

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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APOTEX INC. and APOTEX CORP.,

Petitioners,

v.

NOVARTIS AG,

Patent Owner.

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Case IPR2017-00854

U.S. Patent No. 9,187,405

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**PATENT OWNER'S OBJECTIONS UNDER 37 C.F.R. § 42.64(B)(1) TO  
EXHIBITS SUBMITTED IN THE PRE-TRIAL PHASE FOR  
*INTER PARTES* REVIEW OF U.S. PATENT NO. 9,187,405**

Mail Stop Patent Board  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. § 42.64(b)(1), Novartis AG (“Patent Owner”) objects to the admissibility of the below-referenced exhibits submitted by Petitioners Apotex Inc. and Apotex Corp. (“Petitioners”) in their Petition for *Inter Partes* Review of U.S. Patent No. 9,187,405.

Patent Owner’s objections to the admissibility of exhibits submitted with the Petition are made in accordance with the Federal Rules of Evidence (“FRE”). Patent Owner’s objections are also made pursuant to the Code of Federal Regulations (“C.F.R.”) governing this proceeding, including without limitation 37 C.F.R. §§ 42.61-42.65 and § 42.6(a)(3).

Patent Owner notes that Argentum Pharmaceuticals LLC (“Argentum”) has filed an unopposed motion to join this IPR. *Argentum Pharm. LLC v. Novartis A.G.*, Case IPR2017-01550 (Mot. Join June 9, 2017) (Paper 3). Argentum’s exhibits are identical to those filed by Petitioners, except for the addition of one exhibit, Exhibit 1041. As of today, the Board has not yet ruled on the motion for joinder submitted by Argentum. In the event the Board grants the motion for joinder, the objections below apply equally to Argentum and additionally, Patent Owner has included herein its objections to Argentum’s additional exhibit.

## **I. OBJECTIONS TO PETITIONER’S EXHIBITS**

### **A. Exhibit 1002**

Patent Owner objects to the admissibility of Exhibit 1002, particularly those

portions related to references and pieces of art that post-date the filing of the ‘405 patent (e.g. Ex. 1002 ¶¶ 99–100, 144–46, 148), which lack relevance to any issue in this case. FRE 402.

In addition, Patent Owner objects that at least part of Exhibit 1002 is beyond the declarant’s “knowledge, skill, experience, training or education” and “based on insufficient facts or data,” and is therefore improper expert evidence (e.g. *id.* ¶¶ 113, 116–19, 139–40, 148). Exhibit 1002 is also based on legally erroneous claim construction, including without limitation erroneous interpretations of “a subject in need” and recited “A method for . . .” preambles (e.g. *id.* ¶¶43–47). FRE 702, 703.

Furthermore, Patent Owner objects to the admissibility of Exhibit 1002 to the extent it was not cited in the Petition, as uncited evidence may not be incorporated by reference (e.g. *id.* ¶¶ 5–14, 16–18, 22–26, 31–38, 42, 48, 73, 89, 93, 96, 99, 101–103, 130). 37 C.F.R. §42.6(a)(3).

### **B. Exhibit 1003**

Patent Owner objects to the admissibility of Exhibit 1003 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

Patent Owner also objects to the admissibility of Exhibit 1003 because it lacks relevance to any issue in this case. FRE 402.

**C. Exhibit 1004**

Patent Owner objects to the admissibility of Exhibit 1004 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

**D. Exhibit 1005**

Patent Owner objects to the admissibility of Exhibit 1005 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

**E. Exhibit 1006**

Patent Owner objects to the admissibility of Exhibit 1006 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

**F. Exhibit 1007**

Patent Owner objects to the admissibility of Exhibit 1007 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

**G. Exhibit 1008**

Patent Owner objects to the admissibility of Exhibit 1008 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

**H. Exhibit 1009**

Patent Owner objects to the admissibility of Exhibit 1009 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

**I. Exhibit 1010**

Patent Owner objects to the admissibility of Exhibit 1010 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

**J. Exhibit 1011**

Patent Owner objects to the admissibility of Exhibit 1011 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

**K. Exhibit 1012**

Patent Owner objects to the admissibility of Exhibit 1012 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

**L. Exhibit 1013**

Patent Owner objects to the admissibility of Exhibit 1013 because it contains inadmissible hearsay to the extent its contents are offered for the truth of any matter asserted therein. FRE 802.

Patent Owner also objects to the admissibility of Exhibit 1013 because it lacks

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