IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
VIATRIS INC. and MYLAN PHARMACEUTICALS INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), for their Complaint against Defendants Viatris Inc. ("Viatris") and Mylan Pharmaceuticals Inc. ("MPI") (collectively, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

2. Plaintiff Novo Nordisk A/S ("NNAS") is an entity organized and existing under the laws of the Kingdom of Denmark, having its principal place of business at Novo Allé, 2880 Bagsvaerd Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

3. On information and belief, Viatris is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317. On information and belief, acting in concert with MPI, Viatris is in the business of making and selling generic pharmaceutical products, which they distribute in the State of Delaware and throughout the United States.

4. On information and belief, MPI is a corporation organized and existing under the laws of the State of West Virginia with a place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317. On information and belief, acting in concert with Viatris, MPI is in the business of making and selling generic pharmaceutical products, which they distribute in the State of Delaware and throughout the United States. On information and belief, MPI is an agent, affiliate, wholly owned subsidiary and/or alter ego of Viatris and subsumed within Viatris.

5. On information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell generic pharmaceutical products in the State of Delaware and throughout the United States.

6. On information and belief, MPI is an agent of Viatris, with Viatris exercising considerable control over MPI with respect to generic pharmaceutical products, and approves significant decisions of MPI such as allowing MPI to act as its agent in connection with the preparation, submission, approval and maintenance of ANDAs, including ANDAs as submitted and amendments thereto. Viatris's 2021 10-K report defines Viatris as "the Company" and identifies MPI as a "wholly owned subsidiary." *See* Viatris Inc. Form 10-K (Mar. 1, 2021), https://www.sec.gov/ix?doc=/Archives/edgar/data/0001792044/000179204422000010/vtrs-20211231.htm (last visited Jan. 19, 2023).

7. On information and belief, Viatris attributes FDA submissions and approvals of ANDAs submitted by MPI as Viatris's FDA ANDA submissions and approvals. *See, e.g.*, *Viatris: Complex Injectable Pipeline Opportunities Worth at Least $1bn*, GENERICS BULLETIN, Pharma Intelligence (Nov. 8, 2022), https://generics.pharmaintelligence.informa.com/GB152279/Viatris-Complex-Injectable-Pipeline-Opportunities-Worth-At-Least-$1bn (last visited Jan. 19, 2023) ("A generic version of

Novo Nordisk's GLP-1 receptor against Wegovy (semaglutide) treatment for obesity is among seven complex generic injectables for which Viatris is claiming first-to-file status, as it looks to growth in 2024 and beyond."); *Mylan Launches First Generic Restasis. (RX/Generic Drugs)*, CHAIN DRUG REV. at 31 (Feb. 21, 2022), https://mydigitalpublication.com/publication/?i=738336&article_id=4212714&view=articleBrowser (last visited Jan. 19, 2023) ("Rajiv Malik, president of [Mylan Pharmaceuticals Inc.'s] parent company, Viatris Inc., said: 'I am pleased that Viatris has received the first FDA approval for generic Restasis . . . .'" and "Viatris Developed Markets President Tony Mauro said: 'The approval of generic Restasis reinforces our ongoing commitment to deliver innovative solutions . . . . We look forward to quickly bringing this important product to millions of Americans'"); *Viatris Inc. Announces Receipt of the First FDA Approval for Generic Version of Symbicort® Inhalation Aerosol, BreynaTM (Budesonide and Formoterol Fumarate Dihydrate Inhalation Aerosol), in Partnership with Kindeva* (Mar. 16, 2022), https://newsroom.viatris.com/2022-03-16-Viatris-Inc-Announces-Receipt-of-the-First-FDA-Approval-for-Generic-Version-of-Symbicort-R-Inhalation-Aerosol,-Breyna-TM-Budesonide-and-Formoterol-Fumarate-Dihydrate-Inhalation-Aerosol-,-in-Partnership-with-Kindeva (last visited Jan. 19, 2023) ("Viatris President Rajiv Malik added: 'The momentous FDA final approval of Breyna is further evidence of our well- established development expertise and proven ability to move up the value chain with more complex products by leveraging our robust scientific capabilities to target gaps in healthcare and patient needs. This approval also builds on our past successes of bringing other complex products first to market and demonstrates the continued delivery of our strong pipeline.'").

8. On information and belief, MPI acts as an agent for Viatris for purposes including, but not limited to, corresponding with the United States Food and Drug Administration ("FDA").

On information and belief, products identified by FDA as products of "Mylan Pharmaceuticals Inc." or "Mylan Pharmaceuticals Inc., a Viatris Company" are identified on Viatris's website as Viatris products. *E.g.*, *compare,* FDA Listing of Authorized Generics as of December 15, 2022, https://www.fda.gov/media/77725/download (last visited Jan. 19, 2023) *with* Viatris Inc.'s Product Catalog, https://www.viatris.com/en-us/lm/countryhome/us-products/productcatalog/ (last visited Jan. 19, 2023).

9. On information and belief, MPI acts as an agent for Viatris for purposes including, but not limited to, providing notice of Paragraph IV certifications to patent owners and NDA holders in connection with Defendants' ANDA filings and defending against any subsequent infringement claims under 35 U.S.C. § 271(e)(2). Viatris's 2021 10-K states: "Viatris invests significant sums in R&D and in manufacturing capacity. [Viatris] also often incur[s] substantial litigation expense as a result of defending or challenging brand patents or exclusivities." Form 10-K (Mar. 1, 2021), https://www.sec.gov/ix?doc=/Archives/edgar/data/0001792044/000179204422000010/vtrs-20211231.htm (last visited Jan. 19, 2023). Viatris's 2021 10-K report further states: "The Company is involved in a number of patent litigation lawsuits involving the validity and/or infringement of patents held by branded pharmaceutical manufacturers including but not limited to the matters described below. The Company uses its business judgement to decide to market and sell certain products, in each case based on its belief that the applicable patents are invalid and/or that its products do not infringe, notwithstanding the fact that allegations of patent infringement(s) or other potential third party rights have not been finally resolved by the courts." *Id.* In connection with that statement, Viatris's 2021 10-K report identifies multiple Hatch-Waxman litigations in which MPI is involved. *Id.*

10. On information and belief, since the merger of Mylan N.V., MPI's former parent company, and Upjohn Inc. to create Viatris in November 2020, any corporate separateness that may have existed between Viatris and MPI shortly after the formation of Viatris has dissolved, and MPI is now no more than an alter ego for Viatris, subsumed within Viatris.

11. On information and belief, MPI holds itself out to the public, including through press releases posted to Viatris's website and communications to FDA, as "Mylan Pharmaceuticals Inc., a Viatris company." *See, e.g.*, https://newsroom.viatris.com/2022-01-18-Mylan-Pharmaceuticals-Inc-,-a-Viatris-Company,-Conducting-Voluntary-Recall-of-One-Batch-of-Semglee-R-insulin-glargine-injection-,-100-units-mL-U-100-,-3-mL-Prefilled-Pens,-Due-to-the-Potential-for-a-Missing-Label-in-the-Batch (last visited Jan. 23, 2023; https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-pharmaceuticals-inc-viatris-company-conducting-voluntary-recall-one-batch-semgleer-insulin (last visited Jan. 23, 2023).

