IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., WATSON LABORATORIES, INC., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., and SUN PHARMACEUTICALS INDUSTRIES LTD.[1]
Petitioners,

v.

MERCK SHARP & DOHME CORP.
Patent Owner.

U.S. Patent No. 7,326,708 to Cypes et al.
Issue Date: February 5, 2008
Title: Phosphoric acid salt of a dipeptidyl peptidase-IV inhibitor

Inter Partes Review No.: IPR2020-00040

Reply Declaration of Dr. Mukund Chorghade, Ph.D.

[1] Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc. were joined as a party to this proceeding via Motion for Joinder in IPR2020-01045; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. were joined as a party to this proceeding via a Motion for Joinder in IPR2020-01060; and Sun Pharmaceuticals Industries Ltd. was joined as a party to this proceeding via Motion for Joinder in IPR2020-01072.

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I, Mukund Chorghade, Ph.D., do hereby declare and state as follows:

1. I am the same Mukund Chorghade that provided the Declaration of Mukund Chorghade in connection with this matter. EX1002. I provide this testimony below:

2. My experience and qualifications are provided in EX1002. In addition to my prior qualifications, I have recently been elected Fellow of the Indian Chemical Society and the International Union of Pure and Applied Chemistry.

3. I have been retained on behalf of the Petitioner Mylan Pharmaceuticals Inc. for the above-captioned *inter partes* review ("IPR"). I am being compensated for my time as stated in EX1002. My compensation does not depend in any way on the outcome of this IPR.

I. LIST OF MATERIALS CONSIDERED

4. In formulating my opinions, I have considered the materials referenced in this Declaration.[2]

II. PERSON OF ORDINARY SKILL IN THE ART ("POSA")

[2] My review includes EX2101, EX2103, EX1001, EX1004, EX2192, EX2221, EX2222, EX2223, EX2224, EX2225, EX2226, EX2227, and EX2051 and any other document referenced in this Declaration.

5. The opinions in this Declaration are from the perspective of a POSA as previously defined (and applying the same relevant priority date). EX1002.

6. I have reviewed the POSA definitions of Dr. Matzger (EX2103, ¶¶63-64) and Dr. Myerson (EX2101, ¶¶39-40). My opinions in this Declaration and my Opening Declaration (EX1002) would not change if I applied the definition of a POSA proposed by Dr. Matzger or Dr. Myerson instead of my own.

III. LEGAL STANDARD

7. My understanding of the applicable legal standards is provided in EX1002.

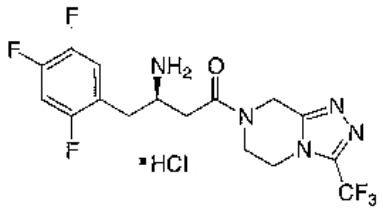
IV. REPLY OPINIONS

8. After reviewing the Matzger and Myerson Declarations, I remain of the opinion that under the prior art process of WO498 (Example 7), the sitagliptin base can *only* be monopronated at the primary amine, which results in formation of the dihydrogen phosphate salt every time. Put simply, all experimental evidence indicates "there is only one possible molecular ratio, a 1:1 ratio, that will be present as a pharmaceutically suitable salt of sitagliptin and phosphoric acid, namely sitagliptin dihydrogen phosphate." EX2225, ¶¶52, ¶24 (4063-19-01 (using 1:5.01)); EX1004, Example 7. As I have explained, as of the priority date, if the excess of highly saturated HCl solution of Example 7 of WO498 only created a 1:1 sitagliptin HCl salt, then phosphoric acid (which is a slightly weaker acid when compared to

HCl) would fare no different. EX2051, 55:3-8, 53:14-18, 145:22-147:5; EX1025, 155:16-20, 150:7-13.

9. The **only** sitagliptin salt exemplified in WO498 is a **1:1** HCl salt (Example 7):

EXAMPLE 7



7-[(3*R*)-3-Amino-4-(2,4,5-trifluorophenyl)butanoyl]-3-(trifluoromethyl)-5,6,7,8-tetrahydro-1,2,4-triazolo[4,3-*a*]pyrazine, hydrochloride

EX1025, 96:22-97:4. Example 7 was done in methanol and at ambient conditions. EX1025, 93:2-94:2; EX1004, 46:23 (cross-referencing Example 1). WO498 includes a list of only eight particularly preferred acids for forming such salts, including explicitly phosphoric acid, to use with basic drug substances like sitagliptin. I agree with Dr. Matzger that looking at Example 7, when replacing phosphoric acid for HCl, a POSA "can imagine that the [1:1 phosphoric acid salt] would exist." EX1025, 146:21-147:5.

10. In connection with this Declaration, I have been asked to comment on certain uncontested and unrebutted experiments described in EX2225, ¶¶24-52 and evaluate whether a POSA would consider any of them reproductions of Example 7

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