

Filed on behalf of Breckenridge Pharmaceutical, Inc.,

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BRECKENRIDGE PHARMACEUTICAL, INC.,

Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Patent Owner.

Case IPR2017-01592
Patent No. 8,410,131

**PETITIONER'S OBJECTIONS TO EVIDENCE SUBMITTED BY
NOVARTIS PHARMACEUTICALS CORPORATION WITH THE
PATENT OWNER RESPONSE**

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Breckenridge Pharmaceutical, Inc. ("Breckenridge" or "Petitioner"), hereby submits its objections to certain evidence that Patent Owner Novartis Pharmaceuticals Corp. ("Novartis" or "Patent Owner") submitted in connection with IPR2017-01592. These objections are being filed within five business days of Patent Owner's Response. These objections are being made without prejudice to Breckenridge's ability to use such exhibits or to recall or remove any objections at a later date.

Exhibits 2004-2005, 2006, 2007, 2009-2016, 2023-2025, 2028-2030, 2032, 2034-2040, 2046-2051, 2056-2059, 2061-2063, 2065, 2069, 2071-2077, 2082, 2083, 2085, 2089-2091, 2095-2101

Breckenridge objects to the aforementioned exhibits under FRE 402¹ for lack of relevance, since these exhibits fail to provide any evidence relating to Novartis' positions in this matter. Breckenridge further objects to these exhibits under FRE 403, since any minimal relevance possessed by these exhibits is greatly outweighed by their potential for undue prejudice, confusion, and a waste of judicial resources. For the same reasons Breckenridge objects to these exhibits

¹ As used herein, "FRE" refers to the Federal Rules of Evidence.

under FRE 702 and 703, as well as 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(2) and (b)(5), and 35 U.S.C. § 311(b).²

Breckenridge further objects to the aforementioned exhibits under FRE 802 and 37 C.F.R § 42.61(c) as impermissible hearsay to the extent Novartis is attempting to rely on the substance of any of the documents for the truth of the matter asserted therein.

Exhibits 2001, 2002, 2017-2022, 2024, 2026, 2054, 2081

Breckenridge objects to the aforementioned exhibits under 35 U.S.C. § 312(a)(3) and 37 C.F.R. §§ 42.22(a)(2), 42.24(a), 42.104(b), and 42.105 since these exhibits were not cited in the Patent Owner's Response. Breckenridge objects to any attempt to rely on these documents in any manner, whether in an expert declaration or in subsequent briefing, as untimely and improper incorporation by reference.

Breckenridge further objects to the aforementioned exhibits under FRE 402 for lack of relevance, since these exhibits fail to provide any evidence supporting Novartis' positions in this matter and are therefore irrelevant. Breckenridge further

² As used herein, "CFR" refers to the Code of Federal Regulations.

objects to these exhibits under FRE 403, since any minimal relevance possessed by these exhibits is greatly outweighed by their potential for undue prejudice, confusion, and a waste of judicial resources. For the same reasons Breckenridge objects to these exhibits under FRE 702 and 703, as well as 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(2) and (b)(5), and 35 U.S.C. § 311(b).

Breckenridge further objects to the aforementioned exhibits under FRE 802 and 37 C.F.R § 42.61(c) as impermissible hearsay to the extent Novartis is attempting to rely on the substance of any of the documents for the truth of the matter asserted therein.

Exhibits 2003, 2006, 2017-2021, 2045, 2052-2055, 2064, 2066, 2067, 2068, 2086-2088

Breckenridge objects to the aforementioned exhibits under FRE 402 for lack of relevance, since these exhibits fail to provide any evidence supporting Novartis' claims and defenses in this matter and are therefore irrelevant. Breckenridge further objects to the aforementioned exhibits under FRE 402 as not relevant to any of Novartis' positions in this matter because Novartis has failed to demonstrate that the documents were publicly available prior to the priority date of the patent at issue in this matter.

Breckenridge further objects to these exhibits under FRE 403, since any minimal relevance possessed by these exhibits is greatly outweighed by their potential for undue prejudice, confusion, and a waste of judicial resources. For the same reasons Breckenridge objects to these exhibits under FRE 702 and 703, as well as 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(2) and (b)(5), and 35 U.S.C. § 311(b).

Breckenridge further objects to the aforementioned exhibits under FRE 802 and 37 C.F.R § 42.61(c) as impermissible hearsay to the extent Novartis is attempting to rely on the substance of any of the documents for the truth of the matter asserted therein.

Exhibits 2008, 2020-2021, 2031, 2033, 2041, 2044, 2045, 2054-2055, 2060, 2066, 2067, 2078, 2079, 2084, 2086-2088

Breckenridge objects to the aforementioned exhibits under FRE 901 because Novartis has failed to provide sufficient evidence that these documents are authentic. Novartis has similarly failed to provide sufficient evidence demonstrating that the aforementioned exhibits are self-authenticating under the Federal Rules of Evidence.

Breckenridge further objects to the aforementioned exhibits under FRE 402 for lack of relevance, since these exhibits fail to provide any evidence supporting Novartis' positions in this matter and are therefore irrelevant. Breckenridge further

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