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Paper No. 13
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.,
Petitioner,

v.

BAYER INTELLECTUAL PROPERTY GMBH,
Patent Owner.

Case IPR2018-01143
Patent 9,539,218 B2

Before JACQUELINE WRIGHT BONILLA, *Acting Deputy Chief Administrative Patent Judge*, RAMA G. ELLURU and TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–4 of U.S. Patent No. 9,539,218 B2 (Ex. 1001, "the '218 patent"). Paper 2 ("Pet."). Bayer Intellectual Property GmbH ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply to the Preliminary Response (Paper 8, "Reply"), and Patent Owner filed a Surreply (Paper 10 (confidential version); Paper 11 (public version) ("Surreply")).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the arguments and evidence, we determine that it is appropriate to exercise our discretion to deny institution under 35 U.S.C. §§ 314(a) and 325(d). Accordingly, we decline to institute an *inter partes* review of the challenged claims of the '218 patent.

A. Related Proceedings

Patent Owner has asserted the '218 patent against Petitioner in a pending lawsuit styled *Bayer Intellectual Property GmbH v. Mylan Pharmaceuticals Inc.*, No. 1:17-cv-00584-RGA (D. Del.). Pet. 14; Paper 5, 2. Patent Owner identifies nine other pending cases involving the '218 patent in the U.S. District Court of Delaware, which, along with the above-referenced case, have been consolidated into the case *Bayer Intellectual Property GmbH v. Taro Pharmaceutical Industries Ltd.*, 1:17-cv-462-RGA (D. Del.). Paper 5, 2–3.

B. The '218 Patent

The '218 patent relates to a method of treating a thromboembolic disorder by administering a direct factor Xa inhibitor once daily. Ex. 1001, 1:4–7. Factor Xa plays a key role in the blood coagulation cascade. *Id.* at 1:25–26. A preferred embodiment of the invention relates to 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide, which is referred to as rivaroxaban by the parties. *Id.* at 3:18–21. Rivaroxaban is a low molecular weight, orally administrable direct inhibitor of factor Xa. *Id.* at 3:21–22.

C. Illustrative Claim

Petitioner challenges claims 1–4 of the '218 patent, of which claim 1 is the only independent claim. Claim 1 is illustrative and is reproduced below:

> 1. A method of treating a thromboembolic disorder comprising:
>
> administering a direct factor Xa inhibitor that is 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive 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.

Ex. 1001, 10:63–11:5.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–4 of the '218 patent on the following grounds:

References
'610 Publication[1] and Kubitza Abstracts[2]
'610 Publication, Kubitza Abstracts, and Forsman[3]

Petitioner also relies on the Declarations of Leslie Z. Benet, Ph.D. (Ex. 1002) and Neil E. Doherty, III, M.D., FACC (Ex. 1003) to support its assertions.

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have had an advanced degree in pharmacology, drug design and formulation,

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[1] Straub et al., US 2003/0153610 A1, published Aug. 14, 2003 ("the '610 Publication," Ex. 1005).

[2] Kubitza et al., *Multiple Dose Escalation Study Investigating the Pharmacodynamics, Safety, and Pharmacokinetics of BAY 59-7939 an Oral Direct Factor Xa Inhibitor in Healthy Male Subjects*, 102 BLOOD 811a, Abstract # 3004 (Nov. 16, 2003) ("Kubitza # 3004"); Kubitza et al., *Single Dose Escalation Study Investigating the Pharmacodynamics, Safety, and Pharmacokinetics of BAY 59-7939 an Oral, Direct Factor Xa Inhibitor in Healthy Male Subjects*, 102 BLOOD 813a, Abstract # 3010 (Nov. 16, 2003) ("Kubitza # 3010"); Harder et al., *Effects of BAY 59-7939, an Oral, Direct Factor Xa Inhibitor, on Thrombin Generation in Healthy Volunteers*, 102 BLOOD 811a, Abstract # 3003 (Nov. 16, 2003) ("Kubitza # 3003"). Kubitza # 3004, # 3010, and # 3003 are collectively referred to by Petitioner as the "Kubitza Abstracts." Ex. 1006.

[3] Forsman et al., WO 00/13671, published Mar. 16, 2000 ("Forsman," Ex. 1007).

medicinal chemistry, or a related field. Pet. 11–12. Petitioner also asserts that a person of ordinary skill in the art would have had some combination of skill and experience, including experience in pharmacology, pharmacokinetics, toxicology, and formulation, and an understanding of the role of anticoagulants in treating thromboembolic disorders. *Id.* at 11 (citing Ex. 1002 ¶¶ 42–43; Ex. 1003 ¶ 19). Patent Owner does not contest Petitioner's assertions in this regard. Prelim. Resp. 4.

