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

MERCK SHARP & DOHME CORP., *Plaintiff*, v. MYLAN PHARMACEUTICALS INC., *Defendant*.	C.A. No. 1:19-cv-00101 (IMK)

STIPULATIONS OF FACT

Pursuant to the Court's Scheduling Order dated August 30, 2021, and for the purpose of this case only (which shall not be used for any other proceeding, including any appeal concerning IPR2020-00040 and/or before the PTAB),[1] the parties stipulate to the following facts, which require no proof at trial:

I. PARTIES

1. Plaintiff Merck Sharp & Dohme Corp. ("Merck") is a corporation organized and existing under the laws of the State of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a corporation organized and existing under the laws of the State of West Virginia, having its corporate offices and a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

[1] Neither party will use nor refer to any stipulated fact(s) herein before the PTAB or the Federal Circuit in connection with IPR2020-00040 or any appeal of IPR2020-00040. Both sides may refer to this document in any appeal from this Action.

II. MERCK'S PRODUCTS

3. Merck is the holder of New Drug Application ("NDA") No. 21995 for JANUVIA®, which has been approved by the U.S. Food and Drug Administration ("FDA").

4. Merck is the holder of NDA No. 22044 for JANUMET®, which has been approved by the FDA.

5. JANUVIA® and JANUMET® are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

6. Sitagliptin is an orally active inhibitor of the dipeptidyl peptidase (DPP-4) enzyme.

7. JANUVIA® and JANUMET® contain as an active pharmaceutical ingredient the (R)-enantiomer of 1:1 sitagliptin phosphate monohydrate, which is known chemically as 7-[(3R)-3-amino-1-oxo-4-(2,4,5-trifluorophenyl)butyl]-5,6,7,8-tetrahydro-3-(trifluoromethyl)-1,2,4-triazolo[4,3-a]pyrazine phosphate (1:1) monohydrate.

III. PATENTS-IN-SUIT

A. The '708 Patent

8. U.S. Patent No. 7,3626,708 ("the '708 patent") was issued by the U.S. Patent & Trademark Office on February 5, 2008.

9. The title of the '708 patent is "PHOSPHORIC ACID SALT OF A DIPEPTIDYL PEPTIDASE-IV INHIBITOR."

10. The '708 patent lists Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr. as the inventors.

11. The '708 patent issued from U.S. Patent Application No. 10/874,992, which was filed on June 23, 2004.

12. The '708 patent claims priority and/or benefit to U.S. Provisional Application No. 60/482,161, which was filed on June 24, 2003.

13. Merck is the owner and assignee of the '708 patent.

14. The '708 patent has been listed in connection with JANUVIA® and JANUMET® in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").[2]

15. The Orange Book lists the expiration date of the '708 patent, excluding pediatric exclusivity, as November 24, 2026.

16. The Orange Book lists the expiration date of the '708 patent, inclusive of pediatric exclusivity, as May 24, 2027.

17. At the time of this stipulation, Merck is asserting each of claims 1–7 and 19 of the '708 patent against Mylan.

B. The '921 Patent

18. U.S. Patent No. 8,414,921 ("the '921 patent") was issued by the U.S. Patent & Trademark Office on April 9, 2013.

19. The title of the '921 patent is "PHARMACEUTICAL COMPOSITIONS OF COMBINATIONS OF DIPEPTIDYL PEPTIDASE-4 INHIBITORS WITH METFORMIN."

20. The '921 patent lists Ashkan Kamali, Laman Alani, Kyle A. Fliszar, Soumojeet Ghosh, and Monica Tijerina as the inventors.

[2] Merck is also the holder of NDA No. 202270 for JANUMET® XR, which has been approved by the FDA. The '708 patent has also been listed in connection with JANUMET® XR in the FDA's Orange Book.

21. The ’921 patent issued from U.S. Patent Application No. 12/085,722, which is the national stage entry under 35 U.S.C. § 371 of international application PCT/US2006/047380, filed on May 29, 2008.

22. The ’921 patent claims priority and/or benefit to U.S. Provisional Application No. 60/750,954 filed on December 16, 2005.

23. Merck is the owner and assignee of the ’921 patent.

24. The ’921 patent has been listed in connection with JANUMET® in the FDA’s Orange Book.

25. The Orange Book lists the expiration date of the ’921 patent, excluding pediatric exclusivity, as July 21, 2028.

26. The Orange Book lists the expiration date of the ’921 patent, inclusive of pediatric exclusivity, as January 21, 2029.

27. At the time of this stipulation, Merck is asserting claim 1 of the ’921 patent against Mylan.

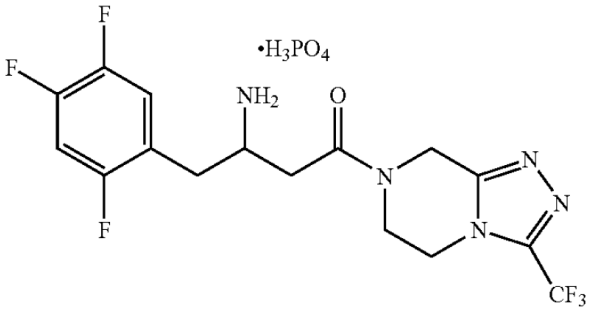
IV. ASSERTED CLAIMS

A. ’708 Patent

28. Claim 1 of the ’708 patent recites the following:

> A dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-l-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I:

(I)

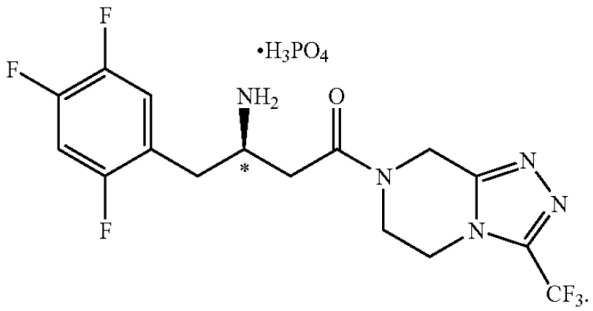


or a hydrate thereof.

29. Claim 2 of the ’708 patent recites the following:

The salt of claim 1 of structural formula II having the (R)-configuration at the chiral center marked with an *

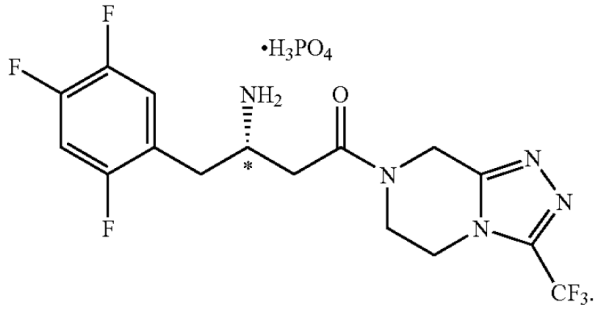
(II)



30. Claim 3 of the ’708 patent recites the following:

The salt of claim 1 of structural formula III having the (S)-configuration at the chiral center marked with an *

(III)



31. Claim 4 of the ’708 patent recites the following:

The salt of claim 2 characterized in being a crystalline monohydrate.

32. Claim 5 of the ’708 patent recites the following:

The salt of claim 4 characterized by characteristic diffraction peaks obtained from the X-ray powder diffraction pattern corresponding to d-spacings of 7.42, 5.48, and 3.96 angstroms.

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