

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

TEAMSTERS LOCAL 237 RETIREE FUND, on
behalf of itself and all others similarly situated,

Plaintiff,

v.

NOVO NORDISK INC. and NOVO NORDISK A/S,

Defendants.

Case No.: _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Teamsters Local 237 Retiree Fund (“Plaintiff” or “Teamsters 237”) brings this action on behalf of itself and all others similarly situated, against Novo Nordisk Inc. and Novo Nordisk A/S (collectively “Novo” or “Defendant”). These allegations are based on investigations of counsel, publicly available materials, and knowledge, information, and belief.

INTRODUCTION

1. This case arises from Defendants’ illegal scheme to delay competition in the United States and its territories for Victoza, a prescription medication containing the active pharmaceutical ingredient liraglutide (a GLP-1 receptor agonist) and approved by the U.S. Food and Drug Administration (“FDA”) to improve glycemic control in patients 10 years or older with type 2 diabetes, and to reduce the risk of major adverse cardiovascular events in patients with type 2 diabetes and established cardiovascular disease. Plaintiff seeks overcharge damages arising from (a) Novo’s unlawful agreement with Teva not to compete in the market for Victoza in the domestic Victoza market, and (b) Novo’s wrongful listing of certain patents in the FDA’s list of Approved

Drug Products and Therapeutic Equivalence Evaluations (commonly referred to as the “Orange Book”).

2. In January 2017, Teva filed a first-to-file application for FDA approval of a generic version of Victoza. In March 2017, Novo sued Teva for infringement of a number of patents. As discussed in detail below, Novo’s patents were weak, and Teva would inevitably have been successful in the litigation.

3. Nonetheless, in March 2019 Teva agreed to quit its challenge to Novo’s patents in exchange for Novo’s promise not to launch an authorized generic (“AG”) of Victoza, but instead to give that right to Teva. Because a Novo AG would have taken market share from Teva and driven down the price of Teva’s generic Victoza, this AG deal was incredibly valuable to Teva. For its part, Teva agreed not to launch a competing liraglutide product until June 2024.¹

4. The settlement with Teva eroded the incentive for later-filing generics to challenge Novo’s patents, each of which agreed to delay its launch of generic liraglutide until after Teva’s Victoza AG had the market to itself for 180 days.

5. As of August 22, 2022, all of Novo’s patents covering the drug liraglutide were expired. Because Novo also received six months of pediatric exclusivity for Victoza, robust generic competition for Victoza would have begun on February 23, 2023 but for the Teva settlement and other anticompetitive conduct alleged in this complaint.

6. Absent Novo’s anticompetitive conduct, Plaintiff and Class Members would have purchased lower-priced generic Victoza in place of the branded Victoza product they actually

¹ As discussed in detail below, Teva agreed not to launch until December 2023, or June 2024 in the event that Novo received pediatric exclusivity for Victoza. Shortly after the agreement Novo did receive pediatric exclusivity, so the agreement was for a June 2024 launch.

purchased, and, with unrestrained generic competition starting earlier, they would have paid lower prices for the generics they did purchase.

7. Moreover, because Novo used the 16 months of delay that it purchased from Teva to move market share from its first-generation GLP-1 product, Victoza (liraglutide), to its second generation GLP-1 product, Ozempic (semaglutide), Plaintiff and Class Members would have also purchased lower-priced generic Victoza instead of branded Ozempic.

8. Plaintiff brings this action as an end payor of Victoza, generic liraglutide, and Ozempic on its own behalf and on behalf of a class of all similarly situated end payors (the “Class”). End payors are the final link in the chain of distribution of pharmaceuticals; they include consumers and those who pay for any portion of the price the consumer does not pay for (*e.g.* insurers and health benefit plans like Plaintiff). Defendants’ unlawful conduct delayed generic liraglutide manufacturers from entering the market with competing generic products and has cost Plaintiff and the Class hundreds of millions of dollars in overcharge damages.

9. Plaintiff and the Class seek to recover damages, including multiple damages, under state antitrust and consumer protection laws. Plaintiff and the Class also seek injunctive relief under federal law.

JURISDICTION AND VENUE

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs; there are more than one hundred members of the class; and at least one member of the class is a citizen of a state different from that of one of the Defendants.

11. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

12. Venue is appropriate within this District under 28 U.S.C. § 1391. Defendants transact business within this District and/or have agents in and/or that can be found in this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

13. The Court has personal jurisdiction over each of the Defendants. Defendants have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District. Personal jurisdiction lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary defendants.

THE PARTIES

A. Plaintiff

14. Plaintiff Teamsters Local 237 Retirees' Benefit Fund is a self-insured health plan with a principal place of business in New York. During the Class Period, as defined below, Teamsters Local 237 purchased, paid, and/or provided reimbursement for some or all of the purchase price of Victoza and its AB-rated generic equivalent for personal and/or household use from pharmacies located in and/or on behalf of members located in, among other states, New York, Florida, and North Carolina.

B. Defendants

15. Defendant Novo Nordisk Inc. is a Delaware corporation with its principal place of business in Plainsboro, New Jersey, registered to conduct business in the State of New York. Novo Nordisk is the holder of the Victoza NDA.

16. Defendant Novo Nordisk A/S is organized and headquartered in Denmark. Novo Nordisk A/S is the parent of Defendant Novo Nordisk Inc, and is the owner and/or licensee of all of the Victoza patents at issue in this case.

17. Novo Nordisk A/S identifies Novo Nordisk Inc. as its authorized agent in the United States.

18. Novo Nordisk Inc. and Novo Nordisk A/S either directly or through one or more of their agents, developed and manufacture Victoza, which they market, distribute, and sell throughout the United States.

19. The Defendants' wrongful actions described in this complaint are part of, and were taken in furtherance of, the illegal monopolization scheme and restraint of trade alleged herein. These actions were authorized, ordered, and/or undertaken by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' affairs within the course and scope of their duties and employment and with their actual, apparent, or ostensible authority.

REGULATORY BACKGROUND

A. Approval Of A First Entrant

20. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., manufacturers that create a new drug must obtain approval from the Food and Drug Administration ("FDA") to sell the product by filing a New Drug Application ("NDA").² An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.³

² 21 U.S.C. §§ 301-392.

³ 21 U.S.C. §§ 355(a), (b).

21. As part of a brand pharmaceutical manufacturer's NDA, the manufacturer must provide information identifying 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" that is the subject of the NDA, and that either (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."⁴ Submission of patents that do not meet these criteria is prohibited by law. 21 U.S.C. § 355(c)(2) ("Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.").

22. After the FDA approves the NDA, all submitted patents are automatically listed in the Orange Book.⁵ The Orange Book catalogs all drugs approved under NDAs and ANDAs, along with approval dates and formulation data. NDA holders must submit patents that could reasonably be asserted against unlicensed generic competitors, and FDA publishes these patents in the Orange Book.

23. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it lacks the resources and authority to verify the validity and applicability of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

⁴ 21 U.S.C. § 355(b)(1)(A)(viii).

⁵ 21 U.S.C. §§ 355(b)(1), (c)(2).

24. When they do not face generic competition, brand manufacturers can usually sell the branded drug far above the marginal cost of production, generating profit margins well in excess of 70% while making hundreds of millions of dollars in sales.

B. Approval Of A Generic Drug

25. Under the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the “Hatch-Waxman Act”) competitors wishing to sell a generic equivalent of a branded drug may file an abbreviated new drug application (“ANDA”), which relies in substantial part on the scientific findings of safety and efficacy contained in the branded drug manufacturer’s NDA. The brand drug is called the reference listed drug (“RLD”).

26. To gain FDA approval, generic drugs must be bioequivalent to their branded counterparts. Bioequivalence means that the active ingredient of the proposed generic is present in the blood of a patient to the same extent and for the same amount of time as the active ingredient of the brand.⁶ Bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. The FDA assigns an “AB” rating to generics that are bioequivalent to their branded counterparts.

27. Because generic drugs are therapeutically equivalent to brand-name drugs, generic companies compete by offering their drugs at low prices. Entry of a single generic can result in steep price reductions for purchasers. Entry of several generics tends to result in even steeper price reductions, driving prices down close to marginal manufacturing costs.

⁶ 21 U.S.C. § 355(j)(8)(B).

