

**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.,

Petitioner,

v.

NOVARTIS AG,

Patent Owner.

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Case IPR2016-01479

Patent No. 9,006,224

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

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Novartis AG (“Novartis”) objects to the admissibility of the following exhibits filed prior to institution of the trial by Petitioner Par Pharmaceutical Inc. (“Par”) 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 1002, 1004, 1007, 1008, 1010, 1016, 1019, 1020, 1021, 1022, 1024, 1025, 1026, 1030, 1032, 1040, 1050, 1053, 1055, 1060, 1062, 1063, 1064**

Novartis objects to Exhibits 1002, 1004, 1007, 1008, 1010, 1016, 1019, 1020, 1021, 1022, 1024, 1025, 1026, 1030, 1032, 1040, 1050, 1053, 1055, 1060, 1062, 1063, and 1064 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time).

Novartis further objects to Exhibit 1030 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 1060 under F.R.E. 901(authentication). No information about the source of Exhibit 1060 has been provided.

Novartis further objects to Exhibit 1064 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.104(b)(2) and (b)(5), and 42.105, as this document was not published until after the November 21, 2005 priority date of the '224 Patent and this document 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 Exhibits 1002, 1004, 1007, 1008, 1010, 1016, 1019, 1020, 1021, 1022, 1024, 1025, 1026, 1030, 1032, 1040, 1050, 1053, 1055, 1060, 1062, 1063, and 1064 under 37 C.F.R. §§ 42.22(a)(2), 42.23, and 42.24(c)(1) as these documents are not cited in the Petition, and 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 further objects to Exhibits 1002, 1004, 1007, 1008, 1010, 1016, 1019, 1020, 1021, 1022, 1024, 1025, 1026, 1030, 1032, 1040, 1050, 1053, 1055, 1060, 1062, 1063, and 1064 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 Petition, and therefore any attempt by Par to later rely on these Exhibits to establish unpatentability is improper and untimely.

### **Exhibits 1001**

Novartis objects to Exhibit 1001 under F.R.E. 802 (hearsay) and 37 C.F.R. § 42.61(c) (hearsay).

### **Exhibit 1003**

Novartis objects to Exhibit 1003 under F.R.E. 802 (hearsay), F.R.E. 702 (improper expert testimony), F.R.E. 703 (bases for expert opinion), and 37 C.F.R. § 42.65 as Dr. Ratain's scientific, technical, or other specialized knowledge will not help the trier of fact to understand the evidence or to determine a fact in issue, the testimony is not based on sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case. In particular, the challenged claims concern the treatment of pancreatic neuroendocrine tumors (PNETs) (*see, e.g.*, Ex. 1003 ¶¶ 20, 25), and Dr. Ratain admitted that he is not an expert in PNETs. *See* Ex. 2024, Ratain Trial Tr. I at 995.

Novartis objects to Exhibit 1003 under 35 U.S.C. § 312(a)(3), 37 C.F.R. §§ 42.65 and 42.104(b)(5), F.R.E. 702 (improper expert testimony), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time) for failing to identify with

particularity the underlying facts and data on which the opinion is based; Exhibit 1003 ¶¶ 29, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 53, 59, 62, 65, 69, 78, 79, 82, 83, 94, 99, 100, 101, 103, 104, 108, 112, 114, 117, 119, 125, 126, 129, 132, 133, 134, 135, 136, 137, 138, 140, 141, 142, 143, 145, 147, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 162, 163, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, and 177 fail to cite any support at all, include statements that do not cite any support, or include statements that are not supported by the cite(s) provided; and Exhibit 1003 ¶¶ 54, 59, 69, 70, 72, 73, 74, 75, 76, 78, 79, 87, 90, 92, 112, 133, 135, and 139 cite to entire articles, book chapters or other references without identifying which aspects of those references are relied upon.

Novartis also objects to Exhibit 1003 ¶¶ 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27, 28, 29, 30, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 50, 51, 52, 54, 58, 61, 64, 68, 93, 95, 109, 124, 128, 144, 145, 147, 148, 154, 155, 158 and 175 under F.R.E. 402 (relevance) and F.R.E. 403 (confusing, waste of time), as these paragraphs are not cited in Par's Petition.

Novartis also objects to Exhibit 1003 ¶¶ 54, 59, 65, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 95, 96, 97, 98, 99, 100, 101, 102, 104, 106, 107, 108, 110, 111, 112, 113, 114, 115, 116, 117, 119, 120, 121, 122, 123, 125, 126, 127, 129, 130, 131, 132, 133, 134, 135, 136, 137,

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