On this record, we adopt Petitioner's definition of the level of ordinary skill in the art. We also note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Claim Construction

In an *inter partes* review petition filed before November 13, 2018, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings); 83 Fed. Reg. 51,340 (Oct. 11, 2018) (changing the standard for interpreting claims in *inter partes* reviews filed on or after November 13, 2018). Under that standard, and absent any special definitions, we generally give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*,

504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The parties contest the meaning of "rapid-release tablet," which appears in claim 1 of the '218 patent. Petitioner asserts that the ordinary and customary meaning of "rapid-release tablet" is a "conventional tablet[] that [has] not been formulated to release the active compound in a modified manner, such as through delayed or extended release." Pet. 22 (citing Ex. 1002 ¶¶ 46, 49; Ex. 1003 ¶¶ 28–30). Patent Owner asserts that the term should be construed according to its express definition in the '218 specification: "a tablet which, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minutes) of 75%." Prelim. Resp. 5 (citing Ex. 1001, 8:21–24). Patent Owner further notes that the Board in a previous *ex parte* appeal decision (Ex. 1004, 116) and the district court judge in the copending case (Ex. 2002, 1) have both construed the term according to Patent Owner's proposed definition. Prelim. Resp. 6–9.

Having considered the parties' respective arguments and evidence, we determine Patent Owner's proposed interpretation is the broadest reasonable interpretation. We find—as the prior panel at the Board and the district court judge have found—that the '218 patent specification expressly defines the term "rapid-release tablet." Specifically, the '218 patent specification states:

> The term "oral dosage forms" is used in a general sense to reference pharmaceutical products administered orally. Oral dosage forms are recognized by those skilled in the art to include such forms as liquid formulations, granules, gelcaps, hard gelatin capsules or sachets filled with granules, and tablets releasing the active compound rapidly or in a modified manner.

> Tablets are preferred, in particular tablets rapidly releasing the active compound. *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 minute) of 75%.*

Ex. 1001, 8:12–24 (emphasis added). Thus, the specification sets forth with reasonable clarity and deliberateness the definition of "rapid-release tablets" as being "in particular those [tablets] which, according to the USP release method using apparatus 2 (paddle), have a Q value (30 minute) of 75%." *Id.* at 8:22–24.

Petitioner does not identify any evidence that persuades us to deviate from the prior Board decision, the district court's decision, and, most importantly, the '218 patent specification. For example, as support, Petitioner quotes the following passage from the specification, arguing that the specification uses the term in its customary manner:

> Oral dosage forms are recognized by those skilled in the art to include . . . tablets releasing the active compound rapidly or in a modified manner. Tablets are preferred, in particular tablets rapidly releasing the active compound.

Pet. 22 (quoting Ex. 1001, 8:14–30). But, as Patent Owner notes, Petitioner's block quotation is misleading. Prelim. Resp. 10. As seen in a fuller reading of the relevant passage in the specification itself, Petitioner has omitted the paragraph break after the first sentence. When viewed in context, we agree with Patent Owner that the specification identifies "tablets releasing the active compound rapidly or in a modified manner" as an example of an "oral dosage form." Ex. 1001, 8:12–19. After the paragraph break, however, the specification goes on to discuss tablets and specifically defines "rapid-release tablets" "[i]n the context of the present invention." *Id.* at 8:21–22.

We are not persuaded to construe the term otherwise based on Petitioner's assertion that the term is not in quotation marks in the specification. *See* Reply 2. A lack of quotation marks is not dispositive, especially given the definition is in the section of the specification where "the following terms and abbreviations are defined." *See* Ex. 1001, 7:22–24. Thus, we are persuaded that the specification has provided a clear and express definition of the term that is narrower than that proposed by Petitioner.

To further support its construction, Petitioner cites extrinsic evidence in the form of testimony from its declarants and definitions from various textbooks and other publications. Pet. 22–24. We are not persuaded, as such extrinsic evidence cannot outweigh the clear definition of "rapid-release tablet" expressly set forth by the patent specification. *See Tempo Lighting, Inv. v. Tivoli, LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014) (finding that "extrinsic evidence is not irrelevant, but has relatively little probative value in view of the prevailing intrinsic evidence").

Finally, Petitioner points to alleged concessions made by Patent Owner to the European Patent Office in an Opposition proceeding (Pet. 25–26) and to the district court in the copending litigation (Reply 1–2). Petitioner argues that Patent Owner agreed in the European Opposition that a "rapid-release tablet" means "any tablet that is not a sustained- or retarded-release tablet." Pet. 25–26. Like the district court, we are persuaded that Patent Owner's alleged concession appears to have been a position taken to streamline the European litigation. *See* Prelim. Resp. 15; Ex. 1015, 28 ("To simplify matters for the present proceedings, we will adopt for the purpose of the present proceedings the understanding proposed by the majority of the

opponents . . . ."); *see also* Ex. 2002, 3 (district court's Markman Order accepting Patent Owner's explanation).

