IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICALS INC. and JANSSEN PHARMCEUTICA NV, *Plaintiffs*, v. TOLMAR, INC., *Defendant*.	§ § § § § § § § § § § §	Civil Action No. 21-1784-WCB **FILED UNDER SEAL**

MEMORANDUM OPINION AND ORDER

In this Hatch-Waxman Act patent case, plaintiffs Janssen Pharmaceuticals Inc. and Janssen Pharmaceutica NV (collectively, "Janssen") have filed a motion for summary judgment. Dkt. No. 101. In that motion, Janssen argues that certain invalidity references asserted by defendant Tolmar, Inc., do not qualify as prior art under the version of 35 U.S.C. § 102 that was in effect prior to the enactment of the America Invents Act (referred to as "pre-AIA 35 U.S.C. § 102"). For the reasons set forth below, the motion is GRANTED IN PART and DENIED IN PART.

I. Background

Janssen has asserted U.S. Patent No. 9,439,906 ("the '906 patent") against Tolmar in this action. The '906 patent is generally directed to dosing regimens for long-acting injectable paliperidone palmitate, a compound that is used as an antipsychotic medication. The parties dispute the priority date of the claims of the '906 patent. For purposes of the present motion, claim 1 is representative. It recites as follows:

> 1. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising

> (1) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;
>
> (2) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and
>
> (3) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose.

'906 patent, cl. 1.

On its face, the '906 patent claims priority to one provisional patent application filed on December 19, 2007, and another filed on December 5, 2008. Tolmar contends that the claims are not entitled to a priority date earlier than December 5, 2008. Janssen disagrees and argues that the inventors reduced the invention to practice by June 2007 and are therefore entitled to a priority date of June 2007 at the latest.

In its invalidity case, Tolmar has alleged that several references are prior art to the claims of the '906 patent. Three of those references (referred to here as the "Disputed References") are the focus of Janssen's motion for summary judgment. The first, "NCT 577," is a summary of a clinical study protocol that was published online on November 13, 2008. Dkt. No. 103-1, Exh. 4. The second, "Cleton 2008," describes two studies involving the administration of peridone palmitate and was published in March 2008. Dkt. No. 103-1, Exh. 5. The third, the "Kramer Document," is a poster that Tolmar contends was displayed at a conference in October 2007. Dkt. No. 103-1, Exh. 6. Janssen's position is that the inventors of the '906 patent reduced their invention to practice prior to the publication of the three Disputed References.

II. Legal Standard

The court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In deciding a motion for summary judgment, the court must draw all factual inferences in favor of the non-movant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). In the case of an issue on which the nonmoving party bears the burden of proof at trial, the party seeking summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (quoting Fed. R. Civ. P. 56(c) as of 1986). The burden on the moving party in that situation can be satisfied "by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325. If the moving party carries its burden, the nonmovant must "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (cleaned up); *see also* 10A Charles Alan Wright et al., *Federal Practice & Procedure* § 2727.1 (4th ed., April 2022 update).

III. Discussion

In its motion for summary judgment, Janssen raises two principal arguments. First, Janssen argues that none of the Disputed References is prior art under pre-AIA 35 U.S.C. § 102(a) because the inventors reduced the invention of the '906 patent to practice prior to the publication of those references. Second, Janssen argues that the Kramer Document does not qualify as prior art under pre-AIA 35 U.S.C. § 102(b) because there is insufficient evidence in the record on which the court

could base a finding that the Kramer Document is a printed publication. I address each issue separately below.

A. 35 U.S.C. § 102(a)

I begin by addressing the question whether the Disputed References qualify as prior art under pre-AIA 35 U.S.C. § 102(a). Under pre-AIA section 102(a), an invention is anticipated if it was publicly disclosed "before the invention thereof by the applicant for a patent." Accordingly, the key question is whether the claims of the '906 patent are entitled to a priority date earlier than October 2007, which is the earliest publication date of the three Disputed References.

Janssen contends that it reduced its invention to practice by June 2007 and that the claims of the '906 patent are therefore entitled to a priority date no later than that. By that time, Janssen asserts, there were two ongoing clinical trials that "perform[ed] embodiments of the claimed dosing regimen." Dkt. No. 102 at 10 (citing Dkt. No. 103-1, Exhs. 7, 10). Janssen adds that it had determined by June 2007 "that the claimed dosing regimen would work for its intended purpose." *Id.* (citing Dkt. No. 103-1, Exhs. 3, 11).