28. To benefit from these low prices, every state has adopted substitution laws requiring or permitting pharmacies to substitute AB-rated generic equivalents when filling branded drug prescriptions, unless the prescribing physician specifically directs otherwise. Due in part to these substitution laws, the launch of AB-rated generics causes a rapid price decline and shift from branded to generic drug sales. A generic often captures 80% or more of the market within the first six months of entry, regardless of the number of generic entrants. The effects of generic entry are still more dramatic after a year. The FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and prices had dropped 85% with multiple generics on the market.⁷

29. Through the Hatch-Waxman amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

30. The Hatch-Waxman amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled \$21.6 billion; by 2013, total prescription

⁷ See Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-payoffs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

drug revenues had climbed to more than \$329.2 billion, with generics accounting for 86% of prescriptions.⁸ Generics are dispensed about 95% of the time when a generic form is available.⁹

C. Regulatory Exclusivities

31. A “new chemical entity” is a drug that does not contain an active moiety (which is the part of the drug responsible for the physiological or pharmacological action of the drug) that the FDA has approved in another NDA.¹⁰ Approval of an NDA with a new chemical entity provides a five-year exclusivity during which the FDA cannot approve an ANDA for a drug containing the same active moiety as the new chemical entity (“NCE exclusivity”).¹¹ An ANDA “may be submitted after 4 years” if it contains a paragraph IV certification, described below.¹²

32. When a generic drug manufacturer submits an ANDA to the FDA seeking permission to market a generic version of an approved NDA product, if there are no patents listed in the Orange Book for the corresponding NDA product, the ANDA must include a certification to that effect.¹³ This is known as a paragraph I certification.

33. If there are patents listed in the Orange Book for the corresponding NDA product, the ANDA must contain one of the following patent certifications for each patent that claims the RLD or a use of the RLD for which the applicant is seeking approval:

- i. The patent has expired (a “paragraph II certification”);

⁸ See IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* 30, 51 (2014), https://ncpa.org/sites/default/files/2020-12/IMS_2013_drug_report.pdf (last accessed on Feb. 2, 2026).

⁹ *Id.* at 51.

¹⁰ 21 C.F.R. § 314.108(a).

¹¹ 21 C.F.R. § 314.108(b)(2).

¹² 21 C.F.R. § 314.108(b)(2).

¹³ 21 U.S.C. § 355 (j)(2)(A)(vii)(I).

ii. The patent will expire on a specific date, and the applicant will not market the drug before then (a “paragraph III certification”); or

iii. The patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug (a “paragraph IV certification”).¹⁴

34. For a properly-listed method of use patent that covers a use of the RLD for which the applicant is not seeking approval, an ANDA may instead contain a statement “acknowledging that a given method of use patent has been listed, but stating that the patent at issue does not claim a use for which the applicant seeks approval.”¹⁵ This statement is referred to as a “little viii statement.”

35. If the ANDA contains only paragraph I certification(s) and/or paragraph II certification(s), the FDA may approve the ANDA immediately.¹⁶

36. If the ANDA contains paragraph III certifications and no paragraph IV certification, the FDA may approve the ANDA on the latest patent expiration date certified in the paragraph III certifications.¹⁷

37. If an ANDA contains one or more paragraph IV certifications, the ANDA applicant must provide notice of same to the NDA holder and owner(s) of the corresponding patent(s) and provide a “detailed statement of the factual and legal basis for the opinion that the patent is invalid or will not be infringed.”¹⁸

¹⁴ See 21 U.S.C. 355(j)(2)(A)(vii).

¹⁵ See § 505(j)(2)(A)(viii) of the FD&C Act.

¹⁶ 21 U.S.C. § 355 (j)(5)(B)(i).

¹⁷ 21 U.S.C. §355 (j)(5)(B)(ii).

¹⁸ 21 U.S.C. §355 (j)(2)(B)(iv)(II).

38. The first generic manufacturer to file an ANDA with a paragraph IV certification qualifies as a “first applicant” under Hatch-Waxman. More than one applicant may qualify as a first applicant if they submit paragraph IV certifications at substantially the same time.

39. Hatch-Waxman encourages generic companies to challenge patents by affording first applicants a 180-day exclusivity period in which the FDA may not grant final approval to any other generic manufacturer’s ANDA for the same drug.¹⁹ During this 180-day period, the first applicant competes only with the brand manufacturer and any other first applicants. To compete more effectively, the brand manufacturer sometimes lowers the price of the brand drug or introduces an “authorized generic” or “AG,” which is chemically identical to the brand drug and sold under the brand’s NDA, but sold as a generic, typically either through a subsidiary or a third-party distributor.

40. The Supreme Court has recognized that “this 180-day period of exclusivity can prove valuable, possibly ‘worth several hundred million dollars’” to the first filer.²⁰

41. With respect to a subsequent ANDA filer whose ANDA contains a paragraph IV certification, until both the 30-month stay and 180-day exclusivity lapse (or the 180-day exclusivity is forfeited), the FDA may grant tentative approval, but not final approval, *i.e.*, it cannot authorize the generic manufacturer to market its product. The FDA may grant tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay and/or first filer’s exclusivity period.

¹⁹ 21 U.S.C. § 355(j)(5)(B)(iii).

²⁰ *FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

42. Second filers can thus be “bottlenecked” behind a first filer’s 180-day exclusivity period if it extends past the 30-month stay.

43. There are several ways around the bottleneck, according to the FDA.

44. In a Guidance for Industry entitled “180-Day Exclusivity: Questions and Answers,” the FDA poses the following question: “Does 180-day exclusivity block approval of all ANDAs that reference the same RLD?”²¹

45. The FDA answers: “No. 180-day exclusivity blocks only the approval of subsequent ANDAs that also contain a paragraph IV certification. There are several examples in which 180-day exclusivity does not block approval of another ANDA referencing the same [brand Reference Listed Drug]: . . . If an ANDA applicant seeks to omit the approved method(s) of use covered by a listed patent with a section viii statement, another ANDA applicant’s paragraph IV certification to that same patent, and any related 180-day exclusivity, would not block approval of the ANDA that contained the section viii statement.”²²

46. The Hatch-Waxman Act is clear that where a subsequent ANDA filer submits only section viii statements and no paragraph IV certifications, the 180-day exclusivity is not a bar to the second ANDA filer’s approval.²³

47. If an ANDA contains a paragraph IV certification against a patent that expires, the FDA will construe the application as including a paragraph II certification, and the ANDA will be eligible for immediate approval.

²¹ FDA Guidance for Industry, 180-Day Exclusivity: Questions and Answers at 12-13, available at <https://www.fda.gov/media/102650/download>.

²² *Id.*

²³ See 21 U.S.C. § 355(j)(5)(B)(iv)(I) (noting that the FDA is barred from approving an ANDA as to a drug “for which a previous application has been submitted” only “[i]f the application contains a [paragraph IV] certification.”).

48. ANDAs with paragraph III certifications in addition to section viii statements are also eligible for approval upon expiration of the latest-expiring patent subject to a paragraph III certification.

D. Hatch-Waxman Patent Infringement Litigation

49. If a generic manufacturer submits a paragraph IV certification, and the brand manufacturer has an objectively reasonable basis to claim that the generic drug will infringe the brand's valid patent, the brand can sue the generic for infringement. If the brand files such an action within 45 days after receiving notice of the paragraph IV certification, the FDA will not grant final approval until the earlier of (a) 30 months' passage, or (b) entry of a final judgment holding that the patent is invalid or not infringed by the generic formulation.²⁴

50. A generic manufacturer facing a claim of patent infringement may defend by counterclaiming that the patent is invalid or unenforceable, or that the generic does not infringe the patent.

51. These defenses often succeed. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002.²⁵ An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a patent challenger stays the course until a decision on the merits, the generic wins 74% of the time.²⁶

²⁴ 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

²⁵ FTC, *Generic Drug Entry Prior to Patent Expiration: AN FTC Study* vi-vii (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

²⁶ John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014) (“[P]atentees won only 164 of the 636 definitive merits rulings, or 26%,” and “that number is essentially unchanged” from a decade ago.).

E. Pay-For-Delay Or Reverse Payment Settlements

52. A brand manufacturer may attempt to settle its patent infringement claim against a generic manufacturer that has submitted a paragraph IV certification. In a “pay-for-delay” or “reverse payment” settlement, the brand pays the generic in exchange for the generic’s agreement not to enter the market for a specified amount of time. This structure is the opposite of a typical settlement structure because the plaintiff alleging infringement pays the defendant, rather than *vice versa*.

53. Reverse payments can be anticompetitive.²⁷ The brand may offer to divide its monopoly profits with the generic so that each makes greater profits under the brand’s monopoly than either would make under competitive conditions.²⁸ In this way, even a brand manufacturer with a facially invalid patent can convince a generic manufacturer to settle because the value of the settlement to the generic exceeds the value of its winning the patent suit.

54. Even if the brand manufacturer’s patent is invalid or unenforceable, a pay-for-delay agreement diminishes other generics’ incentives to challenge the patent. The private agreement enables the first applicant to retain the statutory 180-day period of exclusivity. Even if a later-filing generic manufacturer could successfully defend a claim of patent infringement, it would thereby acquire only the right to enter the market at the same time as every other generic manufacturer. And in such a competitive market, profits are relatively low.

55. In short, a pay-for-delay agreement allows a brand manufacturer whose patent is invalid or unenforceable to share some of its unjustified monopoly profits with a first-filer generic manufacturer in exchange for delayed generic entry. That sort of agreement violates antitrust law.

²⁷ See *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

²⁸ *Id.* at 154.

