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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LANNETT HOLDINGS, INC.,
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2015-01630
Patent 7,220,767 B2

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Lannett Holdings, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–16 of U.S. Patent No. 7,220,767 B2 ("the '767 patent," Ex. 1001). Paper 2 ("Pet."). AstraZeneca AB ("Patent Owner") timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). Patent Owner argues that it had asserted the '767 patent against Petitioner more than one year before the Petition was filed. *Id.* at 1–7. Thus, Patent Owner contends, the Petition is time-barred under 35 U.S.C. § 315(b). *Id.* We authorized further briefing on the issue of § 315(b) bar. Paper 8. Thereafter, Petitioner filed a Reply (Paper 9), and Patent Owner filed a Sur-reply (Paper 11).

For the reasons provided below, we determine that the Petition is barred under 35 U.S.C. § 315(b). We, therefore, deny the Petition.

Related Proceedings

According to the parties, the '767 patent is the subject of *Impax Laboratories, Inc. v. Lannett Holdings, Inc.*, Case No. 1:14-cv-00984 (D. Del. filed July 25, 2014), and *Impax Laboratories, Inc. v. Lannett Holdings, Inc.*, case No. 1:14-cv-00999 (D. Del. Filed July 30, 2014). Pet. 7; Paper 5, 2. The two cases have been consolidated. Pet. 7; Paper 5, 2–3.

Petitioner also concurrently filed a petition in IPR2015-01629, seeking an *inter partes* review of U.S. Patent No. 6,750,237 B1, a patent in the same family as the '767 patent.

The '767 Patent

The '767 patent relates to pharmaceutical formulations of the anti-migraine drug zolmitriptan for nasal application. Ex. 1001, 1:17–19. Before or at the time of the '767 patent invention, zolmitriptan was developed for the acute treatment of migraine in the tablet form. *Id.* at 1:29–32. According to the '767 patent, despite the success of the oral formulation, there was "a continuing need for alternative methods for the . . . treatment of migraine." *Id.* at 1:33–38. The '767 patent describes its invention as "a formulation of zolmitriptan that achieved fast relief whilst maintaining high efficacy," and "was convenient, effective and acceptable to the patient and did not cause any unnecessary irritancy or side-effects." *Id.* at 1:53–62.

Illustrative Claims

Claims 1–12 are directed to pharmaceutical formulations suitable for intranasal administration of zolmitriptan; claims 13 and 14 are directed to intranasal administration devices containing the pharmaceutical formulations; and claims 15 and 16 are directed to aqueous solutions of zolmitriptan. Claims 1, 13, and 15 are illustrative and are reproduced below:

> 1. A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is less than 6.0.
> 13. An intranasal administration device containing a pharmaceutical formulation as defined in any one of claims 1, 2, 6 or 7.
> 15. An aqueous solution of zolmitriptan in a buffer at a pH of less than 6.0.

ANALYSIS

Under 35 U.S.C. § 315(b), an *inter partes* review may not be instituted "if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent."

Patent Owner asserts that the Petition, filed on July 28, 2015, is barred under 35 U.S.C. § 315(b) because it was filed more than one year after July 25, 2014, the date on which Petitioner was served with a complaint alleging infringement of the '767 patent.[1] Prelim. Resp. 1–7. Petitioner contends that (1) the July 25, 2014 service was ineffective; and (2) the district court lacked subject matter jurisdiction over that action. Reply 3–7. As a result, Petitioner argues, the § 315(b) time bar is inapplicable. *Id.* at 1. Based on the record before us, we are not persuaded by Petitioner's argument.

Undisputed Facts

According to the parties, on July 25, 2014, AstraZeneca AB, Patent Owner in the instant proceeding, together with the exclusive licensee of the '767 patent, filed a complaint in district court against Petitioner, alleging infringement of the '767 patent ("the First Action"). Prelim. Resp. 1–2; Reply 1; Ex. 2001. On July 30, 2014, the co-plaintiffs in the First Action, joined by AstraZeneca UK Limited, filed another complaint in the same district court against Petitioner, again alleging infringement of the '767

[1] Because July 25, 2015 was a Saturday, the one-year date extended to the next business day, on July 27, 2015. *See* 37 C.F.R. § 1.7.

patent ("the Second Action"). Prelim. Resp. 5; Reply 2; Ex. 2005. Petitioner was served with the second complaint on July 31, 2014. Ex. 1030.

The first complaint states that "AstraZeneca AB is the owner by assignment of the '767 patent and has the right to sue for infringement thereof." Ex. 2001 ¶ 26. The second complaint states that "AstraZeneca AB and AstraZeneca UK Limited own all rights, title, and interest in the '767 patent and have the right to sue for infringement thereof." Ex. 2005 ¶ 27.

On September 24, 2014, Petitioner filed a motion to dismiss the First Action for lack of subject matter jurisdiction. Exs. 2007, 2008. In the motion, Petitioner argued that the statement in the Second Action that "AstraZeneca AB and AstraZeneca UK Limited own all rights, title, and interest in the '767 patent" "constitutes a judicial admission" that AstraZeneca UK Limited, a co-owner of the '767 patent, is missing from the First Action. Ex. 2008, 5.

The district court denied Petitioner's motion to dismiss "without prejudice to its renewal after discovery is complete, should [Petitioner] believe that there then is a point to the motion." Ex. 2011, 3. According to the district court, based on the record evidence in that proceeding, it "cannot tell" whether AstraZeneca UK should have been joined in the First Action. *Id.* In the same Order, the district court consolidated the two actions "FOR ALL PURPOSES." *Id.* at 1.