Tolmar does not appear to dispute that the June 2007 clinical trials practiced the claimed dosing regimens. Instead, it argues that Janssen has not provided evidence that it conceived of the "a month (±7 days)" limitation, recited in the third step of claim 1, prior to the filing of the December 2008 provisional patent application. As the parties point out, the 2007 clinical trials "permitted a ±3 day dosing window around the 'monthly' maintenance doses." Dkt. No. 106 at 5; *see also* Dkt. No. 104 at 5.

The problem for Tolmar is that in order to establish priority to an invention, the inventor "need[] only prove either that it reduced its invention to practice first or that it conceived of the invention first and was diligent in reducing it to practice." *Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d

1300, 1304 (Fed. Cir. 2012). If reduction to practice is established, then evidence of conception is not necessary. *Id.* at 1304–05 ("Since [the patentee] reduced the invention to practice in 1995, . . . it does not need to prove conception."); *Dionex Softron GmbH v. Agilent Techs., Inc.*, 56 F.4th 1353, 1359 n.4 (Fed. Cir. 2023). Accordingly, if Janssen can establish that it reduced the invention to practice prior to the publication of the Disputed References, it is irrelevant whether there is evidence that the inventors conceived of the "a month (±7 days)" limitation prior to that time. *See Cornell Univ. v. Illumina, Inc.*, No. 10-433, 2017 WL 89165, at *10 (D. Del. Jan. 10, 2017) ("Reduction to practice before the critical date, alone, is sufficient to antedate references. . . . The concepts of conception and diligence are relevant only when reduction to practice takes place after the critical date.").

Tolmar cites several cases in support of its argument that evidence of conception is required in addition to evidence of reduction to practice. Those cases, however, address situations that are different from the one presented by this case, and they are not inconsistent with the general principle that reduction to practice is sufficient to establish priority independent of the inventor's conception and diligence. *See, e.g.*, *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1075–78 (Fed. Cir. 2019) (patentee provided evidence of both conception and reduction to practice at trial, and the court held that the evidence was sufficient to support the jury's verdict); *Solvay S.A. v. Honeywell Int'l Inc.*, 742 F.3d 998, 999–1000 (Fed. Cir. 2014) (addressing the question whether "an invention conceived by a foreign inventor and reduced to practice in the United States qualifies as prior art under [35 U.S.C.] § 102(g)(2)"); *Cooper v. Goldfarb*, 154 F.3d 1321 (Fed. Cir. 1998) ("[P]riority of invention goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive of the invention and that it exercised reasonable diligence in later reducing that invention to practice."); *Depomed, Inc. v.*

Purdue Pharma L.P., No. 13-571, 2017 WL 2804953, at *5–7 (D.N.J. June 28, 2017) (declining to dismiss an inequitable conduct claim because the accused infringer plausibly alleged that the inventors misrepresented when they first reduced an embodiment of the claimed invention to practice); *Mycogen Plant Sci. v. Monsanto Co.*, 243 F.3d 1316, 1332 (Fed. Cir. 2001) (priority may be established in "two ways"—actual reduction to practice, or conception followed by reasonable diligence).

Reduction to practice occurs when the inventor (1) constructs an embodiment or performs a process that meets all the claim limitations; and (2) determines that the invention would work for its intended purpose. *Fox*, 700 F.3d at 1305. Tolmar does not appear to seriously dispute that either of those elements were satisfied by Janssen's 2007 clinical trials. Instead, Tolmar devotes the section 102(a) portion of its brief to arguing that Janssen must show evidence that it conceived of the full scope of the claims even if it shows an actual reduction to practice. As noted, that contention is incorrect.

