IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG and JANSSEN PHARMACEUTICALS, INC., Plaintiffs, v. TARO PHARMACEUTICAL INDUSTRIES LTD., TARO PHARMACEUTICALS U.S.A., INC., et al., Defendants.	Civil Action No. 17-462-TBD CONSOLIDATED

SUPPLEMENTAL MARKMAN OPINION & ORDER

This opinion and order further addresses the meaning of the term "rapid-release tablet" in claims 1–4 of U.S. Patent No. 9,539,218 ("the '218 patent"). Before the court are Joint Pretrial Order, ECF No. 150, Stipulation Regarding Infringement, ECF No. 152, and the parties' briefs on supplemental claim construction, Bayer's Br., ECF No. 153; Mylan's Br., ECF No. 154.

I

On May 19, 2017, Bayer Intellectual Property GmbH, Bayer AG, and Janssen Pharmaceuticals, Inc. (collectively, "Bayer") filed suit against Mylan Pharmaceuticals Inc. ("Mylan"), alleging infringement of claims 1–4 of the '218 patent. The alleged act of infringement is Mylan's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use,

or sale of its proposed rivaroxaban tablets prior to the expiration of the '218 patent.[1]

Claim 1 of the '218 patent recites:

> 1. A method of treating a thromboembolic disorder comprising
>
> > administering [rivaroxaban] no more than once daily for at least five days in a rapid-release tablet to a patient in need thereof, wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke.

'218 patent, col. 10, l. 63–col. 11, l. 5 (emphasis added). Claims 2, 3, and 4 are dependent claims and recite the method of claim 1, wherein the thromboembolic disorder is pulmonary embolisms, deep vein thromboses, and stroke, respectively. *Id.* col. 11, ll. 6–11.

Earlier in this case, Bayer argued that the patent expressly defines the term "rapid-release tablet" as "a tablet which, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minutes) of 75%." Joint Claim Construction Br. 3, ECF No. 82. Mylan argued that the term should be construed as "a tablet that is not a modified- (e.g., sustained- or retarded-) release tablet." *Id.* On July 3, 2018, the court agreed with Bayer and adopted Bayer's proposed construction in a Markman order construing the term "rapid-release tablet" in the claims as "a tablet which, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minutes) of 75%." Markman Order, ECF No. 91. The parties now dispute whether "a tablet which, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minutes) of 75%" covers tablets that release more than 75% of the active ingredient within 30 minutes.

[1] Bayer filed complaints alleging infringement of claims 1–4 of the '218 patent against numerous generic drug companies. *See* Civil Action Nos. 17-462, 17-483, 17-560, 17-584, 17-648, 17-675, 17-812, 17-1047, 17-1129, 17-1163, 18-1926. The parties agreed to consolidate those matters in Civil Action No. 17-462. Stip. & Order of Consolidation, ECF No. 30; Stip. & Order, ECF No. 146. All defendants in the consolidated action other than Mylan have stipulated to stay the proceedings against them and be bound by the final judgment. Stip. & Order, ECF No. 33; Stip. & Order, ECF No. 40; Stip. & Order, ECF No. 43; Stip. & Order, ECF No. 47; Stip. & Order, ECF No. 59; Stip. & Order, ECF No. 79; Stip. & Order, ECF No. 119; Stip. & Order, ECF No. 130; Stip. & Order, ECF No. 134; Stip. & Order, ECF No. 146.

On March 20, 2019, this court held a final pretrial conference and determined that this claim construction dispute should be resolved by the court prior to trial. Therefore, the court ordered the parties to submit simultaneous supplemental claim construction briefs on whether the court's construction of "rapid-release tablet" covers tablets that release more than 75% of the active ingredient within 30 minutes.

On March 27, 2019, the parties submitted supplemental claim construction briefs and attached expert testimony on the issue. Bayer's Br; Mylan's Br. The parties agreed that no evidentiary hearing is necessary on this issue. After reviewing the parties' filings, the court agrees that no evidentiary hearing is necessary to resolve this claim construction dispute.

