan;

- Minn. Stat. § 325d.49 *et seq.*, and Minn. Stat. § 8.31 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Minnesota;

- Miss. Code. Ann. § 75-21-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Mississippi;

- Mont. Code Ann. § 30-14-205 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Montana;

- Neb. Code Ann. § 59-801 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Nebraska;

- Nev. Rev. Stat. Ann. § 598A.210 *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for Spiriva Respimat and its generic equivalents in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. § 356:2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Hampshire;

- N.J. State. Ann. § 56:9-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Jersey;

- N.M. Stat. Ann. § 57-1-2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Mexico;

- N.C. Gen. Stat. § 75-2.1 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in North Carolina;

- N.D. Cent. Code § 51-08.1-01 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in North Dakota;
- Ore. Rev. Stat. § 646.705 *et seq.*, and § 646.725 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Oregon;
- R.I. Gen. Laws § 6-36-4 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Rhode Island;
- S.D. Codified Laws § 37-1-3.2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in South Dakota;
- Utah Code Ann. § 76-10-3104 *et seq.*, with respect to the purchases of Spiriva Respimat and its generic equivalents by plaintiff and class members who reside in or are citizens of Utah;
- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Vermont;
- W. Va. Code § 47-18-1 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in West Virginia;
- Wis. Stat. § 133.01 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for Spiriva Respimat and its generic equivalents purchased in Wisconsin.

785. As a direct and proximate result of Boehringer's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Boehringer's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their tiotropium bromide

products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type that antitrust laws were designed to prevent and remedy, and flows from that which makes Boehringer's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

786. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Boehringer's violations of the above statutes.

787. The plaintiff, through its counsel, has sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Colo. Rev. Stat. § 6-4-116; Conn. Gen. Stat. Ann. §§ 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Nevada Revised Statute § 598A.210(3); Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

TENTH CLAIM FOR RELIEF
Monopolization Under State Antitrust Laws – Sham Litigation
Against all defendants

788. The plaintiff incorporates by reference and re-allege all preceding paragraphs and allegations, as though set forth fully herein.

789. A litigation is a sham if (1) the claims, positions, or arguments advanced are objectively meritless, such that no reasonable brand-name drugmaker in Boehringer's position could reasonably have expected to prevail and (2) the suit is subjectively motivated by an intention to harm competition by using the litigation process as a weapon. In the context of pharmaceutical Hatch-Waxman patent

infringement suits, courts in this District have recognized two ways in which the first part of this test is satisfied.

790. First, a litigation may be objectively unreasonable if a reasonable brand-name drugmaker in Boehringer's position would have known or should have known that the asserted patents could not be adjudicated in a pre-generic launch Hatch-Waxman litigation because they were not properly listable in the Orange Book to begin with.

791. Second, a litigation may be objectively unreasonable if a reasonable brand-name drugmaker in Boehringer's position would not have reasonably expected to succeed in proving that its asserted patents were valid, enforceable, and infringed.

792. As alleged above, Boehringer's lawsuit against Anobri is a sham because a reasonable company in Boehringer's position would have or should have known—especially because of the First Circuit's *Lantus* decision mere months earlier that reaffirmed the plain language of the statutory listing requirements—that the patents it asserted against Anobri should not have been listed in the Orange Book, and that, therefore, it had no standing to sue over those patents until after a generic product launched.

793. Boehringer ignored this because its intent, aim, and goal was to use those litigations to frustrate competition. By simply suing, it triggered automatic thirty-month delays in the approval of Anobri's product.

794. Boehringer's sham litigation substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for

Boehringer's actions that outweighs their harmful effects. Even if there were a conceivable justification that Boehringer could assert, Boehringer conduct is and was broader than necessary to achieve such a purpose.

795. But for Boehringer's sham litigations, generic manufacturers of inhaled beclomethasone dipropionate would have been able to fairly compete with Boehringer in a full and timely manner, and the plaintiff and class members, who are third-party payors, would have substituted lower-priced generic tiotropium bromide for some or all of their Spiriva Respimat purchases and/or paid lower prices for their branded Spiriva Respimat purchases.

796. Through its sham litigation, Boehringer intentionally and wrongfully maintained its market power with respect to Spiriva Respimat in violation of the following state laws:[103]

- Ariz. Rev. Stat. § 44-1403 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Arizona;
- Colo. Rev. Stat. § 6-4-115 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Colorado;
- Conn. Gen. Stat. Ann. § 35-26 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Connecticut;
- D.C. Code § 28-4503 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in the District of Columbia;

[103] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under Mass. Gen. L. ch. 93A, with respect to purchases of Spiriva Respimat in Massachusetts, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute.

