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Paper 70
Entered: December 13, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP.,
Petitioner,

v.

MAYNE PHARMA INTERNATIONAL PTY LTD.,
Patent Owner.

Case IPR2016-01186
Patent 6,881,745 B2

Before TONI R. SCHEINER, ERICA A. FRANKLIN, and JACQUELINE T. HARLOW, *Administrative Patent Judges.*

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Patent Owner's Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Merck Sharp & Dohme Corp. ("MSD" or "Petitioner") filed a Petition (Paper 1, "Pet.") on June 11, 2016 requesting an *inter partes* review of claims 1–3, 5–7, and 9–14 of U.S. Patent No. 6,881,745 B2 (Ex. 1001, "the '745 patent"). Mayne Pharma International Pty Ltd. ("Mayne" or "Patent Owner") filed a Preliminary Response (Paper 8, "Prelim. Resp.").

In our Decision on Institution (Paper 10, "Decision" or "Dec."), we determined that Petitioner had established a reasonable likelihood that it would prevail in its challenges to claims 1–3, 5–7, 9, 11, 12, and 14 as anticipated by Kai;[1] claims 1, 3, 5, and 7 as anticipated by Thorpe;[2] and claims 1–3, 5–7, and 9–14 as obvious over Kai, Sangekar,[3] and Babcock,[4] and instituted trial on those three grounds. Dec. 15–21, 23–25, 25–27. Subsequently, we granted Patent Owner's Motion to Amend (Paper Nos. 29, 61), canceling claims 1, 3, 5, and 7. Consequently, the grounds remaining for consideration in this trial are:

Claims 2, 6, 9, 11, 12, and 14 under 35 U.S.C. § 102 as anticipated by Kai; and claims 2, 6, and 9–14 under 35 U.S.C. § 103 as obvious over Kai, Sangekar, and Babcock.

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[1] Toshiya Kai et al, *Oral Absorption Improvement of Poorly Soluble Drug Using Solid Dispersion Technique*, 44 CHEM. PHARM. BULL. 568–571 (1996) ("Kai") (Ex. 1007).
[2] John E. Thorpe et al., *Effect of Oral Antacid Administration on the Pharmacokinetics of Oral Fluconazole*, 34 ANTIMICROBIAL AGENTS AND CHEMOTHERAPY 2032–2033 (1990) ("Thorpe") (Ex. 1020).
[3] WO 98/00113 A1, Surendra Sangekar et al., published January 8, 1998 ("Sangekar") (Ex. 1015).
[4] EP 1 027 886 A2, Walter Christian Babcock et al., published August 16, 2000 ("Babcock") (Ex. 1009).

In its Request for Rehearing (Paper 13, "Rehearing Request" or "Req. Reh'g"), Patent Owner argues that we abused our discretion in not finding the Petition incomplete for failing to name Merck & Co., Inc. ("MCI"), the parent company of Merck Sharp & Dohme Corp., as a real party in interest (Req. Reh'g 1), and also in relying on the incomplete, unsworn declarations of Drs. Grainger and Blaschke (*id.* at 2). Patent Owner requests that we vacate the filing date of the Petition, and deny institution of an *inter partes* review. *Id.* at 3.

We deny the relief requested.

II. ANALYSIS

A party requesting rehearing bears the burden of showing that the decision should be modified. 37 C.F.R. § 42.71(d). The party "must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." *Id.*

When reconsidering a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may be determined if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *Star Fruits S.N.C. v. U.S.*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold Partnership v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000).

Real Party in Interest

The Petition indicates that "Merck is the real party-in-interest." Pet. 56. The Petition further indicates that "Merck has been charged with

infringement of the '745 patent in the parallel litigation *Mayne Pharma International Pty Ltd. v. Merck & Co., Inc.*, Case No. 15-cv-00438 (D. Del.), filed May 29, 2015" (*id.*) and "Petitioner was served with the complaint in that litigation on June 12, 2015 (*id.*). The full title of the parallel litigation is *Mayne Pharma International Pty Ltd. v. Merck & Co., Inc. and Merck Sharp & Dohme Corp.* Paper 5 (Patent Owner's Initial Mandatory Notices), 2.

The statute governing *inter partes* proceedings sets forth certain requirements for a petition for *inter partes* review, including that "the petition identif[y] all real parties in interest." 35 U.S.C. § 312(a); *see also* 37 C.F.R. § 42.8(b)(1) (providing a requirement to identify real parties in interest in mandatory notices). The Board's precedential decision in *Lumentum Holdings, Inc. v. Capella Photonics, Inc.*, Case IPR2015-00739, slip op. at 5 (PTAB Mar. 4, 2016) (Paper 38), states that "§ 312(a) sets forth requirements that must be satisfied for the Board to give consideration to a petition, however, a lapse in compliance with those requirements does not deprive the Board of jurisdiction over the proceeding, or preclude the Board from permitting such lapse to be rectified." *See also Elekta, Inc. v. Varian Med. Sys., Inc.*, Case IPR2015-01401, slip op. at 6–10 (PTAB Dec. 31, 2015) (Paper 19) (holding that disclosing additional real parties in interest via an updated disclosure does not mandate a change in petition filing date).

Our Trial Practice Guide describes the "core functions" of the real party in interest ("RPI") requirement as follows:

> [T]o assist members of the Board in identifying potential conflicts, and to assure proper application of the statutory estoppel provisions. The latter, in turn, seeks to protect patent owners from harassment via successive petitions by the same or related parties, to prevent parties from having a "second bite at the apple," and to protect the integrity of both the USPTO and

> Federal Courts by assuring that all issues are promptly raised and vetted.

Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012). Absent any indication of an attempt to circumvent estoppel rules, a petitioner's bad faith, or prejudice to a patent owner caused by the delay, permitting a petitioner to amend a challenged RPI disclosure while maintaining the original filing date promotes the core functions described in the Trial Practice Guide, while also promoting "the just, speedy, and inexpensive resolution of our proceedings." 37 C.F.R. § 42.1(b).

In this case, Petitioner has agreed to update its Mandatory Notices to add Merck & Co., Inc. as a real party in interest, provided the addition would not change the filing date of the Petition. *See* Ex. 2063, 15:6–11; Reply 26. There is no indication of intentional concealment, bad faith on Petitioner's part, an attempt to circumvent estoppel rules, or any other material benefit to Petitioner in Petitioner's delay in naming MCI as an RPI. The names "Merck Sharp & Dohme Corp.," "Merck," and "Merck & Co., Inc." all appear in the Petition as originally filed (Pet. 56), reasonably apprising the Board of any potential conflicts. Moreover, Petitioner has provided evidence that "Merck & Co., Inc.," MSD's co-defendant in the district court litigation, pledged to "be bound by any estoppel effect flowing from the IPR." Ex. 1098,[5] 8 n.3. Finally, we perceive no prejudice to Patent Owner—that is, a negative effect on Patent Owner's ability to challenge the Petition—as a result of the delay. Had MCI, MSD's co-

[5] Exhibit 1098 is the "Defendant's Brief in Support of Their Motion to Stay Proceedings Pending an *Inter Partes* Review . . . of U.S. Patent No. 6,881,745," dated and served January 19, 2017.

defendant in the district court litigation, been named as an RPI originally, Patent Owner would have been in the same position it is now.

Our rules provide that a late action may be excused "upon a Board decision that consideration on the merits would be in the interests of justice." 37 C.F.R. § 42.5(c)(3). We determine that permitting Petitioner to update its mandatory notices to include MSD's parent company, MCI, as a real party in interest in this matter—without affecting the Petition's filing date—promotes the core functions described in the Trial Practice Guide with respect to RPIs, and serves the interests of justice. Accordingly, we are not persuaded that we should have denied institution of an *inter partes* review on this basis.

The Grainger and Blaschke Declarations

In support of its Petition, Petitioner submitted documents titled "Declaration of David W. Grainger, Ph.D." (Ex. 1005) and "Declaration of Terrence F. Blaschke, M.D." (Ex. 1006). Both documents were signed and dated, and both Dr. Grainger and Dr. Blaschke stated "If cross examination is required of me, I will appear for cross examination within the United States during the time allotted." Ex. 1005 ¶ 67; Ex. 1006 ¶ 28. Neither document, however, included language indicating that the signatories were aware that "willful false statements and the like are punishable by fine or imprisonment, or both," thus, neither document was in compliance with the requirements of 37 C.F.R. § 1.68 for written declarations.

In deciding whether to institute an *inter partes* review, we declined to exclude Exhibits 1005 and 1006 from consideration. Instead, we treated Patent Owner's arguments in the Preliminary Response as an objection to Exhibits 1005 and 1006, and gave Petitioner an opportunity to correct the

omission. Dec. 13–14. Subsequently, Petitioner submitted sworn declarations in compliance with 37 C.F.R. § 1.68, but otherwise identical to Exhibits 1005 and 1006. Ex. 1066 ¶ 68; Ex. 1067 ¶ 29.

Patent Owner contends that we should not have treated its arguments in its Preliminary Response as objections to evidence because objections to evidence must be submitted after institution of the trial. Req. Reh'g 12. Patent Owner also contends Petitioner should have requested supplementation, but did not. *Id.* Patent Owner further contends "[i]t is prejudicial for the Board to ignore the statute, regulations and rules of evidence *sua sponte* to accommodate a petitioner that has made no effort to seek the Board's permission or assistance to correct the non-compliant declarations." *Id.*

Nevertheless, as discussed above, 37 C.F.R. § 42.1(b) dictates that Part 42 of 37 C.F.R. "shall be construed to secure the just, speedy and inexpensive resolution of every proceeding." Furthermore, 37 C.F.R. § 42.5(b) provides that "[t]he Board may waive or suspend a requirement of . . . [part] 42 and may place conditions on the waiver or suspension." A late action may be excused "upon a Board decision that consideration on the merits would be in the interests of justice." 37 C.F.R. § 42.5(c)(3). In addition, 35 U.S.C. § 26 authorizes the Director to provisionally accept "a defective execution, provided a properly executed document is submitted within such times as may be prescribed." *See In re Bennett*, 766 F.2d 524 (Fed. Cir. 1985) (en banc) (applying § 26 to permit a corrected reissue oath to be filed after a two-year statutory deadline).

Patent Owner's objections were clearly set forth in its Preliminary Response, and we essentially waived the requirement that the objections be served after institution. Regarding the need for Petitioner to request supplementation, our rules do not require that the Petitioner request permission to supplement its declaration. Petitioner has a right to do so in response to evidentiary objections. 37 C.F.R. § 42.64(b)(2).

Mistakes not affecting the merits of a case can occur without bad faith on anyone's part, and we see nothing to indicate bad faith in this instance. The full substance of each Declaration was available to Patent Owner when the Petition was filed, and Patent Owner, much to its credit, addressed the Declarations in its Preliminary Response. We perceive no prejudice to Patent Owner—that is, a negative effect on Patent Owner's ability to challenge the Petition—as a result of the delay.

III. CONCLUSION

We have considered Patent Owner's Request for Rehearing, but are not persuaded that we abused our discretion in instituting an *inter partes* review of claims 2, 6, and 9–14 of the '745 patent.

IV. ORDER

Accordingly, it is

ORDERED that Patent Owner's Request for Rehearing of the Decision instituting an *inter partes* review in U.S. Patent No. 6,881,745 B2 is *denied.*

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