A close examination of Janssen's evidence regarding the clinical trials further supports the conclusion that those trials resulted in the performance of a process that meets the limitations of the asserted claims. Claim 1 requires three doses to be administered: (1) a 150 mg-eq. dose in the deltoid muscle on the first day of treatment; (2) a 100 mg-eq. dose in the deltoid muscle on the sixth to about the tenth day of treatment; and (3) a monthly maintenance dose one month (± 7 days) later, either in the deltoid or gluteal muscle, in an amount between 25 mg-eq. and 150 mg-eq. '906 patent, cl. 1. The documentation regarding Janssen's clinical trials indicates that the doses administered in those trials were consistent with the requirements of claim 1. *See* Dkt. No. 103-1, Exh. 10, at 26–27, 36–37 (initial deltoid injection of 150 mg eq., 100 mg eq. deltoid injection on day 8, and a deltoid or gluteal injection of 50 mg eq. or 100 mg eq. on day 36); Dkt. No. 103-1,

Exh. 7, at JANUS01655059, JANUS01657129–39 (identifying clinical trial patients who were in a treatment group consistent with the claimed dosage regimen). And Janssen has made a prima facie showing, unrebutted by Tolmar, that Janssen had determined by that time that the invention would work for its intended purpose. *See* Dkt. No. 103-1, Exh. 11, at 9–15 (Janssen presentation proposing a modification to the dosage regimen that would match the regimen recited in claim 1); Dkt. No. 103-1, Exh. 3, at 1093:5–1094:23 (One of the named inventors testifying that, at the time of the modification, he had a "[v]ery high level of confidence" that the dosage regimen as modified "would be safe and effective").

In view of the above evidence, it is clear that Janssen actually reduced the invention claimed in the '906 patent to practice by June 2007. Tolmar has not put forth sufficient evidence to create a triable issue of fact on that question. Accordingly, the inventors' reduction to practice pre-dates the publication date of each of the Disputed References, and those references therefore cannot serve as prior art under pre-AIA section 102(a).

Tolmar argues that the claimed dosage regimen was not invented prior to the publication of the Disputed References because Janssen did not conceive of the limitation providing for a plus-or-minus seven-day dosing window for the first maintenance dose, to be administered a month after the second loading dose. That is, because the evidence does not show that by June 2007 Janssen had conceived that the first maintenance dose, to be given a month after the second loading dose, could be given within a period of seven days more or seven days less than a month, Janssen is not entitled to the claimed June 2007 priority date for its invention.

As Janssen points out, that argument is based on a flawed premise. Proof of prior invention can consist of either proof of conception before the date of a prior art reference, followed by diligence leading to a subsequent reduction to practice or, alternatively, proof of reduction to

practice prior to the date of the prior art reference, without the need to separately prove conception. *See Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1304 (Fed. Cir. 2012); *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1332 (Fed. Cir. 2001). In this case, Janssen has offered evidence that it reduced the claimed invention to practice before the publication of the Disputed References by showing that it "(1) constructed an embodiment or performed a process that met all the claim limitations and (2) determined that the invention would work for its intended purpose." *Fox*, 700 F.3d at 1305. Contrary to Tolmar's argument, because Janssen reduced the invention to practice in that fashion, and did so prior to the publication of the Disputed References, Janssen was not required to show when it conceived of the plus-or-minus seven-day window recited in the claims. Tolmar's argument is addressed to a situation in which the patentee is relying on prior conception but reduction to practice after the publication of the prior art references. The authorities on which it relies do not apply to a case such as this one, in which Janssen showed an actual reduction to practice before the publication of the asserted prior art.[1]

B. 35 U.S.C. § 102(b)

Separately from its contentions regarding section 102(a), Tolmar also contends that the Kramer Document is prior art under pre-AIA 35 U.S.C. § 102(b). As relevant here, an invention is anticipated under pre-AIA section 102(b) if the invention was "patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." Tolmar argues that the Kramer Document is a printed publication

[1] Tolmar asserts that Janssen's experts "concede that the '906 patent is not entitled to the December 2007 filing date." Dkt. No. 104 at 3–4. That is not so. The experts were not asked to, and did not, express an opinion as to the priority date for the patent, which Janssen sought to prove by other evidence. *See* Dkt. No. 105-1, Exh. C ¶¶ 45 n.1, 50 n.2; Dkt. No. 105-1, Exh. I, at 134:9–13; Dkt. No. 105-1, Exh. D ¶ 83. That does not constitute a concession on the part of Janssen or its experts.

that was published in October 2007, more than one year prior to the December 2008 provisional application. Janssen has moved for summary judgment that the Kramer Document is not a printed publication for purposes of section 102(b).