- Haw. Rev. Stat. § 480 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Hawaii;

- Ill. Comp. Stat. Ann. § 505/1 *et seq.*, and 740 Ill. Comp. Stat. § 10/3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Illinois;

- Iowa Code § 553.4 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Iowa;

- Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Maine;

- Md. Code Ann. Com. Law, § 11-204 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Maryland;

- Mich. Comp. Laws Ann. § 445.771 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Michigan;

- Minn. Stat. § 325d.49 *et seq.*, and Minn. Stat. § 8.31 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Minnesota;

- Miss. Code. Ann. § 75-21-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Mississippi;

- Mont. Code Ann. § 30-14-205 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Montana;

- Neb. Code Ann. § 59-801 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Nebraska;

- Nev. Rev. Stat. Ann. § 598A.210 *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for Spiriva Respimat

and its generic equivalents in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. § 356:2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Hampshire;

- N.J. State. Ann. § 56:9-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Jersey;

- N.M. Stat. Ann. § 57-1-2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Mexico;

- N.C. Gen. Stat. § 75-2.1 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in North Carolina;

- N.D. Cent. Code § 51-08.1-01 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in North Dakota;

- Ore. Rev. Stat. § 646.705 *et seq.*, and § 646.725 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Oregon;

- R.I. Gen. Laws § 6-36-4 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Rhode Island;

- S.D. Codified Laws § 37-1-3.2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in South Dakota;

- Utah Code Ann. § 76-10-3104 *et seq.*, with respect to the purchases of Spiriva Respimat and its generic equivalents by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Vermont;

- W. Va. Code § 47-18-1 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in West Virginia;

- Wis. Stat. § 133.01 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for Spiriva Respimat and its generic equivalents purchased in Wisconsin.

797. As a direct and proximate result of Boehringer's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Boehringer's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their tiotropium bromide products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type that antitrust laws were designed to prevent and remedy, and flows from that which makes Boehringer's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

798. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Boehringer's violations of the above statutes.

799. The plaintiff, through its counsel, has sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Colo. Rev. Stat. § 6-4-116; Conn. Gen. Stat. Ann. §§ 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General

Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Nevada Revised Statute § 598A.210(3); Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

ELEVENTH CLAIM FOR RELIEF
Attempted Monopolization and Monopolistic Scheme Under State Antitrust Laws
Overarching scheme claim against all defendants

800. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

801. As detailed above, Boehringer engaged in restrictive or exclusionary conduct to keep generic versions of Spiriva Respimat from entering the market.

802. Boehringer has willingly, knowingly, and with specific intent to do so, attempted to monopolize the Spiriva Respimat Relevant Market.

803. Boehringer knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rate generic versions of Spiriva Respimat in an attempt to monopolize the relevant market. This scheme included:

- Wrongfully causing ineligible device patents to be listed in the Orange Book as Spiriva Respimat drug product patents to extend Boehringer's monopoly from August 2020 until today;
- Asserting its wrongfully listed patents against a would-be competitor in litigation to improperly gain an automatic stay of FDA final approval of Anobri's ANDA filing with the intent to delay generic Spiriva Respimat competition; and
- Falsely recertifying ineligible device patents to the FDA to thwart efforts to correct Boehringer's wrongful patent listings through regulatory means.

804. Based on Boehringer's anticompetitive conduct, it has monopoly power, or at a minimum, a dangerous probability of acquiring monopoly power, in the Spiriva Respimat Relevant Market.

805. Boehringer's scheme substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for Boehringer's actions that outweighs the scheme's harmful effects. Even if there were a conceivable justification that Boehringer could assert, the scheme is and was broader than necessary to achieve such a purpose.

806. The plaintiff and the class members have sustained injury as a direct and proximate result of Boehringer's unlawful conduct. But for Boehringer's illegal conduct, generic manufacturers of tiotropium bromide would have been able to fairly compete with Boehringer in a full and timely manner, and the plaintiff and class members, who are third-party payors, would have substituted lower-priced generic tiotropium bromide for some or all of their Spiriva Respimat purchases and/or paid lower prices for their branded Spiriva Respimat purchases.

807. Through its scheme, Boehringer intentionally, willfully, and wrongfully engaged in attempted monopolization in violation of the following state laws:[104]

- Ariz. Rev. Stat. § 44-1403 *et seq*., with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Arizona;

[104] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under Mass. Gen. L. ch. 93A, with respect to purchases of Spiriva Respimat in Massachusetts, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute.

- Colo. Rev. Stat. § 6-4-115 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Colorado;

- Conn. Gen. Stat. Ann. § 35-26 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Connecticut;

- D.C. Code § 28-4503 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in the District of Columbia;

- Haw. Rev. Stat. § 480 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Hawaii;

- Ill. Comp. Stat. Ann. § 505/1 *et seq.*, and 740 Ill. Comp. Stat. § 10/3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Illinois;

- Iowa Code § 553.4 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Iowa;

- Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Maine;

- Md. Code Ann. Com. Law, § 11-204 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Maryland;

- Mich. Comp. Laws Ann. § 445.771 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Michigan;

- Minn. Stat. § 325d.49 *et seq.*, and Minn. Stat. § 8.31 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Minnesota;

- Miss. Code. Ann. § 75-21-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Mississippi;

- Mont. Code Ann. § 30-14-205 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Montana;

