UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KOIOS PHARMACEUTICALS LLC,
Petitioner

v.

MEDAC GESELLSCHAFT FUER KLINISCHE SPEZIALPRÄPARATE MBH, Patent Owner

Case No. IPR2016-01370 Patent Number 8,664,231

Before JACQUELINE WRIGHT BONILLA, TONI R. SCHEINER, and ERICA A. FRANKLIN, *Administrative Patent Judges*

PATENT OWNER'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE EVIDENCE



Patent Owner medac Gesellschaft für Klinische Spezialpräparate mbH ("Medac") replies to Petitioner's Response to Medac's Motion to Exclude Evidence ("Resp."). 37 C.F.R. §§ 42.23 and 42.64.

I. Exhibits 1041-1046 Should be Excluded

The Board should exclude Exhibits 1041-46. They are irrelevant, inadmissible hearsay, and/or improperly authenticated.

A. Exhibit 1041 Should be Excluded

Exhibit 1041 is an e-mail exchange between counsel. It is far from an "invitation" to take depositions (Resp. at 1). It is a notice that only a single day and a single place was available for each of the possible depositions.

Petitioner's assertion that Exhibit 1041 is not offered as evidence of why Medac "refused" to take depositions (*id.*) contradicts its reliance on the Exhibit to argue that Medac "refused" to depose its experts due to the "quality" of their opinions. Petitioner's Response at 1, 3, 20. And, if Petitioner is not offering Exhibit 1041 for that purpose (as it claims), then it is simply irrelevant. Petitioner's "inference" argument, likewise, does not carry the day. Resp. at 1. There are many reasons for not deposing an expert aside from the alleged "quality" of any opinion. Given Petitioner's misleading statements about Exhibit 1041, and its lack of relevance to any substantive issue, it should be excluded. F.R.E. 402, 403.



B. Exhibit 1042 Should be Excluded

Exhibit 1042 purports to be a UK High Court decision regarding a UK patent. It is not self-authenticating (Resp. at 2). It is a website printout and is not signed or attested to by an authorized person nor accompanied by the required certification. F.R.E. 902(3). Petitioner has also not provided any other authentication. F.R.E. 901(a).

Exhibit 1042 is also irrelevant. Despite any alleged similarity between the claims said to be before the High Court and the claims in this IPR (Resp. at 2), the two proceedings involve different claims, different legal standards and different art. Notwithstanding these critical differences, Petitioner improperly invites the Board to compare the claims of both patents and to infer that the UK decision somehow applies here. *Id.* Petitioner also asserts that the **obviousness** decision in Exhibit 1042 is somehow relevant to Medac's **novelty** argument. *Id.* This is contrary to U.S. patent law. 35 U.S.C. § 102.

Finally, Petitioner admits that it is relying on Exhibit 1042 for "the truth of what those decisions concluded" (Resp. at 2), but has not pointed any hearsay exception. F.R.E. 803. Indeed, judicial decisions generally are inadmissible for their findings. *See*, *e.g.*, *Nipper v. Snipes*, 7 F.3d 415, 417 (4th Cir. 1993).

For all of these reasons, Exhibit 1042 should be excluded. F.R.E. 401-403, 802 and 901-902.



C. Exhibits 1043 and 1046 Should be Excluded

Exhibit 1043 purports to be a copy of an online third-party news summary of a non-U.S. court decision regarding a Netherlands patent. In response to Medac's original objection, Petitioner served and filed Exhibit 1046, which purports to be that non-U.S. court decision.

Medac objects to Exhibit 1046. It is not self-authenticating because it is neither signed or attested to nor accompanied by a certification. F.R.E. 902(3). Petitioner also has not provided any other authentication. F.R.E. 901(a). Exhibit 1046 is also in a foreign language, and Petitioner has not submitted the required translation and attestation affidavit. 37 C.F.R. § 42.63(b). For both reasons, Exhibits 1043 and 1046 should be excluded.

Exhibits 1043 and 1046 are also irrelevant. F.R.E. 401, 402, and 403. The decision in Exhibit 1046 (summarized in Exhibit 1043) involved different claims, different legal standards, and different art than those at issue here. Petitioner also incorrectly asserts that the **inventive step** decision in Exhibit 1046 is relevant to Medac's **novelty** argument. Resp. at 3. This is contrary to U.S. patent law. 35 U.S.C. § 102.

Exhibits 1043 and 1046 should also be excluded as impermissible hearsay because Petitioner has offered the decision for the truth of the matters asserted. F.R.E. 802. Petitioner, however, has not pointed to any hearsay exception that



applies to either Exhibit 1043 or 1046. F.R.E. 803. See also, Nipper, 7 F.3d at 417.

D. Exhibits 1044 and 1045 Should be Excluded

Exhibits 1044 and 1045 are portions of the file history of an application that claims benefit of the application that issued as the '231 patent. Petitioner implies that the PTO's non-final rejection (Exhibit 1044), and applicant's abandonment (Exhibit 1045), indicate that the claims in this IPR are invalid. Resp. at 4. Moreover, Petitioner uses Exhibit 1045 improperly to contend that Medac "had no response" to the rejection (Reply at 1). Neither is correct. Medac has continued to prosecute the very same claims in continuation application 15/592,882. Accordingly, Petitioner's reliance on Exhibit 1045 is misleading, inaccurate, and unfairly prejudicial. Weight versus admissibility (Resp. at 4) does not cure those problems.

Both exhibits are also irrelevant. F.R.E. 401, 402, and 403. The **non-final** obviousness rejection involves different claims and relies on art that is not in this IPR. *See* Ex. 1044 at 4, 6, 7, 9, 10. Exhibit 1044, therefore, does not make it any more or less likely that the challenged claims in this IPR are unpatentable.

II. Improper Testimony Elicited from Ms. Shoemaker Should be Excluded

The Board should exclude the objected-to testimony of Ms. Shoemaker. It is outside the permissible scope of cross-examination. 37 C.F.R. § 42.53(d)(5)(ii). Ms. Shoemaker's declaration addressed only a prior consulting relationship



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