Filed on behalf of Patent Owners Bristol-Myers Squibb Company and Pfizer Inc.

By: Heather M. Petruzzi, Reg. No. 71,270 (Lead Counsel)
Timothy A. Cook, Reg. No. 74,073 (Back-up Counsel)
Amy K. Wigmore (*Pro Hac Vice*)
Kevin S. Prussia (*Pro Hac Vice*)
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
Tel: (202) 663-6028
Email: Heather.Petruzzi@wilmerhale.com

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 Owner.

Case IPR2018-00892
Patent 9,326,945 B2

PATENT OWNERS' OBJECTIONS TO EVIDENCE PURSUANT TO 37 C.F.R. § 42.64

Pursuant to 37 C.F.R. § 42.64, Patent Owners hereby object under the Federal Rules of Evidence ("FRE") and 37 C.F.R. § 42.62 to the admissibility of evidence that Petitioner submitted on April 5, 2018 in support of its Petition. Patent Owners' objections apply equally to Petitioner's reliance on these exhibits in any subsequently-filed documents. These objections are timely, having been filed within ten business days of the Institution Decision (October 15, 2018).

Exhibit 1002

Patent Owners object to Exhibit 1002, Declaration of Dr. Park. Patent Owner specifically objects to ¶¶ 36, 39, 41, 43, 44, 45, 49, 52, 53, 54, 113, 120, 136, 146, 160, 163, 165, 166, 167, 169, 173, 175, 178, 190, 224 of Exhibit 1002, and all paragraphs that rely on those paragraphs. These paragraphs lack a disclosed basis of sufficient facts or data (FRE 705; 37 C.F.R. § 42.65), are not based on sufficient facts or data, are not the product of reliable principles and methods, and/or are not a reliable application of the principles and methods to the facts (FRE 702, 703). The paragraphs also do not have a probative value that is substantially outweighed by the risk of prejudice to Patent Owners (FRE 703), are misleading and/or confusing (FRE 403), and are irrelevant (FRE 402).

Exhibit 1004

Patent Owners object to Exhibit 1004, what purports to be a copy of Carreiro et al., "Apixaban, an oral direct Factor Xa inhibitor: awaiting the verdict," Expert Opin. Investig. Drugs, 17(12):1937-1945 (2008).

Patent Owners object to this document under Fed. R. Evid. 401, 402, and 403 as lacking relevance and because its probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, or needlessly presenting cumulative evidence. Patent Owners also object to this Exhibit as not properly authenticated under FRE 901 because Petitioner has not presented sufficient evidence that the document is authentic nor that the document is self-authenticating under FRE 902. Patent Owners further object as not being an original document under FRE 1002, an authentic duplicate under FRE 1003, nor a document that falls under any exceptions to the original-document requirement, including those of FRE 1004. Petitioner has not established that the document is a "printed publication" under 35 U.S.C. §102(b) with a copyright date of 2008. 35 U.S.C. § 311(b).

Exhibit 1010

Patent Owners object to Exhibit 1010, what purports to be a copy of Rudnic et al., "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).

Patent Owners object to this document under Fed. R. Evid. 401, 402, and 403 as lacking relevance and because its probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, or needlessly presenting cumulative evidence. Patent Owners also object to this Exhibit as not properly authenticated under FRE 901 because Petitioner has not presented sufficient evidence that the document is authentic nor that the document is self-authenticating under FRE 902. Patent Owners further object as not being an original document under FRE 1002, an authentic duplicate under FRE 1003, nor a document that falls under any exceptions to the original-document requirement, including those of FRE 1004. Petitioner has not established that Rudnic is a "printed publication" under 35 U.S.C. §102(b) that was published in 2002 at least because the Exhibit bears no library stamp, the cover page of the Exhibit does not appear to be a photocopy of a hardcopy textbook, nothing in the Exhibit associates the Rudnic chapter to the specific version of the textbook, and inconsistent markings within the Exhibit suggest that it is a compilation of multiple documents pieced together by Petitioner.

Exhibit 1015

Patent Owners object to Exhibit 1015, what purports to be a copy of Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral

Dosage Forms, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) (Aug. 1997)

Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) (Aug. 1997).

Patent Owners object to this document under Fed. R. Evid. 401, 402, and 403 as lacking relevance and because its probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, or needlessly presenting cumulative evidence. Petitioner has not established that the FDA Dissolution Guidance is a "printed publication" under 35 U.S.C. §102(b) by establishing that it was printed and/or publicly accessible as of a certain date.

Respectfully submitted,

Date: October 29, 2018

By: /Heather M. Petruzzi/
Heather M. Petruzzi
Reg. No. 71,270
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006

Counsel for Patent Owners

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