- Neb. Code Ann. § 59-801 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Nebraska;

- Nev. Rev. Stat. Ann. § 598A.210 *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for Spiriva Respimat and its generic equivalents in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. § 356:2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Hampshire;

- N.J. State. Ann. § 56:9-3 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Jersey;

- N.M. Stat. Ann. § 57-1-2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in New Mexico;

- N.C. Gen. Stat. § 75-2.1 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in North Carolina;

- N.D. Cent. Code § 51-08.1-01 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in North Dakota;

- Ore. Rev. Stat. § 646.705 *et seq.*, and § 646.725 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Oregon;

- R.I. Gen. Laws § 6-36-4 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Rhode Island;

- S.D. Codified Laws § 37-1-3.2 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in South Dakota;

- Utah Code Ann. § 76-10-3104 *et seq.*, with respect to the purchases of Spiriva Respimat and its generic equivalents by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Vermont;

- W. Va. Code § 47-18-1 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in West Virginia;

- Wis. Stat. § 133.01 *et seq.*, with respect to the plaintiff's and class members' purchases of Spiriva Respimat and its generic equivalents in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for Spiriva Respimat and its generic equivalents purchased in Wisconsin.

808. As a direct and proximate result of Boehringer's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Boehringer's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their tiotropium bromide products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type that antitrust laws were designed to prevent and remedy, and flows from that which makes Boehringer's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

809. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Boehringer's violations of the above statutes.

810. The plaintiff, through its counsel, have sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Colo. Rev. Stat. § 6-4-116; Conn. Gen. Stat. Ann. §§ 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Nevada Revised Statute § 598A.210(3); Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

TWELFTH CLAIM FOR RELIEF
Unfair Methods of Competition, and Unfair and Deceptive Acts, in Violation of State Consumer Protection Laws
Overarching scheme claim against all defendants

811. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

812. Boehringer has engaged in unfair competition, and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Boehringer's anticompetitive, deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated generic versions of Spiriva Respimat, and were instead forced to pay higher prices.

813. Boehringer's overarching scheme, as alleged in this Complaint and in the Eighth Claim for Relief, violates the following state consumer protection laws:[105]

[105] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under the following statutes, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute: (1) Ind. Code Ann. § 24-5-0.5-1 *et seq*., with respect to purchases of Spiriva Respimat in Indiana or by

- Alaska Stat. § 45.50.471 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Alaska by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Alaska;

- Ark. Code Ann. § 4-88-107 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Arkansas by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Arkansas;

- Cal. Bus. & Prof. Code § 17200 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in California by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in California. In particular, Boehringer has engaged in unlawful business practices in violation of Cal. Bus. & Prof. Code § 17200 *et seq*. by violating Cal. Bus. & Prof. Code § 16700 *et seq*. and Cal. Health and Safety Code § 134002;

- Conn. Gen. Stat. § 42-110a *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Connecticut by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Connecticut;

- Del. Code. Ann., tit. 6 § 2511 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Delaware by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Delaware;

- D.C. Code § 28-3901 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in District of Columbia by class members and/or purchases of Spiriva

class members residing in Indiana; (2) 5 Me. Rev. Stat. § 207 *et seq*., with respect to purchases of Spiriva Respimat in Maine or by class members residing in Maine; (3) Mass. Gen. L. ch. 93A with respect to purchases of Spiriva Respimat in Massachusetts or by class members residing in Massachusetts; (4) Miss. Code. § 75-24-1 *et seq*., with respect to purchases of Spiriva Respimat in Mississippi or by class members residing in Mississippi; (5) Tex. Bus. & Prof. Code § 17.41 *et seq*., with respect to purchases of Spiriva Respimat in Texas or by class members residing in Texas; and (6) Wyo. Stat. Ann. § 40-12-101 *et seq*., with respect to purchases of Spiriva Respimat in Wyoming or by class members residing in Wyoming.

Respimat and its generic equivalents by class members residing in District of Columbia;

- Fla. Stat. § 501.201 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Florida by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Florida;

- Haw. Rev. Stat. § 480 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Hawaii by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. § 505/1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Illinois by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Illinois;

- Iowa Code § 714H.3 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Iowa by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Iowa;

- Md. Code Ann., Com. Law § 13-101 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Maryland by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Maryland;

- Minn. Stat. § 8.31, 325F.67, 325F.68 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Minnesota by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Minnesota;

- Neb. Rev. Stat. § 59-1601 *et seq.*, with respect to purchases of tiotropium bromide products in Nebraska by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Nebraska;

- Nev. Rev. Stat. § 598.0903 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Nevada

by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Nevada;

- N.H. Rev. Stat. § 358-A:1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New Hampshire by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New Hampshire;

- N.J. Stat. Ann. § 56:8-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New Jersey by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New Jersey;

- N.M. Stat. § 57-12-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New Mexico by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New York by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New York.[106]

- N.C. Gen. Stat. § 75-1.1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in North Carolina by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in North Carolina;

- N.D. Cent. Code. § 51-15-01 *et seq.* with respect to purchases of Spiriva Respimat and its generic equivalents in North Dakota by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in North Dakota;

- Ohio Rev. Code Ann. § 1345.01 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents

[106] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

in Ohio by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Ohio;

- Okla. Stat. tit. 15, § 751 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Oklahoma by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Oklahoma;

- S.D. Codified Laws § 37-24-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in South Dakota by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in South Dakota;

- Utah Code Ann. § 13-11-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Utah by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Vermont by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Vermont;

- Va. Stat. Ann. § 59.1-196 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Virginia by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Virginia;

- Wash. Rev. Code § 1986.010 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Washington by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Washington.

