

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC.,
Patent Owners.

U.S. Patent No. 9,326,945 to Patel *et al.*

Inter Partes Review IPR2018-00892

SECOND SUPPLEMENTAL DECLARATION OF KINAM PARK, PH.D.

MYLAN EXHIBIT 1044

1. I, Kinam Park, Ph.D., have been retained by counsel for Petitioner Mylan Pharmaceuticals Inc. (“Mylan”) and have previously submitted an expert Declaration (Ex. 1002) (“my Original Declaration”) in support of Mylan’s Petition for *inter partes* review (“IPR”) of U.S. Patent No. 9,326,945 to Patel *et al.* (“the ’945 patent”) (Paper No. 2). I understand that the Patent Trial and Appeal Board (“PTAB”) instituted trial in this IPR on October 15, 2018 (Paper No. 24).

2. I further submitted a supplemental expert Declaration (“Supplemental Declaration”) in response to post-institution objections from Patent Owners challenging the authenticity and availability of certain prior art references submitted in Mylan’s Petition and discussed in my Original Declaration. I understand that my Supplemental Declaration was served on Patent Owners in conjunction with other supplemental evidence on November 9, 2018, but has not been filed with the PTAB.

3. I submit this Second Supplemental Declaration in support of Petitioner’s Motion to Correct a Typographical or Clerical Mistake in the Petition Under 37 C.F.R. § 42.104(c) and/or Petitioner’s Motion to File Supplemental Information Pursuant to 37 C.F.R. § 42.123(a).

I. THE CITATION TO THE RUDNIC REFERENCE CONTAINED IN THE PETITION AND MY ORIGINAL DECLARATION CONTAINED AN OBVIOUS TYPOGRAPHICAL ERROR

4. I note that Ex. 1010 as referred in both the Petition and my

Declaration (*see, e.g.*, Ex. 1002, header ii and ¶¶140-143) contained an inadvertent typographical error in its citation. The citation referred to Rudnic as being published in the fourth edition of the textbook *Modern Pharmaceutics* in 2002. This is incorrect. The citation should have instead referred to the third edition of *Modern Pharmaceutics* published in 1996. This inadvertent typographical error resulted from Petitioner being provided with an incorrect citation by a third party which further resulted in the incorrect cover and publishing pages from the fourth edition being placed on the copy of Rudnic supplied to me as Ex. 1010 rather than the correct pages from the third edition.

II. REPLACEMENT OF THE RUDNIC REFERENCE TO CORRECT THE TYPOGRAPHICAL ERROR DOES NOT CHANGE THE SUBSTANCE OF THE RUDIC REFERENCE

5. I have been provided by counsel with the copy of Chapter 10 from the third edition of *Modern Pharmaceutics* obtained from Wisconsin TechSearch (“Rudnic –WTS”) and attached as Ex. 1042. I understand supplemental evidence submitted in response to Patent Owners’ post-institution objections establishes that Rudnic – WTS is an authentic copy of Rudnic from the third edition of *Modern Pharmaceutics*, including the correct cover page. I have reviewed Rudnic - WTS and confirm that Rudnic, submitted as Ex. 1010 to the Petition, is correctly contained therein at the page numbers referenced. In other words, although the citation to Rudnic incorrectly referred to the reference as the fourth edition rather

than the third edition, the page numbers cited throughout my Original Declaration correctly corresponded to cited pages of the third edition. This confirms that the error in Ex. 1010 as originally submitted was purely typographical in nature.

6. I have further reviewed the fourth edition of *Modern Pharmaceutics*, a true and accurate copy of which was attached to my Supplemental Declaration as Ex. 1043, and note the same chapter with substantially the same disclosure, albeit at different page numbers and with different formatting, appears in that textbook as well. For example, as I stated in my Original Declaration, Rudnic teaches that “[f]or many drugs, particularly those for which absorption is limited by the rate of dissolution, attainment of therapeutic levels may depend on achieving a small particle size.” (Ex. 1002, ¶ 141). This identical sentence appears on page 335 of the third edition and on page 289 of the fourth edition (*Compare* Ex. 1042 with Ex. 1043). The only differences between the two sentences are insubstantial and are the uses of “whose” instead of “for which” and “upon” instead of “on.” As further stated in my Original Declaration, Rudnic “lists sodium lauryl sulfate as a lubricant (*e.g.*, antifrictional agent) that is commonly used in tablets and other solid dosage forms” and “further notes that when tablets using sodium lauryl sulfate as a lubricant were compared with those using magnesium stearate as a lubricant, the tablets containing sodium lauryl sulfate exhibited a significantly higher rate of dissolution.” (Ex. 1002, ¶ 142). These identical teachings are

found on pages 354-355 of the third edition and on pages 302-303 of the fourth edition. (*Compare* Ex. 1042 *with* Ex. 1043). Accordingly, a POSA would have readily recognized the error in the citation provided for Ex. 1010 and would have understood that the disclosure of Ex. 1010 originated from the third edition of *Modern Pharmaceuticals* rather than the fourth edition.

7. Moreover, a POSA would also have known that either edition was publicly available well prior to the earliest filing date of the '945 patent. The publication pages of each of the references show that they were published in 1996 and 2002, respectively, by CRC Press and provide an ISBN number. In addition, a POSA, seeking to purchase the third edition online would have noted that vendors selling this text book indicate that the third edition of *Modern Pharmaceuticals* was published in 1996 (*see, e.g.*, Ex. 1042) and the fourth edition was published in 2002 (*see, e.g.*, Ex. 1043). Therefore, a POSA would have known that Rudnic was publicly available as of its respective publication dates in the third and fourth editions.

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