

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

ELECTRONICALLY
FILED
Mar 18 2022
U.S. DISTRICT COURT
Northern District of WV

NOVO NORDISK INC. and NOVO)	
NORDISK A/S,)	
)	
Plaintiffs,)	
)	
v.)	
)	C.A. No. <u>1:22-cv-23 (Keeley)</u>
MYLAN PHARMACEUTICALS INC.,)	
)	
Defendant.)	
)	
)	

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, “Novo Nordisk”), by their undersigned attorneys, for their Complaint against Defendant Mylan Pharmaceuticals Inc. (“Mylan”), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Mylan’s submission of an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”), by which Mylan seeks approval to market a generic version of Novo Nordisk’s pharmaceutical product Ozempic® prior to the expiration of United States Patent Nos. 8,114,833 (the “833 patent”), 8,129,343 (the “343 patent”), 8,536,122 (the “122 patent”), 8,684,969 (the “969 patent”), 8,920,383 (the “383 patent”), 9,108,002 (the “002 patent”), 9,132,239 (the “239 patent”), 9,457,154 (the “154 patent”), 9,616,180 (the “180 patent”), 9,687,611 (the “611 patent”), 9,775,953 (the “953 patent”), 9,861,757 (the “757 patent”), 10,220,155 (the “155 patent”), 10,335,462 (the “462 patent”), 10,357,616 (the “616 patent”), 10,376,652 (the “652 patent”),

11,097,063 (the “’063 patent”), and RE46,363 (the “’363 patent”) which cover *inter alia*, Ozempic® and/or its use.

THE PARTIES

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

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

4. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of West Virginia and throughout the United States.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over Defendant Mylan Pharmaceuticals Inc. by virtue of, *inter alia*, its presence in West Virginia, being a West Virginia corporation; and having engaged in systematic and continuous contacts with the State of West Virginia; previously consenting to personal jurisdiction in this Court; and having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see e.g., Merck Sharp & Dohme BV v. Mylan Pharmaceuticals Inc.*, C.A. No. 20-00061 (N.D. W.

Va. Apr. 2, 2020); *Celgene Corp. v. Mylan Pharmaceuticals Inc.*, C.A. No. 20-00003 (N.D. W. Va. Jan. 3, 2020)).

7. On information and belief, Mylan intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product, directly or indirectly, throughout the United States and in this District. Mylan's filing of Mylan's ANDA confirms this intention and further subjects Mylan to the specific personal jurisdiction of this Court.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

9. On February 14, 2012, the United States Patent and Trademark Office issued the '833 patent, entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and for Use in Injection Devices," a copy of which is attached to this Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the '833 patent.

10. On March 6, 2012, the United States Patent and Trademark Office issued the '343 patent, entitled "Acylated GLP-1 Compounds," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '343 patent.

11. On September 17, 2013, the United States Patent and Trademark Office issued the '122 patent, entitled "Acylated GLP-1 Compounds," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '122 patent.

12. On April 1, 2014, the United States Patent and Trademark Office issued the '969 patent, entitled "Injection Device with Torsion Spring and Rotatable Display," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '969 patent.

13. On December 30, 2014, the United States Patent and Trademark Office issued the '383 patent, entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '383 patent.

14. On August 18, 2015, the United States Patent and Trademark Office issued the '002 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '002 patent.

15. On September 15, 2015, the United States Patent and Trademark Office issued the '239 patent, entitled "Dial-Down Mechanism for Wind-Up Pen," a copy of which is attached to this Complaint as Exhibit G. NNAS is the owner of all right, title, and interest in the '239 patent.

16. On October 4, 2016, the United States Patent and Trademark Office issued the '154 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is attached to this Complaint as Exhibit H. NNAS is the owner of all right, title, and interest in the '154 patent.

17. On April 11, 2017, the United States Patent and Trademark Office issued the '180 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit I. NNAS is the owner of all right, title, and interest in the '180 patent.

18. On June 27, 2017, the United States Patent and Trademark Office issued the '611 patent, entitled "Injection Device with Torsion Spring and Rotatable Display," a copy of which is attached to this Complaint as Exhibit J. NNAS is the owner of all right, title, and interest in the '611 patent.

19. On October 3, 2017, the United States Patent and Trademark Office issued the '953 patent, entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," a copy of which is attached to this Complaint as Exhibit K. NNAS is the owner of all right, title, and interest in the '953 patent.

20. On January 9, 2018, the United States Patent and Trademark Office issued the '757 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is attached to this Complaint as Exhibit L. NNAS is the owner of all right, title, and interest in the '757 patent.

21. On March 5, 2019, the United States Patent and Trademark Office issued the '155 patent, entitled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism," a copy of which is attached to this Complaint as Exhibit M. NNAS is the owner of all right, title, and interest in the '155 patent.

22. On July 2, 2019, the United States Patent and Trademark Office issued the '462 patent, entitled "Use of Long-Acting GLP-1 Peptides," a copy of which is attached to this Complaint as Exhibit N. NNAS is the owner of all right, title, and interest in the '462 patent.

23. On July 23, 2019, the United States Patent and Trademark Office issued the '616 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is attached to this Complaint as Exhibit O. NNAS is the owner of all right, title, and interest in the '616 patent.

24. On August 13, 2019, the United States Patent and Trademark Office issued the '652 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit P. NNAS is the owner of all right, title, and interest in the '652 patent.

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