814. The plaintiff and members of the class have been injured in their business and property by reason of Boehringer's anticompetitive, unfair, unconscionable, and/or deceptive acts or practices alleged in this Court. Their injury consists of paying higher prices for tiotropium bromide products than they would

have paid in the absence of these violations. This injury is of the type that the state consumer protection statutes were designed to prevent and directly results from Boehringer's unlawful conduct.

815. The plaintiff, through its counsel, has sent or will send letters to the relevant state attorney general as required by Iowa Code § 714H.7.

THIRTEENTH CLAIM FOR RELIEF
Violations of State Consumer Protection Laws – Wrongful Spiriva Respimat Orange Book Listings
Against all defendants

816. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

817. Boehringer has engaged in unfair competition, and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Boehringer's anticompetitive, deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated generic versions of Spiriva Respimat, and were instead forced to pay higher prices.

818. Boehringer's conduct as alleged in this Complaint and in the Ninth Claim for Relief violates the following state consumer protection laws:[107]

[107] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under the following statutes, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute: (1) Ind. Code Ann. § 24-5-0.5-1 *et seq*., with respect to purchases of Spiriva Respimat in Indiana or by class members residing in Indiana; (2) 5 Me. Rev. Stat. § 207 *et seq*., with respect to purchases of Spiriva Respimat in Maine or by class members residing in Maine; (3) Mass. Gen. L. ch. 93A with respect to purchases of Spiriva Respimat in Massachusetts or by class members residing in

- Alaska Stat. § 45.50.471 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Alaska by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Alaska;

- Ark. Code Ann. § 4-88-107 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Arkansas by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Arkansas;

- Cal. Bus. & Prof. Code § 17200 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in California by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in California. In particular, Boehringer has engaged in unlawful business practices in violation of Cal. Bus. & Prof. Code § 17200 *et seq*. by violating Cal. Bus. & Prof. Code § 16700 *et seq*. and Cal. Health and Safety Code § 134002;

- Conn. Gen. Stat. §§ 42-110a *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Connecticut by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Connecticut;

- Del. Code. Ann., tit. 6 § 2511 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Delaware by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Delaware;

- D.C. Code § 28-3901 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in District of Columbia by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in District of Columbia;

Massachusetts; (4) Miss. Code. § 75-24-1 *et seq.*, with respect to purchases of Spiriva Respimat in Mississippi or by class members residing in Mississippi; (5) Tex. Bus. & Prof. Code § 17.41 *et seq.*, with respect to purchases of Spiriva Respimat in Texas or by class members residing in Texas; and (6) Wyo. Stat. Ann. § 40-12-101 *et seq.*, with respect to purchases of Spiriva Respimat in Wyoming or by class members residing in Wyoming.

- Fla. Stat. § 501.201 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Florida by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Florida;

- Haw. Rev. Stat. § 480 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Hawaii by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. § 505/1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Illinois by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Illinois;

- Iowa Code §§ 714H.3 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Iowa by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Iowa;

- Md. Code Ann., Com. Law § 13-101 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Maryland by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Maryland;

- Minn. Stat. § 8.31, 325F.67, 325F.68 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Minnesota by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Minnesota;

- Neb. Rev. Stat. § 59-1601 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Nebraska by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Nebraska;

- Nev. Rev. Stat. § 598.0903 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Nevada by class members and/or purchases of Spiriva Respimat

and its generic equivalents by class members residing in Nevada;

- N.H. Rev. Stat. § 358-A:1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New Hampshire by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New Hampshire;

- N.J. Stat. Ann. § 56:8-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New Jersey by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New Jersey;

- N.M. Stat. § 57-12-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New Mexico by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New York by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New York;[108]

- N.C. Gen. Stat. § 75-1.1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in North Carolina by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in North Carolina;

- N.D. Cent. Code. § 51-15-01 *et seq.* with respect to purchases of Spiriva Respimat and its generic equivalents in North Dakota by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in North Dakota;

- Ohio Rev. Code Ann. § 1345.01 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Ohio by class members and/or purchases of Spiriva

[108] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

Respimat and its generic equivalents by class members residing in Ohio;

- Okla. Stat. tit. 15, § 751 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Oklahoma by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Oklahoma;

- S.D. Codified Laws § 37-24-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in South Dakota by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in South Dakota;

- Utah Code Ann. § 13-11-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Utah by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Vermont by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Vermont;

- Va. Stat. Ann. § 59.1-196 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Virginia by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Virginia;

- Wash. Rev. Code § 1986.010, *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Washington by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Washington.