12. On information and belief, Viatris's website states: "Viatris was formed in 2020 through the combination of Mylan and Upjohn . . . . By integrating the strengths of these two companies, including our global workforce of ~38,000, we aim to deliver increased access to affordable, quality medicines for patients worldwide. Our global portfolio includes best-in-class . . . generics, including branded and complex generics; [and] biosimilars . . . . We are domiciled in the United States. . . . And we maintain an industry-leading pipeline, composed of numerous complex generic, biosimilars and global key brands. . . . As we work to fully transition to the Viatris brand commercially and operationally around the world, you may continue to see both the Mylan and Upjohn names in certain markets." *See* https://www.viatris.my/en-my/about-us/our-story#:~:text=Viatris%20was%20formed%20in%202020,quality%20medicines%20for%

20patients%20worldwide (last visited Jan. 19, 2023); https://newsroom.viatris.com/2020-11-16-Viatris-Inc-Launches-as-a-New-Kind-of-Healthcare-Company-Positioned-to-Meet-the-Worlds-Evolving-Healthcare-Needs#:~:text=Formed%20in%20November%202020%20through,than%20165%20countries%20and%20territories (last visited Jan. 23, 2023).

13. On information and belief, Viatris is transitioning the Viatris brand around the world, both commercially and operationally. As part of the transition, Viatris has been divesting MPI properties, assuming MPI corporate responsibilities, absorbing MPI employees, commingling funds with MPI, and subsuming MPI. For instance, on information and belief, by March 7, 2022, Viatris closed MPI's facility located at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505 and auctioned off its equipment. *See, e.g.*, https://www.wboy.com/news/local/monongalia-and-preston/former-mylan-viatris-facility-auctions-off-equipment/ (last visited Jan. 19, 2023); https://www.hgpauction.com/auctions/110662/viatris-morgantown-2/ (last visited Jan. 19, 2023). On information and belief, on March 31, 2022, West Virginia University assumed ownership of 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505, after purchasing the property for $1 from Viatris. *See, e.g.*, https://www.wvnews.com/news/wvnews/former-mylan-plant-purchased-by-west-virginia-university-for-1-with-plans-to-house-business/article_5af8d6d0-b9f8-11ec-9574-6b3dce9aba75.html (last visited Jan. 19, 2023).

14. On information and belief, upon the creation of Viatris, the former executive chairman of Mylan N.V., Robert J. Coury, became Viatris's executive chairman. *See, e.g.*, https://www.viatris.com/en/about-us/our-leaders/robert-j-coury (last visited on January 19, 2023). On information and belief, Mr. Coury "leads the [Viatris] board of directors, oversees the strategic direction of the company in collaboration with executive management, and advises the management team as they execute on the company's strategy to drive value creation . . ." *Id.*

15. On information and belief, one or more of MPI's corporate officers and employees are shared with or have been subsumed by Viatris. *See, e.g.*, https://www.fiercepharma.com/pharma/mylan-crowns-former-ceo-coury-as-executive-chairman-as-upjohn-merger-deal-faces-delays (last visited Jan. 19, 2023); https://www.viatris.com/en/about-us/our-leaders (last visited January 19, 2023); https://www.wsj.com/market-data/quotes/VTRS/company-people/executive-profile/268055 (last visited Jan. 19, 2023); https://www.sec.gov/Archives/edgar/data/1792044/000119312521313437/d163117ddef14a.htm (last visited Jan. 19, 2023)). On information and belief, the shared and subsumed corporate officers and employees demonstrates that MPI is subsumed within, and an alter ego of, Viatris.

16. On information and belief, MPI's shared or subsumed officers maintain their offices at Viatris's principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317. *See, e.g.*, https://www.sec.gov/Archives/edgar/data/1792044/000119312521313437/d163117ddef14a.htm (last visited Jan. 19, 2023). On information and belief, Defendants' use of the same office or business location demonstrates that MPI is subsumed within, and an alter ego of, Viatris.

17. On information and belief, upon formation, Viatris assumed various agreements between MPI and certain MPI officers, including retention agreements and retirement benefit agreements. *See, e.g.*, https://www.sec.gov/Archives/edgar/data/1792044/000119312521313437/d163117ddef14a.htm (last visited Jan. 19, 2023).

18. On information and belief, attempts to access the website for all Mylan entities, including MPI, mylan.com, result in a pop-up window, which redirects access to Viatris, along with a statement that: "Mylan is now part of Viatris, a new global healthcare company committed to empowering people to live healthier at every stage of life." *See* https://www.mylan.com (last

visited Jan. 19, 2023). On information and belief, the LinkedIn website for Mylan entities, including MPI, states: "Follow us on our new journey as Viatris. www.linkedin.com/company/viatris" and "We have combined with Upjohn, a legacy division of Pfizer, and are now Viatris. Follow along on our new journey as we empower people worldwide to live healthier at every stage of life. www.linkedin.com/company/viatris." *See* https://www.linkedin.com/company/mylan/ (last visited Jan. 19, 2023). On information and belief, MPI's holding itself out as Viatris and the redirection from mylan.com to the website of Viatris demonstrates that MPI is subsumed within, and an alter ego of, Viatris.

19. On information and belief, MPI employees presently identify as employees of Viatris. *See, e.g.*, https://www.linkedin.com/in/brandon-mcmahon-2754a263/ (last visited Jan. 19, 2023). On information and belief, MPI employees presently identifying as employees of Viatris demonstrates that MPI is subsumed within, and an alter ego of, Viatris.

20. On information and belief, present MPI job listings indicate employment is with Viatris, demonstrating that MPI is subsumed within, and an alter ego of, Viatris. *See, e.g.*, https://www.indeed.com/jobs?q=Mylan%20Pharmaceuticals%20Inc.&l=Morgantown%2C%20WV&from=mobRdr&utm_source=%2Fm%2F&utm_medium=redir&utm_campaign=dt&vjk=8203d5b1e393f80f (last visited Jan. 19, 2023).

21. On information and belief, Viatris and certain lenders entered into a $4.0 billion revolving facility agreement with (the "2021 Revolving Facility") on July 1, 2021, to which MPI has or has had access. *See* Viatris Inc. Form 10-K (Mar. 1, 2021) https://www.sec.gov/ix?doc=/Archives/edgar/data/0001792044/000179204421000009/vtrs-20201231.htm (last visited Jan. 19, 2023). On information and belief, Viatris and MPI operate as

a single entity with the ability to borrow funds from certain lenders with whom Viatris has instituted revolving loan accounts.

22. On information and belief, Viatris entered into a $400 million "Receivables Facility" agreement in 2020 for a period of two-years, which expired in April 2022. *Id.* MPI "has access to $400 million under the Receivables Facility." *Id.* On information and belief, MPI, operating as a single entity with Viatris, is able to sell MPI's accounts receivables to Mylan Securitization LLC, a Viatris subsidiary, under Viatris's Receivables Facility agreement for the purpose of accessing instant funds from outstanding unpaid invoices. *Id.* On information and belief, MPI is thereby funded through Viatris's subsidiary Mylan Securitization LLC. On information and belief, Viatris and MPI's joint use of the 2021 Revolving Facility and 2020 Receivables Facility demonstrates the commingling of funds and that MPI is subsumed within, and is an alter ego of, Viatris.

