

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.
Petitioner,

v.

UCB BIOPHARMA SPRL,
Patent Owner.

Case IPR2019-00400
Patent 8,633,194

**PATENT OWNER'S NOTICE OF OBJECTIONS UNDER 37 C.F.R. § 42.64
TO EVIDENCE SUBMITTED IN SUPPORT OF PETITIONER'S REPLY**

Pursuant to 37 C.F.R. § 42.64, Patent Owner UCB Biopharma Sprl (“Patent Owner”) objects to the admissibility of the documents identified below that were submitted by Petitioner Apotex Inc. (“Petitioner”) in support of Petitioner’s Reply to Patent Owner’s Complete Response (Paper 33), dated and served on January 16, 2020. Patent Owner’s objections are based on the Federal Rules of Evidence (“FRE”), relevant case law, and the Rules of the Patent Trial and Appeal Board (“PTAB”). Patent Owner’s objections are stated with particularity below.

A. Exhibit 1031

Patent Owner objects to the admissibility of Exhibit 1031, described as the Compilation from Niazi, Handbook of Pharmaceutical Manufacturing Formulations, 1st Ed., Vols. 1-6, for at least the following reasons:

Patent Owner objects to Petitioner’s Exhibit 1031 under FRE 801-802, and no exception applies.

B. Exhibit 1032

Patent Owner objects to the admissibility of Exhibit 1032, described as Niazi, Handbook of Pharmaceutical Manufacturing Formulations, Compressed Solid Products, Volume 1, for at least the following reasons:

Patent Owner objects to Petitioner’s Exhibit 1032 under FRE 801-802, and no exception applies. Patent Owner objects to Exhibit 1032 under FRE 1002 for being incomplete.

C. Exhibit 1033

Patent Owner objects to the admissibility of Exhibit 1033, described as Niazi, Handbook of Pharmaceutical Manufacturing Formulations, Compressed Solid Products, Volume 2, for at least the following reasons:

Patent Owner objects to Petitioner's Exhibit 1033 under FRE 801-802, and no exception applies. Patent Owner objects to Exhibit 1033 under FRE 1002 for being incomplete.

D. Exhibit 1034

Patent Owner objects to the admissibility of Exhibit 1034, described as Niazi, Handbook of Pharmaceutical Manufacturing Formulations, Liquid Products, Volume 3 for at least the following reasons:

Patent Owner objects to Petitioner's Exhibit 1034 under FRE 801-802, and no exception applies. Patent Owner objects to Exhibit 1034 under FRE 1002 for being incomplete.

E. Exhibit 1035

Patent Owner objects to the admissibility of Exhibit 1035, described as Niazi, Handbook of Pharmaceutical Manufacturing Formulations, Semisolid Products, Volume 4, for at least the following reasons:

Patent Owner objects to Petitioner's Exhibit 1035 under FRE 801-802, and no exception applies. Patent Owner objects to Exhibit 1035 under FRE 1002 for being

incomplete.

F. Exhibit 1036

Patent Owner objects to the admissibility of Exhibit 1036, described as Niazi, Handbook of Pharmaceutical Manufacturing Formulations, Over-the-Counter Products, Volume 5 for at least the following reasons:

Patent Owner objects to Petitioner's Exhibit 1036 under FRE 801-802, and no exception applies. Patent Owner objects to Exhibit 1036 under FRE 1002 for being incomplete.

G. Exhibit 1037

Patent Owner objects to the admissibility of Exhibit 1037, described as Niazi, Handbook of Pharmaceutical Manufacturing Formulations, Sterile Products, Volume 6, for at least the following reasons:

Patent Owner objects to Petitioner's Exhibit 1037 under FRE 801-802, and no exception applies. Patent Owner objects to Exhibit 1037 under FRE 1002 for being incomplete.

H. Exhibit 1038

Patent Owner objects to the admissibility of Exhibit 1038, described as Copyright Materials for Naizi [sic] Series, for at least the following reasons:

Patent Owner objects to Exhibit 1038 under FRE 401-403 as lacking relevance and causing prejudice at least because Exhibit 1038 is presented solely for

the purposes of establishing the copyright date of Exhibits 1032-37, which are inadmissible as described herein.

I. Exhibit 1040

Patent Owner objects to the admissibility of Exhibit 1040, described as Amazon: Handbook of Pharmaceutical Manufacturing Formulations, Third Edition, for at least the following reasons:

Patent Owner objects to Petitioner's Exhibit 1040 under FRE 801-802, and no exception applies. Patent Owner objects to Exhibit 1038 under FRE 401-403 as lacking relevance and causing prejudice at least because Exhibit 1038 is presented solely for the purposes of establishing certain information pertaining to Exhibits 1032-37 and Exhibit 1041, which are inadmissible as described herein.

J. Exhibit 1041

Patent Owner objects to the admissibility of Exhibit 1041, described as Niazi, Handbook of Pharmaceutical Manufacturing Formulations, Liquid Products, Volume 3, Second Edition, for at least the following reasons:

Patent Owner objects to Petitioner's Exhibit 1041 under FRE 801-802, and no exception applies.

K. Exhibit 1044

Patent Owner objects to the admissibility of Exhibit 1044, described as Official Copyright Certificates of Naizi [sic] Series, for at least the following

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