The parties also filed a stipulation regarding infringement, which the court entered on March 25, 2019. Stip. Regarding Infringement. Pursuant to that stipulation, if the court agrees with Bayer's proposed supplemental construction of "rapid-release tablet," the parties stipulate that "Mylan literally infringes each of claims 1–4 of the '218 patent." *Id.* ¶ 3. If the court agrees with Mylan's proposed supplemental construction of "rapid-release tablet," the parties stipulate that "Mylan does not literally infringe any claim of the '218 patent." *Id.* ¶ 5.

II

The "rapid-release tablet" language of the claims is ambiguous. The court's original claim construction was based on the patent specification, which states:

> In the context of the present invention, rapid-release tablets are in particular those which, according to the USP release method using apparatus 2 (paddle), have a Q value (30 minutes) of 75%. Very particularly preferred are rapid-release tablets containing [rivaroxaban] as active ingredient. Preparation of such tablets is for example described in PCT/04/01289, whose disclosure is hereby included by way of reference.

'218 patent, col. 8, ll. 21–30 (emphasis added). The language of the court's construction mirrors the language of the specification.

The U.S. Pharmacopeia ("USP") referenced in the specification is a publication that "provides information about various pharmaceutical products." Myerson Rpt. ¶ 27, ECF No. 153-1; *see* USP, ECF No. 153-1. Many pharmaceutical products are formulated as tablets, like those described in the '218 patent, which are designed to dissolve and release the active ingredient(s). Myerson Rpt. ¶ 26. The USP describes several methods of performing dissolution testing of pharmaceutical products. *Id.* ¶ 27; USP at 2412–14.

One method described in the USP is the "paddle" method, which is also referred to as "Apparatus 2." Myerson Rpt. ¶ 28; USP at 2413. The paddle method employs "a paddle formed from a blade and a shaft . . . as the stirring element" for the dissolution test. USP at 2413. The USP explains that in general, a specific volume of solvent is added to the vessel of the apparatus, one tablet or capsule is placed in the apparatus, and then the apparatus is operated at a specified rate. *Id.* After a period of time, the remaining tablet or capsule that has not dissolved is withdrawn from the solvent. *Id.* at 2413–14. The quantity of the active ingredient dissolved in the sample is then determined. *Id.* at 2414. The USP defines the "quantity" or "Q" as "the amount of dissolved active ingredient . . . expressed as a percentage of the labeled content." *Id.*

Bayer argues that a person of ordinary skill in the art would understand that the term "rapid-release tablet" in the context of the '218 patent specification covers tablets that release 75% or more of the active ingredient within 30 minutes. Bayer's Br. 1. Mylan argues that a person of ordinary skill in the art would understand that "rapid-release tablet" in the context of the specification does not cover tablets that release more than 75% of the active ingredient within 30 minutes, but includes only those that release exactly 75% of the active ingredient within 30 minutes. Mylan's Br. 1, 4 & n.3; Parr Rpt. ¶ 73, ECF No. 155-1.

The court concludes that Bayer's construction is correct for two reasons. First, the construction is supported by application PCT/04/012897, which is referenced in the '218 patent. The '218 patent specification states that "[p]reparation of [rapid-release] tablets is for example described in PCT/04/01289, whose disclosure is hereby included by way of reference." '218 patent, col. 8, ll. 28–30.

Mylan points out that the patent cites "the ***wrong number*** for the [PCT] application." Mylan's Br. 6 (emphasis in original). Bayer argues that the reference to "PCT/04/01289" in the '218 patent is a typographical error, and that a person of ordinary skill in the art would understand the reference to refer to "PCT/04/012897." Bayer's Br. 3–4 & n.1. Mylan argues that the court cannot take account of the typographical error in the '218 patent in construing "rapid-release tablet." That is incorrect.

It is well-settled that, in a patent infringement suit, a district court can construe a patent to correct an obvious error. *I.T.S. Rubber Co. v. Essex Rubber*, 272 U.S. 429, 441–42 (1926); *see Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1355 (Fed. Cir. 2003) ("[U]nder *Essex*, certain obvious errors in the patent can be corrected by the district court in construing the patent."). "[A] district court can act to correct an error in a patent by interpretation of the patent . . . only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus.*, 350 F.3d at 1354. "Those determinations must be made from the point of view of one skilled in the art." *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009). This does not involve a formal order of correction, but a court can take account of a typographical error in construing the patent. *See Novo Indus.*, 350 F.3d at 1354–55, 1357.