819. The plaintiff and members of the class have been injured in their business and property by reason of Boehringer's anticompetitive, unfair, unconscionable, and/or deceptive acts or practices alleged. Their injury consists of paying higher prices for tiotropium bromide products than they would have paid in

the absence of these violations. This injury is of the type that the state consumer protection statutes were designed to prevent and directly results from Boehringer's unlawful conduct.

820. The plaintiff, through its counsel, have sent or will send letters to the relevant state attorney general as required by Iowa Code § 714H.7.

FOURTEENTH CLAIM FOR RELIEF
Violations of State Consumer Protection Laws – Sham Litigation
Against all defendants

821. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

822. Boehringer has engaged in unfair competition, and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Boehringer's anticompetitive, deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated generic versions of Spiriva Respimat, and were instead forced to pay higher prices.

823. Boehringer conduct as alleged in this Complaint and in the Tenth Claim for Relief violates the following state consumer protection laws:[109]

[109] Following pre-suit notice to the defendants, mailed contemporaneously with the filing of this complaint, the plaintiff intends to amend this complaint to add claims under the following statutes, unless Boehringer proposes, and the plaintiff accepts, a reasonable pre-suit resolution of this dispute: (1) Ind. Code Ann. § 24-5-0.5-1 *et seq*., with respect to purchases of Spiriva Respimat in Indiana or by class members residing in Indiana; (2) 5 Me. Rev. Stat. § 207 *et seq*., with respect to purchases of Spiriva Respimat in Maine or by class members residing in Maine; (3) Mass. Gen. L. ch. 93A with respect to purchases of Spiriva Respimat in Massachusetts or by class members residing in Massachusetts; (4) Miss. Code. § 75-24-1 *et seq*., with respect to purchases of Spiriva Respimat in

- Alaska Stat. § 45.50.471 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Alaska by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Alaska;

- Ark. Code Ann. §§ 4-88-107 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Arkansas by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Arkansas;

- Cal. Bus. & Prof. Code § 17200 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in California by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in California. In particular, Boehringer has engaged in unlawful business practices in violation of Cal. Bus. & Prof. Code § 17200 *et seq*. by violating Cal. Bus. & Prof. Code § 16700 *et seq*. and Cal. Health and Safety Code § 134002;

- Conn. Gen. Stat. § 42-110a *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Connecticut by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Connecticut;

- Del. Code. Ann., tit. 6 § 2511 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Delaware by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Delaware;

- D.C. Code § 28-3901 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in District of Columbia by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in District of Columbia;

Mississippi or by class members residing in Mississippi; (5) Tex. Bus. & Prof. Code § 17.41 *et seq*., with respect to purchases of Spiriva Respimat in Texas or by class members residing in Texas; and (6) Wyo. Stat. Ann. § 40-12-101 *et seq*., with respect to purchases of Spiriva Respimat in Wyoming or by class members residing in Wyoming.

- Fla. Stat. § 501.201 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Florida by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Florida;

- Haw. Rev. Stat. § 480 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Hawaii by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. § 505/1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Illinois by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Illinois;

- Iowa Code § 714H.3 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Iowa by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Iowa;

- Md. Code Ann., Com. Law § 13-101 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Maryland by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Maryland;

- Minn. Stat. § 8.31, 325F.67, 325F.68 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Minnesota by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Minnesota;

- Neb. Rev. Stat. § 59-1601 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Nebraska by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Nebraska;

- Nev. Rev. Stat. § 598.0903 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Nevada by class members and/or purchases of Spiriva Respimat

and its generic equivalents by class members residing in Nevada;

- N.H. Rev. Stat. § 358-A:1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New Hampshire by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New Hampshire;

- N.J. Stat. Ann. § 56:8-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New Jersey by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New Jersey;

- N.M. Stat. § 57-12-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New Mexico by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in New York by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in New York;[110]

- N.C. Gen. Stat. § 75-1.1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in North Carolina by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in North Carolina;

- N.D. Cent. Code. § 51-15-01 *et seq.* with respect to purchases of Spiriva Respimat and its generic equivalents in North Dakota by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in North Dakota;

- Ohio Rev. Code Ann. § 1345.01 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Ohio by class members and/or purchases of Spiriva

[110] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

Respimat and its generic equivalents by class members residing in Ohio;

- Okla. Stat. tit. 15, § 751 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Oklahoma by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Oklahoma;

- S.D. Codified Laws § 37-24-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in South Dakota by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in South Dakota;

- Utah Code Ann. § 13-11-1 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Utah by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Utah;

- Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Vermont by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Vermont;

- Va. Stat. Ann. § 59.1-196 *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Virginia by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Virginia;

- Wash. Rev. Code § 1986.010, *et seq.*, with respect to purchases of Spiriva Respimat and its generic equivalents in Washington by class members and/or purchases of Spiriva Respimat and its generic equivalents by class members residing in Washington.

