

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PANACEA BIOTEC LTD.,
Petitioner,

v.

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

Case IPR2015-01496
Patent 8,404,703 B2

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

FRANKLIN, *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 1–27 of U.S. Patent No. 8,404,703 B2 (Ex. 1001, “the ’703 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). When another proceeding involving the same patent is before us, we have discretion under 35 U.S.C. § 325(d) to reject a subsequent petition that raises the same or substantially the same prior art or arguments. Upon considering the Petition and Preliminary Response, we determine that the Petition challenges the same patent involved in a pending proceeding and raises the same prior art and arguments presented in that proceeding. Accordingly, we exercise our discretion and decline to institute an *inter partes* review of any challenged claim.

A. *Related Proceedings*

Panacea and Patent Owner identify, as a related proceeding involving the ’703 patent, litigation consolidated as *Eli Lilly and Co., et al. v. Accord Healthcare, Inc., et al.*, No. 1:14-cv-00389-SEB-TAB and pending in the U.S. District Court for the Southern District of Indiana. Pet. 7; Paper 5, 2. The parties also identify *Eli Lilly and Co., et al. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, No. 1:15-cv-00673-SEB-TAB and *Eli Lilly and Co., et al. v. HEC Pharm USA, Inc. and HEC Pharm Co., Ltd.*, No. 1:15-cv-

00792-SEB-TAB as pending in the U.S. District Court for the Southern District of Indiana and involving the '703 patent. Pet. 7–8; Paper 5, 3.

Additionally, the '703 patent is the subject of an *inter partes* review instituted in Case IPR2015-00864 (“IPR '864”). Pet. 8; Paper 5, 3. The '703 patent is also the subject of a petition requesting an *inter partes* review in Case IPR2015-01882. *Id.* The claims of a related patent, U.S. Patent 8,569,325, are the subject of an *inter partes* review instituted in Case IPR2015-00865, and the subject of a petition requesting an *inter partes* review in Case IPR2015-01492. *Id.*

B. The '703 Patent (Ex. 1001)

The '703 patent relates to methods for preventing or treating diseases caused by thrombus or embolus by administering an effective amount of 2-acetoxy-5-(α -cyclopropylcarbonyl-2-fluorobenzyl)-4,5,6,7-tetrahydrothieno [3,2-c]pyridine,¹ or a pharmaceutically acceptable salt thereof, and aspirin to warm-blooded animals, particularly humans. Ex. 1001, 1:24–30. The Specification explains that, prior to the invention, both active ingredients were well known to possess inhibitory activity against platelet aggregation, wherein 2-acetoxy-5-(α -cyclopropylcarbonyl-2-fluorobenzyl)-4,5,6,7-tetrahydrothieno[3,2-c]pyridine activity is potent, and aspirin activity is low. *Id.* at 1:31–37.

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

Claim 1 of the '703 patent is illustrative and reproduced below:

1. A method for treatment of a disease caused by thrombus or embolus, said method consisting of: administering (i) 2-acetoxy-5-(α -cyclopropylcarbonyl-2-fluorobenzyl)-4,5,6,7-tetrahydrothieno[3,2-c]pyridine or a pharmaceutically acceptable salt thereof, (ii) aspirin, and (iii) one or more pharmaceutically acceptable excipients, lubricants, binders, disintegrators, emulsifiers, stabilizers, corrigents and/or diluents, wherein (i) and (ii) are administered in pharmacologically effective amounts, to a human in need of reduction of thrombogenesis or reduction of platelet aggregation.

D. The Prior Art

Panacea relies upon the following prior art references:

Coniglio	WO 99/65500, published Dec. 23, 1999.	Ex. 1003
Bernat	US Patent No. 5,989,578, issued Nov. 23, 1999.	Ex. 1006
Asai	Asai et al., <i>CS-747, A New Platelet ADP Receptor Antagonist</i> , 51 ANNU. REP. SANKYO RES. LAB. 1-44 (1999).	Ex. 1010
Koike	US Patent No. 5,288,726, issued Feb. 22, 1994.	Ex. 1012

Panacea also relies upon the Declarations of Jack Hirsch, M.D. (Ex. 1002) and Paul A. Gurbel, M.D. (Ex. 1025).

E. The Asserted Grounds of Unpatentability

Panacea challenges the patentability of claims 1-27 of the '703 patent on the following grounds (Pet. 2, 11):

Claims Challenged	Basis	Reference
1–27	§ 103(a)	Coniglio
1–27	§ 103(a)	Bernat in view of Asai
1–27	§ 103(a)	Bernat in view of Koike
1–27	§ 103(a)	Coniglio in view of Bernat, Asai, and Koike

II. ANALYSIS

The Petition is substantively identical to the petition in IPR ’864. Indeed, Panacea “recognizes that the instant Petition presents the same prior art and arguments that have been presented to the Office in the petition in Case IPR2015-00864.” Pet. 8. In IPR ’864, the patent owner asserted in the preliminary response that the petition should be denied because the petitioners, including Panacea, failed to identify all of the real parties-in-interest as required by 35 U.S.C. § 312(a)(2). IPR ’864, Paper 17. In the Petition, Panacea disagrees with that allegation, but nonetheless asserts that “in the event that the Office agrees with the patent owners and denies the petition in Case IPR2015-00864 on that basis, [Panacea] respectfully submits that the prior art and arguments presented in the instant Petition, which would not have been previously considered by the Board on the merits in Case IPR2015-00864, 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 IPR ’864. Patent Owner asserts, among other reasons, that the Petition should be denied as duplicative. Prelim. Resp. 3, 15–17.

When a petition for *inter partes* review challenges the same patent raised in a proceeding already before us, our decision whether to institute a trial is guided by 35 U.S.C. §§ 315(d) and 325(d). Section 315(d) states that “during 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, chapter 30, or chapter 31,² 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.

Because the Petition presents the same prior art and arguments to challenge the same claims of the ’703 patent that were previously presented in IPR ’864, and because Panacea is also a petitioner in that instituted proceeding, we determine, under the current circumstances, that our 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 of an *inter partes* review for any of the challenged claims.

² 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.

III. CONCLUSION

Because the Petition challenges the same patent based upon the same art and arguments as presented in the Petition in IPR '864, to which the Petitioner is also a party, we exercise our discretion to deny institution of an *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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