23. On information and belief, Viatris's 2021 10-K report to the SEC states that references to "Viatris" within the 10-K refer to "Viatris Inc. and its subsidiaries." *See* Viatris Inc. Form 10-K (Mar. 1, 2021), https://www.sec.gov/ix?doc=/Archives/edgar/data/0001792044/000179204422000010/vtrs-20211231.htm (last visited Jan. 19, 2023). MPI is identified in the Viatris 2021 10-K report as a Viatris subsidiary, and references the "Viatris Charter." *Id.* Upon information and belief, the "Viatris Charter" is the "amended and restated certificate of incorporation of Viatris Inc." According to Viatris's 2021 10-K report, Delaware is designated by the "Viatris Charter" "as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by Viatris's stockholders, which could discourage lawsuits against Viatris and its directors and officers . . . . To the fullest extent permitted by law, this exclusive forum provision will apply to state and federal law claims, including claims under the federal securities

laws . . . . This exclusive forum provision may limit the ability of Viatris's stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with Viatris or its directors or officers, which may discourage such lawsuits against Viatris or its directors or officers." *Id.*

24. On information and belief, to resolve class action cases pending in the U.S. District Court for the District of Kansas, Viatris agreed to pay settlement fees of $264 million on behalf of defendants, including MPI. *See* Viatris Inc. Form 10-Q, dated May 9, 2022, https://www.sec.gov/ix?doc=/Archives/edgar/data/0001792044/000179204422000017/vtrs-20220331.htm (last visited Jan. 19, 2023); *In Re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation*, MDL No. 2785, 17-md-2785-DDC-TJJ (D. Kan. March 11, 2022). On information and belief, the payment of debt incurred by Viatris and its subsidiaries demonstrates a commingling of funds between Viatris and its subsidiaries, including MPI, a lack of corporate separateness, and Viatris subsuming Mylan subsidiaries, including MPI.

NATURE OF THE ACTION

25. This action arises under the patent laws of the United States, Title 35, United States Code, § 100 *et seq*., including 35 U.S.C. §§ 271(a), (b), (c), (e), and (f), arising from Defendants' submission of an Abbreviated New Drug Application ("ANDA") No. 217705 (the "Defendants' ANDA") to the United States Food and Drug Administration ("FDA"), by which Defendants seek approval of a generic version of Novo Nordisk's pharmaceutical product WEGOVY® (semaglutide) injection prior to the expiration of United States Patent Nos. 8,129,343 (the "'343 Patent"), 8,536,122 (the "'122 Patent"), 9,764,003 (the "'003 Patent"), 10,888,605 (the "'605 Patent"), and 11,318,191 (the "'191 Patent") (collectively, the "Asserted Patents"), which cover, *inter alia*, WEGOVY® (semaglutide) injection and/or its use.

26. NNAS is the owner of all rights, title, and interest in the Asserted Patents.

27. NNI is the holder of New Drug Application ("NDA") No. 215256 for WEGOVY® (semaglutide) injection, for subcutaneous use, administered with 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL and 2.4 mg/0.75 mL Pre-filled Single-dose Pens, which NNI sells under the trade name WEGOVY®. NNI holds the exclusive right to sell, distribute, and market WEGOVY® (semaglutide) injection in the United States.

28. The Asserted Patents are listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with WEGOVY ® and the related NDA.

NOVO NORDISK'S WEGOVY®

29. The WEGOVY® Label states that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of []:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)."

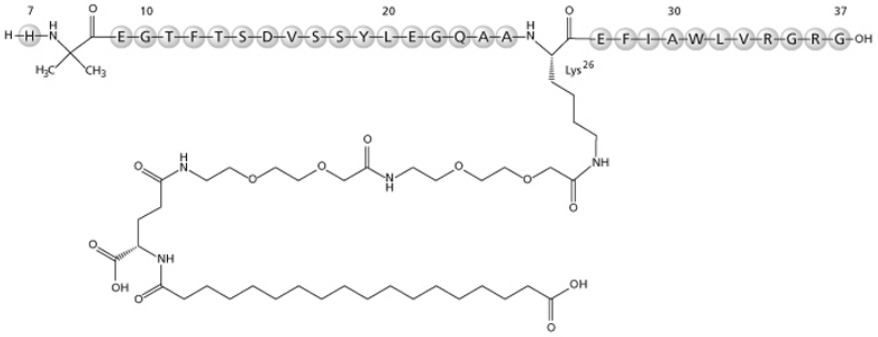
30. WEGOVY® is to be administered once weekly by subcutaneous injection.

31. The WEGOVY® Label provides limitations of use, instructing that WEGOVY® should not be used in combination with other semaglutide-containing products or any other GLP-1 receptor agonist.

32. The WEGOVY® Label further instructs to administer WEGOVY® once weekly according to a dose escalation schedule that includes an initiating dosage at 0.25 mg of semaglutide for four weeks, 0.5 mg for the next four weeks, and 1 mg for the next four weeks after that.

33. The active ingredient in WEGOVY® is semaglutide and its structure is:

Figure 1. Structural Formula of semaglutide



34. WEGOVY® is an aqueous solution. Each 0.5 mL single-dose pen (i.e., prefilled syringe with needle) contains a solution of WEGOVY® containing 0.25 mg, 0.5 mg or 1 mg of semaglutide; and each 0.75 mL single-dose pen contains a solution of WEGOVY® containing 1.7 or 2.4 mg semaglutide. Thus, each 1 mL of WEGOVY® contains 0.5 mg, 1 mg or 2 mg, or 2.3 mg or 3.2 mg depending on the dosage.

35. Each 1 mL of WEGOVY® contains the following inactive ingredients: 1.42 mg disodium phosphate dihydrate (also known as disodium hydrogen phosphate dihydrate), 8.25 mg sodium chloride, and water for injection. WEGOVY® has a pH of approximately 7.4. Hydrochloric acid or sodium hydroxide may be added to adjust pH.

DEFENDANTS' ANDA AND PARAGRAPH IV CERTIFICATION

36. On information and belief, Defendants submitted Defendants' ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *i.e.*, 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use and/or sell Defendants' ANDA Product.

37. On information and belief, Defendants' ANDA refers to and relies upon WEGOVY®'s NDA and contains data that, according to Defendants, demonstrate the bioequivalence of Defendants' ANDA Product and WEGOVY®.

38. On information and belief, Defendants made and included in Defendants' ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in their opinion and to the best of their knowledge, the Asserted Patents are invalid.

39. Novo Nordisk received written notice of Defendants' ANDA and Paragraph IV Certification as to the Asserted Patents ("Notice Letter"), which was dated December 16, 2022, along with an enclosed statement that is required to state all the factual and legal bases for stating that the commercial manufacture, use, or sale of Defendants' ANDA Product allegedly will not infringe any valid claim of the Asserted Patents, and/or that the claims of the Asserted Patents allegedly are invalid and/or unenforceable (the "Detailed Statement").

40. Defendants' Detailed Statement does not allege or provide any separate factual bases for stating that the Asserted Patents will not be infringed by Defendants' ANDA Product apart from arguing that the Asserted Patents are invalid.

41. Defendants' Detailed Statement does not allege or provide any separate factual bases to assert that the Asserted Patents are unenforceable.

42. This action is being commenced within 45 days of receipt of the Notice Letter.

43. Defendants have infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by filing Defendants' ANDA with a Paragraph IV Certification and seeking FDA approval of Defendants' ANDA before the expiration of the Asserted Patents or any extensions thereof.

44. Defendants have infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by the submission of Defendants' ANDA, including any amendments or supplements thereof, seeking FDA approval to commercially manufacture, use, offer for sale, sell,

distribute in, or import into the United States of Defendants' ANDA Product before the expiration of the Asserted Patents or any extensions thereof.

45. Defendants will infringe one or more claims of the Asserted Patents under 35 U.S.C. § 271(a), (b), (c) or (f) should they engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Defendants' ANDA Product before the expiration of the Asserted Patents or any extensions thereof.

JURISDICTION

46. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

47. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, with MPI acting as an agent of Viatris, have committed and/or have aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting Defendants' ANDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), including its amendments, which acts have led to foreseeable harm and injury to NNI, a Delaware corporation

48. On information and belief, Defendants, with MPI acting as an agent of Viatris, have submitted Defendants' ANDA, including amendments seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product in or into the United States, including Delaware, prior to the expiration of the Asserted Patents.