Here, there is no debate that the reference to "PCT/04/01289" in the '218 patent is an obvious typographical error and that it should be "PCT/04/012897." The published version of international application PCT/04/012897 (i.e., WO 2005/060940) is listed on the face of the '218 patent under "Foreign Patent Documents."[2] There is no international application PCT/04/01289, so a person of ordinary skill in the art would understand there to be a typographical error. Myerson Rpt. ¶ 38 & n.3.

The parties also debate whether the PCT application is incorporated by reference into the '218 patent specification. Whether or not the PCT application is incorporated does not make a difference. It is relevant because it is specifically referenced in the '218 patent.

The PCT application, which the '218 patent states "describe[s]" "[p]reparation of [rapid-release] tablets," makes clear that Bayer's proposed supplemental construction is correct. '218 patent, col. 8, ll. 25–30. The PCT application states:

> Tablets are preferred, in particular, tablets that rapidly release the active ingredient [(rivaroxaban)]. In the context of the present invention, rapid-release tablets are, in particular, those that, according to the USP release method using apparatus 2 (paddle), such as described in the experimental part in chapter 5.2.2, have a Q value (30 minutes) of 75%."

PCT application at 5, ECF No. 153-1. The PCT application thus uses the same definition of "rapid-release tablet" as the '218 patent. Chapter 5.2.2 of the PCT application, in turn, contains a table showing "[t]he amounts of active ingredient released, based on the declared total content" of

[2] Published application WO 2005/060940 is in German, but Bayer submitted a certified English translation of the published application. WO 2005/060940, ECF No. 153-1; Cert. Engl. Transl. of WO 2005/060940 (hereinafter, "PCT application"), ECF No. 153-1. No party contends that there is any difference between application PCT/04/012897 and the published version (i.e., WO 2005/060940). Therefore, for purposes of this opinion, the court refers to application PCT/04/012897 and published application WO 2005/060940 interchangeably as "the PCT application" and cites to the certified English translation of the published application.

tablets that were evaluated according to the USP release method using apparatus 2 (paddle). *Id.* at 11.

TABLE 1 In-vitro release

	15 min.	30 min.	45 min.	60 min.
Tablet A	87%	92%	93%	94%
Tablet B	94%	95%	96%	96%

(USP paddle, 900 ml of acetate buffer pH 4.5 + 0.5% sodium lauryl sulfate, 75 rpm)

Id. As shown in Table 1, Tablet A and Tablet B released 92% and 95%, respectively, of the active ingredient within 30 minutes (i.e., more than 75%). *Id.* Accordingly, the intrinsic record of the '218 patent shows that the term "rapid-release tablet," as that term is defined in the '218 patent and the PCT application, includes tablets that release 75% or more of the active ingredient within 30 minutes, in accordance with Bayer's proposed construction.

Second, Bayer's construction is consistent with the general understanding of a person of ordinary skill in the art. Dr. Myerson, Bayer's expert witness, testified that "the general understanding of a [person of ordinary skill in the art is] that a reference to a particular 'Q' value together with a specified point in time in a dissolution test (*e.g.*, 30 minutes) refers to the minimum amount of active pharmaceutical ingredient that must be released at that point in time." Myerson Rpt. ¶ 30.

Dr. Myerson's testimony is supported by the USP's description of the apparatus 2 (paddle) test. The USP states that "[w]here a single time specification is given" (e.g., 30 minutes), "the test may be concluded in a shorter period if the requirement for minimum amount dissolved is met" (e.g., 75%). USP at 2413; Myerson Rpt. ¶ 36; Myerson Dep. Tr. at 32:1–33:4, ECF No. 153-1.

Dr. Myerson's testimony is also supported by arguments and an expert declaration presented by Mylan in a petition for inter partes review ("IPR") with respect to these claims filed by Mylan at the Patent Trial and Appeal Board ("Board"). Mylan's expert before the Board stated that:

> A person of ordinary skill in the art would have had a reasonable expectation of success in manufacturing a rapid-release tablet of rivaroxaban having a Q value of at least 75% (30 minutes) . . . . Indeed, Forsman states that after 30 minutes the immediate release tablet of Example 1a released 94% of anticoagulant . . . . Forsman's tablet necessarily released 75% of the anticoagulant within 30 minutes because it released 94% of the anticoagulant within 30 minutes.

