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

DECLARATION OF KAREN L. CARROLL

MYLAN EXHIBIT 1045

I, Karen L. Carroll, hereby declare under penalty of perjury:

1. I am a partner at Parker Poe Adams & Bernstein LLP and back-up counsel for Mylan Pharmaceuticals Inc. ("Mylan" or "Petitioner") in the above-captioned *inter partes* review ("IPR"). I am registered to practice before the United States Patent and Trademark Office ("USPTO") with registration number 50,748. I am a member in good standing of the Bars of the States of Illinois and Georgia. I respectfully submit this 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 Petitioner's Motion to File Supplemental Information Pursuant to 37 C.F.R. § 42.123(a).

2. On December 28, 2016, Mylan filed with the United States Food and Drug Administration ("FDA"), an Abbreviated New Drug Application ("ANDA") for a generic version of apixaban tablets, 2.5 mg and 5 mg, which is marketed by Bristol-Myers Squibb Company as Eliquis®. Pursuant to 21 U.S.C. § 355(b)(2)(a)(4), Mylan filed with its ANDA a certification with respect to each patent listed in the Orange Book for Eliquis®, including U.S. Patent No. 9,326,945 ("the '945 patent"), which is the patent-at-issue in this IPR. As a part of its due diligence for its certification, Mylan's counsel solicited a third party to conduct a prior art search for the '945 patent, the contents of which are protected under at least under the attorney-work product doctrine.

3. As part of that search, the third party provided a chapter – Chapter 10 – from the treatise *Modern Pharmaceutics*, entitled "Tablet Dosage Forms" and authored by E.M. Rudnic and M.K. Kottke. The page numbers of the Chapter 10 provided were pages 333-359. The reference was not provided with a cover page, table of contents, or publication date information; however the third-party search provided the following citation: Rudnic, E.M. and M.K. Kottke, "Tablet Dosage Forms," in *Modern Pharmaceutics*, 4th ed., G.S. Banker and C.T. Rhodes, eds., Taylor & Francis Group, Boca Raton, FL, pp. 333-359 (2002). Thus, the third-party prior art search identified the Rudnic reference as from the fourth edition of *Modern Pharmaceutics* published in 2002. Mylan did not have any basis at that time to doubt either the accuracy of the reference or the corresponding citation provided by the third party prior art search.

4. Pursuant to § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and §§ 314.94 and 314.95 of Title 21 of the Code of Federal Regulations, Mylan provided information to Patent Owners via letter, dated March 2, 2017, regarding the filing of Mylan's ANDA, which included the foregoing citation to the Rudnic reference provided by the third party vendor.

5. In preparing the Petition (Paper No. 2) and the Declaration of Kinam Park, Ph.D. (Ex. 1002) ("the Park Declaration") for this IPR proceeding, Mylan and its counsel similarly relied upon the version of the Rudnic reference and

citation provided by the third party vendor, including providing a copy of said reference to Dr. Park for his review and consideration.

6. When compiling the references for submission for this IPR proceeding, we reviewed the copy of said reference and instructed our paralegal that it lacked a cover page and publication date information. Accordingly, in reliance of the citation provided by the third party prior art search, our paralegal contacted the law firm's librarian and requested a cover page and publication date information for the fourth edition of *Modern Pharmaceutics*. This cover page and publication information was attached to Chapter 10 of the Rudnic reference provided by the third party search firm and was submitted with the Petition and the Park Declaration as Ex. 1010.

7. In their Preliminary Response Under 37 C.F.R. § 42.107, Patent Owners challenged Ex. 1010, stating that: "the Table of Contents for the 2002 version of Rudnic does not state that Chapter 10: Tablet Dosage Forms begins on page 333. *Compare* Ex. 2019 at 6 (identifying page 287 as the beginning of Chapter 10: Tablet Dosage Forms), *with* Ex. 1010 at 333 (identifying page 333 as the beginning of Chapter 10: Tablet Dosage Forms)." (Paper No. 18 at pp. 42-43.)

8. As a result of Patent Owners' allegations in their Preliminary Response, Mylan investigated the Rudnic reference and discovered that, because of the reliance on the incorrect citation provided by the third party prior art search, the

incorrect cover page and publication date information was attached to Ex. 1010 and an incorrect citation was provided in the Petition and in the Park Declaration. In particular, Mylan obtained a full copy of the fourth edition of *Modern Pharmaceutics* and confirmed that, although the disclosure was virtually identical, the pagination did not align with the third edition. Accordingly, through further investigation, Mylan determined that the Rudnic reference provided by the third party prior art search and submitted as a part of Ex. 1010 originated from the third edition of *Modern Pharmaceutics*, which published in 1996, and not the fourth edition published in 2002.

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