49. On information and belief, Defendants, with MPI acting as an agent of Viatris, have committed an act of infringement by submitting Defendants' ANDA, including amendments, with the intent to make, use, sell, offer for sale, and/or import Defendants' ANDA Product in or into

this judicial district, prior to the expiration of the Asserted Patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novo Nordisk.

50. On information and belief, Viatris has attributed MPI's submission of Defendants' ANDA as to Wegovy as Viatris's ANDA filing: "A generic version of Novo Nordisk's GLP-1 receptor against Wegovy (semaglutide) treatment for obesity is among seven complex generic injectables for which Viatris is claiming first-to-file status, as it looks to growth in 2024 and beyond." *See Viatris: Complex Injectable Pipeline Opportunities Worth at Least $1bn*, GENERICS BULLETIN, Pharma Intelligence (Nov. 8, 2022), https://generics.pharmaintelligence.informa.com/GB152279/Viatris-Complex-Injectable-Pipeline-Opportunities-Worth-At-Least-$1bn (last visited Jan. 19, 2023).

51. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, with MPI acting as an agent of Viatris, upon approval of Defendants' ANDA, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under Defendants' ANDA that will be purposefully directed at Delaware, including the marketing of Defendants' ANDA Product in Delaware, prior to the expiration of the Asserted Patents.

52. On information and belief, MPI acted as an agent of Viatris in the preparation and submission of Defendants' ANDA, including amendments, and, if Defendants' ANDA is approved, MPI will continue to act as an agent of Viatris to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product in or into the United States, including Delaware, prior to the expiration of the Asserted Patents.

53. On information and belief, Defendants, with MPI acting as an agent of Viatris, have taken the costly, significant step of applying to the FDA for approval, including submission of

Defendants' ANDA and amendments thereto, to engage in future activities, including the marketing of Defendants' ANDA Product, that will be purposefully directed at Delaware and elsewhere.

54. On information and belief, MPI, acting as an agent of Viatris, has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

55. On information and belief, Viatris has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

56. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, acting in concert, with MPI and Viatris acting as a single enterprise, have committed and/or have aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting Defendants' ANDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), including their amendments, which acts have led to foreseeable harm and injury to NNI, a Delaware corporation.

57. On information and belief, MPI, acting as an alter ego of Viatris, develops, manufactures, distributes, sells and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

58. On information and belief, including, based on, inter alia, Defendants' website, public SEC filings, and public press releases, Defendants hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including Delaware.

59. On information and belief, Defendants act in concert, with MPI and Viatris acting as a single enterprise, with respect to the preparation, submission, approval and maintenance of ANDAs, including ANDAs and amendments thereto. On information and belief, MPI, acting as an alter ego of Viatris, has submitted Defendants' ANDA for Defendants' ANDA Product, including amendments seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product in or into the United States, including Delaware, prior to the expiration of the Asserted Patents.

60. MPI, acting as an alter ego of Viatris, has committed an act of infringement by submitting Defendants' ANDA, including amendments, with the intent to make, use, sell, offer for sale, and/or import Defendants' ANDA Product in or into this judicial district, prior to the expiration of the Asserted Patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novo Nordisk.

61. On information and belief, Viatris has claimed MPI's submission of the Defendants' ANDA as to WEGOVY® as Viatris's ANDA filing: "A generic version of Novo Nordisk's GLP-1 receptor against Wegovy (semaglutide) treatment for obesity is among seven

complex generic injectables for which Viatris is claiming first-to-file status, as it looks to growth in 2024 and beyond." *See Viatris: Complex Injectable Pipeline Opportunities Worth at Least $1bn*, GENERICS BULLETIN, Pharma Intelligence (Nov. 8, 2022), https://generics.pharmaintelligence.informa.com/GB152279/Viatris-Complex-Injectable-Pipeline-Opportunities-Worth-At-Least-$1bn (last visited Jan. 19, 2023).

62. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, acting in concert, with MPI and Viatris acting as a single enterprise, upon approval of Defendants' ANDA, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under Defendants' ANDA that will be purposefully directed at Delaware, including the marketing of Defendants' ANDA Product in Delaware, prior to the expiration of the Asserted Patents.

63. On information and belief, Defendants acted in concert, with MPI and Viatris acting as a single enterprise, in the preparation and submission of Defendants' ANDA, including amendments, and, if Defendants' ANDA is approved, will continue to act in concert, with MPI and Viatris acting as a single enterprise, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product in or into the United States, including Delaware, prior to the expiration of the Asserted Patents.

64. On information and belief, Defendants, acting in concert, with MPI and Viatris acting as a single enterprise, have taken the costly, significant step of applying to the FDA for approval, including submission of Defendants' ANDA and amendments thereto, to engage in future activities, including the marketing of Defendants' ANDA Product, that will be purposefully directed at Delaware and elsewhere.

65. This Court also has personal jurisdiction over Defendants because, on information and belief, each such Defendant's affiliations with the State of Delaware, including Viatris's incorporation in Delaware, Viatris's ownership of and actions in concert and as a single enterprise with MPI, are sufficiently continuous and systematic as to render each Defendant essentially at home in this forum.

66. On information and belief, MPI, acting as an alter ego of Viatris, has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

67. On information and belief, Viatris has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

68. On information and belief, it would be unfair not to impute Viatris's residence to MPI as the alter ego of Viatris when Viatris has so dominated and subsumed MPI into Viatris.

69. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MPI, and Viatris in this judicial district.

VENUE

70. The allegations above are incorporated herein by reference.

71. Venue is proper in this Court for this action because Viatris is incorporated in the State of Delaware and therefore resides in this judicial district and because MPI acted and will continue to act as an agent of Viatris, including in the submission of Defendants' ANDA, including amendments, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product in or into the United States, including Delaware, prior to the expiration of the Asserted Patents. Thus, venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

72. Venue also is proper in this Court because Viatris's Delaware residence should be imputed to MPI as an alter ego of Viatris due to a lack of corporate separateness between Viatris and MPI. *See* Mylan Pharmaceuticals Inc.'s, Mylan Laboratories Limited's and Viatris Inc.'s Answer, Affirmative Defenses, and Mylan Pharmaceuticals Inc.'s Counterclaims to Complaint, D.I. 49, C.A. No. 22-1395-RGA (D. Del.).

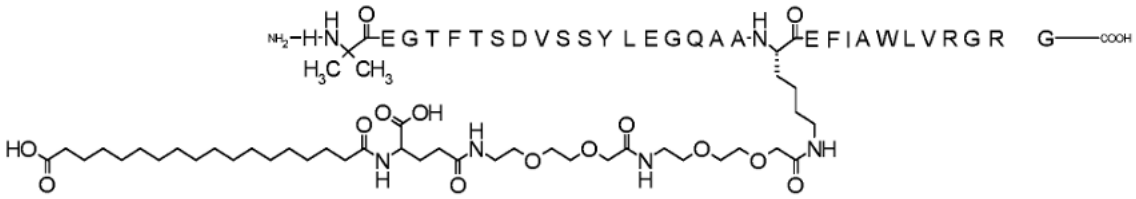
THE PATENTS-IN-SUIT

U.S. Patent No. 8,129,343

73. The allegations above are incorporated herein by reference.

74. Novo Nordisk A/S is the owner of all rights, title, and interest in the '343 Patent, entitled "Acylated GLP-1 Compounds." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '343 Patent on March 6, 2012. The '343 Patent names Jesper Lau, Paw Bloch, and Thomas Kruse Hansen as inventors. All named inventors assigned the '343 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '343 Patent and sue for infringement thereof. A true and correct copy of the '343 Patent is attached to this Complaint as Exhibit 1.

