## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS X LLC, Petitioner,

v.

ANACOR PHARMACEUTICALS, INC., Patent Owner.

Case No. IPR2015-01776 Patent No. 7,582,621

PATENT OWNER'S OBJECTIONS TO EVIDENCE UNDER 37 C.F.R. § 42.64(b)(1)



Patent Owner, Anacor Pharmaceuticals, Inc., submits the following objections to evidence served by Petitioner, Coalition For Affordable Drugs X LLC, with its Reply (Paper 47). These objections are timely filed within five (5) business days from the service date (Aug. 24, 2016) of Petitioner's Reply.

## Exhibit 1051 – Press Release, Anacor

Exhibit 1051 cited in Petitioner's Reply is inadmissible for at least the following reasons, including under the Federal Rules of Evidence ("FRE").

Patent Owner objects to Exhibit 1051 as lacking authentication, and thus inadmissible under FRE 901. Exhibit 1051 purports to be a copy of a 2009 press release describing prestigious scientific awards received by two of Anacor's cofounders. Ex. 1080 ¶ 5. However, Petitioner may not rely on the content of the website printout without proper authentication. Although the testimony of Petitioner's counsel, Ryan James Fletcher, may establish that the exhibit is a true and correct printout from the identified website, Petitioner has not provided the testimony of any witness with personal knowledge of the website, and therefore the exhibit lacks authentication. *See Neste Oil OYJ v. Reg Synthetic Fuels, LLC*, IPR2013-00578, Paper 53 at 3–4 (P.T.A.B. Mar. 12, 2015).

Patent Owner also objects to Exhibit 1051 as inadmissible hearsay under FRE 801 and FRE 802, as Exhibit 1051 is not being offered as evidence of what it describes. Rather, Petitioner offers Exhibit 1051 to prove Dr. Benkovic's scientific



views about boron-containing compounds in 2002, relying on a quote from a different person in 2009. *See* Reply (Paper 47) p. 5.

Patent Owner further objects to Exhibit 1051 as being inadmissible under FRE 402 as lacking relevance.

## Exhibit 1067 - ASTM® D5134 Qualitative Reference Naphtha Standard

Exhibit 1067 is inadmissible for at least the following reasons, including under the Federal Rules of Evidence ("FRE").

Patent Owner objects to Exhibit 1067 as lacking authentication, and thus inadmissible under FRE 901. Exhibit 1067 purports to be a printout of an online Safety Data Sheet from a chemical supply company's website. Ex.  $1080 \ \P \ 9$ . However, Petitioner may not rely on the content of the website printout without proper authentication. Although the testimony of Petitioner's counsel, Ryan James Fletcher, may establish that the exhibit is a true and correct printout from the identified website, Petitioner has not provided the testimony of any witness with personal knowledge of the website, and therefore the exhibit lacks authentication. See Neste Oil OYJ v. Reg Synthetic Fuels, LLC, IPR2013-00578, Paper 53 at 3–4 (P.T.A.B. Mar. 12, 2015).

Patent Owner further objects to Exhibit 1067 as being inadmissible under FRE 402 as lacking relevance because the Exhibit is not prior art. Exhibit 1067 states that it was revised in 2015. Ex. 1067 p. 1. Petitioner, however, cites Exhibit



1067 to suggest that a POSA in 2005 would have attributed any overlapping toxicity between naphtha and Biobor JF<sup>®</sup> to the naphtha component of Biobor JF<sup>®</sup>, and not to the active dioxaborinane ingredients. *See* Reply (Paper 47) p. 22.

## Exhibit 1068 - Tavaborole, Material Safety Data Sheet

Exhibit 1068 is inadmissible for at least the following reasons, including under the Federal Rules of Evidence ("FRE").

Patent Owner objects to Exhibit 1068 as lacking authentication, and thus inadmissible under FRE 901. Exhibit 1068 purports to be a printout of an online Material Safety Data Sheet from a chemical supply company's website. Ex. 1080 ¶ 10. However, Petitioner may not rely on the content of the website printout without proper authentication. Although the testimony of Petitioner's counsel, Ryan James Fletcher, may establish that the exhibit is a true and correct printout from the identified website, Petitioner has not provided the testimony of any witness with personal knowledge of the website, and therefore the exhibit lacks authentication. *See Neste Oil OYJ v. Reg Synthetic Fuels, LLC*, IPR2013-00578, Paper 53 at 3–4 (P.T.A.B. Mar. 12, 2015).

Patent Owner further objects to Exhibit 1068 as being inadmissible under FRE 402 as lacking relevance because the Exhibit is not prior art. Exhibit 1068 states, "Date: 08.19.2016." Ex. 1068 p. 1. Petitioner, however, cites Exhibit 1068 to suggest that a POSA in 2005 would not have been dissuaded from topically



applying the compounds of BioborJF<sup>®</sup>, despite strong warnings in the MSDS that the product causes severe skin irritation, in part because the MSDS of tavaborole (*i.e.*, Exhibit 1068) lists similar warnings. *See* Reply (Paper 47) p. 22.

## Exhibits 1069 & 1071 – FDA Approval Packages

Exhibits 1069 ("Approval Package for Jublia") and 1071 ("Approval Package for Kerydin") are inadmissible for at least the following reasons, including under the Federal Rules of Evidence ("FRE").

Patent Owner objects to Exhibits 1069 and 1071 as lacking authentication, and thus inadmissible under FRE 901. Both Exhibits purport to be printouts from an FDA website. Ex. 1080 ¶¶ 11 & 13. However, Petitioner may not rely on the content of the website printouts without proper authentication. Although the testimony of Petitioner's counsel, Ryan James Fletcher, may establish that the exhibits are true and correct printouts from the identified website, Petitioner has not provided the testimony of any witness with personal knowledge of the website, and therefore the exhibit lacks authentication. *See Neste Oil OYJ v. Reg Synthetic Fuels, LLC*, IPR2013-00578, Paper 53 at 3–4 (P.T.A.B. Mar. 12, 2015).

Patent Owner further objects to Exhibits 1069 and 1071 as being inadmissible under FRE 402 as lacking relevance because neither Exhibit is prior art. Both Exhibits expressly list dates in 2014. Ex. 1069 p. 8; Ex. 1071 p. 9. Petitioner, however, cites Exhibits 1069 and 1071 to suggest that there was not a



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