FACTS

A. Victoza

56. Victoza was first approved for sale in the United States on January 25, 2010 to help lower blood sugar levels when coupled with diet, exercise, and other diabetes medicines.²⁹

57. On August 25, 2017, Victoza was approved for a new indication “to reduce the risk of major adverse cardiovascular (CV) events, heart attack, stroke, and CV death, in adults with type 2 diabetes and established CV disease.”³⁰

58. Victoza has been a blockbuster drug. In 2018, the year that Novo and Teva entered into the reverse-payment agreement, Victoza generated revenue of more than \$5 million.

B. Victoza Patents

59. Novo owns the following patents that purportedly relate to liraglutide:

| Patent No. | Title | Issued | Exp. Date |
|------------|--|------------|------------|
| 6,004,297 | Injection Syringe | 12/12/1999 | 1/28/2019 |
| RE 43,834 | Injection Syringe | 11/27/2012 | 1/28/2019 |
| RE 41,956 | Dose Setting Limiter | 11/23/2010 | 7/21/2021 |
| 8,846,618 | Stable Formulation of Modified GLP-1 | 9/30/2014 | 6/27/2022 |
| 6,268,343 | Derivatives of GLP-1 Analogs | 7/31/2001 | 8/22/2022 |
| 8,579,869 | Needle Mounting System and a Method for Mounting a Needle Assembly | 11/12/2013 | 12/30/2023 |

²⁹ <https://www.drugs.com/newdrugs/fda-approves-novo-nordisk-s-diabetes-victoza-1965.html>.

³⁰ <https://www.drugs.com/newdrugs/victoza-liraglutide-approved-reduce-risk-three-major-adverse-cardiovascular-events-type-2-diabetes-4582.html>.

| | | | |
|-----------|--|------------|------------|
| 7,762,994 | Needle Mounting System and a Method for Mounting a Needle Assembly | 07/27/2010 | 11/23/2024 |
| 8,114,833 | Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices | 2/14/2012 | 2/13/2026 |
| 9,968,659 | Liraglutide in cardiovascular conditions | 5/15/2018 | 1/09/2037 |
| 9,265,893 | Injection Button | 2/23/2016 | 3/23/2033 |

60. Of these, the '343 patent was the last true impediment to generic entry. The '343 patent expired on August 22, 2022, and its exclusionary effect was extended by six months to February 22, 2023 *via* pediatric exclusivity.

61. Three of the five later-expiring patents were device patents that should never have been listed in the Orange Book. The '869 and '994 patents were both device patents covering a "Needle Mounting System and a Method for Mounting a Needle Assembly, while the '893 patent was a device patent covering an "Injection Button." Because these patents do not cover liraglutide or a method of using liraglutide, they should not have been listed in the Orange Book, where they could, and did, trigger an automatic 30-month stay of generic approval.

62. In fact, the FTC in September 2023 issued a policy statement putting "market participants on notice that the FTC intends to scrutinize improper Orange Book listings" and urging all NDA holders "to immediately remove any patents that fail to meet the listing requirements."³¹ In April 2024 the FTC targeted a warning directly at Novo's patents listed for Victoza, calling out the '994 and '893 patents as "improperly or inaccurately listed in the Orange Book."³² The FTC reissued its warning on June 8, 2024; Novo responded two days later that it

³¹ https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf

³² https://www.ftc.gov/system/files/ftc_gov/pdf/novo-nordisk-ozempic-saxenda-victoza-_4302024.pdf

would not make any changes to its Orange Book listing.³³ Novo did eventually remove all three of these device patents ('869, '994, and '893), in an apparent acknowledgement that they were wrongfully listed. The only patents that are listed in the Orange Book today are the '833 and '659 patents.³⁴

63. As discussed in more detail below, the '833 patent was invalid, not infringed, or otherwise was not a barrier to generic entry.

64. The '659 patent, entitled "Liraglutide in Cardiovascular Conditions", was a method-of-use patent that could easily be carved out by a section viii statement. Indeed, that is exactly what Hikma did, and the FDA finally approved Hikma's Victoza ANDA (with the cardiovascular indication carved out of the label) in December 2024.³⁵

C. Teva Files The First Liraglutide ANDA And Novo Sues

65. In January 2017, Teva submitted an ANDA for liraglutide as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.³⁶ The ANDA contained paragraph IV certifications to a number of Novo's patents. Teva subsequently notified Novo of its ANDA submission and the paragraph IV certifications contained in that submission.

66. On March 3, 2017, Novo sued Teva for infringement of the following patents:

³³ <https://www.fda.gov/media/105080/download?attachment>

³⁴ See, Orange Book: Patent and Exclusivity for NO22341, Liraglutide (Victoza) Solution https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=022341&Appl_type=N

³⁵ https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2025/215503Orig1s000ltr.pdf.

³⁶ <https://www.tevapharm.com/news-and-media/latest-news/teva-confirms-generic-victoza-patent-challenge-in-the-united-states>

| Patent No. | Title | Issued | Exp. Date |
|------------|--|------------|-----------|
| RE 41,956 | Dose Setting Limiter | 11/23/2010 | 7/21/2021 |
| 8,846,618 | Stable Formulation of Modified GLP-1 | 9/30/2014 | 6/27/2022 |
| 6,268,343 | Derivatives of GLP-1 Analogs | 7/31/2001 | 8/22/2022 |
| 8,114,833 | Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices | 2/14/2012 | 2/13/2026 |
| 9,265,893 | Injection Button | 2/23/2016 | 3/23/2033 |

67. During the prosecution of that case, Teva admitted infringement of the ‘618 and ‘343 patents, which expired in 2022, but presented extensive evidence that the ‘833 patent was invalid and that its generic Victoza could not infringe the ‘893 “Injection Button” device patent because the delivery device had no “injection button” at all.

68. The ‘833 patent is invalid and/or not infringed. In essence, the ‘833 patent claims nothing more than the routine inclusion of the isotonic agent propylene glycol in an already known formulation to permit dispensing through an injection pen without clogging. As Teva demonstrated in the patent litigation, this was well known.

69. Specifically, as Teva explained in a February 25, 2019 submission in anticipation of the March 2019 Victoza trial, prior to the patent’s effective filing date, GLP-1 derivative formulations for Victoza, including the formulation described in the ‘833 patent itself, were widely known and disclosed. The prior art also taught the use of pharmaceutically acceptable carriers, preservatives, isotonic agents, and buffers to maintain the stability and solubility of GLP-1 derivatives, expressly including propylene glycol.

70. A person of ordinary skill in the art would have been motivated to combine these disclosures, along with other prior art, as reflected in the claims of the ‘833 patent. Accordingly,

the '833 patent was at least invalid as anticipated and/or obvious in view of the prior art. Teva also asserted additional grounds of invalidity and non-infringement.

71. Absent Novo's agreement to pay Teva to abandon its challenge by awarding Teva all generic Victoza sales following Teva's delayed June 2024 launch, the '833 patent would not have survived adjudication at the March 2019 Victoza trial.

72. The '893 "Injection Button" patent is likewise invalid and/or not infringed. GLP-1 agonists such as liraglutide are delivered *via* intramuscular injection and therefore do not require a complex injection mechanism. The particular injection "button" recited in the '893 patent was unnecessary, and the prior art disclosed numerous alternative designs.

73. As Teva explained in its February 25, 2019 submission, the '893 patent was invalid as anticipated or obvious in view of the prior art. In addition, Teva's proposed generic Victoza product did not infringe the '893 patent because it did not include an "injection button" at all.

74. Novo's trial strategy further underscored the weakness of the '893 patent. Novo intended to assert only two dependent claims (Claims 3 and 4) and only under the doctrine of equivalents rather than literal infringement. That approach exposed Novo to additional defenses, including well-established limitations on the doctrine of equivalents such as ensnarement, which prevents a patentee from extending a claim's scope to cover what the prior art already disclosed.

75. If Novo had proceeded to trial and argued that Teva infringed Claims 3 and/or 4 of the '893 patent under the doctrine of equivalents, the asserted claim scope would necessarily have expanded to encompass the prior art. As a result, either Teva's liraglutide ANDA device did not infringe the '893 patent, or the patent was invalid for ensnaring the prior art. In either scenario, the '893 patent would not have impeded generic entry, and without its pay-for-delay agreement with Teva, Novo could not have avoided this dilemma.

76. The remaining patent-in-suit, the ‘956 patent, expired in 2021 and thus could not block generic entry.

D. To Avoid Generic Competition, Novo Paid Teva to Quit Its Patent Challenge and Delay Its Generic Liraglutide Launch

77. To avoid a trial that was likely to strip Novo of any protection provided by the ‘833 and ‘893 patents, Novo settled with Teva on the courthouse steps. The threat posed by Teva’s litigation was significant, because a Teva victory would not only allow Teva to launch on February 23, 2023, but it would likely pave the way for other generic competitors to enter the market.

78. Under the terms of the settlement, Teva agreed not to launch a generic liraglutide product, “except as expressly licensed” by Novo, until *all* of Novo’s patents expire, including the ‘659 CV patent, which covers only the CV indication and was not at issue in the Teva patent litigation.