75. The ’343 Patent claims a compound of the following structure, as well as a pharmaceutical composition comprising the same compound with the following structure and a pharmaceutically acceptable excipient:



76. The ’343 Patent also claims a method of treatment by administering a pharmaceutical composition comprising the claimed compound and a pharmaceutically acceptable excipient.

U.S. Patent No. 8,536,122

77. The allegations above are incorporated herein by reference.

78. Novo Nordisk A/S is the owner of all rights, title, and interest in the ’122 Patent, entitled “Acylated GLP-1 Compounds.” The USPTO duly and legally issued the ’122 Patent on September 17, 2013. The ’122 Patent names Jesper Lau, Florencio Zaragoza Doerwald, Paw Bloch, and Thomas Kruse Hansen as inventors. All named inventors assigned the ’122 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the ’122 Patent and sue for infringement thereof. A true and correct copy of the ’122 Patent is attached to this Complaint as Exhibit 2.

79. The ’122 Patent claims compounds of GLP-1 analogs and pharmaceutical compositions comprising a GLP-1 analog, including semaglutide.

80. The ’122 Patent also claims a method of treatment by administering a GLP-1 analog, including semaglutide.

U.S. Patent Nos. 9,764,003

81. The allegations above are incorporated herein by reference.

82. Novo Nordisk A/S is the owner of all rights, title, and interest in the ’003 Patent, entitled “Use of Long-Acting GLP-1 Peptides.” The USPTO duly and legally issued the ’003 Patent on September 19, 2017. The ’003 Patent names Christine B. Jensen as the sole inventor, who assigned the ’003 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the ’003 Patent and sue for infringement thereof. A true and correct copy of the ’003 Patent is attached to this Complaint as Exhibit 3.

83. The ’003 Patent claims a method for reducing body weight, comprising administering semaglutide once weekly in an amount of at least 0.7 mg and up to 1.6 mg to a subject in need thereof, wherein the said semaglutide is administered without another therapeutic agent.

U.S. Patent Nos. 10,888,605

84. The allegations above are incorporated herein by reference.

85. Novo Nordisk A/S is the owner of all rights, title, and interest in the ’605 Patent, entitled “GLP-1 Compositions and Uses Thereof.” The USPTO duly and legally issued the ’605 Patent on January 12, 2021. The ’605 Patent names Eva Horn Moeller, Michael Duelund Soerensen, and Joakim Lundqvist as inventors. All named inventors assigned the ’605 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the ’605 Patent and sue for infringement thereof. A true and correct copy of the ’605 Patent is attached to this Complaint as Exhibit 4.

86. The ’605 Patent claims a liquid pharmaceutical composition for parenteral administration comprising 0.5 to 5 mg/mL semaglutide, no more than 0.1 mg/mL phenol, at least 60% (w/w) water, and with at least one pharmaceutically acceptable excipient consisting of a buffer or an isotonic agent, where the pH of the composition is in between 7.0 and 7.8.

87. The ’605 Patent also claims a method of treatment comprising administering to a subject in need thereof a therapeutically effective amount of the parenterally administered liquid

pharmaceutical composition at least 60% (w/w) water, comprising 0.5 to 5 mg/mL semaglutide, less than 0.1 mg/mL phenol, water, and at least one pharmaceutically acceptable excipient consisting of a buffer or an isotonic agent, where the pH of the composition is in between 7.0 and 7.8.

U.S. Patent Nos. 11,318,191

88. The allegations above are incorporated herein by reference.

89. Novo Nordisk A/S is the owner of all rights, title, and interest in the '191 Patent, entitled "GLP-1 Compositions and Uses Thereof." The USPTO duly and legally issued the '191 Patent on May 3, 2022. The '191 Patent names Dorthe Kot Engelund, Soeren Snitker, and Andrew Mark Louw as inventors. All named inventors assigned the '191 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '191 Patent and sue for infringement thereof. A true and correct copy of the '191 Patent is attached to this Complaint as Exhibit 5.

90. The '191 Patent claims a liquid pharmaceutical composition comprising 0.5 to 10 mg/mL semaglutide, 0.0% (w/w) to 0.1% (w/w) phenol, and 8.2 to 8.9 mg/mL sodium chloride.

91. The '191 Patent also claims a method of treatment comprising administering to a subject in need thereof a therapeutically effective amount of the liquid pharmaceutical composition comprising 0.5 to 10 mg/mL semaglutide, 0.0% (w/w) to 0.1% (w/w) phenol, and 8.2 to 8.9 mg/mL sodium chloride.

COUNT I
(INFRINGEMENT OF THE '343 PATENT)

92. The allegations above are incorporated herein by reference.

93. Defendants submitted Defendants' ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '343 Patent, and any extensions thereof.

94. The Notice Letter states that Defendants' ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '343 Patent. The Notice Letter represents that Defendants' ANDA was submitted with a Paragraph IV Certification that "no valid claim of the ['343 Patent] will be infringed, prior to the expiration of the patent," by the commercial manufacture, use, or sale of Defendants' ANDA Product, and/or that the '343 Patent is invalid and/or unenforceable.

95. Defendants have actual knowledge of the '343 Patent.

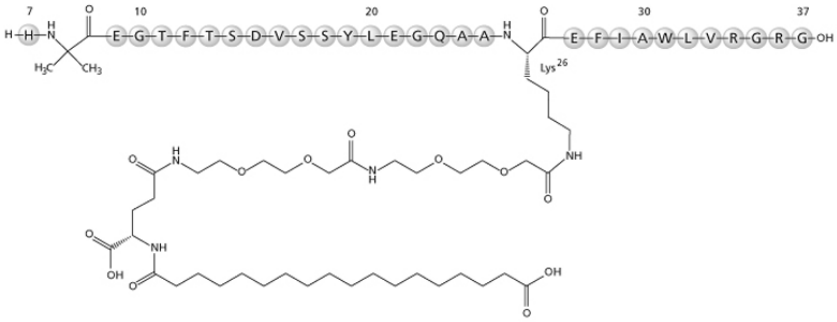
96. Defendants were required to include in their Detailed Statement for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See* 21 CFR § 314.95(c)(7).

97. The Detailed Statement does not provide any separate factual bases for stating that the '343 Patent will not be infringed by Defendants' ANDA Product apart from arguing that the '343 Patent is invalid. If Defendants had any reasonable basis for asserting that their ANDA Product is not covered by the claims of the '343 Patent, they were required to provide a full and detailed explanation as to why. Accordingly, on information and belief, Defendants' ANDA Product is covered by at least claim 1 of the '343 Patent, and Defendants have therefore infringed the '343 Patent. The Detailed Statement does not allege that the '343 Patent is unenforceable.

98. The WEGOVY® Label states that the active ingredient in WEGOVY® is semaglutide and that WEGOVY® contains inactive ingredients.

99. The WEGOVY® Label states that the structure of semaglutide is:

Figure 1. Structural Formula of semaglutide



100. WEGOVY® is covered by at least claim 1 of the ’343 Patent.

101. The WEGOVY® Label instructs physicians that “WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of []:

• 30 kg/m2 or greater (obesity) or
• 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).”

102. The use of WEGOVY® is covered by, among others, at least claim 3 of the ’343 Patent.

103. Thus, WEGOVY® and any corresponding generic semaglutide injection are covered by at least claims 1 and 3 of the ’343 Patent.

104. The ’343 Patent is listed in the Orange Book for WEGOVY®.

105. On information and belief, Defendants’ ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Defendants’ ANDA Product is identical to that in WEGOVY®.