Petitioner also argues that the definition in the specification is unclear, as evidenced by the fact that Patent Owner asked the district court to further construe the construction of "rapid-release tablet." Reply 1–2. The district court denied Patent Owner's request, stating that Patent Owner's request for further construction amounts to an issue of fact to be determined at trial. Ex. 1069, 1. Because the issues in the district court case that gave rise to Patent Owner's request are not at issue here, we are not persuaded that Patent Owner's request for further construction in that case justifies adopting Petitioner's construction here.

Accordingly, on this record, we construe the term "rapid-release tablet" to mean "a tablet that, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minute) of 75%."

We determine that it is unnecessary to construe any other term for purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

C. Whether to Exercise Our Discretion Under 35 U.S.C. § 325(d) for Ground 1

Institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining "the PTO is permitted, but never compelled, to institute an IPR proceeding"). For instance, § 325(d) states "[i]n determining whether to institute or order a proceeding under this chapter . . . [t]he Director may take into account

whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office."

In evaluating whether the same or substantially the same prior art or arguments were previously presented to the Office under § 325(d), the Board has considered a number of non-exclusive factors, including, for example:

(a) the similarities and material differences between the asserted art and the prior art involved during examination;

(b) the cumulative nature of the asserted art and the prior art evaluated during examination;

(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

(d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguished the prior art;

(e) whether Petitioner has pointed out sufficiently how the Examiner erred in its consideration of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the asserted prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, Case IPR2017-01586, slip op. 17–18 (PTAB Dec. 15, 2017) (Paper 8) (informative) ("the *Becton Dickinson* factors").

1. The Prior Board Decision

During prosecution of the '218 patent application, the examiner issued a final rejection of the pending claims as obvious over the '610 Publication,

"Kubitza 1,"[4] and Kubitza # 3010 (referred to by the Board as "Kubitza 2"). Ex. 1004, 111. On appeal, the Board found that the claims directed to a "rapid-release oral dosage form" were obvious over the cited art. *Id.* at 113–16. Then-pending claim 5, however, recited a "rapid-release tablet," which the Board interpreted according to the "express definition thereof provided in the Specification." *Id.* at 116. The Board could not determine based on the evidence of record whether the disclosure of Kubitza # 3010 taught or suggested a "rapid-release tablet" according to that interpretation. *Id.* at 116–17. Thus, the Board reversed the rejection of claim 5. *Id.* at 117.

After the appeal, the examiner entered an examiner's amendment that amended the claims to recite a "rapid-release tablet" instead of a "rapid-release oral dosage form." Ex. 1004, 53–54. The Examiner stated in the Reasons for Allowance that the cited prior art "does not teach, disclose nor render obvious the instantly claimed method wherein a rapid-release tablet is utilized." *Id.* at 55.

2. Application of Our Discretion Under 35 U.S.C. § 325(d)

Patent Owner argues that we should exercise our discretion to deny institution under § 325(d) because substantially the same prior art or arguments were previously presented to the Office. Pet. 20–25.

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[4] The Board identified "Kubitza 1" as Kubitza et al., *Oral, Direct Factor Xa Inhibitor—In Healthy Male Subjects*, 102 BLOOD 811a (Nov. 16, 2003). Ex. 1004, 110. The cited page 811a of BLOOD, however, does not include an abstract with that title. *See* Ex. 1006, 811a. Nevertheless, Petitioner appears to equate Kubitza 1 with Kubitza # 3004. *See* Reply 3–4 (citing the Board's prior decision and referring to "Kubitza abstracts # 3004 and # 3010 and the '610 publication"). Regardless, the relied-upon portions of Kubitza 1 appear to be substantially similar to the disclosures in Kubitza # 3004. *Compare* Ex. 1004, 112 (FF8 and FF9) *with* Ex. 1006, 811a. We, therefore, consider Kubitza 1 to be substantially similar to Kubitza # 3004.

Specifically, Patent Owner argues that Ground 1 is premised on the arguments that (1) the Board incorrectly construed the term "rapid-release tablet"; (2) the Board should adopt a different construction here; and (3) the claims are obvious in view of that different construction. *Id.* at 21. Because there is no reason to construe the term differently now, Patent Owner asserts we should exercise our discretion under § 325(d) because the substantive obviousness positions of Ground 1 were already considered and rejected by the Office during prosecution of the patent. *Id.* at 20.

Petitioner asserts that the Petition includes new evidence not presented during prosecution or before the Board in the *ex parte* appeal. Pet. 15-18 (citing new testimony and supporting reference evidence). But the new evidence regarding Ground 1 relates to evidence in support of Petitioner's proposed construction of the term "rapid-release tablet," which, as explained above, we do not find persuasive. *See id.* at 15–17; *see also supra*. In response to Patent Owner's § 325(d) argument for Ground 1, Petitioner simply argues that Patent Owner's argument is unavailing because the Board should adopt its construction. Reply 3.

