

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
WOCKHARDT BIO AG,  
TEVA PHARMACEUTICALS USA, INC.,  
AUROBINDO PHARMA U.S.A., INC.,  
Petitioners,

v.

ASTRAZENECA AB,  
Patent Owner.

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Case: IPR2015-01340<sup>1</sup>  
U.S. Patent No. RE44,186

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**ASTRAZENECA'S OBJECTIONS TO  
EVIDENCE PURSUANT TO 37 C.F.R. § 42.6**

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<sup>1</sup> Petitioner Wockhardt from IPR2016-01029, Petitioner Teva from IPR2016-01122, and Petitioner Aurobindo from IPR2016-01117 have been added as Petitioners to this proceeding.

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Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner objects to the admissibility of the following Exhibits filed by Petitioners on November 7, 2016, and any reference or reliance on these Exhibits in Petitioners' Reply, in future filings, or in any future argument before the Board.

These objections are timely filed and served on November 15, 2016, i.e., "within five business days of service," as November 11, 2016 was a federal holiday. *See* 37 C.F.R. §§ 42.2, 42.64(b)(1); 5 U.S.C. § 6103.

Reference to a "Rule" herein means the Federal Rules of Evidence as modified by 37 C.F.R. § 42.62(c).

**I. TRANSCRIPTS AND RELATED EXHIBITS - EX1028 TO EX1031 AND EX1073**

**OBJECTIONS TO EXHIBIT 1028**

Exhibit 1028 is a copy of the trial transcript of the cross-examination of Dr. Lenhard, Patent Owner's expert declarant in this proceeding. Patent Owner objections are already of record in the transcript.

**OBJECTIONS TO EXHIBIT 1029**

Exhibit 1029 is a copy of the trial transcript of the cross-examination of Dr. Meyer, Patent Owner's expert declarant in this proceeding. In addition to the objections already of record in the transcript per 37 C.F.R. § 42.64(a), pursuant to

the parties' stipulation (Paper 35 at ¶ 6), Patent Owner objects to the following portions of Exhibit 1029 for being outside the scope of Dr. Meyer's declaration: 441:2-443:19.

### OBJECTIONS TO EXHIBIT 1073

Exhibit 1073 is a copy of the transcript of the deposition of Dr. Weber, Patent Owner's expert declarant in this proceeding. In addition to the objections already of record in the transcript per 37 C.F.R. § 42.64(a), Patent Owner objects to Exhibit 1073 for lacking a signed certificate. *See* 37 C.F.R. § 42.53(f)(6).

Patent Owner further objects to Exhibit 1073 under Rule 106 (incomplete) and Rule 403 (misleading, confusing, unfair prejudice) to the extent it lacks Dr. Weber's errata sheet. Dr. Weber was unable to complete her review of the transcript prior to submission by Petitioner. Patent Owner understands that Petitioners have been notified by the Board that the errata sheet can be included.

### OBJECTIONS TO EXHIBITS 1030 AND 1031

Exhibits 1030 and 1031 are 2016 printouts from webpages regarding Januvia and Tradjenta, respectively. Patent Owner objects to Exhibits 1030 and 1031 under Rule 402 (lack of relevance) and Rule 403 (misleading, confusing, unfair prejudice, waste of time, needlessly cumulative). These exhibits have no bearing

on the obviousness of the claims of RE 44,186, as each exhibit post-dates the invention and does not relate to RE 44,186 or the products of the claims, Onglyza and Kombiglyze XR. Notably, Petitioners elected not to rely on Exhibits 1030 and 1031 in the Reply brief and, thus, the exhibits have no relevance in this IPR. Any future reliance on these exhibits would be, among other things, unduly prejudicial, misleading, and a waste of the Board's time.

Finally, Patent Owner further objects to Exhibits 1030 and 1031 under Rules 801/802 (hearsay), 805 (hearsay within hearsay), and 901 (lack of authentication). Exhibits 1030 and 1031 cite and report alleged facts that constitute hearsay and, to the extent they are relied on for the truth of those alleged facts, constitute hearsay themselves. Exhibits 1030 and 1031 have not been authenticated by any witness, including Dr. Meyer who was questioned on them, and are not self-authenticating.

## **II. DECLARATIONS AND REPORTS - EX1035, EX1041, EX1060/EX1060A, AND EX1074**

### **OBJECTIONS TO EXHIBIT 1035**

Exhibit 1035 is a reply report of Dr. Hoffman from the copending district court litigation. Patent Owner objects to Exhibit 1035 under Rules 801/802 (hearsay) and 805 (hearsay within hearsay) and 37 C.F.R. § 1.68 (lacking requirements for submission). As Exhibit 1035 is not sworn testimony, it is rank hearsay. Indeed, despite Petitioners' attempt to use Exhibit 1035 during the district court trial, it was not included on the Admitted Trial Exhibit List. Further, as

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