106. On information and belief, if Defendants' ANDA is approved, Defendants will make, use, offer for sale, sell, or import Defendants' ANDA Product in a manner that would infringe at least claims 1 and 3 of the '343 Patent.

107. On information and belief, Defendants' ANDA essentially copies the WEGOVY® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(8)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients infringe at least claim 3 of the '343 Patent.

108. On information and belief, if Defendants' ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Defendants' ANDA Product and thereby infringe at least claims 1 and 3 of the '343 Patent.

109. WEGOVY® and any corresponding generic semaglutide injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1 and 3 of the '343 Patent. On information and belief, Defendants' ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 1 and 3 of the '343 Patent.

110. Defendants have infringed at least claims 1 and 3 of the '343 Patent under 35 U.S.C. § 271(e)(2)(A) by their submission of Defendants' ANDA to FDA seeking to obtain approval for Defendants' ANDA Product, which is covered by at least claims 1 and 3 of the '343 Patent, before the expiration of the '343 Patent.

111. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendants' ANDA would directly infringe at least claim 1 of the '343 Patent under 35 U.S.C. §§ 271(a) and/or (f).

112. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendants' ANDA would infringe directly or contribute to or induce infringement of at least claims 1 and 3 of the '343 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

113. Novo Nordisk seeks an order requiring that Defendants amend its Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

114. Novo Nordisk seeks an order declaring that Defendants have infringed at least claims 1 and 3 of the '343 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

115. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), including an order that the effective date of any FDA approval of Defendants' ANDA be a date that is not earlier than the expiration of the '343 Patent or any later expiration of extensions, adjustments, and exclusivities for the '343 Patent to which Novo Nordisk becomes entitled.

116. Novo Nordisk seeks an order declaring that Defendants will infringe at least claims 1 and 3 of the '343 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Defendants' ANDA Product before the expiration of the '343 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

117. Novo Nordisk will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to the infringement of at least claims 1 and 3 of the '343 Patent. Pursuant to 35 U.S.C. § 283, Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

118. On information and belief, Defendants' Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '343 Patent is devoid

of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

119. To the extent Defendants commercialize Defendants' ANDA Product prior to the expiration of the '343 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284.

COUNT II
(INFRINGEMENT OF THE '122 PATENT)

120. The allegations above are incorporated herein by reference.

121. Defendants submitted Defendants' ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '122 Patent, and any extensions thereof.

122. The Notice Letter states that Defendants' ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '122 Patent. The Notice Letter represents that Defendants' ANDA was submitted with a Paragraph IV Certification that "no valid claim of the ['122 Patent] will be infringed, prior to the expiration of the patent," by the commercial manufacture, use, or sale of Defendants' ANDA Product, and/or that the '122 Patent is invalid and/or unenforceable.

123. Defendants have actual knowledge of the '122 Patent.

124. Defendants were required to include in their Detailed Statement for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See*, 21 CFR § 314.95(c)(7).

125. The Detailed Statement does not provide any separate factual bases for stating that the '122 Patent will not be infringed by Defendants' ANDA Product apart from arguing that the '122 Patent is invalid, except for claim 12, which Defendants alleged does not disclose

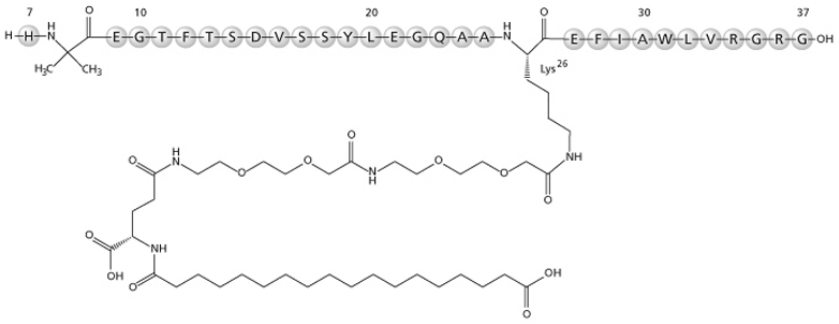
semaglutide. If Defendants had any reasonable basis for asserting that their ANDA Product is not covered by claims 1–2, 4–11, 13, and 15 of the '122 Patent, they were required to provide a full and detailed explanation as to why. Accordingly, on information and belief, Defendants' ANDA Product is covered by claims 1–2, 4–11, 13, and 15 of the '122 Patent, and Defendants have therefore infringed claims 1–2, 4–11, 13, and 15 of the '122 Patent.

126. The Detailed Statement does not allege that the '122 Patent is unenforceable.

127. The WEGOVY® Label states that the active ingredient in WEGOVY® is semaglutide and that WEGOVY® contains inactive ingredients.

128. The WEGOVY® Label states that the structure of semaglutide is:

Figure 1. Structural Formula of semaglutide



129. WEGOVY® is covered by claims 1–2, 4–11, and 13 of the '122 Patent.

130. The WEGOVY® Label instructs physicians that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of []:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)."

131. The use of WEGOVY® is covered by claim 15 of the '122 Patent.

132. Thus, WEGOVY® and any corresponding generic semaglutide injection are covered by claims 1–2, 4–11, 13, and 15 of the ’122 Patent.

133. The ’122 Patent is listed in the Orange Book for WEGOVY®.

134. On information and belief, Defendants’ ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Defendants’ ANDA Product is identical to that in WEGOVY®.

135. On information and belief, if Defendants’ ANDA is approved, Defendants will make, use, offer for sale, sell, or import Defendants’ ANDA Product in a manner that would infringe claims 1–2, 4–11, 13, and 15 of the ’122 Patent.

136. On information and belief, Defendants’ ANDA essentially copies the WEGOVY® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(8)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients infringe claim 15 of the ’122 Patent.

137. On information and belief, if Defendants’ ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Defendants’ ANDA Product and thereby infringe claims 1–2, 4–11, 13, and 15 of the ’122 Patent.

138. WEGOVY® and any corresponding generic semaglutide injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe claims 1–2, 4–11, 13, and 15 of the ’122 Patent. On information and belief, Defendants’ ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claims 1–2, 4–11, 13, and 15 of the ’122 Patent.

139. Defendants have infringed claims 1–2, 4–11, 13, and 15 of the ’122 Patent under 35 U.S.C. § 271(e)(2)(A) by their submission of Defendants’ ANDA to FDA seeking to obtain approval for Defendants’ ANDA Product, which is covered by claims 1–2, 4–11, 13, and 15 of the ’122 Patent, before the expiration of the ’122 Patent.

140. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendants’ ANDA would directly infringe claims 1–2, 4–11, and 13 of the ’122 Patent under 35 U.S.C. §§ 271(a) and/or (f).

141. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendants’ ANDA would infringe directly or contribute to or induce infringement of claims 1–2, 4–11, 13, and 15 of the ’122 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

142. Novo Nordisk seeks an order requiring that Defendants amend its Paragraph IV Certification in Defendants’ ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

143. Novo Nordisk seeks an order declaring that Defendants have infringed claims 1–2, 4–11, 13, and 15 of the ’122 Patent by submitting Defendants’ ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

144. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of Defendants’ ANDA be a date that is not earlier than the expiration of the ’122 Patent or any later expiration of extensions, adjustments, and exclusivities for the ’122 Patent to which Novo Nordisk becomes entitled.

145. Novo Nordisk seeks an order declaring that Defendants will infringe claims 1–2, 4–11, 13, and 15 of the ’122 Patent by commercially manufacturing, using, offering to sell, selling,

distributing, or importing Defendants' ANDA Product before the expiration of the '122 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

146. Novo Nordisk will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to the infringement of claims 1–2, 4–11, 13, and 15 of the '122 Patent. Pursuant to 35 U.S.C. § 283, Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

147. On information and belief, Defendants' Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '122 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

148. To the extent Defendants commercialize Defendants' ANDA Product prior to the expiration of the '122 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284.

