IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVO NORDISK INC. and NOVO NORDISK A/S,

Plaintiffs,

v.

VIATRIS INC. and MYLAN PHARMACEUTICALS INC.,

Defendants.

Civil Action No. **1:23-CV-13 (Kleeh)**

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 West Virginia 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 3711 Collins Ferry Road, Morgantown, West Virginia 26505. 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 West Virginia 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 West Virginia 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

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