79. Importantly, Teva was allowed to, and did, maintain its paragraph IV certifications to Novo’s patents, thus “parking” its first-filer exclusivity and blocking entry by later-filing generics until after the expiration of Teva’s 180-day exclusivity period.

80. Although the terms of the settlement agreement between Novo and Teva have not been disclosed, a Novo 6-K SEC filing disclosed that “Teva [was] licensed to launch a generic version of Victoza as of 22 December 2023... If Novo Nordisk is granted six months pediatric extension for Victoza, all above-mentioned timelines will be extended by six months. All other terms of the agreement are confidential.” Novo did receive pediatric exclusivity for Victoza, so the date of Teva’s licensed launch was pushed back to June 22, 2024.

81. On June 24, 2024, Teva launched an authorized generic Victoza, pursuant to the agreement with Novo. Novo did not launch a competing authorized generic Victoza, giving Teva 180 days as the only generic liraglutide on the market, allowing it to charge much higher prices

and enjoy a much higher share of generic sales than it would have if it had launched an ANDA generic and Novo had launched an AG.

82. In short, rather than compete for sales of liraglutide during Teva's 180 days of exclusivity, Novo and Teva instead cooperated and shared the monopoly rent. Given the size of the liraglutide market, this cooperation was worth hundreds of millions of dollars, and vastly exceeded Novo's avoided litigation costs. Notably, 180 days of exclusivity without an AG is better than Teva could have achieved with a patent victory, because Novo would have been heavily incentivized to, and on information and belief, would have launched a competing AG.

83. Absent Novo's anticompetitive reverse payment to Teva, Teva would have won the patent litigation, obtained FDA approval, and launched on or around February 23, 2023.

84. In the alternative, absent Novo's anticompetitive reverse payment to Teva, Teva would have demanded an earlier entry date.

E. Mylan Files a Liraglutide ANDA and Novo Sues

85. In June or July 2019 Mylan submitted an ANDA for liraglutide as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The ANDA contained paragraph IV certifications to a number of Novo's patents.

86. On July 9, 2019, Mylan notified Novo of its liraglutide ANDA and the paragraph IV certifications contained in that submission.

87. On August 22, 2019, Novo sued Mylan for infringement of the following patents:

| Patent No. | Title | Issued | Exp. Date |
|------------|--------------------------------------|------------|-----------|
| RE 41,956 | Dose Setting Limiter | 11/23/2010 | 7/21/2021 |
| 8,846,618 | Stable Formulation of Modified GLP-1 | 9/30/2014 | 6/27/2022 |
| 6,268,343 | Derivatives of GLP-1 Analogs | 7/31/2001 | 8/22/2022 |

| | | | |
|-----------|--|------------|------------|
| 8,579,869 | Needle Mounting System and a Method for Mounting a Needle Assembly | 11/12/2013 | 12/30/2023 |
| 7,762,994 | Needle Mounting System and a Method for Mounting a Needle Assembly | 07/27/2010 | 11/23/2024 |
| 8,114,833 | Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices | 2/14/2012 | 2/13/2026 |
| 9,265,893 | Injection Button | 2/23/2016 | 3/23/2033 |

88. In addition to counterclaiming for a declaration that all of these patents were invalid and/or not infringed by Mylan's generic liraglutide, in December 2019 Mylan filed an *inter partes* review (IPR) petition with the Patent Trial and Appeal Board (PTAB) challenging the validity of the '833 patent. Mylan's IPR petition tracked Teva's evidence-supported final pretrial submission.

89. *Inter partes* review allows a patent challenger to obtain expedited re-review of the patent application to determine whether the patent is anticipated or obvious in light of prior art patents or printed publications. The PTAB will not conduct the re-review unless "there is a reasonable likelihood that the petitioner would prevail." 35 U.S.C. § 314(a).

90. On June 23, 2020, the PTAB instituted Mylan's petition, agreeing to re-review "all of the challenged claims on all asserted grounds." The IPR trial was set for March 2021.

91. Pfizer, a brand drug manufacturer that has never held a Victoza ANDA, also filed for IPR review of the '833 patent. That petition was granted and was joined with Mylan's ongoing IPR proceedings.

92. In the patent litigation, on July 1, 2020, Novo agreed to dismiss its claims as to the '869 and '994 patents.

93. On July 15, 2020, Mylan amended its counterclaims to require Novo to delist the '893 and '956 device patents.

94. In October 2020, Novo agreed to dismiss its claims as to the ‘956 patent, leaving only the following patents at issue in the litigation:

| Patent No. | Title | Issued | Exp. Date |
|------------|--|-----------|-----------|
| 8,846,618 | Stable Formulation of Modified GLP-1 | 9/30/2014 | 6/27/2022 |
| 6,268,343 | Derivatives of GLP-1 Analogs | 7/31/2001 | 8/22/2022 |
| 8,114,833 | Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices | 2/14/2012 | 2/13/2026 |
| 9,265,893 | Injection Button | 2/23/2016 | 3/23/2033 |

95. Thus, the only two patents-in-suit that could block generic entry after February 23, 2023, were the ‘833 patent, set for IPR trial in March 2021, and the ‘893 patent.

96. Cross motions for judgment on the pleadings as to the ‘893 patent de-listing issue were filed in December 2020 and January 2021, and were fully briefed by February 2021.

97. Thus, the stage was set for the invalidity of the ‘833 patent to be recognized and the wrongfully-listed ‘893 patent to be de-listed in early 2021. These rulings would have allowed Mylan to launch a generic liraglutide in February 23, 2023.

F. Novo paid Mylan to quit its patent challenge and delay generic entry.

98. Novo announced on March 26, 2021, the first day of Mylan’s IPR trial, that it had resolved its dispute with Mylan through settlement. Within weeks, by April 7, 2021, Novo and Mylan jointly sought termination of the IPR, and the PTAB granted that request shortly thereafter.

99. Several days later, on March 31, 2021, Novo and Mylan filed in the related paragraph IV Hatch-Waxman action a stipulated dismissal, agreeing to dismiss all claims, counterclaims, and defenses without prejudice. These coordinated resolutions ensured that neither

the '833 patent nor Novo's improperly listed device patents were ever tested on the merits, leaving them intact and available for Novo to deploy against other potential generic challengers.

100. By settling with and providing inducements to Mylan, Novo preserved the regulatory bottleneck created by Teva's unused first-to-file exclusivity. That "parked" exclusivity continued to bar the FDA from approving any other generic Victoza ANDA until the 181st day following Teva's delayed June 2024 launch.

G. Sandoz Files A Liraglutide ANDA And Novo Sues

101. In early 2020, Sandoz submitted an ANDA for liraglutide as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The ANDA contained paragraph IV certifications to a number of Novo's patents.

102. In April 2020, Sandoz notified Novo of its liraglutide ANDA and the paragraph IV certifications contained in that submission.

103. On June 3, 2020, Novo sued Sandoz for infringement of the following patents:

| Patent No. | Title | Issued | Exp. Date |
|------------|--|------------|------------|
| 8,846,618 | Stable Formulation of Modified GLP-1 | 9/30/2014 | 6/27/2022 |
| 6,268,343 | Derivatives of GLP-1 Analogs | 7/31/2001 | 8/22/2022 |
| 8,579,869 | Needle Mounting System and a Method for Mounting a Needle Assembly | 11/12/2013 | 12/30/2023 |
| 7,762,994 | Needle Mounting System and a Method for Mounting a Needle Assembly | 07/27/2010 | 11/23/2024 |
| 8,114,833 | Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices | 2/14/2012 | 2/13/2026 |
| 9,265,893 | Injection Button | 2/23/2016 | 3/23/2033 |

104. On June 10, 2021, Novo agreed to dismiss its claims as to the '869 and '994 patents.

105. In October 2021, Sandoz requested leave to file a motion for judgment of non-infringement of the ‘833 patent, explaining that Novo did not submit an expert report on the infringement questions and that Novo had admitted that it was no longer pursuing any claim of infringement of the ‘833 patent. Despite this admission, Novo would not agree to a consent judgment.

106. Sandoz needed a judgment of non-infringement to uncork the bottleneck created by Teva’s first-to-file exclusivity; a mere voluntary dismissal by Novo would not be enough. For its part, Novo needed the bottleneck to remain corked for its monopolization scheme to work.

107. In November 2021, Novo stipulated to the dismissal of the ‘618 and ‘343 patents as moot, leaving only two questions for trial: 1) validity and infringement of the ‘893 patent; and 2) whether the court should enter a judgment of non-infringement on the ‘833 patent given Novo’s admission that it was no longer claiming any infringement of that patent.

108. Sandoz’ final pretrial submission provided substantial evidence that the ‘893 patent was neither valid nor infringed by Sandoz’ generic liraglutide.

H. Novo Paid Sandoz to Quit its Patent Challenge and Delay its Launch

109. In March 2022, Novo and Sandoz settled the patent litigation, avoiding the crumbling of Novo’s patent protection and preserving the bottleneck created by Teva’s first-to-file exclusivity.