824. The plaintiff and members of the class have been injured in their business and property by reason of Boehringer's anticompetitive, unfair, unconscionable, and/or deceptive acts or practices alleged in this Court. Their injury consists of paying higher prices for tiotropium bromide products than they would

have paid in the absence of these violations. This injury is of the type that the state consumer protection statutes were designed to prevent and directly results from Boehringer's unlawful conduct.

825. The plaintiff, through its counsel, have sent or will send letters to the relevant state attorney general as required by Iowa Code § 714H.7.

C. Claims for relief by both the Combivent Respimat Class and Spiriva Respimat Class

FIFTEENTH CLAIM FOR RELIEF
Injunctive Relief Under Section 2 of the Sherman Act
(15 U.S.C. § 2)
Against all defendants

826. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

827. That conduct involves unlawfully delaying generic competition to Boehringer's Combivent Respimat and Spiriva Respimat franchise.

828. Unless enjoined, Boehringer will continue to thwart competition in the market for (i) ipratropium bromide and albuterol sulfate and (ii) tiotropium bromide, including by submitting information for, and maintaining, improper Orange Book listings and leveraging unlawfully listed patents against would-be competitors.

829. The plaintiff requests that the Court grant injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, as may be necessary and appropriate to prevent Boehringer from further destroying competition and to restore competition in the Combivent Respimat relevant market and Spiriva Respimat relevant market.

SIXTEENTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law
Against all defendants

830. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

831. To the extent required, this claim is pleaded in the alternative to the other claims in this complaint.

832. Boehringer has financially benefitted from overcharges on sales of (i) ipratropium bromide and albuterol sulfate and (ii) tiotropium bromide products, which resulted from the unlawful and inequitable conduct alleged in this complaint. The plaintiff and members of the classes have borne these overcharges when they purchased and/or reimbursed all or part of the purchase price of (i) ipratropium bromide and albuterol sulfate and (ii) tiotropium bromide products.

833. The benefits conferred on the defendants are substantial and measurable: the extent to which the defendants have been unjustly enriched by their overarching anticompetitive scheme may be ascertained by review of sales records.

834. There is a gross disparity between the price that the plaintiff and class members paid for Combivent Respimat and Spiriva Respimat and what they would have paid for less expensive generic versions of the drug product, which should and would have been available as 2014 and 2020, respectively, and no later than 2020 in any event, but for Boehringer's unlawful and inequitable conduct.

835. Boehringer repeatedly and continuously received financial benefits at the expense of the plaintiff and the classes each time the plaintiff or a class member

paid for all or part of a prescription of Combivent Respimat or Spiriva Respimat on or after the date on which generic (i) ipratropium bromide and albuterol sulfate and (ii) tiotropium bromide products should have become available.

836. It would be futile for the plaintiff and members of the classes to seek a remedy from any party with whom they had or have privity of contract. The defendants have paid no consideration to any other person for any of the benefits they received indirectly from the plaintiff and members of the classes.

837. It would be futile for the plaintiff and members of the classes to seek to exhaust any remedy against an intermediary in the chain of distribution from which they purchased (i) ipratropium bromide and albuterol sulfate and (ii) tiotropium bromide products, as those intermediaries cannot reasonably be expected to compensate the plaintiff and members of the classes for Boehringer's unlawful conduct.

838. The financial benefits that Boehringer derived rightfully belong to the plaintiff and members of the classes, who paid anticompetitive prices that inured to Boehringer's benefit.

839. It would be inequitable under the unjust enrichment principles of the states listed below for Boehringer to retain any of the overcharges that the plaintiff and members of the classes paid for (i) ipratropium bromide and albuterol sulfate and (ii) tiotropium bromide products, which were derived from Boehringer's anticompetitive, unfair, unconscionable, and/or deceptive methods, acts, or trade practices.

840. Boehringer should be compelled to disgorge all unlawful or inequitable proceeds received by them into a common fund for the benefit of the plaintiff and members of the classes.

841. A constructive trust should be imposed upon all unlawful or inequitable sums that Boehringer received, which arise from overpayments for Combivent Respimat and Spiriva Respimat by the plaintiff and members of the classes.

842. The plaintiff and members of the classes have no adequate remedy at law.

843. By engaging in the foregoing unlawful or inequitable conduct, which deprived the plaintiff and members of the classes of the opportunity to purchase lower-priced generic versions of (i) ipratropium bromide and albuterol sulfate and (ii) tiotropium bromide products and forced them to pay higher prices for Combivent Respimat and Spiriva Respimat, Boehringer has been unjustly enriched in violation of the common law of all fifty states and commonwealths.

844. By virtue of the foregoing, the plaintiff and members of the classes are entitled to recover the amount of Boehringer's unjust enrichment, to be determined at trial, and other relief permitted by law.

XII. JURY DEMAND

845. The plaintiff, on behalf of itself and the classes, demands a jury trial on all issues triable as of right before a jury.