COUNT III
(INFRINGEMENT OF THE '003 PATENT)

149. The allegations above are incorporated herein by reference.

150. Defendants submitted Defendants' ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '003 Patent, and any extensions thereof.

151. The Notice Letter states that Defendants' ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '003 Patent. The Notice Letter represents that Defendants' ANDA was submitted with a Paragraph IV Certification that "no valid claim of the ['003 Patent] will be infringed, prior to the

expiration of the patent," by the commercial manufacture, use, or sale of Defendants' ANDA Product, and/or that the '003 Patent is invalid and/or unenforceable.

152. Defendants have actual knowledge of the '003 Patent.

153. Defendants were required to include in their Detailed Statement for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See*, 21 CFR § 314.95(c)(7).

154. The Detailed Statement does not provide any separate factual bases for stating that the '003 Patent will not be infringed by Defendants' ANDA Product apart from arguing that the '003 Patent is invalid. If Defendants had any reasonable basis for asserting that their ANDA Product is not covered by the claims of the '003 Patent, they were required to provide a full and detailed explanation as to why. Accordingly, on information and belief, Defendants' ANDA Product is covered by at least claim 1 of the '003 Patent, and Defendants have therefore infringed the '003 Patent

155. The Detailed Statement does not allege that the '003 Patent is unenforceable.

156. The WEGOVY® Label instructs physicians that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of []:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)".

The label further instructs to administer WEGOVY® once weekly.

157. The WEGOVY® Label provides limitations of use, instructing that WEGOVY® should not be used in combination with other semaglutide-containing products or any other GLP-1 receptor agonist.

158. The WEGOVY® Label states that the active ingredient in WEGOVY® is semaglutide.

159. The WEGOVY® Label instructs to administer WEGOVY® once weekly according to a dose escalation schedule that includes an initiating dosage at 0.25 mg of semaglutide for four weeks, 0.5 mg for the next four weeks, and 1 mg for the next four weeks after that.

160. The use of WEGOVY® is claimed in at least claim 1 of the ’003 Patent.

161. Thus, WEGOVY® and any corresponding generic semaglutide injection are covered by at least claim 1 of the ’003 Patent.

162. The ’003 Patent is listed in the Orange Book for WEGOVY®.

163. On information and belief, Defendants’ ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Defendants’ ANDA Product is identical to that in WEGOVY®.

164. On information and belief, if Defendants’ ANDA is approved, Defendants will make, use, offer for sale, sell, or import Defendants’ ANDA Product in a manner that would infringe at least claim 1 of the ’003 Patent.

165. On information and belief, Defendants’ ANDA essentially copies the WEGOVY® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(8)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients infringe at least claim 1 of the ’003 Patent.

166. On information and belief, if Defendants’ ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Defendants’ ANDA Product and thereby infringe at least claim 1 of the ’003 Patent.

167. WEGOVY® and any corresponding generic semaglutide injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe at least claim 1 of the '003 Patent. On information and belief, Defendants' ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 1 of the '003 Patent.

168. Defendants have infringed at least claim 1 of the '003 Patent under 35 U.S.C. § 271(e)(2)(A) by their submission of Defendants' ANDA to FDA seeking to obtain approval for Defendants' ANDA Product, which is covered by at least claim 1 of the '003 Patent, before the expiration of the '003 Patent.

169. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendants' ANDA would infringe directly or contribute to or induce infringement of at least claim 1 of the '003 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

170. Novo Nordisk seeks an order requiring that Defendants amend its Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

171. Novo Nordisk seeks an order declaring that Defendants have infringed at least claim 1 of the '003 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

172. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of Defendants' ANDA be a date that is not earlier than the expiration of the '003 Patent or any later expiration of extensions, adjustments, and exclusivities for the '003 Patent to which Novo Nordisk becomes entitled.

173. Novo Nordisk seeks an order declaring that Defendants will infringe at least claim 1 of the '003 Patent by commercially manufacturing, using, offering to sell, selling, distributing,

or importing Defendants' ANDA Product before the expiration of the '003 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

174. Novo Nordisk will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to the infringement of at least claim 1 of the '003 Patent. Pursuant to 35 U.S.C. § 283, Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

175. On information and belief, Defendants' Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '003 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

176. To the extent Defendants commercialize Defendants' ANDA Product prior to the expiration of the '003 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284.

COUNT IV
(INFRINGEMENT OF THE '605 PATENT)

177. The allegations above are incorporated herein by reference.

178. Defendants submitted Defendants' ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '605 Patent, and any extensions thereof.

179. The Notice Letter states that Defendants' ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '605 Patent. The Notice Letter represents that Defendants' ANDA was submitted with a Paragraph IV Certification that "no valid claim of the ['605 Patent] will be infringed, prior to the expiration

of the patent," by the commercial manufacture, use, or sale of Defendants' ANDA Product, and/or that the '605 Patent is invalid and/or unenforceable.

180. Defendants have actual knowledge of the '605 Patent.

181. Defendants were required to include in their Detailed Statement for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See*, 21 CFR § 314.95(c)(7).

182. The Detailed Statement does not provide any separate factual bases for stating that the '605 Patent will not be infringed by Defendants' ANDA Product apart from arguing that the '605 Patent is invalid. If Defendants had any reasonable basis for asserting that their ANDA Product is not covered by the claims of the '605 Patent, they were required to provide a full and detailed explanation as to why. Accordingly, on information and belief, Defendants' ANDA Product is covered by at least claim 1 of the '605 Patent, and Defendants have therefore infringed the '605 Patent.

183. The Detailed Statement does not allege that the '605 Patent is unenforceable.

184. The WEGOVY® Label states that each 0.5 mL single-dose pen (i.e., prefilled syringe with needle) contains a solution of WEGOVY® containing 0.25 mg, 0.5 mg or 1 mg of semaglutide; and each 0.75 mL single-dose pen contains a solution of WEGOVY® containing 1.7 or 2.4 mg semaglutide.

185. The WEGOVY® Label lists the inactive ingredients in each 1 mL of WEGOVY®, namely 1.42 mg disodium phosphate dihydrate (also known as disodium hydrogen phosphate dihydrate), 8.25 mg sodium chloride, and water for injection. The WEGOVY® Label states that WEGOVY® has a pH of approximately 7.4 and that hydrochloric acid or sodium hydroxide may be added to adjust pH.

186. The WEGOVY® Label states WEGOVY® should be administered subcutaneously.

187. The WEGOVY® formulation is covered by at least claim 1 of the '605 Patent.

188. The WEGOVY® Label instructs physicians that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of []:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)".

189. The use of WEGOVY® is claimed, among others, in at least claim 14 of the '605 Patent.

190. Thus, WEGOVY® and any corresponding generic semaglutide injection are covered by at least claims 1 and 14 of the '605 Patent.

191. The '605 Patent is listed in the Orange Book for WEGOVY®.

192. On information and belief, Defendants' ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Defendants' ANDA Product is identical to that in WEGOVY®.

193. On information and belief, if Defendants' ANDA is approved, Defendants will make, use, offer for sale, sell, or import Defendants' ANDA Product in a manner that would infringe at least claims 1 and 14 of the '605 Patent.

194. On information and belief, Defendants' ANDA essentially copies the WEGOVY® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(8)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients infringe at least claims 1 and 14 of the '605 Patent.

195. On information and belief, if Defendants' ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Defendants' ANDA Product and thereby infringe at least claims 1 and 14 of the '605 Patent.