110. Although the terms of the settlement remain confidential, Novo’s SEC filings confirm that Sandoz is licensed to launch generic liraglutide after expiration of Teva’s exclusivity.

I. Novo Continued to Use the ‘833 and Device Patents to Force Settlements With Other ANDA Holders

111. In addition to Teva, Mylan, and Sandoz, eight additional manufacturers filed liraglutide ANDAs: Hikma Pharmaceuticals USA Inc. (“Hikma”), Sun Pharmaceutical Industries,

Inc. (“Sun”), Biocon Pharma Ltd. (“Biocon”), Orbicular Pharmaceutical Technologies Pvt. Ltd. (“Orbicular”), Lupin Ltd. (“Lupin”), ScinoPharm Taiwan Ltd., Meitheal Pharmaceuticals, Inc./Nanjing King Friend (“Meitheal”), Dr. Reddy’s Laboratories, Ltd. (“DRL”), and Rio Biopharmaceuticals, Inc. (“Rio”). Novo settled with each in turn to protect its monopoly.

J. The Results of Novo’s Scheme

112. On June 21, 2024, FDA tentatively approved Hikma’s liraglutide ANDA, meaning that Hikma had satisfied all regulatory requirements and the only impediment to a Hikma liraglutide launch was Teva’s exclusivity. Given the timing of FDA’s approval, it is likely that Hikma could have obtained approval earlier if the Teva exclusivity was not blocking a Hikma launch.

113. Teva launched a Victoza AG on June 24, 2024. Novo did not launch a competing AG.

114. FDA finally approved Hikma’s generic liraglutide ANDA on December 23, 2024, the final day of Teva’s exclusivity period, and Hikma launched the next day. Hikma’s label carved out the cardiovascular method of use protected by the ‘659 patent.

115. FDA approved Meitheal’s generic liraglutide ANDA on April 2, 2025, and it launched the same day.

116. FDA approved Lupin’s generic liraglutide ANDA on July 22, 2025, and Lupin subsequently launched its product.

117. During the period of delay caused by Novo’s anticompetitive conduct, Novo continued to move prescriptions for Victoza, its first-generation GLP-1 drug, to its second-generation GLP-1 drug, Ozempic. This second-generation GLP-1 is covered by ingredient patents with multiple years of unexpired patent life left presumptively protecting Ozempic from generic competition for years to come. Novo therefore used its delay period to squeeze every last dollar

out of its final Victoza sales, while ramping up and moving Victoza prescriptions to its newer blockbuster brand Ozempic franchise that, unlike Victoza, did not face imminent generic competition.

118. Novo knew that when generic Victoza entered the market, it would rapidly take market share through the operation of automatic substitution at the pharmacy counter. Such automatic substitution of lower-priced AB-rated and/or authorized generics is the most efficient means by which generic competition reduces prescription drug prices in the United States.

119. But generic Victoza can only be automatically substituted for brand Victoza. If a patient has a prescription for Ozempic, the pharmacist cannot automatically substitute a Victoza generic in its place. But, as market participants like Novo understand, once switched to the Victoza generic, market demand is more likely to continue with the generic rather than move to the more expensive Ozempic brand.

120. Thus, for each patient Novo was able to switch from Victoza to Ozempic, Novo avoided having its brand product be automatically substituted for a generic at the pharmacy counter and thereby preserved its brand revenues and profits.

121. It is well known in the pharmaceutical industry that for a brand to successfully move prescriptions from an older generation product to a newer generation product, the brand needs to switch the market sufficiently in advance of generic competition for the older generation products.

122. Novo bought that time by paying for delayed generic entry. As industry analysts noted in June 2019: “Novo is hoping it can stave off generic competition to Victoza long enough

to build up sales for its next-gen GLP-1, semaglutide. In March [2019], Novo inked a deal with Teva to put off its Victoza generic's launch until [2024]."³⁷

123. Novo's reverse payment agreement with Teva in March 2019 bought Novo 16 extra months beyond February 2023 in which it could carefully plan and orchestrate the switching of the Victoza prescriptions to its second-generation GLP-1 product, Ozempic. During this time, Novo successfully converted significant numbers of Victoza sales to Ozempic.

124. Novo first introduced Ozempic in 2018. By the time of Ozempic's 2018 introduction, Novo had over \$4 billion in Victoza U.S. sales revenue. For 2022, just a couple of months prior to the would-be February 2023 expiration of Victoza's exclusivity, Novo had Victoza U.S. sales of approximately \$3.8 billion. By the time of Teva's delayed June 2024 generic Victoza launch, Victoza's sales in the 12 months ending June 2024 had dropped to about \$2 billion. Over the same time frame, Ozempic U.S. sales soared. For 2022, Novo had Ozempic U.S. sales of nearly \$19 billion (almost double Novo's 2021 Ozempic sales); for 2024, those sales topped \$44 billion.

125. Thus, by the time Victoza generics became available, the prescription base for Victoza had been significantly impaired by Novo's scheme.

126. Absent Novo's monopolization scheme, there would have been purchasers that switched some portion of their brand Victoza purchases to generic Victoza and would have continued purchasing lower-priced generic Victoza (liraglutide) rather than switching to and paying premium brand pricing for the newer Ozempic semaglutide. As a result of Novo's scheme, however, these would-be generic Victoza liraglutide purchasers were switched to brand Ozempic before automatic generic liraglutide substitution occurred and, as a result, paid and continue to pay

³⁷ Kyle Blankenship, *The Top 20 Drugs by 2018 U.S. Sales* (June 17, 2019), <https://www.fiercepharma.com/special-report/top-20-drugs-by-2018-u-s-sales>.

premium brand pricing on their Ozempic purchases because there is no generic Ozempic available for those patients to purchase.

127. This is because, when generic liraglutide became available, there was predictable, effective price competition between Victoza and generic liraglutide at the pharmacy, and resultant switches from Victoza to generic liraglutide. Novo knew that convincing these switched generic liraglutide patients (or their physicians or health insurers) to then switch to Ozempic would be difficult. Novo would need to convince them to leave an effective, inexpensive generic drug and pay significantly more for a brand product.

128. However, if Novo could manage to persuade patients, physicians, and insurers to switch to Ozempic prior to generic liraglutide entry, then Novo would be able to prevent manufacturers of generic liraglutide from engaging in effective price competition for these patients. This is because generic liraglutide would not be AB-rated to Ozempic, and therefore a pharmacist would not be able to substitute lower-priced generic liraglutide for Ozempic under state substitution laws. Consequently, Novo knew that switching a large portion of the patient base from Victoza to Ozempic prior to the entry of generic liraglutide would, by preventing the application of generic substitution laws, allow Novo to retain a significantly higher portion of its brand GLP-1 franchise sales in the face of generic substitution than it would have otherwise.

MARKET POWER AND DEFINITION

129. The pharmaceutical marketplace is characterized by a “disconnect” between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Victoza, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient’s doctor chooses which product the patient will buy while the patient (and in most cases his or her insurer) has the obligation to pay for the product.

130. Brand manufacturers, including Novo, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

131. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call "the price elasticity of demand," which is the extent to which unit sales go down when price goes up. This lower price elasticity, in turn, gives brand manufacturers the ability to raise prices substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Victoza.

132. Throughout the relevant time period, Novo has had monopoly power in the market for Victoza because it had the power to exclude competition and/or raise or maintain the price of liraglutide at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

133. A small but significant non-transitory increase to the price of brand Victoza would not have caused a significant loss of sales sufficient to make the price increase unprofitable.

134. Brand Victoza does not exhibit significant, positive cross-elasticity of demand with respect to price with any other brand product.

135. Brand Victoza is differentiated from all other brand products currently on the market.

136. Novo needed to control only brand Victoza and its AB-rated generic equivalents, and no other products, in order to maintain the price of liraglutide profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions would render Novo unable to profitably maintain their prices for Victoza without losing substantial sales.

137. Novo had, and exercised, the power to exclude generic competition to brand Victoza.

138. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected branded Victoza from the forces of price competition.

139. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Novo's ability to control the price of Victoza and generic liraglutide, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, among other things, the following facts: (a) generic liraglutide would have entered the market at a substantial discount to brand Victoza but for Defendants' anticompetitive conduct; (b) Novo's gross margin on Victoza at all relevant times was very high; and (c) Novo never lowered the price of Victoza to the competitive level in response to the pricing of other brand or generic drugs.

140. To the extent proof of monopoly power by defining a relevant product market is required, Plaintiff alleges that the relevant antitrust market is the market for Victoza and its AB-rated generic equivalents.

141. Novo's anticompetitive reverse payment to Teva demonstrates that Novo enjoyed market and/or monopoly power with respect to liraglutide.

142. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

143. Novo's market share in the relevant market has been 100% at all times during the relevant time period, implying substantial monopoly power.