XIII. PRAYER FOR RELIEF

The plaintiff requests that the Court enter judgment in their favor and grant the following relief:

846. Treble or at least double damages under the applicable state laws;

847. Compensatory and punitive damages;

848. Appropriate equitable and injunctive relief;

849. Court costs and reasonable attorneys' fees;

850. Prejudgment and post-judgment interest; and

851. Any further relief the Court deems proper and just.

Dated: March 6, 2024

Respectfully submitted,

/s/ Kristie A. LaSalle

Leslie R. Stern (BBO #631201)
Steven L. Groopman (BBO #568933)
Kristie A. LaSalle (BBO #692891)
Brooke Lowell (BBO #712633)
BERMAN TABACCO
One Liberty Square
Boston, MA 02109
Telephone: (617) 542-8300
Facsimile: (617) 542-1194
lstern@bermantabacco.com
sgroopman@bermantabacco.com
klasalle@bermantabacco.com
blowell@bermantabacco.com

Todd A. Seaver (BBO #645874)
Matthew D. Pearson (*pro hac vice* forthcoming)
BERMAN TABACCO
425 California St, Suite 2300
San Francisco, CA 94104
Telephone: (415) 433-3200
Facsimile: (415) 433-6382
tseaver@bermantabacco.com
mpearson@bermantabacco.com

Gregory S. Asciolla (*pro hac vice* forthcoming)
Matthew J. Perez (*pro hac vice* forthcoming)
DICELLO LEVITT LLP
485 Lexington Avenue, Suite 1001
New York, NY 10017
Telephone: (646) 933-1000
gasciolla@dicellolevitt.com
mperez@dicellolevitt.com

Natasha J. Fernández-Silber (*pro hac vice* forthcoming)
EDELSON PC
350 North LaSalle, 14th Floor
Chicago, IL 60654
Telephone: (312) 589-6370
Facsimile: (312) 589-6378
nfernandezsilber@edelson.com

Yaman Salahi (*pro hac vice* forthcoming)
EDELSON PC
150 California Street, 18th Floor
San Francisco, CA 94111
Telephone: (415) 212-9300
Facsimile: (415) 373-9435
ysalahi@edelson.com

Marvin A. Miller (*pro hac vice* forthcoming)
Matthew E. Van Tine (BBO # 541943)
Lori A. Fanning (*pro hac vice* forthcoming)
Andrew Szot (*pro hac vice* forthcoming)
Kate E. Boychuck (*pro hac vice* forthcoming)
MILLER LAW LLC
53 West Jackson Boulevard, Suite 1320
Chicago, IL 60604
Telephone: (312) 332-3200
mmiller@millerlawllc.com
mvantine@millerllc.com
lfanning@millerlawllc.com
aszot@millerlawllc.com
kboychuck@millerlawllc.com

APPENDIX A: Combivent Respimat Patent Listing History

Patent No.	Title	Issue Date	Listing Date	Expiry	Validly claims albuterol sulfate and ipratropium bromide drug product?
5,405,084	*Nozzle assembly for preventing back-flow*	4/11/1995	10/2011	4/11/2012	No
5,472,143	*Atomising nozzle and filter and spray generation device*	12/5/1995	10/2011	9/29/2013	No
5,497,944	*Atomising devices and methods*	3/12/1996	10/2011	3/12/2013	No
5,662,271	*Atomizing devices and methods*	9/2/1997	10/2011	9/2/2014	No
5,911,851	*Atomizing nozzle and filter and spray generating device*	6/15/1999	10/2011	9/29/2013	No
5,964,416	*Device for producing high pressure in a fluid in miniature*	10/12/1999	10/2011	10/4/2016	No[1]
6,007,676	*Atomizing nozzle and filter and spray generating device*	12/28/1999	10/2011	9/29/2013	No
6,149,054	*Mechanical counter for a metering apparatus*	11/21/2000	10/2011	12/19/2016	No
6,176,442	*Device for mounting a component exposed to a pressurized fluid*	1/23/2001	10/2011	10/4/2016	No
6,453,795	*Locking mechanism for a spring-actuated device*	9/24/2002	10/2011	12/5/2016	No
6,503,362	*Atomizing nozzle on filter and spray generating device*	1/7/2003	10/2011	9/29/2013	No
6,726,124	*Device for producing high pressure in a fluid in miniature*	4/27/2004	10/2011	10/4/2016	No[1]
6,846,413	*Microstructured filter*	1/25/2005	10/2011	8/28/2018	No[1]
6,977,042	*Microstructured filter*	12/20/2005	10/2011	8/28/2018	No[1]
6,988,496	*Cartridge for a liquid*	1/24/2006	10/2011	2/23/2020	Yes
7,104,470	*Device for producing high pressure in a fluid in miniature*	9/12/2006	10/2011	10/4/2016	Yes

[1] The identified patent mentions some combination of ipratropium bromide, salbutamol, albuterol and/or Combivent in its *specifications*, but it does not *claim* the drug in any valid claim.

