

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

_____)	
IMPAX LABORATORIES, INC. and)	
ASTRAZENECA AB,)	
)	
Plaintiffs,)	
v.)	C.A. No. 1:14-cv-984 (RGA)
)	
LANNETT HOLDINGS, INC., and)	
LANNETT COMPANY, INC.,)	
)	
Defendants.)	
_____)	

**OPENING MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
LANNETT HOLDINGS, INC. AND LANNETT COMPANY, INC.'S RULE 12(b)(1)
MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION**

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Inc. and Lannett Company, Inc.*

Dated: September 24, 2014

Pursuant to Fed. R. Civ. P. 12(b)(1), Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively “Lannett”), by counsel, hereby move to dismiss the above-captioned action for lack of subject matter jurisdiction.

I. Nature and Stage of the Proceedings

By virtue of the Complaint filed in the above-captioned case, Plaintiffs have brought an action against Lannett for alleged infringement of U.S. Patent Nos. 6,750,237 (“the ’237 patent”) and 7,220,767 (“the ’767 patent”) (hereinafter “the First Action.”).

The allegations of infringement in the First Action are based upon the submission to the U.S. Food and Drug Administration (“FDA”) by Lannett Holdings of Abbreviated New Drug Application No. 206350 (the “Lannett ANDA”).

According to the Complaint in the First Action, “AstraZeneca AB is the owner by assignment of the ’767 patent and has the right to sue for infringement thereof.” *See* D.I. 1 at ¶ 26.

According to the Complaint in the First Action, “AstraZeneca AB is the owner by assignment of the ’237 patent and has the right to sue for infringement thereof.” *See* D.I. 1 at ¶ 27.

On July 30, 2014, a second Complaint for patent infringement was filed on behalf of the same two Plaintiffs in the First Action and an additional plaintiff, namely, AstraZeneca UK Limited and has been docketed as 1:14-cv-00999 (hereinafter the “Second Action”).

The allegations of infringement in the Second Action are based upon the same Lannett ANDA and the same patents, namely the ’237 patent and ’767 patent, as in the First Action.

The Complaint in the Second Action differs from the First Action, *inter alia*, in the identification of the ownership of the patents. Specifically, in the Second Action the Plaintiffs state “AstraZeneca AB and AstraZeneca UK Limited own all rights, title, and interest in

the '237 patent and have the right to sue for infringement thereof." *See* C.A. No. 14-999, D.I. 1 at ¶ 25 (emphasis added). Similarly, in the Second Action, the Plaintiffs state "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." *See* C.A. No. 14-999, D.I. 1 at ¶ 27 (emphasis added).

AstraZeneca UK Limited is not a party to the First Action.

II. Argument

A. Legal Standards

Under Article III of the U.S. Constitution, a federal court does not have subject matter jurisdiction to decide a claim unless there is an actual case or controversy between the parties, and the court has either federal question jurisdiction or diversity jurisdiction over that case or controversy. U.S. CONST. art. III, § 2, cl. 1; *Warth v. Seldin*, 422 U.S. 490, 498-502 (1975); 28 U.S.C. §§ 1331, 1332. Subject matter jurisdiction cannot be waived. *Sosna v. Iowa*, 419 U.S. 393, 398 (1975). Therefore, objections to subject matter jurisdiction may be raised at any time during litigation and the Court is duty-bound to resolve the issue. *Ins. Corp of Ireland v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982).

Motions challenging subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) may present either a facial or factual challenge. *CNA v. U.S.*, 535 F.3d 132, 139 (3d Cir. 2008). In reviewing a factual challenge to the Court's subject matter jurisdiction, the Court is not confined to the allegations of the Complaint, and no presumption of truthfulness attaches to the plaintiff's allegations. *Id.* at 145. Further, once the Court's subject matter jurisdiction over a Complaint is challenged, the plaintiff must bear the burden of persuasion and establish that subject matter jurisdiction exists. *Id.*

This Court has federal question jurisdiction over claims for patent infringement. 28 U.S.C. §1338(a) (“The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents.”).

There are two fundamental prerequisites to every patent infringement claim: (1) existence of a valid and enforceable patent, and (2) a plaintiff who owns all substantial rights to that patent. *See* 35 U.S.C. § 281 (“A patentee shall have remedy by civil action for infringement of his patent.”) (emphasis added); *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1339-40 (Fed. Cir. 2007) (discussing standing requirements in patent cases).

Standing is a constitutional requirement pursuant to Article III and it is a threshold jurisdictional issue. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992).

Relying on Supreme Court precedent, the Federal Circuit has held that “in a patent infringement action, ‘the plaintiff must demonstrate that it held enforceable title to the patent at the inception of the lawsuit’ to assert standing.” *Abraxis Bioscience, Inc., v. Navinta*, 625 F.3d 1359, 1364 (Fed. Cir. 2010) (citations omitted). Moreover, the Federal Circuit “has long applied the rule that a patent co-owner seeking to maintain an infringement suit must join all other co-owners.” *STC.UNM v Intel Corp.*, 754 F.3d 940, 944 (Fed. Cir. 2014); *see also Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456 (Fed. Cir. 1998) (holding that when a patent is co-owned, a co-owner seeking to enforce the patent must join all other co-owners as plaintiffs to establish standing and without this joinder, the plaintiff cannot pursue an infringement suit).

B. By Judicial Admission in the Second Action, Plaintiffs have Conceded that Standing is Not Present in the First Action

Plaintiffs have admitted by virtue of judicial admission in the Second Action that not all co-owners of the ‘237 patent and the ‘767 patent are named as plaintiffs in this case.

Plaintiffs have stated in the Second Action that “AstraZeneca AB **and AstraZeneca UK Limited** own all rights, title, and interest” in each of the patents-in-suit. *See* C.A. No. 14-999, D.I. 1 at ¶¶ 25, 27. Although Lannett does not concede or in any sense admit that the entire ownership is in fact present in the Second Suit, or that either of the Plaintiffs have an ownership interest in the patents-in-suit, this statement by each of the plaintiffs in the Second Action constitutes a judicial admission that at least one co-owner of each of the patents is not a party to the First Action, namely, AstraZeneca UK Limited.

Since the Plaintiffs in this First Action have admitted that they do not constitute all of the co-owners of the patents-in-suit, standing cannot be established, and therefore “... the plaintiff cannot pursue [this] infringement suit.” *STC.UNM*, 754 F.3d at 944.

C. Conclusion

This Court lacks subject matter jurisdiction over the First Action and therefore the Complaint in this case should be dismissed pursuant to Rule 12(b)(1).

Respectfully submitted,

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