Service in the First Action

The parties disagree on whether there was an effective service in the First Action. Patent Owner argues that on July 25, 2014, the first complaint

was served on CSC Entity Services, LLC, a registered agent authorized to accept service of process on behalf of Petitioner. Prelim. Resp. 3–4 (citing Ex. 2002). According to Patent Owner, that service of process complied with the local and federal rules. *Id.* Because the service was effected more than one year before the instant Petition was filed on July 28, 2015, Patent Owner asserts, the Petition is barred under § 315(b). *Id.*

Petitioner does not dispute that CSC is its registered agent in Delaware, or that CSC accepted service of the first complaint on July 25, 2014. Reply 3. Petitioner, however, argues that the service in the First Action fails to meet the requirements of proper service under Delaware Title 6, § 18-105. *Id.* According to Petitioner, because CSC is a limited liability company, service must be made by delivery "*personally to any manager*" of CSC. *Id.* (quoting Del. Code Title 6, § 18-105). The Proof of Service, however, shows CSC, instead of an individual, as having accepted service. *Id.* at 3–4 (citing Ex. 2002). As a result, Petitioner asserts, "there was no service of the first complaint, the time bar of § 315(b) was not triggered." *Id.* at 4. We are not persuaded.

Petitioner is the defendant in the First Action. Thus, it is the entity status of Petitioner, and not its registered agent for accepting service, that dictates the proper procedure for service of process. Petitioner is a corporation. Ex. 2027. Delaware Title 6, § 18-105, the statute Petitioner relies on, addresses "Service of process on domestic limited liability companies." On its face, it does not apply to service on Petitioner, which is not a limited liability company. Petitioner also does not cite any authority under Delaware law applying this statute to a limited-liability-company

agent receiving service on behalf of a corporation. We, therefore, are not persuaded by Petitioner's argument, which is based on this inapplicable statute.

In Delaware, service of process on a corporation "shall be made by delivering a copy personally to . . . the registered agent of the corporation . . . ." 8 Del. C. § 321. Petitioner does not argue that the July 25, 2014 service fails to comply with this applicable statute. Thus, the mere fact that the Proof of Service shows CSC, and not an individual, as having accepted the service, does not persuade us that service on July 25, 2014 was ineffective.

Subject Matter Jurisdiction in the First Action

Petitioner next contends that the district court lacks subject matter jurisdiction over the First Action, and, as a result, "the complaint in that action, regardless of when served, cannot constitute a basis for barring this Petition under § 315(b)." Reply 5. In doing so, Petitioner presents the same arguments as those it did in its motion to dismiss before the district court. *Id.* at 5–7.

A jurisdictionally-deficient action generally would not trigger the § 315(b) time bar. In an infringement action, the failure to name the co-owner of a patent, who has not otherwise transferred all substantial rights in the patent, constitutes a jurisdictional deficiency. *See Israel Bio–Eng'g Project v. Amgen Inc.*, 475 F.3d 1256, 1264–65 (Fed. Cir. 2007) ("Absent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing."). In this case, however, Petitioner does not present

persuasive evidence to show that the First Action is indeed jurisdictionally deficient due to failure to name AstraZeneca UK Limited as a co-plaintiff.

We first note that the assignment records for the '237 patent show only AstraZeneca AB as the assignee for the patent. Exs. 2009, 2010. The recording of an assignment with the PTO "creates a presumption of validity as to the assignment and places the burden to rebut such a showing on one challenging the assignment." *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1328 (Fed. Cir. 2010).

Moreover, as of now, the district court has not dismissed the First Action, but consolidated it with the Second Action. Ex. 2011. Petitioner emphasizes that the district court denied the motion to dismiss "without prejudice to its renewal after discovery is complete." Reply 7 (citing Ex. 2011, 3). Petitioner, however, fails to appreciate that we do not have any more evidence than the district court had when it issued the order more than one year ago. The district court "cannot tell" whether there is proper subject matter jurisdiction in the First Action based on record evidence in that proceeding. Ex. 2011, 3. Neither can we based on the same evidence here.

Petitioner relies on one sentence in the complaint for the Section Action, i.e. "AstraZeneca AB and AstraZeneca UK Limited own all rights, title, and interest in the '767 patent and have the right to sue for infringement thereof." Ex. 2005 ¶ 27. That statement, however, does not necessarily contradict Patent Owner's assertion in the First Action that "AstraZeneca AB is the owner by assignment of the '767 patent and has the right to sue for infringement thereof." Ex. 2001 ¶ 26. Apparently, as the district court

acknowledged, Patent Owner argued that AstraZeneca AB owns the '767 patent, with "some interest" resting with AstraZeneca UK Limited. Ex. 2011, 2.

The district court allowed Petitioner an opportunity for discovery to address the issue. *See id.* at 3 (denied the motion to dismiss "without prejudice to its renewal after discovery is complete"). Over a year has since passed, and only a little over a month is left for discovery. *See* Reply 2 n.2 (stating the discovery cutoff date is March 18, 2016). Yet, Petitioner has not presented any evidence to show the level or type of interest that AstraZeneca UK Limited retains in the '767 patent; nor has Petitioner demonstrated that it sought but was unable to obtain such evidence through discovery. As a result, like the district court, based on the record evidence, we do not find the statement in paragraph 27 of the second complaint, in and of itself, is sufficient to show that AstraZeneca UK Limited is an indispensable party in the First Action. In other words, we cannot conclude that the district court lacks subject matter jurisdiction over the First Action.

CONCLUSION

Based on evidence of the record, Petitioner has not made sufficient showing that it is not barred from requesting an *inter partes* review. 35 U.S.C. § 315(b); 37 C.F.R. § 42.104(a).

ORDER

Accordingly, it is

ORDERED that Petitioner's request for an *inter partes* review of claims 1–16 of the '767 patent is *denied*.

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