

Mylan Exhibit 1029

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

Case No. IPR2020-00040
U.S. Patent No. 7,326,708

SECOND DECLARATION OF ADAM J. MATZGER

I, Adam J. Matzger, declare as follows:

1. I have been informed by counsel for Patent Owner Merck that Petitioner Mylan has made a number of objections to my lab notebooks and the data I generated (EX2228, EX2229, and EX2231), which as I described in my Declaration (EX2103) demonstrate the existence of non-1:1 sitagliptin phosphate salts. I have therefore been asked by counsel to provide certain additional information about those experiments and the data I submitted as a part of my Declaration.

2. EX2228 is a true and accurate copy of one of my lab notebooks. I personally performed the experiments described in EX2228, and I contemporaneously recorded them in that lab notebook as I performed the experiments.

3. EX2229 is a true and accurate copy of another one of my lab notebooks. I personally performed the experiments described in EX2229, and I contemporaneously recorded them in that lab notebook as I performed the experiments.

4. EX2231 is a true, accurate, and complete collection of the data generated in connection with my work on this case. It is a ZIP archive containing various electronic data files, which I have organized by the type of experiment into top-level folders: Elemental Analysis, Optical Microscopy, PXRD, Raman, Single

Crystal, and TGA. Within each of those folders, I have applied a consistent file naming convention. The file names in EX2231 correspond to the file names referenced in my Declaration. File names beginning with “AJM” additionally correspond to particular entries in my lab notebooks, and the file names indicate the particular lab notebook and page number corresponding to the data in the file. For example, Figure 6 in my Declaration is a PXRD pattern of the sitagliptin free base supplied from Merck. The caption to Figure 6 identifies the file name as AJM-III-25.1, and the corresponding files (AJM-III-25_1.ras, AJM-III-25_1_Theta_2-Theta.asc, AJM-III-25_1_Theta_2-Theta.raw) are in the PXRD folder of EX2231. The “III” in “AJM-III-25.1” indicates that the relevant entry is in lab notebook 3 (EX2228); the “25” indicates that the relevant entry is on page 25 of the lab notebook; and the “1” indicates that it is the first piece of data generated on that page.

5. In my Declaration, I described several different experimental techniques that I used to characterize the materials I generated through my salt experiments: (1) X-ray powder diffraction (PXRD or XRPD), (2) single crystal X-ray powder diffraction, (3) thermogravimetric analysis (TGA), (4) Raman spectroscopy, and (5) elemental analysis. I describe each in turn.

6. **X-ray diffraction:** X-ray diffraction is a well-known, routine analytical technique (it is, for example, referred to in the specification of the '708

patent) that is used to identify crystalline forms and determine the crystal structure of a material. It can be performed on both a powder sample (X-ray powder diffraction – PXRD) of a crystalline substance or a single crystal (single crystal X-ray powder diffraction). X-ray diffraction works by irradiating a material with X-rays of a particular wavelength and then measuring the intensities and scattering angles of the X-rays that are diffracted. Because the distances between the atoms in a crystal are of a length similar to the X-ray wavelength, the presence of a crystal structure in the sample will produce an observable pattern. This pattern is unique to the crystal structure and thus can be used to identify the particular crystalline form of a material.

7. I describe the protocol I used for PXRD in paragraph 142 of my declaration. I performed the various PXRD experiments detailed in EX2228 in connection with my work on this case. The data generated in connection with these experiments are in the “PXRD” folder of EX2231.

8. I describe the protocol I used for single crystal X-ray diffraction in paragraph 147 of my declaration. I performed the various single crystal X-ray diffraction experiments detailed in EX2228, including the collection of single crystal data in the Rigaku XtaLAB Synergy-S X-ray diffractometer, which is in my laboratory. Additionally, I directed the collection of single crystal data on an additional piece of equipment, the Rigaku AFC10K Saturn 944+ CCD-based X-ray

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