Filed: June 6, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and
DR. REDDY'S LABORATORIES, INC.
Petitioners

v.

HORIZON PHARMA USA, INC. and NUVO PHARMACEUTICALS (IRELAND) DESIGNATED ACTIVITY COMPANY,
Patent Owners

Case No. IPR2018-00272[1]
U.S. Patent No. 9,393,208

PATENT OWNERS' REPLY TO PETITIONERS' OPPOSITION TO MOTION TO EXCLUDE EVIDENCE

[1] Petitioner Dr. Reddy's Laboratories, Inc., from IPR2018-01341, has been joined as a Petitioner to this proceeding.

Patent Owners submit this reply to Petitioners' opposition ("Opp." (Paper 58)) to Patent Owners' motion to exclude certain evidence. ("PO Mot." (Paper 55).)

I. ARGUMENT

A. Purported Drug Labels (Exs. 1009, 1010, 1020, and 1030) and Printouts of Web Pages (Ex. 1008 and 1083) Should Be Excluded for Containing Hearsay, Lacking Authentication, and Not Supporting Petitioners' Characterization of the Truth of the Matter Asserted

At the outset, Petitioners attempt to rely on a procedural argument to avoid the exclusion of any of its purported drug labels or printouts of FDA web pages. Petitioners argue that Patent Owners have waived all objections to evidence cited in *Mylan's* Petition. (Opp. at 2-3.) Patent Owners did not waive objections, as timely evidentiary objections were raised in response to the institution of *Dr. Reddy's* Petition in IPR2018-01341. Petitioner Mylan does not dispute this. (Opp. at 4.) Moreover, Petitioners cannot dispute that the evidence cited in Dr. Reddy's Petition is the same evidence cited in Mylan's Petition. (*See* IPR2018-01341, Paper 3 at 4-6; Paper 21 at 2-3.) IPR2018-01341 was instituted and joined with IPR2018-00272 on April 1, 2019. (*See* IPR2018-01341, Paper 21.) Petitioners Mylan and Dr. Reddy's cite no authority for ignoring Patent Owners' timely objections in the joined proceedings.[2]

[2] Moreover, Petitioner Mylan cannot argue prejudice or surprise here, as Patent

Significantly, Patent Owners identified the evidentiary problems with the EC-Naprosyn label (Exhibit 1009) in Patent Owners' Response. (*See* Paper 32 at 25-29.) These included issues related to the authenticity of the document. For example, the copyright notice on the document is represented as "1999-2007" with a strike through the "7" and portions of the document appeared to have been modified in September 2007 although Petitioners asserted that Ex. 1009 was available on the FDA website in January 2007. The only evidence that Petitioners pointed to in related IPR2017-01995 to prove that Exhibit 1009 is the same EC-Naprosyn label that was publicly available in 2007 is a declaration from Petitioners' counsel providing the web address from which the document was downloaded (presumably in 2018, although the declaration does not state when Exhibit 1009 was actually downloaded). (PO Mot. at 26-27.)

Although these issues with Exhibit 1009 were raised in Patent Owner's Response, Petitioners failed to adduce sufficient evidence to establish that Ex. 1009 is an authentic copy of the EC-Naprosyn label as it existed in 2007.

Owners raised the same evidentiary objections against the identical evidence cited in related IPR2017-01995. In response to Patent Owners' Motion to Exclude in this proceeding, Petitioners served an attorney declaration identical to the declaration they filed in IPR2017-01995. (*Compare* Ex. 1090 with Ex. 2068 in IPR2017-01995; *see also* PO Mot. at 1-5.)

Petitioners' argument that Patent Owners have somehow waived any objection to the admissibility of Exhibit 1009 is meritless.

Petitioners now argue that Exhibit 1009, and, by extension, the other challenged drug labels (Exs. 1010, 1020, and 1030) are authentic under Fed. R. Evid. 901(b)(4) because they bear company trademarks and mandated label formatting. They further argue that such labels are self-authenticating under Fed. R. Evid. 902 because they include "trade inscriptions, trademarks, and other affixations indicating origin, ownership, or control of the labeling information." (Opp. at 7.) Petitioners argue that the FDA web pages (Exs. 1008 and 1083) are authentic because they bear an FDA web address. But Petitioners arguments miss the mark—company trademarks, label formatting, and web addresses are not evidence that the document is an authentic copy of the label *as it existed at the time Petitioners purport it was publicly available.*

Petitioners point to a declaration of Dr. Metz (Ex. 1091, also submitted in IPR2017-01995), attesting to his personal knowledge that Exhibit 1010 is a true and correct of the Zegerid drug label as it existed before 2007. However, when questioned at his deposition about Exhibit 1010, Dr. Metz admitted that he was uncertain whether Exhibit 1010 was an identical copy of the Zegerid label as it existed in 2004. (Ex. 2027 at 72:10-74:18 ("If you are asking me if every single word in this label was exactly the same in 2004 as it is now, I can't be 100 percent

sure of that. . . .This is not a copy of the label that I would have seen in 2004. I - - you mean, the exact copy? No.").) Petitioners cannot therefore rely on Dr. Metz's testimony to bolster the authenticity of Exhibit 1010.

With respect to hearsay, Petitioners only state that each of these exhibits is offered for a non-hearsay purpose. (Opp. at 10-11, n.7.) This assertion belies Petitioners reliance on the copyright date of Ex. 1009 for the truth of the matter asserted, i.e., that the document was published as of that date. The same argument applies to the other drug labels and FDA web pages—Petitioners rely on the copyright dates to establish that these documents were publicly available. The Board has found that copyright dates are "entitled to any greater weight than that afforded to hearsay in determining public accessibility." *ServiceNow, Inc. v. Hewlett-Packard Co.*, IPR2015-00707, Paper 14 at 9-10 (P.T.A.B. Nov. 2, 2015); *see also QSC Audio Prods., LLC v. Crest Audio, Inc.*, IPR2014-00129, Paper 41 at 9–11 (P.T.A.B. Apr. 29, 2015) (noting that a copyright date was hearsay). Petitioners have identified no exception to the hearsay rule that would apply here.

B. Portions of Dr. Mayersohn's Reply Declaration (Ex. 1074) and Exhibits Cited Therein (Exs. 1064, 1065, 1066, 1076 and 1088) Should be Excluded as Improper New Opinion Testimony

Petitioners again attempt to rely on a procedural argument to excuse their reliance on new opinion testimony of Dr. Mayersohn and related exhibits, they do not dispute that these exhibits were not included with their Petition and were only

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