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Filed On Behalf Of:
Novartis Pharmaceuticals Corporation

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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

PATENT OWNER'S OBJECTIONS UNDER 37 C.F.R. § 42.64 TO EVIDENCE SUBMITTED BY BRECKENRIDGE PHARMACEUTICAL, INC. WITH ITS PETITION FOR *INTER PARTES* REVIEW

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Novartis Pharmaceuticals Corporation ("Novartis") objects to the admissibility of the following exhibits filed prior to institution of the trial by Petitioner Breckenridge Pharmaceutical, Inc. ("Breckenridge") on the grounds set forth below.

In this paper, a reference to "F.R.E." means the Federal Rules of Evidence, a reference to "C.F.R." means the Code of Federal Regulations, and "the '131 Patent" means U.S. Patent No. 8,410,131. All objections under F.R.E. 802 (hearsay) and 37 C.F.R § 42.61(c) (hearsay) apply to the extent Breckenridge relies on the exhibits identified in connection with that objection for the truth of the matters asserted therein. Novartis's objections to Breckenridge's exhibits are without prejudice to Novartis's reliance on or discussion of those exhibits in Novartis's papers in this proceeding.

Novartis's objections are as follows:

Exhibits 1001, 1012 – 1014

Novartis objects to Exhibits 1001, and 1012 – 1014 under F.R.E. 802 (hearsay) and 37 C.F.R § 42.61(c) (hearsay).

Novartis objects to Exhibits 1001, and 1012 – 1014 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.104(b)(2) and (b)(5), 35 U.S.C. § 311(b), F.R.E. 702 (improper expert testimony), F.R.E. 703 (bases for expert opinion), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time), as the disclosures of these

documents are not prior art under 35 U.S.C. § 102 nor admissions of the disclosures of the prior art and these documents are not the type of documents upon which a person of ordinary skill in the art at the time of invention would rely.

Novartis further objects to Exhibit 1014 under 37 C.F.R. § 42.104(b)(5) (failure to identify specific portions of evidence).

Exhibits 1002 – 1009, 1016 – 1021, 1026, 1029 – 1039, 1041 – 1057, 1059 – 1069, 1073, 1075 – 1077, 1079 – 1087, 1090, 1091, 1093 – 1101, 1104 – 1106, 1108 – 1111

Novartis objects to Exhibits 1002 – 1009, 1016 – 1021, 1026, 1029 – 1039, 1041 – 1057, 1059 – 1069, 1073, 1075 – 1077, 1079 – 1087, 1090, 1091, 1093 – 1101, 1104 – 1106, and 1108 – 1111 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time).

Novartis objects to Exhibits 1002, 1003, 1018, 1019, 1021, 1026, 1036 - 1039, 1048, 1051, 1052, 1065, 1066, 1067, and 1073 under 37 C.F.R § 42.61(c) (hearsay).

Novartis further objects to Exhibits 1002 – 1005, 1008, 1009, 1017, 1020, 1045 – 1049, 1053, 1054 – 1057, 1060, 1063, 1065, 1069, 1075, 1090, and 1091 under F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time), F.R.E. 702 (improper expert testimony), and F.R.E. 703 (bases for expert opinion) as they are not relevant to any issue in this IPR proceeding, and are not the type of documents

upon which a person of ordinary skill in the art at the time of invention would rely because they relate to the field of immunosuppression and/or transplantation and/or are in a separate field of endeavor and/or are not pertinent to the entire problem solved by the '131 Patent.

Novartis further objects to Exhibits 1005, 1029, 1060, 1069, 1085, and 1086 under F.R.E. 901 (authentication). Breckenridge has not provided sufficient evidence that these exhibits are authentic or that the exhibits are self-authenticating under F.R.E. 902.

Novartis further objects to Exhibits 1018, 1019, 1029 – 1039, 1041 – 1057, 1059 – 1069, 1073, 1075 – 1077, 1079 – 1087, 1090, 1091, 1093 – 1101, 1104 – 1106, and 1108 – 1111 under 37 C.F.R. § 42.104(b)(5) (failure to identify specific portions of evidence).

Novartis further objects to Exhibits 1002, 1005, 1023, 1024, 1029, 1036 – 1039, 1064, 1073, 1093, 1094, 1104 – 1106, and 1108 – 1111 under 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(2) and (b)(5), 35 U.S.C. § 311(b), F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time), F.R.E. 702 (improper expert testimony), and F.R.E. 703 (bases for expert opinion) as these documents were not published until after the February 19, 2001 priority date of the '131 Patent, the October 17, 2001 priority date of the '131 Patent, or the February 18, 2002 application date of the

’131 Patent, and are not the type of documents upon which a person of ordinary skill in the art at the time of invention would rely.

Novartis further objects to Exhibits 1031, 1059, 1061, 1077, and 1095 – 1096 under 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(2) and (b)(5), 35 U.S.C. § 311(b), F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time), F.R.E. 702 (improper expert testimony), and F.R.E. 703 (bases for expert opinion) as these documents are stamped with dates after the February 19, 2001 priority date of the ’131 Patent, the October 17, 2001 priority date of the ’131 Patent, or the February 18, 2002 application date of the ’131 Patent, were not published until after the February 19, 2001 priority date of the ’131 Patent, the October 17, 2001 priority date of the ’131 Patent, or the February 18, 2002 application date of the ’131 Patent, and are not the types of documents upon which a person of ordinary skill in the art at the time of invention would rely.

Novartis further objects to Exhibits 1060, 1069, 1076, 1085, 1086, and 1098 under 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(2) and (b)(5), and 42.105, 35 U.S.C. § 311(b), F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time), F.R.E. 702 (improper expert testimony), and F.R.E. 703 (bases for expert opinion) as Breckenridge has not provided evidence to prove that these documents were published before the February 19, 2001 priority date of the ’131 Patent, the October 17, 2001 priority date of the ’131 Patent, or the February 18, 2002

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