Myerson Rpt. ¶ 40 (quoting Declaration of Leslie Z. Benet, *Mylan Pharm. Inc. v. Bayer Intellectual Prop. GmbH*, IPR2018-1143, Ex. 1002 ¶ 138 (P.T.A.B. May 24, 2018)). Relying on the expert testimony above, Mylan argued in its petition for IPR that

> Forsman thus demonstrated that its Example 1A rapid-release tablet had a Q value (30 minutes) of 75% according to the USP release method using apparatus 2 (paddle) because it resulted in at least 75% dissolution within 30 minutes.

Mylan's IPR Pet. at 47, ECF No. 153-1; *see also* Myerson Rpt. ¶ 40.

On the other hand, Mylan's expert, Dr. Parr, only stated that "[t]he USP may state the Q value as 'not less than' a . . . percentage," and that a person of ordinary skill in the art would understand this to be "different than a Q value of a specified percentage," "the latter delineating a specific and exact percentage at the specified time." Parr Rpt. ¶ 73, ECF No. 155-1. I credit Dr. Myerson's statements over Dr. Parr's conclusory and unsupported statements. In view of Dr. Myerson's testimony, I conclude that a person of ordinary skill in the art would understand that "a tablet which, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minutes) of 75%" covers tablets that release 75% or more of the active ingredient within 30 minutes.[3]

[3] Bayer also points to correspondence from the FDA regarding Mylan's proposed rivaroxaban product, which releases more than 75% of the active ingredient within 15 minutes. Bayer's Br. 8–9. The court notes that the correspondence from the FDA is consistent with the court's construction of "rapid-release tablet." *See* May 25, 2016 FDA Ltr. at MYL_RIV_218_00000238, ECF No.

Mylan argues that the patentees acted as their owner lexicographers in the '218 patent and defined "rapid-release tablet" as "a tablet which, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minutes) of 75%." Mylan's Br. 1–5 (emphasis added). Mylan contends that use of the word "of," instead of the terms "at least" or "more than" in the definition of "rapid-release tablet," shows how Mylan's construction is correct, and the court cannot "re-write the definition of the claim to mean 'at least 75%' rather than 'of 75%.'" *Id.* (citing *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371 (Fed. Cir. 2004)). But the absence of "at least" or "more than" in the specification does not mean that a person of ordinary skill in the art, in light of the reference to the PCT application, would not understand the definition to include a tablet that releases more than 75% of the active ingredient within 30 minutes. Nor does the Federal Circuit's decision in *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371 (Fed. Cir. 2004), support Mylan's position. That case involved a different patent with different claim language. *See id.* at 1371–72. The fact that the court in *Chef America* adopted a claim construction that rendered the claimed process inoperable hardly suggests that such a construction is uniformly preferred. *See id.* at 1373–74.

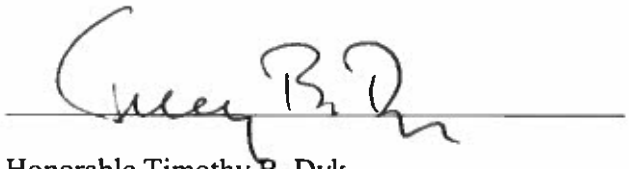
III

Accordingly, the court concludes that "rapid-release tablet" covers tablets that release 75% or more of the active ingredient. Because of the parties' stipulation that "Mylan literally infringes each of claims 1–4 of the '218 patent" if the court determines that "rapid-release tablet" covers tablets that release more than 75% of the active ingredient, Stip. Regarding Infringement ¶ 3, the

153-1 (informing Mylan that dissolution data for its tablets "support an acceptance criterion of Q = 80% at 15 min"); Myerson Rpt. ¶ 34.

court concludes that Mylan's proposed rivaroxaban tablets literally infringe claims 1–4 of the '218 patent, subject to a determination of patent invalidity.

IT IS SO ORDERED this 2nd day of April, 2019.



Honorable Timothy B. Dyk
United States Circuit Judge, sitting by designation