Paper No. ____
Date Filed: August 10, 2017

Filed On Behalf Of:
Novartis AG

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,

Petitioner,

v.

NOVARTIS AG,

Patent Owner.

Case IPR2016-01479
Patent No. 9,006,224

PATENT OWNER'S OBJECTIONS UNDER 37 C.F.R. § 42.64 TO EVIDENCE SUBMITTED BY PAR PHARMACEUTICAL, INC. WITH ITS REPLY

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Novartis AG ("Novartis") objects to the admissibility of the following exhibits filed by Petitioner Par Pharmaceutical, Inc. ("Par") with its Reply (Paper 21) 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 '224 Patent" means U.S. Patent No. 9,006,224. All objections under F.R.E. 802 (hearsay) apply to the extent Par relies on the exhibits identified in connection with that objection for the truth of the matters asserted therein. Novartis's objections to Par'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 1071, 1072, 1073, 1075, 1076, 1077, 1078, 1079, 1081, 1082, 1083, 1085, 1089, 1090, 1091, 1092, 1095, 1096, 1097, 1098, 1100, 1101, 1102, 1104, 1106, 1107, 1108, 1109, 1111, 1112, 1114, 1115, 1116, 1118, 1120, 1121, 1122, 1123, And 1124

Novartis objects to Exhibits 1071, 1072, 1073, 1075, 1076, 1077, 1078, 1079, 1081, 1082, 1083, 1085, 1089, 1090, 1091, 1092, 1095, 1096, 1097, 1098, 1100, 1101, 1102, 1104, 1106, 1107, 1108, 1109, 1111, 1112, 1114, 1115, 1116, 1118, 1120, 1121, 1122, 1123, and 1124 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time).

Novartis also objects to Exhibit 1121 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 of an expert opinion), because it is not relevant to any issue in this IPR proceeding, and is not the type of document upon which a person of ordinary skill in the art at the time of invention would rely. Novartis further objects to Exhibit 1121 under F.R.E. 106 (completeness).

Novartis also objects to Exhibits 1075, 1097, 1100, 1104, and 1108 under F.R.E. 901(authentication). Par has not provided any information that these exhibits are authentic or that the exhibits are self-authenticating under F.R.E. 902.

Novartis also objects to Exhibits 1076, 1077, 1079, 1089, 1095, 1102, 1106, 1107, 1109, 1111, 1114, and 1120 under 37 C.F.R. §§ 42.22(a)(2), 42.23, and 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 exhibits were not published until after the November 21, 2005 priority date of the '224 Patent and these exhibits are not the type of documents upon which a person of ordinary skill in the art at the time of invention would rely.

Novartis also objects to Exhibits 1071 and 1108 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. 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 Par has presented no evidence that these exhibits were published before the November 21, 2005 priority date of the '224 Patent and these exhibits are not the type of documents upon which a person of ordinary skill in the art at the time of invention would rely.

Novartis also objects to Exhibits 1075, 1097, 1100, and 1104 under 37 C.F.R. §§ 42.22(a)(2), 42.23, and 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 are stamped with dates after the November 21, 2005 priority date of the '224 Patent, Par has presented no evidence that these exhibits were publicly available prior to November 21, 2005, and these exhibits are not the type of documents upon which a person of ordinary skill in the art at the time of invention would rely.

Novartis also objects to Exhibits 1066, 1067, 1068, 1069,[1] 1071, 1072, 1073, 1075, 1077, 1078, 1079, 1081, 1082, 1083, 1085, 1089, 1090, 1091, 1092, 1097, 1098, 1100, 1101, 1102, 1104, 1106, 1107, 1108, 1109, 1111, 1112, 1114, 1116, 1118, 1120, 1121, and 1122 under 37 C.F.R. §§ 42.22(a)(2), 42.23, and 42.24(c)(1) as these documents are not cited in the Reply or Par's previously filed Petition, and

[1] Novartis maintains the objections to Exhibits 1066, 1067, 1068, and 1069 that it raised during the July 12, 2017 Deposition of Matthew H. Kulke, M.D.

therefore any attempt by Par to rely on these Exhibits to establish unpatentability (either directly by citing these Exhibits, or indirectly by citing paragraphs of Par's expert declaration that discuss these Exhibits) will constitute an improper incorporation by reference under 37 C.F.R. § 42.6(a)(3).

Novartis also objects to Exhibits 1066, 1067, 1068, 1069, 1071, 1072, 1073, 1075, 1077, 1078, 1079, 1081, 1082, 1083, 1085, 1089, 1090, 1091, 1092, 1097, 1098, 1100, 1101, 1102, 1104, 1106, 1107, 1108, 1109, 1111, 1112, 1114, 1116, 1118, 1120, 1121, and 1122 under 35 U.S.C. § 312(a)(3) and 37 C.F.R. §§ 42.22(a)(2), 42.104(b) and 42.105 as these documents are not cited in the Reply or Par's previously filed Petition, and therefore any attempt by Par to later rely on these Exhibits to establish unpatentability is improper and untimely.

Novartis also objects to Exhibits 1066, 1068, 1071, 1072, 1073, 1075, 1076, 1078, 1079, 1081, 1085, 1089, 1090, 1091, 1092, 1095, 1096, 1097, 1098, 1100, 1101, 1104, 1106, 1111, 1112, 1115, 1116, 1118, 1120, 1121, 1122, 1123, and 1124 as improper and untimely to the extent they are cited in support of Par's *prima facie* case as they should have been included in the evidence served with Par's Petition as required by 35 U.S.C. § 312(a)(3) and 37 C.F.R. §§ 42.22(a)(2), 42.104(b), and 42.105.

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