

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner

v.

ALCON RESEARCH, LTD,
Patent Owner

Case IPR2017-01053
Patent 8,268,299

ALCON RESEARCH, LTD.'S OBJECTIONS TO EVIDENCE

Patent Owner Alcon Research, Ltd. (“Alcon”) objects pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence (“FRE”) to the admissibility of exhibits served by Petitioner Argentum Pharmaceuticals LLC on March 10, 2017. The exhibits objected to, and grounds for Alcon’s objections, are listed below.

I. IDENTIFICATION OF CHALLENGED EVIDENCE AND GROUNDS FOR OBJECTIONS

A. Exhibit 1005

Alcon objects to Exhibit 1005 under FRE 401 because it is irrelevant. Exhibit 1005 purports to be an article from the American Journal of Microbial Ecology titled *Microorganisms and Heavy Metal Toxicity*. Petitioner contends that Exhibit 1005 “qualifies as prior art to the ’299 patent under 35 U.S.C. § 102(b)” because it was “published in 1978, long before the [earliest possible priority date] of the ’299 patent.” Pet. at 33. Exhibit 1005 is not analogous art, and thus may not be considered as § 102(b) art in evaluating obviousness, because it is not from the field of the invention, nor is it pertinent to the problems addressed by the claimed invention. It is therefore inadmissible under FRE 401.

B. Exhibit 1008

Alcon objects to Exhibit 1008 under FRE 901, 1002, and 1003. Exhibit 1008 purports to be a copy of the file for U.S. Patent Application No. 11/858,781, but it is incomplete. It has not been authenticated under FRE 901, is not self-

authenticating under FRE 902, and is not a “duplicate” as defined by FRE 1001(e).

Exhibit 1008 is therefore inadmissible under FRE 901, 1002, and 1003.

C. Exhibit 1009

Alcon objects to Exhibit 1009 under FRE 401 and 403. Exhibit 1009 is the Joint Claim Construction Statement containing the construction of certain claim terms in the '299 patent that Alcon agreed to in *Alcon v. Mylan Pharmaceuticals Inc. et al.*, No. 1:13-cv-1332-SLR (D. Del.). The construction of terms in a different proceeding, particularly one that applies a different standard for claim construction, is irrelevant. Even if relevant, because of the different standard for claim construction applied in *inter partes* reviews, the minimal probative weight of Exhibit 1009 is substantially outweighed by the danger of confusion or unfair prejudice. Exhibit 1009 is therefore inadmissible under FRE 401 and 403.

D. Exhibit 1010

Alcon objects to Exhibit 1010 under FRE 901, 1002, and 1003. Exhibit 1010 purports to be a copy of the file for U.S. Patent Application No. 13/086,950, but it is incomplete. It has not been authenticated under FRE 901, is not self-authenticating under FRE 902, and is not a “duplicate” as defined by FRE 1001(e). Exhibit 1010 is therefore inadmissible under FRE 901, 1002, and 1003.

E. Exhibit 1011

Alcon objects to Exhibit 1011 under FRE 901, 1002, and 1003. Exhibit 1011 purports to be a copy of the file for U.S. Patent Application No. 12/441,995, but it is incomplete. It has not been authenticated under FRE 901, is not self-authenticating under FRE 902, and is not a “duplicate” as defined by FRE 1001(e). Exhibit 1011 is therefore inadmissible under FRE 901, 1002, and 1003.

F. Exhibit 1012

Alcon objects to Exhibit 1012 under FRE 106 and 401 because it is irrelevant and incomplete. Dr. Xia cites Exhibit 1012 for information that would allegedly be known to a person of ordinary skill in the art. *See* Argentum Ex. 1002 ¶¶ 22, 50. However, Exhibit 1012 is not analogous art, and thus may not be considered in evaluating obviousness, because it is not from the field of the invention, nor is it pertinent to the problems addressed by the claimed invention. In addition, Exhibit 1012 is incomplete in that it is only an excerpt from INDIRECT FOOD ADDITIVES AND POLYMERS, but under FRE 106 the entirety of INDIRECT FOOD ADDITIVES AND POLYMERS should in fairness be included in the exhibit. Exhibit 1012 is therefore inadmissible under FRE 106 and 401.

G. Exhibit 1013

Alcon objects to Exhibit 1013 under FRE 401 because it is irrelevant. Dr. Xia cites Exhibit 1013 for information that would allegedly be known to a person

of ordinary skill in the art, including what is “common” in the relevant field. *See* Argentum Ex. 1002 ¶ 74. However, Exhibit 1013 is not analogous art, and thus may not be considered in evaluating obviousness, because it is not from the field of the invention, nor is it pertinent to the problems addressed by the claimed invention. It is therefore inadmissible under FRE 401.

Alcon further objects to Exhibit 1013 under FRE 403. Dr. Xia cites Exhibit 1013 for the proposition that “Polyoxyl 40 hydrogenated castor oil is a common surfactant.” Argentum Ex. 1002 ¶ 74. Even if Exhibit 1013 were analogous art that could be considered in evaluating obviousness, its statement that polyoxyl 40 hydrogenated castor oil is “common” in the field of veterinary medicine is not probative of how common it is in ophthalmic compositions for use in humans, is unfairly prejudicial, and may be confusing to the factfinder. Exhibit 1013 is therefore inadmissible under FRE 403.

H. Exhibit 1014

Alcon objects to Exhibit 1014 under FRE 106, 901, 1002, and 1003. Exhibit 1014 is cited as an excerpt from *The United States Pharmacopeia* 27. *See, e.g.,* Argentum Ex. 1002 ¶ 104. It appears, however, to be an excerpt from *The United States Pharmacopeia* 26. In addition, it is not an accurate reproduction of the original publication because it is of such poor quality that words and details cannot

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