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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.*,

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