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Paper 12
Entered: August 24, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS (ADROCA) LLC,
Petitioner,

v.

ACORDA THERAPEUTICS, INC.,
Patent Owner.

Case IPR2015-00817
Patent 8,007,826 B2

Before MICHAEL P. TIERNEY, LORA M. GREEN, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges.*

BONILLA, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Coalition For Affordable Drugs (ADROCA) LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–3, 5–8, and 10–41 of U.S. Patent No. 8,007,826 B2 (Ex. 1001, "the '826 patent"). Paper 1 ("Petition" or "Pet."). Acorda Therapeutics, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp.").

Petitioner advances two grounds of unpatentability under 35 U.S.C. § 103(a) in relation to the challenged claims in the '826 patent. Pet. 14–15. Both grounds rely on the Hayes poster (Ex. 1031),[1] and the second ground further relies on the Goodman poster (Ex. 1030).[2] *Id*. at 14–15, 24–58. For the reasons discussed below, we are not persuaded that Petitioner has shown that the Hayes and Goodman posters constitute prior art to the '826 patent. Petitioner, therefore, has not established that there is a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition, as required under 35 U.S.C. § 314(a).

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[1] Hayes et al., poster titled "*Open-Label, Multiple-Dose Study to Determine the Pharmacokinetics and Safety of Fampridine-SR (Sustained-Release 4-Aminopyridine) in Patients with Chronic Spinal Cord Injury*" (American Neurological Association, Chicago, IL, September 30–October 3, 2001) ("the Hayes poster") (Ex. 1031). *See also* Pet. ix, 19–20; Ex. 1049, 12 ("C148").

[2] Goodman et al., poster titled "*Placebo-Controlled Double-Blinded Dose Ranging Study of Fampridine-SR in Multiple Sclerosis*" (7th Annual Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and 18th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS/ECTRIMS), Baltimore, MD, September 18–21, 2002) ("the Goodman poster") (Ex. 1030). *See also* Pet. viii, 23; Ex. 1042, 6 ("C84"); Ex. 2031, 3 ("C416").

II. ANALYSIS

Petitioner asserts that the Hayes poster constitutes prior art under 35 U.S.C. § 102(b) "because it was published on Sept. 30–October 3, 2001 (a fact admitted by the '685 patent applicants in an October 31, 2011 IDS, see Ex. 1049, at Reference No. C148)," a date that "is more than one year prior to the earliest effective priority date, even if that date is December 2003." Pet. 19 (citing Ex. 1049, 12, "C148"). Petitioner also asserts that the Goodman poster "constitutes prior art under 35 U.S.C. § 102(b) because it was published at least as early as September 18–21, 2002 (a fact admitted by the '826 Patent applicants in a November 24, 2010 Information Disclosure Statement, see Ex. 1019 at Reference No. C84)." *Id*. at 23 (citing Ex. 1019, 6, "C68"; Ex. 1042, 6, "C84"). Exhibit 1049 presents a copy of an Information Disclosure Statement ("IDS") for Application No. 13/187,158 ("the '158 application"), which issued as U.S. Patent No. 8,663,685, a continuation of the '826 patent. Exhibits 1019 and 1042 present copies of IDSs for Application No. 11/010,828 ("the '828 application"), which issued as the '826 patent.

Patent Owner acknowledges that relevant IDSs submitted during prosecution of the '158 and '828 applications state that the Hayes and Goodman posters "were 'presented' at certain meetings." Prelim. Resp. 14–15 (citing Ex. 2031, 3, "C416"; Ex. 1049, 12, "C148"). Patent Owner contends, however, that even so, "that does not establish that the posters are printed publications" that qualify as prior art under § 102. *Id*. (citing *In re Klopfenstein*, 380 F.3d 1345, 1349 n.4 (Fed. Cir. 2004)). We agree.

First, the submission of an IDS does not constitute an admission that a cited reference is material prior art. *ResQNet.com, Inc. v. Lansa, Inc.*, 594

F.3d 860, 866 (Fed. Cir. 2010); *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1279 (Fed. Cir. 2003)); *see also* 37 C.F.R. § 1.97(h) (stating that the filing of an IDS "shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b)"). Moreover, in this case, relevant IDSs state expressly that "[i]dentification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as 'prior art' against the subject application." Prelim. Resp. 22 (quoting Ex. 2031, 1; Ex. 1049, 2).

Second, as also noted by Patent Owner, a "determination of whether a reference is a 'printed publication' under 35 U.S.C. § 102(b) involves a case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public." *Klopfenstein*, 380 F.3d at 1350; Prelim. Resp. 10–11, 14–21. Several factors "aid in resolving whether or not a temporarily displayed reference that was neither distributed nor indexed was nonetheless made sufficiently publicly accessible to count as a 'printed publication' under § 102(b)." *Klopfenstein*, 380 F.3d at 1350. Because Petitioner does not indicate that the Hayes and Goodman posters were distributed (rather than presented) or indexed, we consider those factors now, which include: "[1] the length of time the display was exhibited, [2] the expertise of the target audience, [3] the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and [4] the simplicity or ease with which the material displayed could have been copied." *Id.*; Pet. 19–20, 23; Prelim. Resp. 16–19.

The "duration of the display is important in determining the opportunity of the public in capturing, processing and retaining the

information conveyed by the reference." *Klopfenstein*, 380 F.3d at 1350. Along those lines, "[t]he more transient the display, the less likely it is to be considered a 'printed publication.'" *Id*. at 1350–51. Here, we agree with Patent Owner that Petitioner presents insufficient evidence as to how long the Hayes or Goodman poster was presented at any scientific meeting. Prelim. Resp. 16–17. The only credible evidence of record indicating that the posters were presented at all is in the form of IDSs stating that the posters were "presented."

Similarly, Petitioner presents insufficient evidence in relation to "the expertise of the target audience," i.e., anyone who actually saw either poster. *Id*. at 17. Petitioner likewise presents insufficient evidence in relation to any reasonable expectation that one could have copied the poster material, or evidence regarding the ease with which the poster material could have been copied. *Id*. at 18–19. Overall, evidence of record fails to demonstrate that the posters nonetheless were made sufficiently publicly accessible. For example, evidence of record does not indicate adequately how long the posters were presented to anyone, or to whom exactly, or what conversations anyone might have had with authors about the posters.

In addition, our review of the posters themselves indicates that they both present relatively dense material in a small space. Ex. 1031, 2; Ex. 1030, 2. As stated by the Federal Circuit, the "more complex a display, the more difficult it will be for members of the public to effectively capture its information." *Klopfenstein*, 380 F.3d at 1351.

We are not persuaded that Petitioner has made a threshold showing that the posters were sufficiently publicly accessible to qualify as a "printed publication" under § 102(b). Petitioner has not demonstrated adequately that

the Hayes poster (relied upon in all grounds) or the Goodman poster, as presented in the Petition, constitute prior art to the '826 patent.

III. ORDER

It is

ORDERED that the Petition is denied as to all challenged claims and no trial is instituted.

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