

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PANACEA BIOTEC LTD.,
Petitioner,

v.

DAIICHI SANKYO COMPANY, LIMITED AND
UBE INDUSTRIES, LTD.,
Patent Owner.

Case IPR2015-01492
Patent 8,569,325 B2

Before ERICA A. FRANKLIN, TINA E. HULSE, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner Panacea Biotech Ltd. (“Panacea”) filed a Petition requesting an *inter partes* review of claims 1–26 of U.S. Patent No. 8,569,325 B2 (Ex. 1001, “the ’325 patent”). Paper 2 (“Pet.”). Daiichi Sankyo Company, Ltd. and Ube Industries, Ltd. (collectively, “Patent Owner”) filed a Preliminary Response to the Petition. Paper 8 (“Prelim. Resp.”).

We have jurisdiction 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 Petition and Preliminary Response, we determine that the Petition raises the same prior art and arguments previously presented to the Office in IPR2015-00865. Accordingly, we exercise our discretion and decline to institute an *inter partes* review of any of the ’325 patent claims.

A. *Related Proceedings*

Panacea states that the ’325 patent is asserted in the consolidated action styled *Eli Lilly & Co. v. Accord Healthcare, Inc.*, No. 14-cv-00389-SEB-TAB (S.D. Ind.). Pet. 7. The ’325 patent is also asserted in *Eli Lilly & Co. v. Lupin Ltd.*, No. 1:15-cv-00673-SEB-TAB (S.D. Ind.) and in *Eli Lilly & Co. v. HEC Pharm USA, Inc.*, No. 1:15-cv-00792-SEB-TAB (S.D. Ind.). *Id.*

Panacea has also filed concurrently a petition for *inter partes* review of related U.S. Patent No. 8,404,703 (“the ’703 patent”) in IPR2015-01496. The ’325 patent and the ’703 patent are also, respectively, the subject of pending cases IPR2015-00865 (“the 865 IPR”) and IPR2015-00864 (“the 864 IPR”). We instituted *inter partes* review in the 864 IPR and the 865 IPR on September 15, 2015. 864 IPR, Paper 28; 865 IPR, Paper 28.

Patent Owner also notes that the '325 patent and the '703 patent are the subjects of pending petitions for *inter partes* review in IPR2015-01881 and IPR2015-01882, respectively. Paper 10, 1.

B. The '325 Patent

The '325 patent relates to a method for preventing diseases caused by thrombus or embolus. Ex. 1001, Abstract. 2-acetoxy-5-(α -cyclopropylcarbonyl-2-fluorobenzyl)-4,5,6,7-tetrahydrothieno[3,2-c]pyridine¹ (“prasugrel”) possesses inhibitory activity against platelet aggregation. *Id.* at 1:33–36. Aspirin is also well known to have low inhibiting activity against platelet aggregation. *Id.* at 1:36–38. The claimed method comprises separately administering prasugrel or a pharmaceutically acceptable salt thereof, and aspirin, in their pharmacologically effective amounts, to a warm-blooded animal. *Id.*, Abstract.

According to the '325 patent, the combination of prasugrel and aspirin “possess[es] excellent inhibitory activity against platelet aggregation and thrombogenesis with short onset latency and low toxicity.” *Id.* at 2:64–3:5. The combined use of the drugs results in more potent effectiveness than the use of each component alone. *Id.* at 3:25–29. Moreover, in the case where both agents cannot be mixed technically, “each component can be administered separately.” *Id.* at 3:50–52.

¹ 2-acetoxy-5-(α -cyclopropylcarbonyl-2-fluorobenzyl)-4,5,6,7-tetrahydrothieno [3,2-c]pyridine is also known as “CS-747” and “prasugrel.” See, e.g., Ex. 1044, Niitsu et al., *Pharmacology of CS-747 (Prasugrel, LY640315), a Novel, Potent Antiplatelet Agent with in Vivo p2Y₁₂ Receptor Antagonistic Activity*, 31 SEMINARS IN THROMB. HEMOST., 184–185 (2005) (characterizing the recited compound as “CS-747” and “prasugrel”).

C. Illustrative Claim

Panacea challenges claims 1–26 of the '325 patent. Claim 1 is illustrative and is reproduced below:

1. A method for preventing disease caused by thrombus or embolus, said method consisting of separately administering to a human in need of prevention of said disease:

- (a) 2-acetoxy-5-(α -cyclopropylcarbonyl-2-fluorobenzyl)-4,5,6,7-tetrahydrothieno[3,2-c]pyridine or a pharmaceutically acceptable salt thereof, and one or more pharmaceutically acceptable excipients, lubricants, binders, disintegrators, emulsifiers, stabilizers, corrigents and/or diluents, and
- (b) aspirin, and one or more pharmaceutically acceptable excipients, lubricants, binders, disintegrators, emulsifiers, stabilizers, corrigents and/or diluents,

wherein said 2-acetoxy-5-(α -cyclopropylcarbonyl-2-fluorobenzyl)-4,5,6,7-tetrahydrothieno[3,2-c]pyridine or the pharmaceutically acceptable salt thereof, and aspirin are administered in pharmacologically effective amounts to prevent said disease caused by thrombus or embolus by reducing thrombogenesis or by reducing platelet aggregation in said human, after both (a) and (b) have been administered.

D. The Asserted Grounds of Unpatentability

Panacea challenges the patentability of claims 1–26 of the '325 patent on the following grounds:

References	Basis	Claims challenged
Coniglio ²	§ 103(a)	1–26
Bernat ³ and Asai ⁴	§ 103(a)	1–26
Bernat and Koike ⁵	§ 103(a)	1–26
Coniglio, Bernat, Asai, and Koike	§ 103(a)	1–26

II. ANALYSIS

A. Statutory Discretion to Institute

When a petition for *inter partes* review challenges the same patent raised in a proceeding already before us, our decision as to whether or not to institute a trial is guided by 35 U.S.C. §§ 315(d) and 325(d). Section 315(d) states:

[D]uring the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

Id. Section 325(d) has similar language, and further explains: “In determining whether to institute or order a proceeding under this chapter,

² Coniglio et al., WO 99/65500, published Dec. 23, 1999 (Ex. 1003).

³ Bernat et al., US 5,989,578, issued Nov. 23, 1999 (Ex. 1006).

⁴ Asai et al., CS-747, *a New Platelet ADP Receptor Antagonist*, 51 ANNU. REP. SANKYO. RES. LAB. 1–44 (1999) (Ex. 1010).

⁵ Koike et al., US 5,288,726, issued Feb. 22, 1994 (Ex. 1012).

chapter 30, or chapter 31,⁶ the 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.” *Id.*

With those statutory provisions in mind, we turn to the question of whether the Petition in this proceeding warrants *inter partes* review in light of the trial that has been instituted in the 865 IPR on the same prior art and grounds presented in this Petition.

B. Discussion

The Petition is substantively identical to the petition in the 865 IPR. In the Petition, Panacea admits this fact, stating that it “recognizes that the instant Petition presents the same prior art and arguments that have been presented to the Office in the petition in Case IPR2015-00865.” Pet. 8. At the time Panacea filed this Petition, the petition in the 865 IPR was pending before us. The 865 IPR petition was filed collectively by eighteen different entities, including Panacea. 865 IPR, Paper 10, 1. In the Patent Owner Preliminary Response in the 865 IPR, Patent Owner asserted that the collective Petitioner failed to identify all of the real parties-in-interest, as required by 35 U.S.C. § 312(a)(2), and argued that the petition should be denied. 865 IPR, Paper 17, 5–22.

In this Petition, Panacea states that it disagrees with Patent Owner’s assertion regarding the real parties-in-interest issue, but nonetheless states, “in the event that the Office agrees with the patent owners and denies the petition in Case IPR2015-00865 on that basis, [Panacea] respectfully submits that the prior art and arguments presented in the instant Petition,

⁶ Chapter 31 of the Patent Act covers *inter partes* review proceedings. Thus, although § 325(d) appears in Chapter 32, which is directed to post-grant reviews, it is applicable to *inter partes* reviews.

which would not have been previously considered by the Board on the merits in Case IPR2015-00865, should be considered in this proceeding.”

Pet. 8. Thus, Panacea recognizes the duplicative nature of this Petition and appears to condition our review on our denial of the petition in the 865 IPR.

As mentioned above, we have instituted an *inter partes* review of all challenged claims in the 865 IPR. 865 IPR, Paper 28. Because the Petition in this proceeding presents the same prior art and arguments that were previously presented in the 865 IPR, and because Panacea is also involved in the 865 IPR, we determine, under the current circumstances, that our limited judicial resources are best spent elsewhere. *See Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (stating that when deciding whether to take action in a particular matter, an agency must determine whether its resources are best spent on one matter or another). Thus, we find it is appropriate to exercise our discretion under § 325(d) to deny institution on all of the challenged claims.

III. CONCLUSION

Because the Petition challenges the same patent based upon the same art and arguments presented in the petition for the 865 IPR, to which Panacea is also a party, we exercise our discretion to deny institution of *inter partes* review under 35 U.S.C. § 325(d).

IV. ORDER

In consideration of the foregoing, it is hereby ordered that the Petition is *denied*.

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Patent 8,569,325 B2

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