As the Federal Circuit has explained, the key inquiry in determining whether a reference is a "printed publication" is "whether or not a reference has been made 'publicly accessible.'" *M & K Holdings, Inc. v. Samsung Elecs. Co.*, 985 F.3d 1376, 1379 (Fed. Cir. 2021) (quoting *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004)). A reference is deemed to be publicly accessible if it was "disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence[] can locate it." *Id.* (quoting *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016)). The determination of public accessibility requires an examination of several factors, including "the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied." *Klopfenstein*, 380 F.3d at 1350.

Janssen argues that the Kramer Document cannot be deemed a printed publication because there is "no evidence that the Kramer Document was ever publicly displayed." Dkt. No. 102 at 15 (capitalization altered). Janssen further argues that even if the document was publicly displayed, Tolmar has failed to adduce any evidence "about the facts and circumstances surrounding the Kramer Document's purported disclosure" that would permit a fact finder to conclude that the reference was publicly accessible. *Id.* at 17.

As to the first point, there is sufficient evidence in the record to permit a conclusion that the Kramer Document was publicly displayed. The face of the Kramer Document includes the

following notation: "Poster at the 20th US Psychiatric and Mental Health Congress (USP&MHC), Orlando, Florida, USA, October 11–14, 2007." Dkt. No. 103-1, Exh. 6. The poster index for the USP&MHC event is consistent with that notation, as it indicates that the Kramer Document was scheduled to be "presented during Exhibit Hall hours" on Saturday, October 13, 2007. Dkt. No. 103-2, Exh. 24. In Janssen's view, that evidence "confirms that the poster was slated for presentation at the conference," but does not indicate whether such presentation actually occurred. Dkt. No. 102 at 16. Although there is no direct evidence that the poster was actually displayed at the USP&MHC event, the above evidence is sufficient to allow a fact finder to draw an inference that the Kramer Document was displayed at the USP&MHC event on October 13, 2007.

As to the second point, Tolmar has introduced some evidence regarding the circumstances under which the Kramer Document would have been displayed. One of Tolmar's experts, Dr. Jacinto Dizon, testified in a deposition that although he did not attend the USP&MHC conference, in general at conferences "posters are displayed just like TV commercials, [i.e.,] you want exposure time as long as possible," and that researchers would be frustrated "if you take their posters down." Dkt. No. 103-2, Exh. 16, at 75:10–76:21. Another of Tolmar's experts, Dr. Lisa Coles, was not aware of the specific USP&MHC conference at issue but testified that conference posters are typically "3 feet by 4 feet, something like that." Dkt. No. 103-1, Exh. 12, at 100:4–12. In addition, the poster index made clear that only 25 other posters were scheduled to be displayed alongside the Kramer Document, and it encouraged attendees to "[j]oin your colleagues in a discussion of the latest research." Dkt. No. 103-2, Exh. 24. Under those circumstances, a fact finder could reasonably conclude that the Kramer Document was intended to be viewed by the attendees of the USP&MHC conference without any obligation of confidentiality, and therefore that it was publicly accessible.

Because a fact finder could conclude that the Kramer Document was publicly accessible, and therefore a printed publication for purposes of pre-AIA 35 U.S.C. § 102(b), Janssen is not entitled to summary judgment barring Tolmar from attempting to prove at trial that the Kramer Document qualifies as prior art under section 102(b).

IV. Conclusion

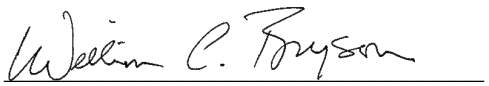
In summary, Janssen's motion for summary judgment is GRANTED with respect to its section 102(a) arguments and DENIED with respect to its 102(b) arguments.

* * * * *

I note that Janssen's reply brief was filed under seal, but that the public version of that brief did not appear to contain any redacted material. Nonetheless, in an abundance of caution, this order has been filed under seal. Within three business days of the issuance of this order, the parties are directed to advise the court by letter whether they wish any portions of the order to remain under seal, and if so which portions. Any request that portions of the order should remain under seal must be supported by a particularized showing of need to limit public access to those portions of the order.

IT IS SO ORDERED.

SIGNED this 8th day of September, 2023.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE