

Filed On Behalf Of: Novartis AG

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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**PAR PHARMACEUTICAL, INC.,  
BRECKENRIDGE PHARMACEUTICAL, INC., AND  
ROXANE LABORATORIES, INC.**

Petitioners,

v.

**NOVARTIS AG,**  
Patent Owner.

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Case IPR2016-00084<sup>1</sup>  
U.S. Patent 5,665,772

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**PATENT OWNER'S OBJECTIONS UNDER 37 C.F.R. § 42.64 TO  
EVIDENCE SUBMITTED BY PETITIONERS WITH THEIR REPLY**

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<sup>1</sup> Breckenridge Pharmaceutical, Inc. was joined as a party to this proceeding via a Motion for Joinder in IPR2016-01023; Roxane Laboratories, Inc. was joined as a party via a Motion for Joinder in IPR2016-01102.

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Novartis AG (“Novartis”) objects to the admissibility of the following exhibits filed with Petitioners’ Par Pharmaceutical, Inc., Breckenridge Pharmaceutical, Inc., and Roxane Laboratories, Inc. (“Petitioners”) Reply 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 “’772 Patent” means U.S. Patent No. 5,665,772. All objections under F.R.E. 802 (hearsay) apply to the extent Petitioners rely on the exhibits identified in connection with that objection for the truth of the matters asserted therein.

Novartis’s objections are as follows:

**Exhibits 1034, 1036 – 1043, 1047 – 1057, 1062 – 1063, 1065 – 1070, 1074, 1077 – 1083, 1085 – 1086, 1088, 1092 – 1093, 1097 – 1100, 1102 – 1106, 1108 – 1110, 1113, 1117, and 1120 – 1121**

Novartis objects to Exhibits 1034, 1036 – 1043, 1047 – 1057, 1062 – 1063, 1065 – 1070, 1074, 1077 – 1083, 1085 – 1086, 1088, 1092 – 1093, 1097 – 1100, 1102 – 1106, 1108 – 1110, 1113, 1117, and 1120 – 1121 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time).

Novartis further objects to Exhibits 1047 – 1050, 1055 – 1057, 1065 – 1069, 1074, 1077 – 1083, 1085 – 1086, 1088, 1092 – 1093, 1097 – 1100, 1102 – 1106, 1108 – 1110, and 1120 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.104(b)(2) and

(b)(5), and 42.105, as these documents were not published until after the October 9, 1992 priority date of the '772 Patent and these documents 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 1036 – 1043, 1047 – 1057, 1062 – 1063, 1065 – 1070, 1074, 1077 – 1083, 1085 – 1086, 1088, 1092 – 1093, 1097 – 1100, 1102 – 1106, 1108 – 1110, 1113, 1117, and 1120 – 1121 under 37 C.F.R. §§ 42.22(a)(2), 42.23, and 42.24(c)(1) as these documents are not cited in Petitioners' Reply, and therefore any attempt by Petitioners to rely on these Exhibits to establish unpatentability (either directly by citing these Exhibits, or indirectly by citing paragraphs of their expert declarations that discuss these Exhibits) will constitute an improper incorporation by reference under 37 C.F.R. § 42.6(a)(3).

Novartis further objects to Exhibits 1038 – 1040, 1043, 1047, 1049 – 1050, 1055 – 1057, 1062, 1065 – 1066, 1070, 1092, 1104, 1109 – 1110, 1113, and 1121 under 37 C.F.R. §§ 42.104(b)(5) and 42.23 as Petitioners have failed to identify which aspects of the documents are relied upon.

Novartis further objects to Exhibits 1034,<sup>2</sup> 1036, 1037, 1062 – 1063, 1065 – 1070, 1102 – 1106, 1113, 1117, 1120, and 1121 as improper and untimely as they should have been included in the evidence served with Petitioners' Petitions 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.

Novartis further objects to Exhibit 1121 as improperly labeled and produced under 37 C.F.R § 42.63 and F.R.E. 1003 (duplicates), as the copy provided appears to have alterations that do not appear in the original document and certain portions of the document are not legible.

#### **Exhibit 1044, 1046, and 1061**

Novartis objects to Exhibits 1044, 1046, and 1061 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time).

Novartis further objects to Exhibits 1044, 1046 and 1061 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.24(c)(1), 42.104(b)(2) and (b)(5), and 42.105, as these documents were not published until after the October 9, 1992 priority date of the '772 Patent, these documents are not the types of documents upon which a person of ordinary skill in the art at the time of invention would rely, and these documents

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<sup>2</sup> Novartis maintains the objections to Exhibit 1034 that it raised during the November 14, 2016 Deposition of Alexander M. Klibanov.

are not cited in Petitioners' Reply, and therefore any attempt by Petitioners to rely on these Exhibits (either directly by citing these Exhibits, or indirectly by citing paragraphs of their expert declarations that discuss these Exhibits) to establish unpatentability will constitute an improper incorporation by reference under 37 C.F.R. § 42.6(a)(3).

### **Exhibits 1045 and 1091**

Novartis objects to Exhibits 1045 and 1091 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time). Novartis further objects to Exhibits 1045 and 1091 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.24(c)(1), 42.104(b)(2) and (b)(5), and 42.105, as these documents were not published until after the October 9, 1992 priority date of the '772 Patent, these documents are not the types of documents upon which a person of ordinary skill in the art at the time of invention would rely, and these documents are not cited in Petitioners' Reply, and therefore any attempt by Petitioners to rely on these Exhibits to establish unpatentability (either directly by citing these Exhibits, or indirectly by citing paragraphs of their expert declarations that discuss these Exhibits) will constitute an improper incorporation by reference under 37 C.F.R. § 42.6(a)(3).

Novartis further objects to Exhibits 1045 and 1091 under F.R.E. 901 (authentication). No information about the source of Exhibit 1045 has been

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