196. WEGOVY® and any corresponding generic semaglutide injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1 and 14 of the '605 Patent. On information and belief, Defendants' ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 1 and 14 of the '605 Patent.

197. Defendants have infringed at least claims 1 and 14 of the '605 Patent under 35 U.S.C. § 271(e)(2)(A) by their submission of Defendants' ANDA to FDA seeking to obtain approval for Defendants' ANDA Product, which is covered by at least claims 1 and 14 of the '605 Patent, before the expiration of the '605 Patent.

198. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendants' ANDA would directly infringe at least claim 1 of the '605 Patent under 35 U.S.C. §§ 271(a) and/or (f).

199. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendants' ANDA would infringe directly or contribute to or induce infringement of at least claims 1 and 14 of the '605 Patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (f).

200. Novo Nordisk seeks an order requiring that Defendants amend its Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

201. Novo Nordisk seeks an order declaring that Defendants have infringed at least claims 1 and 14 of the '605 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

202. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of Defendants' ANDA be a date that is not earlier than the expiration of the '605 Patent or any later expiration of extensions, adjustments, and exclusivities for the '605 Patent to which Novo Nordisk becomes entitled.

203. Novo Nordisk seeks an order declaring that Defendants will infringe at least claims 1 and 14 of the '605 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Defendants' ANDA Product before the expiration of the '605 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

204. Novo Nordisk will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to the infringement of at least claims 1 and 14 of the '605 Patent. Pursuant to 35 U.S.C. § 283, Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

205. On information and belief, Defendants' Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '605 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

206. To the extent Defendants commercialize Defendants' ANDA Product prior to the expiration of the '605 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284.

COUNT V
(INFRINGEMENT OF THE '191 PATENT)

207. The allegations above are incorporated herein by reference.

208. Defendants submitted Defendants' ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '191 Patent, and any extensions thereof.

209. The Notice Letter states that Defendants' ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Defendants' ANDA Product before the expiration of the '191 Patent. The Notice Letter represents that Defendants' ANDA was submitted with a Paragraph IV Certification that "no valid claim of the ['191 Patent] will be infringed, prior to the expiration of the patent," by the commercial manufacture, use, or sale of Defendants' ANDA Product, and/or that the '191 Patent is invalid and/or unenforceable.

210. Defendants have actual knowledge of the '191 Patent.

211. Defendants were required to include in their Detailed Statement for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See*, 21 CFR § 314.95(c)(7).

212. The Detailed Statement does not provide any separate factual bases for stating that the '191 Patent will not be infringed by Defendants' ANDA Product apart from arguing that the '191 Patent is invalid. If Defendants had any reasonable basis for asserting that their ANDA Product is not covered by the claims of the '191 Patent, they were required to provide a full and detailed explanation as to why. Accordingly, on information and belief, Defendants' ANDA Product is covered by at least claim 1 of the '191 Patent, and Defendants have therefore infringed the '191 Patent.

213. The Detailed Statement does not allege that the '191 Patent is unenforceable.

214. The WEGOVY® Label states that each 0.5 mL single-dose pen (i.e., prefilled syringe with needle) contains a solution of WEGOVY® containing 0.25 mg, 0.5 mg or 1 mg of semaglutide; and each 0.75 mL single-dose pen contains a solution of WEGOVY® containing 1.7 or 2.4 mg semaglutide.

215. The WEGOVY® Label lists the inactive ingredients in each 1 mL of WEGOVY®, namely 1.42 mg disodium phosphate dihydrate (also known as disodium hydrogen phosphate dihydrate), 8.25 mg sodium chloride, and water for injection. The WEGOVY® Label states that WEGOVY® has a pH of approximately 7.4 and that hydrochloric acid or sodium hydroxide may be added to adjust pH.

216. The WEGOVY® formulation is claimed in at least claim 1 of the '191 Patent.

217. The WEGOVY® Label instructs physicians that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of []:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)".

218. The use of WEGOVY® is claimed, among others, in at least claim 15 of the '191 Patent.

219. Thus, WEGOVY® and any corresponding generic semaglutide injection and their uses are covered by at least claims 1 and 15 of the '191 Patent.

220. The '191 Patent is listed in the Orange Book for WEGOVY®.

221. On information and belief, Defendants' ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii),

314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Defendants' ANDA Product is identical to that in WEGOVY®.

222. On information and belief, if Defendants' ANDA is approved, Defendants will make, use, offer for sale, sell, or import Defendants' ANDA Product in a manner that would infringe at least claims 1 and 15 of the '191 Patent.

223. On information and belief, Defendants' ANDA essentially copies the WEGOVY® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(8)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients infringe at least claims 1 and 15 of the '191 Patent.

224. On information and belief, if Defendants' ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Defendants' ANDA Product and thereby infringe at least claims 1 and 15 of the '191 Patent.

225. WEGOVY® and any corresponding generic semaglutide injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1 and 15 of the '191 Patent. On information and belief, Defendants' ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 1 and 15 of the '191 Patent.

226. Defendants have infringed at least claims 1 and 15 of the '191 Patent under 35 U.S.C. § 271(e)(2)(A) by their submission of Defendants' ANDA to FDA seeking to obtain approval for Defendants' ANDA Product, which is covered by at least claims 1 and 15 of the '191 Patent, before the expiration of the '191 Patent.

227. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendants' ANDA would directly infringe at least claim 1 of the '191 Patent under 35 U.S.C. §§ 271(a) and/or (f).

228. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendants' ANDA would infringe directly or contribute to or induce infringement of at least claims 1 and 15 of the '191 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

229. Novo Nordisk seeks an order requiring that Defendants amend its Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

230. Novo Nordisk seeks an order declaring that Defendants have infringed at least claims 1 and 15 of the '191 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

231. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of Defendants' ANDA be a date that is not earlier than the expiration of the '191 Patent or any later expiration of extensions, adjustments, and exclusivities for the '191 Patent to which Novo Nordisk becomes entitled.

232. Novo Nordisk seeks an order declaring that Defendants will infringe at least claims 1 and 15 of the '191 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Defendants' ANDA Product before the expiration of the '191 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

233. Novo Nordisk will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to the infringement of at least claims 1 and 15 of the

'191 Patent. Pursuant to 35 U.S.C. § 283, Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

234. On information and belief, Defendants' Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '191 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

235. To the extent Defendants commercialize Defendants' ANDA Product prior to the expiration of the '191 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against Defendant and grant the following relief:

A. an adjudication that Defendants have infringed one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A), by submitting to FDA Defendants' ANDA, including any amendments or supplements thereof, to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Defendants' ANDA Product before the expiration of the Asserted Patents, or any later period of exclusivity to which Plaintiffs are or may become entitled;

B. a judgment declaring that Defendants will infringe directly, contribute to the direct infringement of, and/or induce the direct infringement of one or more claims of each of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), (c) and/or (f) if they market, manufacture, use, offer for sale, sell, distribute in, or import into the United States Defendants' ANDA Product before the expiration of the Asserted Patents, or any later period of exclusivity to which Plaintiffs are or may become entitled;

C. an order requiring that Defendants amend their Paragraph IV certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

D. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Defendants' ANDA for Defendants' ANDA Product be a date that is not earlier than the latest date of the expiration of the Asserted Patents or any later period of exclusivity to which Plaintiffs are or may become entitled;

E. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the Asserted Patents or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in Defendants' ANDA;

F. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the Asserted Patents, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of Defendants' ANDA Product;

G. an assessment of pre-judgment and post-judgment interest and costs against Defendants, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

H. an award to Plaintiffs of their attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

I. such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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