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

IPR2016-01370
Patent No. 8,664,231
Title: Concentrated Methotrexate Solutions

PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION TO EXCLUDE

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I. INTRODUCTION

Medac's objections misstate the nature of the challenged evidence and the purposes for which it was introduced. None of the exhibits or testimony Medac challenges is irrelevant, and none constitutes hearsay.

II. EXHIBITS 1041-45

A. Exhibit 1041

Exhibit 1041 details the correspondence between counsel for Koios and Medac in which Koios invited Medac to take the depositions of its experts, and Medac refused to do so. The exhibit is simply offered to show the Board that exchange. It is not offered as evidence of *why* Medac refused to take the depositions. The assertion that Medac refused to do so because it felt it could not successfully challenge Dr. Schiff and Dr. Miller's opinions through cross-examination is an inference that the Board may draw from Medac's decision—and an argument that Koios has made—but Koios has not offered Exhibit 1041 as direct evidence of that point.

Moreover, Exhibit 1041 is not offered to simply show that Medac did not ultimately take depositions in this proceeding. Rather, it is submitted to show that Koios proactively invited Medac to take its experts' depositions, and Medac refused. That reality is relevant in evaluating the weight and credibility of Medac's

repeated assertions that Koios's experts are not credible or that their testimony is not reliable.

B. Exhibit 1042

Exhibit 1042 is self-authenticating as it is a judicial decision from the UK High Court. Like other self-authenticating documents, the Board and Medac may readily seek out and find the decision independently and verify its authenticity.

The second sentence of the first paragraph of Ex. 1042 makes clear that the patent at issue there "claims the use of a formulation of methotrexate with a concentration of about 50 mg/ml for the treatment of individuals with inflammatory autoimmune diseases by subcutaneous injection." Ex. 1042 at ¶ 1. The Board can readily compare that claim language to claim 1 of the '231 patent, which recites: "A method for the treatment of inflammatory autoimmune diseases in a patient in need thereof, comprising subcutaneously administering to said patient a medicament comprising methotrexate in a pharmaceutically acceptable solvent at a concentration of more than 30 mg/ml."

Exhibit 1042 is offered for the truth of the matter that the UK High Court found the claims of EP (UK) 2 046 332 as invalid for obviousness. Ex. 1042 ¶ 132. Judicial decisions are not hearsay when offered for the truth of what those decisions concluded, as Koios does here. Medac repeatedly argues that it was a novel idea, as of July 2006, to administer MTX subcutaneously in concentrations

above 30 mg/ml for the treatment of inflammatory autoimmune diseases. The UK High Court's decision supports Koios's assertion that: "Two European courts and the U.S. Patent and Trademark Office have recently concluded otherwise."

C. Exhibit 1043

Exhibit 1043 demonstrates that The Hague has also found the European equivalent to the '231 patent, EP 2 046 332, invalid as obvious.

In response to Medac's objections, Koios timely served Ex. 1046 as supplementary evidence, *see* 37 C.F.R. § 42.64(b)(2), and filed it in response to Medac's Motion to Exclude, *see Handi Quilter, Inc. v. Bernina Int'l AG*, IPR2013-00364, Paper 30 (June 12, 2014) (explaining that "supplemental evidence [is] served in response to an evidentiary objection and filed in response to a motion to exclude"). Ex. 1046 shows the claims at issue in The Hague's decision. *See* Ex. 1046 at 4-6. Exhibit 1046 thus supports the relevance of Ex. 1043, *i.e.*, it establishes that The Hague decision discussed in Ex. 1043 was with respect to the same European patent found invalid by the UK High Court in Ex. 1042—a patent in which Medac claimed to have invented subcutaneous administration of methotrexate in concentrations of about 50 mg/ml for treating inflammatory autoimmune diseases.

The fact that Medac has purportedly appealed goes to the weight of Ex. 1043, not its admissibility. Surely if Medac had any decisions it could present to

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