Having considered the parties' respective arguments and evidence, we are persuaded that exercising our discretion under § 325(d) is appropriate for Ground 1. *Becton Dickinson* factors (a)–(d) relate to whether and to what extent the prior art asserted in the Petition was considered and relied upon by the examiner during prosecution. Here, substantially the same prior art that Petitioner asserts in Ground 1 was extensively considered by the examiner and the Board. That is, the examiner and the Board considered whether the claims were obvious over the '610 Publication, Kubitza # 3004 (i.e., Kubitza 1), and Kubitza # 3010 (i.e., Kubitza 2). The Petition also relies on Kubitza # 3003. *See, e.g.*, Pet. 34, 44. But Petitioner does not assert—nor do we

ascertain—that the relied-upon portions of Kubitza # 3003 cure the deficiencies of the '610 publication, Kubitza # 3004, or Kubitza # 3010. *See, e.g*, Pet. 34, 44–45 (discussing Ex. 3003); Reply (no citation to Ex. 3003). Thus, these factors weigh heavily in favor of exercising our discretion to deny institution.

Becton Dickinson factors (e) and (f) look to the Petition and whether Petitioner has made a case for reconsidering the asserted prior art. We find that Petitioner has not. As noted above, we are not persuaded that the prior Board panel (or the district court) erred in construing the term "rapid-release tablet" according to the express definition in the specification. Thus, Petitioner's arguments regarding claim construction do not point out sufficiently how the Board and the examiner erred in its consideration of the cited prior art. Nor has Petitioner identified any additional facts and evidence unrelated to claim construction that justify reconsidering the prior art or arguments set forth in Ground 1.

Accordingly, under the facts and circumstances of this case, we find that substantially the same prior art and arguments were previously presented to the Office. We, therefore, determine that exercising our discretion under § 325(d) to deny institution is appropriate for Ground 1.

D. Whether to Exercise Our Discretion Under 35 U.S.C. § 314(a) for Ground 2

Patent Owner asserts that we should also exercise our discretion under § 325(d) for Ground 2. Prelim. Resp. 21–25. Ground 2, however, differs from Ground 1 because Petitioner asserts that even under the express definition of "rapid-release tablet," the claims are obvious. Pet. 46. To that end, Petitioner additionally relies on Forsman, which was not before the

Office during prosecution and which allegedly teaches the specific requirements for a "rapid-release tablet." Pet. 17–18.

Patent Owner notes, however, that Forsman is at issue in the copending district court case. Surreply 3. Moreover, Petitioner relies on the same declarants (Drs. Benet and Doherty), and the same prior art references (the '610 publication, the Kubitza Abstracts, and the Forsman references) that it relies on in the Petition. *Id.* at 4. The district court also has construed "rapid-release tablet" as we have here, according to the express definition set forth in the specification. Ex. 2002, 1. Finally, Patent Owner indicates that the district court has set trial for April 1, 2019. Surreply 4.

It is well established that we have discretion regarding whether to institute trial under § 314(a). *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (citing § 314(a) and stating the PTO's "decision to deny a petition is a matter committed to the Patent Office's discretion"). As such, even assuming there is a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim (which we do not assess here), we have discretion on whether to institute trial based on the facts and circumstances of each case.

Having considered the parties' respective arguments, we determine that exercising our discretion to not institute trial is appropriate here. Given the advanced stage of the copending district court case and the extensive overlap of the asserted prior art, expert testimony, and claim construction, we find it would be an inefficient use of Board resources to proceed with this *inter partes* review in parallel with the district court case. *See NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752, slip op. at 19–20

(PTAB Sept. 12, 2018) (Paper 8) (finding the advanced state of a copending district court proceeding addressing the same prior art to be an additional factor weighing in favor of denying the petition under § 314(a)). That inefficiency is amplified where the district court trial is set to occur on April 1, 2019, which is more than eight months before our Final Written Decision would be due in December 2019, if we were to institute trial.

Thus, we find that instituting an *inter partes* review of the '218 patent under these facts and circumstances would be contrary to the overall goal of the AIA to "make the patent system more efficient by the use of post-grant review procedures." *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, Case IPR2016-01357, slip op. at 16–17 (PTAB Sept. 6, 2017) (Paper 19) (precedential as to § II.B.4.i). Accordingly, we determine that exercising our discretion to deny institution under § 314(a) is appropriate as to Ground 2.

III. CONCLUSION

For the foregoing reasons, we exercise our discretion under 35 U.S.C. §§ 314(a) and 325(d) and decline to institute an *inter partes* review of the challenged claims of the '218 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all challenged claims of the '218 patent and no trial is instituted.

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