UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., and AKORN INC.¹ Petitioners,

v.

ALLERGAN, INC., Patent Owner.

Case IPR2016-01127 (8,685,930 B2)

Case IPR2016-01128 (8,629,111 B2)

Case IPR2016-01129 (8,642,556 B2)

Case IPR2016-01130 (8,633,162 B2)

Case IPR2016-01131 (8,648,048 B2)

Case IPR2016-01132 (9,248,191 B2)

SAINT REGIS MOHAWK TRIBE'S NOTICE OF OBJECTION TO EVIDENCE



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¹ Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00601., have respectively been joined with the captioned proceedings. The word-for-word identical page is filed in each proceeding identified in the caption pursuant to the Board's Scheduling Order (Paper 10).

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner, the Saint Regis Mohawk Tribe (the "Tribe"), submits the following objections to Exhibits 1144, 1145, 1147, 1149, 1150, and 1152 as listed on each Exhibit List filed by Mylan Pharmaceuticals Inc. ("Mylan") and joined by all other Petitioners. As required by 37 C.F.R. § 42.64(c), the Tribe will identify all objections in order and the bases therefor.

1. Exhibits 1144, 1145, 1146, and 1147.

The Tribe objects that Exhibits 1144, 1145, 1146, and 1147 have no evidentiary value and have been submitted solely to prejudice the Board against the Tribe and its licensee, Allergan, plc. The Exhibits discuss characterizations of the IPR process as unfair and the perception of it as a kangaroo court, which view initiated from former Federal Circuit Chief Judge Randall Rader's characterization of the Board as a patent death squad. The relevance of the Exhibits is nil. The Exhibits are unduly prejudicial and their prejudicial value far outweighs their non-existent probity. *See* FED. R. EVID. 401, 403. The Tribe trusts that the Panel recognizes the cynical purpose for which the Exhibits were offered. It is not the Panel members being referenced, but the system itself described thusly by PTAB Chief Judge James Smith, who told the PTO's Patent Public Advisory Committee on August



14, 2014 that "If we [PTAB] weren't, in part, doing some 'death squadding,' we would not be doing what the statute calls on us to do." EX. 2108.

Exhibits 1144 and 1147 are also hearsay. Petitioners used Exhibit 1144 for a quote from the Tribe's counsel, Michael Shore; they also cited Exhibit 1147 for a similar quotation by Mr. Shore discussing a widely held view of the IPR process. Petitioners' Opposition to Motion to Dismiss at 1; *id.* at n. 2. Mr. Shore is not a party to this proceeding. He made the statements as an individual person with both sovereign and non-sovereign clients affected by the AIA processes, not as "a person whom the party authorized to make a statement on the subject" nor as the Tribe's agent. Therefore, his personal opinions and statements to the press on matters of public policy are not admissible as the statement of a party opponent. FED. R. EVID. 801(d)(2)(C)-(D).

2. Exhibits 1148 and 1150.

The Tribe objects that Exhibit 1148 is irrelevant and therefore inadmissible. FED. R. EVID. 402. It contains no evidentiary value to this proceeding, and it is cumulative of the other articles or news-site interviews—Exhibits 1144, 1146-47, 1150, 1153, 1155, and 1157—with which Petitioners have stuffed the Board's files. FED. R. EVID. 401-403. To the extent it could contain relevant evidence, that



evidence consists solely of unsworn statements offered for their truth and therefore are hearsay. FED. R. EVID. 802. The Board should strike Exhibit 1148.

The same objections apply to Exhibit 1150. Whether two members of a 535-person legislative body dislike the Tribe's transaction with Allergan has no relevance to this proceeding. The Board should strike it.

3. Exhibit 1149.

The Tribe objects to Exhibit 1149 as not relevant and hearsay. Exhibit 1149 is the self-serving statement of various trade groups. It has no relevance to this proceeding, which involves only the Tribe's sovereign immunity and whether that immunity prevents the Board from adjudicating this proceeding. FED. R. EVID. 402. The Exhibit contains only prejudicial material and no probative value. It is also conjectural because it ascribes specific motives to the Tribe but the trade groups have no actual knowledge of the Tribe's state of mind. To the extent it could contain relevant evidence, that evidence consists solely of unsworn statements offered for their truth and therefore are hearsay. FED. R. EVID. 802. The Board should exclude it under FED. R. EVID. 401, 402, 403, and/or 802.

4. Exhibit 1152.

The Tribe objects to Exhibit 1152. This is a "whitepaper" written for the Association for Accessible Medicines ("AAM") by its attorneys. The Board



previously *denied* AAM's request to participate as *amicus curiae* in this matter. To circumvent that ruling, the AAM hired the *same law firm*, Goodwin Procter LLP, that would have filed its amicus brief, had that firm draft a "whitepaper" detailing the AAM's response to the Tribe's exercise of its sovereign rights, and allowed Petitioners to file the whitepaper as an exhibit to work around the Board's denial of amicus status. Such conduct should be sanctioned, not condoned by allowing a "brief" whose filing was denied into the record as an exhibit. The proof is clear: the whitepaper is not only authored by members of the same firm AAM hired to file an amicus brief but also dated *after* the Board's denial of AAM's request to participate as an amicus. The Board prevent Petitioners from subverting the Board's existing rulings, strike Exhibit 1152 and allow the Tribe to file a Motion for Sanctions for its filing.

Exhibit 1152 is cumulative of the information that Mylan, Teva and Akorn will argue in this proceeding, therefore the Board should exclude it under FED. R. EVID. 403. The Exhibit also contains no information that has any tendency to make a fact more or less probable than such fact would be without the evidence and contains no facts that are of consequence in this action and cannot meet the test for relevancy under FED. R. EVID. 401(a)-(b). The Board should strike Exhibit 1152.



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