Patent No.	Title	Issue Date	Listing Date	Expiry	Validly claims albuterol sulfate and ipratropium bromide drug product?
7,246,615	*Atomising nozzle and filter and spray generating device*	7/24/2007	10/2011	5/31/2016	No
7,284,474[2]	*Piston-pumping system having o-ring seal properties*	10/23/2007	10/2011	8/26/2024	No
7,396,341	*Blocking device for a locking stressing mechanism having a spring-actuated output drive device*	7/8/2008	10/2011	10/10/2026	No[1]
7,802,568	*Cartridge for a liquid*	9/28/2010	10/2011	2/23/2020	No[1]
7,837,235	*Device for clamping a fluidic component*	11/23/2010	10/2011	3/13/2028	No[1]
7,896,264	*Microstructured high pressure nozzle with built-in filter function*	3/1/2011	10/2011	5/26/2025	No[1]
7,988,001	*Container provided with a pressure equalization opening*	8/2/2011	10/2011	8/22/2022	No
8,733,341	*Atomizer and method of atomizing fluid with a nozzle rinsing mechanism*	5/27/2014	8/2015	6/7/2030	No[1,3]
9,027,967	*Device for clamping a fluidic component*	5/12/2015	8/2015	3/31/2027	No[1]

[2] Patents highlighted blue are currently listed in the Orange Book for both the Combivent Respimat and Spiriva Respimat products, and asserted by Boehringer against Anobri in the *Combivent Respimat* and *Spiriva Respimat* litigations.

[3] Boehringer may argue that this patent claims Combivent in a Respimat device. However, the claim the defendants may point to is invalid, as explained in the complaint.

Appendix B: Spiriva Respimat Patent Listing History

Patent No.	Title	Issue Date	Listing Date	Expiry	Validly claims tiotropium bromide drug product?
5,964,416	*Device for producing high pressure in a fluid in miniature*	10/12/1999	10/2014	10/4/2016	No[4]
6,149,054	*Mechanical dose counter for a metering apparatus*	11/21/2000	10/2014	12/16/2016	No
6,176,442[5]	*Device for mounting a component exposed to a pressurized fluid*	1/23/2001	10/2014	10/4/2016	No
6,453,795	*Locking mechanism for a spring-actuated device*	9/24/2002	10/2014	12/5/2016	No
6,726,124	*Device for producing high pressure in a fluid in miniature*	4/27/2004	10/2014	10/4/2016	No[4]
6,846,413	*Microstructured filter*	1/25/2005	10/2014	8/28/2018	No[4]
6,977,042	*Microstructured filter*	12/20/2005	10/2014	8/28/2018	No[4]
6,988,496	*Cartridge for a liquid*	1/24/2006	10/2014	2/23/2020	Yes
7,104,470	*Device for producing high pressure in a fluid in miniature*	9/12/2006	10/2014	10/4/2016	Yes
7,246,615	*Atomising nozzle and filter and spray generating device*	7/24/2007	10/2014	5/31/2016	No
RE39,820	*Esters of thienyl carboxylic acids and amino alcohols and their quaternization products*	9/4/2007	10/2014	1/30/2018	Yes
7,284,474[6]	*Piston-pumping system having o-ring seal properties*	10/23/2007	10/2014	8/26/2024	No

[4] The identified patent mentions tiotropium bromide and/or Ba 679 in its *specifications*, but does not *claim* the drug in any valid claim.

[5] Initially, the wrong patent number, 6,176,242, appeared in the Orange Book for this patent; the listing was corrected in 2016. *Compare* FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (34th Ed., Suppl. 10) (Oct. 2014) *with* FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (36th Ed.) (2016).

[6] Patents highlighted blue are currently listed in the Orange Book for both the Combivent Respimat and Spiriva Respimat products, and asserted by Boehringer against Anobri in the *Combivent Respimat* and *Spiriva Respimat* litigations.

Patent No.	Title	Issue Date	Listing Date	Expiry	Validly claims tiotropium bromide drug product?
7,396,341	*Blocking device for a locking stressing mechanism having a spring-actuated output drive device*	7/8/2008	10/2014	10/10/2026	No[4]
7,802,568	*Cartridge for a liquid*	9/28/2010	10/2014	2/23/2020	No[4]
7,837,235	*Device for clamping a fluidic component*	11/23/2010	10/2014	3/13/2028	No[4]
7,896,264	*Microstructured high pressure nozzle with built-in filter function*	3/1/2011	10/2014	5/26/2025	No[4]
7,988,001	*Container provided with a pressure equalization opening*	8/2/2011	10/2014	8/22/2022	No
8,733,341	*Atomizer and method of atomizing fluid with a nozzle rinsing mechanism*	5/27/2014	8/2015	6/7/2030	No[4,7]
9,027,967	*Device for clamping a fluidic component*	5/12/2015	8/2015	3/31/2027	No[4]

[7] Boehringer may argue that this patent claims Spiriva in a Respimat device. However, the claim the defendants may point to is invalid, as explained in the complaint.