MARKET EFFECTS

144. Novo willfully and unlawfully maintained its market power by engaging in an anticompetitive scheme to exclude competition. Novo designed a scheme to delay competition on the products' merits, to further Novo's anticompetitive purpose of forestalling generic competition against Victoza, in which Teva cooperated in order to increase its own profits. Novo carried out the scheme with the anticompetitive intent and effect of maintaining supra-competitive prices for Victoza and generic liraglutide.

145. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Victoza from competition. These actions allowed Novo to maintain a monopoly and exclude competition in the market for Victoza and its AB-rated generic equivalents, to the detriment of Plaintiff and all other members of the Class.

146. Defendants' exclusionary conduct delayed generic competition and unlawfully enabled Defendants to sell Victoza without generic competition. Were it not for Defendants' illegal conduct, one or more generic versions of Victoza would have entered the market on or around February 23, 2023.

147. Competition among drug manufacturers enables all purchasers of the drug to buy drugs, including both the original drug and its subsequent competitors, at substantially lower prices. Consequently, drug manufacturers (and those that share in their profits) have a strong incentive to delay competition, and purchasers experience substantial cost inflation from that

delay.

148. Defendants' illegal acts and conspiracy to delay generic competition for Victoza caused Plaintiff and all members of the Class to pay more than they would have paid for liraglutide absent their illegal conduct.

149. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, Plaintiff and members of the Class would have paid less for brand and generic versions of Victoza by (a) paying lower prices on their remaining brand purchases of Victoza, (b) substituting purchases of less-expensive generic liraglutide for their purchases of more-expensive brand Victoza, and/or (c) substituting purchases of less-expensive generic liraglutide for purchases of brand Ozempic.

150. Thus, Defendants' unlawful conduct deprived Plaintiff and members of the Class of the benefits from the competition that the antitrust laws are designed to ensure.

ANTITRUST IMPACT

151. During the relevant time period, Plaintiff and members of the Class purchased substantial amounts of Victoza and Ozempic indirectly from Defendants. As a result of Defendants' illegal conduct, Plaintiff and the members of the Class were compelled to pay, and did pay, artificially inflated prices for Victoza. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Victoza was artificially inflated by Defendants' illegal conduct, and (2) members of the Class have been deprived of the opportunity to purchase lower-priced generic versions of Victoza. The supracompetitive prices were paid at the point of sale, which is where Plaintiff and the Class suffered antitrust impact.

152. As a consequence, Plaintiff and members of the Class have sustained substantial damages to their business and property in the form of overcharges. The full amount and form of

such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive overcharge passed through the chain of distribution to Plaintiff and members of the Class.

153. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, *FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE* (1994) at 624. According to Professor Hovenkamp, “[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top.”

154. Further, the institutional structure of pricing and regulation in the pharmaceutical industry assures that overcharges at the higher level of distribution result in higher prices paid by members of the Class.

155. The Defendants’ anticompetitive actions enabled Novo to indirectly charge Plaintiff and the Class prices in excess of what they otherwise would have been able to charge absent its unlawful actions described herein.

156. The prices were inflated as a direct and foreseeable result of Defendants’ anticompetitive conduct.

157. The inflated prices the Class paid are traceable to, and the foreseeable result of, the overcharges by Novo.

INTERSTATE AND INTRASTATE COMMERCE

158. During the relevant time period, Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All Defendants engaged in illegal activities, as charged

herein, within the flow of, and substantially affecting, interstate commerce.

159. During the relevant time period, branded Victoza, manufactured and sold by the Novo Defendants, was shipped into each state and was sold to or paid for by Plaintiff and members of the Class.

160. During the relevant time period, in connection with the purchase and sale of branded Victoza, money exchanged hands and business communications and transactions occurred in each state.

161. Defendants' conduct as set forth in this complaint had substantial effects on interstate and intrastate commerce in that, among other things, distributors and retailers within each state were foreclosed from offering cheaper Victoza and generic liraglutide to Plaintiff and members of the Class purchasing inside each state. Defendants' conduct materially deprived the consuming public—including hundreds, if not thousands, of purchasers in each state—of any choice to purchase more affordable versions of Victoza. The absence of competition to Victoza has, and continues to, directly and substantially affect and disrupt commerce within each state. Defendants' unlawful anticompetitive agreement has thus affected commerce in each state.

CLASS ACTION ALLEGATIONS

162. Plaintiff brings this action on its own behalf and on behalf of all others similarly situated as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure (the "Class"):

All end payors in the United States and its territories and possessions, including the Commonwealth of Puerto Rico, who indirectly purchased and/or paid all or part of the purchase price of Victoza, AB-rated generic equivalents to Victoza, and/or Ozempic, other than for resale, from any one of the Defendants at any time on or after February 23, 2023 through and including the date that the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period").

163. Excluded from the Class are:

- a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;
- b. all federal governmental entities;
- c. all persons or entities who purchased Victoza for purposes of resale or directly from Defendants or their affiliates;
- d. fully insured health plans (*i.e.*, health plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);
- e. any "flat co-pay" consumers whose purchases of Victoza were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;
- f. pharmacy benefit managers;
- g. all counsel of record; and
- h. all judges assigned to this case and any members of their immediate families.

164. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that there are hundreds of thousands of members of the Class, in an amount to be determined in discovery and at trial. Further, the identities of class members will be readily ascertainable through business records kept in regular order.

165. Plaintiff's claims are typical of the claims of members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, and all paid artificially inflated prices for Victoza and were deprived of the benefits of competition from less expensive generic versions as a result of Defendants' conduct.

166. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, the Class.

167. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

168. Questions of law and fact common to the Class include:

a. Whether Novo unlawfully maintained monopoly power through all or part of its anticompetitive scheme;

b. whether Defendants' anticompetitive scheme suppressed generic competition to Victoza;

c. as to those parts of Defendants' challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Defendants' challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which Victoza is sold;

d. whether direct proof of Novo's monopoly power is available, and if available, whether it is sufficient to prove Novo's monopoly power without the need to also define a relevant market;

e. to the extent a relevant market or markets must be defined, what that definition is, or those definitions are;

f. determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic, unfair, and unjust conduct caused;

g. whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

h. whether Defendants' scheme, in whole or in part, has substantially affected intrastate commerce;

i. whether Novo's payment to Teva was large and unexplained;

j. whether Novo possessed the ability to control prices and/or exclude competition for Victoza during the Class Period;

k. Whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Victoza;

l. whether Defendants' scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiff and members of the Class in the nature of overcharges; and

m. the quantum of overcharges paid by the Class in the aggregate.

169. Defendants acted or refused to act on grounds that apply generally to the Class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the Class as a whole.

170. Questions of law and fact common to members of the Class predominate over questions, if any, that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

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

172. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF **For Monopolization Under State Law**

173. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

174. As described above, throughout the relevant time period Novo possessed monopoly power nationwide and in each state and territory in the market for liraglutide. No other manufacturer sold a competing version of Victoza during the relevant time period.

175. At all relevant times, Novo possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Novo possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

176. Through its anticompetitive scheme, as alleged above, Novo willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or historic accident, and thereby injured Plaintiff and the Class. Novo's anticompetitive conduct was done with the specific intent to maintain their monopoly in the market for Victoza in the United States.

177. Novo knowingly and intentionally engaged in this anticompetitive scheme to monopolize the liraglutide market as described above. Novo accomplished this scheme by, among other things, (1) wrongfully listing certain patents in the Orange Book and prosecuting patent litigation triggered by those wrongful listings; (2) entering into an illegal agreement which delayed the entry of generic Victoza in order to lengthen the period in which Novo's brand Victoza could monopolize the market and make supracompetitive profits; and (3) raising and maintaining prices so that Plaintiff and Class members would pay for Victoza at supracompetitive prices.

178. The goal, purpose, and effect of Novo's scheme was to prevent and delay the sale of liraglutide in the United States at prices significantly below Novo's prices for Victoza, thereby effectively preventing the average market price of liraglutide from declining dramatically.

179. The goal, purpose and effect of Novo's scheme was also to maintain and extend its monopoly power with respect to liraglutide products. Novo's illegal scheme allowed it to continue charging supracompetitive prices for liraglutide, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

180. Plaintiff and members of the Class purchased substantial amounts of Victoza indirectly from Defendants.

181. As a result of Novo's illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, more than they would have paid for their liraglutide requirements absent Novo's illegal conduct. But for Novo's illegal conduct, competitors would have begun selling generic Victoza during or before the relevant period, and prices for liraglutide products would have been lower, sooner.

182. Had manufacturers of generic Victoza entered the market and lawfully competed with Novo earlier, Plaintiff and other members of the Class would have substituted lower-priced generic liraglutide products for the higher-priced brand-name Victoza and Ozempic for some or all of their GLP-1 product requirements, and/or would have paid lower net prices on their remaining Victoza and/or AB-rated bioequivalent purchases.

183. By engaging in the foregoing conduct, Novo violated the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Arizona by members of the Class.

- b. Cal. Bus. & Prof. Code §§ 16700, with respect to purchases of Victoza and/or Ozempic in California by members of the Class.
- c. C.G.S.A. §§ 35-27, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Connecticut by members of the Class.
- d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Victoza and/or Ozempic in the District of Columbia by members of the Class.
- e. Hawaii Rev. Stat. 480-1, *et seq.* with respect to purchases of Victoza and/or Ozempic in Hawaii by members of the Class.
- f. Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/1, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Illinois by members of the Class;
- g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Victoza and/or Ozempic in Iowa by members of the Class.
- h. Kansas Stat. Ann. § 50-101 *et seq.*, with respect to purchases of Victoza and/or Ozempic in Kansas by members of the Class.
- i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Maine by consumer members of the Class.
- j. Md. Com'l Law Code Ann. § 11-204(a), *et seq.*, with respect to purchases of Victoza and/or Ozempic in Maryland by members of the Class.
- k. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Michigan by members of the Class.
- l. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Minnesota by members of the Class.

m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Mississippi by members of the Class.

n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Nebraska by members of the Class.

o. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Nevada by members of the Class.

p. N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Victoza and/or Ozempic in New Hampshire by members of the Class.

q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Victoza and/or Ozempic in New Mexico by members of the Class.

r. N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchases of Victoza and/or Ozempic in New York by members of the Class.

s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Victoza and/or Ozempic in North Carolina by members of the Class.

t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Victoza and/or Ozempic in North Dakota by members of the Class.

u. N.J.S.A. 56:9-12, *et seq.*, with respect to purchases of Victoza and/or Ozempic in New Jersey by members of the Class.

v. Or. Rev. Stat. § 646.730, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Oregon by members of the Class.

w. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases of Victoza and/or Ozempic in Rhode Island by members of the Class.

x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Victoza and/or Ozempic in South Dakota by members of the Class.

y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Tennessee by members of the Class.

z. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Utah by members of the Class.

aa. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Vermont by consumer members of the Class.

bb. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Victoza and/or Ozempic in West Virginia by members of the Class.

cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Victoza and/or Ozempic in Wisconsin by members of the Class.

184. Plaintiff and members of the Class have been injured in their business or property by reason of Novo's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic liraglutide, and (2) paying higher prices for liraglutide products than they would have paid in the absence of Novo's conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Novo's conduct unlawful.

185. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Novo's violations of the aforementioned statutes.

SECOND CLAIM FOR RELIEF
Unfair or Deceptive Trade Practices

186. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

187. Plaintiff brings this claim on behalf of the Class.

188. Defendants 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 Defendants' anticompetitive, deceptive, unfair and/or unconscionable acts or practices, Plaintiff and Class members were deprived of the opportunity to purchase a less expensive AB-rated bioequivalent of liraglutide and forced to pay higher prices in violation of the following consumer protection statutes:

a. Alaska Stat. Ann. § 45.50.471, et seq., with respect to purchases in Alaska by members of the Class. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce.

b. Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in California by members of the Class. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to Class members. There are no countervailing benefits to Class members and any utility of Defendants' conduct is outweighed by the consequences to Class members.

c. Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

d. Mo. Rev. Stat. §§ 407.020 et seq., with respect to purchases in Missouri by consumer members of the Class.

e. Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by consumer members of the Class. Defendants engaged in unfair and deceptive acts and practices.

f. S.C. Code Ann. §§ 39-5-20, et seq., with respect to purchases in South Carolina by Class members. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.

g. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by consumer members of the Class. Defendants engaged in unfair methods of competition, unfair practices, and deceptive practices in the conduct of trade and commerce.

189. Plaintiff and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair/unconscionable and/or deceptive acts or practices alleged in this Count. Their injury consists of paying higher prices for Victoza, AB-rated generic bioequivalents to Victoza, and/or Ozempic than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

THIRD CLAIM FOR RELIEF
Unjust Enrichment Under State Law

190. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

191. Plaintiff brings this claim on behalf of the Class.

192. To the extent required, this claim is pleaded in the alternative to the other claims in this complaint.

193. As a result of their unlawful conduct described above, Defendants have and will continue to be unjustly enriched. Defendants have been unjustly enriched by the receipt of, at a minimum, unlawfully inflated prices and unlawful profits on Victoza and Ozempic.

194. Defendants' financial benefits are traceable to Plaintiff's and Class members' overpayments for Victoza and Ozempic.

195. Plaintiff and Class members have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from the unlawful overcharges described herein, to the economic detriment of Plaintiff and Class members.

196. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiff and members of the Class for Victoza and/or Ozempic manufactured by Defendants during the Class Period.

197. It would be futile for Plaintiff and Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Victoza and/or Ozempic, as those intermediaries are not liable and would not compensate Plaintiff and Class members for Defendants' unlawful conduct.

198. The economic benefit Defendants derived from overcharging Plaintiff and Class members for Victoza and/or Ozempic is a direct and proximate result of Defendants' unlawful and anticompetitive practices.

199. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiff and Class members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

200. It would be inequitable under unjust enrichment principles under the laws of the states described below for Defendants to retain any of the overcharges Plaintiff and Class members paid for Victoza and/or Ozempic that were derived from Defendants' unfair, anticompetitive and unlawful methods, acts and trade practices.

201. Defendants are aware of and appreciate the benefits that Plaintiff and the Class members have bestowed upon them.

202. Defendants should be ordered to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Class members, who collectively have no adequate remedy at law.

203. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received, which arise from overpayments for branded and generic versions of Victoza and/or Ozempic by Plaintiff and Class members.

204. Plaintiff and Class members have no adequate remedy at law.

205. By engaging in the foregoing unlawful or inequitable conduct, which deprived Plaintiff and Class members of the opportunity to purchase lower-priced generic versions of Victoza and forced them to pay higher prices for branded and generic versions of Victoza, as well as branded Ozempic, Defendants have been unjustly enriched in violation of the common law of various states and commonwealths, as outlined below:

Alabama

206. Defendants unlawfully overcharged end payors who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Alabama at prices that were more than they would have been but for Defendants' actions.

207. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

208. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and Class members.

209. Defendants have benefitted at the expense of Plaintiff and Class members from revenue resulting from unlawful overcharges for branded and generic versions of Victoza and/or Ozempic.

Arizona

210. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Arizona at prices that were more than they would have been but for Defendants' actions.

211. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Victoza and/or Ozempic.

212. Plaintiff has been impoverished by the overcharges for branded and generic versions of Victoza and/or Ozempic resulting from Defendants' unlawful conduct.

213. Defendants' enrichment and Plaintiff's impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received from Plaintiff and Class Members.

214. There is no justification for Defendants' receipt of the benefits causing their enrichment and Plaintiff's impoverishment, because Plaintiff paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

215. Plaintiff and Class members have no remedy at law.

California

216. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in California at prices that were more than they would have been but for Defendants' actions.

217. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

218. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of Plaintiff and Class members.

Florida

219. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Florida at prices that were more than they would have been but for Defendants' actions.

220. Plaintiff and Class Members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

221. Defendants appreciated the benefits bestowed upon them by Plaintiff and the Class members.

222. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiff and the Class members.

Hawaii

223. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Hawaii at prices

that were more than they would have been but for Defendants' actions.

224. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

225. It is unjust for Defendants to retain the benefits received without compensating Plaintiff and Class members.

Illinois

226. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Illinois at prices that were more than they would have been but for Defendants' actions.

227. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

228. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and Class members.

229. It is unjust and inequitable for Defendants to retain the benefits received without compensating Plaintiff and Class members.

Iowa

230. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Iowa at prices that were more than they would have been but for Defendants' actions.

231. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Victoza and/or Ozempic, which revenue resulted from anticompetitive prices paid by Plaintiff and Class members, which inured to Defendants' benefit.

232. Defendants' enrichment has occurred at the expense of Plaintiff and Class members.

233. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Kansas

234. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Kansas at prices that were more than they would have been but for Defendants' actions.

235. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

236. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and Class members.

237. Defendants were unjustly enriched at the expense of Plaintiff and Class members.

Maine

238. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Maine at prices that were more than they would have been but for Defendants' actions.

239. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

240. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and Class members.

241. Defendants were aware of and appreciated the benefit bestowed upon them by Plaintiff and Class members.

242. Defendants were unjustly enriched at the expense of Plaintiff and Class members.

Massachusetts

243. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Massachusetts at prices that were more than they would have been but for Defendants' actions.

244. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

245. Defendants were aware of or appreciated the benefit conferred upon them by Plaintiff and Class members.

246. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Class members. Fairness and good conscience require that Defendants not be permitted to retain the revenue resulting from their unlawful overcharges at the expense of Plaintiff and Class members.

Michigan

247. Defendants unlawfully overcharged end payors, who made purchases of or

reimbursements for branded and generic versions of Victoza and/or Ozempic in Michigan at prices that were more than they would have been but for Defendants' actions.

248. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

249. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and Class members.

250. Defendants were unjustly enriched at the expense of Plaintiff and Class members.

Minnesota

251. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Minnesota at prices that were more than they would have been but for Defendants' actions.

252. Defendants appreciated and knowingly accepted the benefits bestowed upon them by Plaintiff and Class members. Defendants have paid no consideration to any other person for any of the benefits they have received from Plaintiff and Class members.

253. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiff and Class members.

Mississippi

254. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Mississippi at prices that were more than they would have been but for Defendants' actions.

255. Defendants retain the benefit of overcharges received on the sales of branded and generic versions of Victoza, which in equity and good conscience belong to Plaintiff and Class members on account of Defendants' anticompetitive conduct.

Missouri

256. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Missouri at prices that were more than they would have been but for Defendants' actions.

257. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

258. Defendants appreciated the benefit bestowed upon them by Plaintiff and Class members.

259. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and Class members.

Nebraska

260. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Nebraska at prices that were more than they would have been but for Defendants' actions.

261. Defendants received money from Plaintiff and Class members as a direct result of the unlawful overcharges, and have retained this money. Defendants have paid no consideration to any other person in exchange for this money.

262. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to Plaintiff and Class members.

Nevada

263. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Nevada at prices that were more than they would have been but for Defendants' actions.

264. Plaintiff and Class members have conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges for branded and generic versions of Victoza.

265. Defendants appreciated the benefits bestowed upon them by Plaintiff and Class members, for which they have paid no consideration to any other person.

266. Defendants have knowingly accepted and retained the benefits bestowed upon them by Plaintiff and Class members.

267. The circumstances under which Defendants have accepted and retained the benefits bestowed upon them by Plaintiff and Class members are inequitable in that they result from Defendants' unlawful overcharges for branded and generic versions of Victoza and/or Ozempic.

New Hampshire

268. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in New Hampshire at prices that were more than they would have been but for Defendants' actions.

269. Defendants have received a benefit from Plaintiff in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.

270. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

New Mexico

271. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic more than they would have been but for Defendants' actions.

272. Defendants have knowingly benefitted at the expense of Plaintiff and Class members from revenue resulting from unlawful overcharges for branded and generic versions of Victoza and/or Ozempic.

273. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

New York

274. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in New York at prices that were more than they would have been but for Defendants' actions.

275. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Victoza and/or Ozempic, which revenue resulted from anticompetitive prices paid by Plaintiff and Class members, which inured to Defendants' benefit.

276. Defendants' enrichment has occurred at the expense of Plaintiff and Class members.

277. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

North Carolina

278. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in North Carolina at prices that were more than they would have been but for Defendants' actions.

279. Plaintiff and Class Members have conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

280. Plaintiff did not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants.

281. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from Defendants' actions to delay entry of generic versions of Victoza and/or Ozempic to the market.

282. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to unlawful overcharges are ascertainable by review of sales records and the pay-for-delay agreements themselves.

283. Defendants consciously accepted the benefits and continue to do so as of the date of this filing.

North Dakota

284. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in North Dakota at prices that were more than they would have been but for Defendants' actions.

285. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Victoza and/or Ozempic.

286. Plaintiff and Class members have been impoverished by the overcharges for branded and generic versions of Victoza and/or Ozempic resulting from Defendants' unlawful conduct.

287. Defendants' enrichment and Plaintiff's impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received directly or indirectly from Plaintiff and Class members.

288. There is no justification for Defendants' receipt of the benefits causing their enrichment, because Plaintiff and Class members paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

289. Plaintiff and Class members have no remedy at law.

Oregon

290. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Oregon at prices that were more than they would have been but for Defendants' actions.

291. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

292. Defendants were aware of the benefit bestowed upon them by Plaintiff and Class members.

293. It would be inequitable and unjust for Defendants to retain any of the overcharges for Victoza and/or Ozempic derived from Defendants' unfair conduct without compensating Plaintiff and Class members.

Pennsylvania

294. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Pennsylvania at prices that were more than they would have been but for Defendants' actions.

295. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

296. Defendants appreciated the benefit bestowed upon them by Plaintiff and Class members.

297. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Class members.

Rhode Island

298. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Rhode Island at prices that were more than they would have been but for Defendants' actions.

299. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

300. Defendants were aware of and/or recognized the benefit bestowed upon them by Plaintiff and the Class members.

301. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Class members.

South Dakota

302. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in South Dakota at prices that were more than they would have been but for Defendants' actions.

303. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

304. Defendants were aware of the benefit bestowed upon them by Plaintiff and Class members.

305. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing Plaintiff and Class members.

Tennessee

306. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Tennessee at prices that were more than they would have been but for Defendants' actions.

307. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

308. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and Class members.

309. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Class members.

310. It would be futile for Plaintiff and Class members to exhaust all remedies against the entities with which Plaintiff and Class members have privity of contract because Plaintiff and Class members did not purchase branded or generic versions of Victoza and/or Ozempic directly from any Defendant.

Utah

311. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Utah at prices that were more than they would have been but for Defendants' actions.

312. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

313. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and Class members.

314. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Class members.

Vermont

315. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Vermont at prices that were more than they would have been but for Defendants' actions.

316. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

317. Defendants accepted the benefit bestowed upon them by Plaintiff and Class members.

318. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Class members.

West Virginia

319. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in West Virginia at prices that were more than they would have been but for Defendants' actions.

320. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

321. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and Class members.

322. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Class members.

Wisconsin

323. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Wisconsin at prices that were more than they would have been but for Defendants' actions.

324. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

325. Defendants appreciated the benefit bestowed upon them by Plaintiff and Class members.

326. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Class members.

District of Columbia

327. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in the District of Columbia at prices that were more than they would have been but for Defendants' actions.

328. Plaintiff and Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

329. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and Class members.

330. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

Puerto Rico

331. Defendants unlawfully overcharged end payors, who made purchases of or reimbursements for branded and generic versions of Victoza and/or Ozempic in Puerto Rico at prices that were more than they would have been but for Defendants' actions.

332. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Victoza and/or Ozempic.

333. Plaintiff and Class members have been impoverished by the overcharges for

branded and generic versions of Victoza and/or Ozempic resulting from Defendants' unlawful conduct.

334. Defendants' enrichment and Plaintiff's and Class members' impoverishment are connected.

335. There is no justification for Defendants' receipt of the benefits causing their enrichment and Plaintiff's and Class members' impoverishment, because Plaintiff and Class members paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

336. Plaintiff and Class members have no remedy at law.

FOURTH CLAIM FOR RELIEF
Violation of Section 2 of the Sherman Act: Monopolization

337. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

338. As described above, throughout the relevant time period Novo possessed monopoly power nationwide and in each state and territory in the market for liraglutide. No other manufacturer sold a competing version of Victoza during the relevant time period.

339. At all relevant times, Novo possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Novo possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

340. Through its anticompetitive scheme, as alleged above, Novo willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiff and the Class. Novo's anticompetitive conduct was done with the specific intent to maintain its monopoly in the market for Victoza in the United States.

341. Novo knowingly and intentionally engaged in this anticompetitive scheme to monopolize the liraglutide market as described above. Novo accomplished this scheme by, among other things, (1) wrongfully listing certain patents in the Orange Book and prosecuting patent litigation triggered by those wrongful listings; (2) entering into an illegal agreement which delayed the entry of generic Victoza in order to lengthen the period in which Novo's brand Victoza could monopolize the market and make supracompetitive profits; and (3) raising and maintaining prices so that Plaintiff and Class members would pay for Victoza at supracompetitive prices.

342. The goal, purpose, and effect of Novo's scheme was to prevent and delay the sale of liraglutide in the United States at prices significantly below Novo's prices for Victoza, thereby effectively preventing the average market price of liraglutide from declining dramatically while maintaining and extending its monopoly power with respect to liraglutide products.

343. Plaintiff and members of the Class purchased substantial amounts of Victoza indirectly from Novo.

344. As a result of Novo's illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, more than they would have paid for their liraglutide requirements absent Novo's illegal conduct. But for Novo's illegal conduct, competitors would have begun selling generic liraglutide earlier, and prices for liraglutide products would have been lower, sooner.

345. Had manufacturers of generic Victoza entered the market and lawfully competed with Novo earlier, Plaintiff and other members of the Class would have substituted lower-priced generic liraglutide products for the higher-priced brand-name Victoza for some or all of their liraglutide products requirements, and/or would have paid lower net prices on their remaining Victoza and/or AB-rated bioequivalent purchases.

346. Plaintiff and members of the Class will continue to suffer injury, in the form of overcharges paid for Victoza, if Novo's unlawful conduct is not enjoined.

347. Plaintiff and members of the Class therefore seek equitable and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by Novo's unlawful conduct, and to assure that similar anticompetitive conduct and effects do not continue or reoccur in the future.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on its own behalf and on behalf of the proposed Class, prays for judgment against Defendants and that this Court:

1. Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and appoint Plaintiff as the named representatives of the Class;
2. Award Plaintiff and the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;
3. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;
4. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law;
5. Permanently enjoin Defendants both from continuing the unlawful conduct alleged here, and from engaging in similar or related conduct in the future; and
6. Award such other and further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury of all issues so triable.

Dated: April 24, 2026

/s/ Brian D. Brooks

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