IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT HOSPITAL PRODUCTS IP LTD., INO THERAPEUTICS LLC and IKARIA, INC., Plaintiffs, v. PRAXAIR DISTRIBUTION, INC. and PRAXAIR, INC., Defendants.	)	C. A. No. 15-170-GMS

MEMORANDUM

I. INTRODUCTION

On February 19, 2015, Mallinckrodt Hospital Products IP Ltd. ("Mallinckrodt"), INO Therapeutics LLC ("INO Therapeutics"), and Ikaria, Inc. ("Ikaria"), (collectively, "the Plaintiffs") filed a complaint alleging infringement of U.S. Patent Nos. 8,282,966 ("the '966 patent"); 8,293,284 ("the '284 patent"); 8,431,163 ("the '163 patent"); 8,795,741 ("the '741 patent"); 8,846,112 ("the '112 patent"); 8,291,904 ("the '904 patent"); 8,776,794 ("the '794 patent"); 8,573,209 ("the '209 patent"); 8,573,210 ("the '210 patent"); and 8,776,795 ("the '795 patent") (collectively, "the patents-in-suit"). (D.I. 1 at ¶¶ 13–32.) These ten patents cover the Plaintiff's product INOmax®, which is covered by New Drug Application ("NDA") No. N020845. (D.I. 1.) The Plaintiffs allege that Praxair Distribution, Inc. and Praxair Inc. (collectively, "the Defendants") infringe their INOmax patents with their Abbreviated New Drug Application ("ANDA") covering the proposed drug product Noxivent. (D.I. 1 at ¶¶ 7, 12.)

The Defendants filed a counterclaim on July 7, 2015 seeking declaratory judgment of invalidity and de-listing of the patents-in-suit. (D.I. 11.) On May 9, 2016, the Defendants moved for Leave to Amend Counterclaims to add declaratory judgment claims for U.S. Patent Nos. 9,295,802 ("the '802 patent"); 9,265,911 ("the '911 patent"); and 9,279,794 ("the '794 patent"), not previously included in the suit. (D.I. 109.) Presently before the court is the Defendants' motion for Leave to Amend and the Plaintiffs' Motion for Leave to File Sur-reply in Further Opposition to the Defendants' Motion for Leave to Amend. (D.I. 121.) For the foregoing reasons, the court will grant the Defendants' Motion. The Plaintiffs' Motion is denied.

II. BACKGROUND

The '802 patent, '911 patent, and '794 patent (collectively, "the new patents") issued to the Plaintiffs after this action was filed. The '802 Patent was filed by INO Therapeutics and issued to Mallinckrodt on March 29, 2016. (D.I. 109, Ex. C.) The '911 patent was filed by INO Therapeutics and issued to Mallinckrodt on February 23, 2016. (D.I. 109, Ex. D.) The '794 patent was filed by INO Therapeutics and issued to Mallinckrodt on March 8, 2016. (D.I. 109, Ex. E.) Shortly after the new patents issued, Mallinckrodt added them to their Orange Book listing for INOmax®. (D.I. 109 at 2.) On March 29, 2016, the court set a Scheduling Order marking August 29, 2016 as the deadline for Fact Discovery. (D.I. 74.)

On April 22, 2016, the Defendants' counsel emailed the Plaintiffs' counsel soliciting a proposed stipulation to add the three new patents to the case, remarking that "the '911 patent is a continuation of U.S. Patent No. 8,573,209, one of the patents-in-suit, and the '802 patent is a continuation of the '911 patent. The '794 Patent also appears to relate to Plaintiffs' DSIR delivery device." (D.I. 119, Ex. A.) Receiving no reply, the Defendants' counsel reached out to the Plaintiffs' counsel again on April 27, 2016. (D.I. 119, Ex. B.) The Defendants' counsel tried a

third time on April 28, 2016 (D.I. 119, Ex. C), whereupon the Plaintiffs' counsel responded that until the Defendants filed Paragraph IV certifications for the three patents, "we do not see anything to discuss." (D.I. 119, Ex. D.) On May 5, 2016, the Defendants filed expedited Paragraph IV certifications regarding the '802, '911, and '794 Patents. (D.I. 109, Ex. J.) The Plaintiffs received notice of the Defendants' Paragraph IV certification on May 6, 2016. (D.I. 117, Ex. 6.) On May 9, 2016, the Defendants moved for leave to amend their counterclaims. (D.I. 109.)

III. STANDARD OF REVIEW

The court is to "freely give leave" to parties to amend their pleadings "when justice so requires." Fed. R. Civ. P. 15(a)(2). "Leave to amend must generally be granted unless equitable considerations render it otherwise unjust." *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006). Such equitable considerations include the existence or absence of "undue delay, bad faith or dilatory motive on the part of the movant, . . . undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962).

IV. DISCUSSION

The Defendants contend that granting leave to amend their counterclaims and add requests for declaratory judgments against the new patents would produce no undue delay, would not be the product of bad faith, result in undue prejudice to the Plaintiffs, and would not be futile. For the foregoing reasons, the court agrees.

A. Undue Delay or Bad Faith

There is no evidence that the Defendants seek to delay the litigation by amending their complaints. The Plaintiffs added the new patents to INOmax's Orange Book listing in March 2016. (D.I. 109, Exs. C–E.) Less than one month later, the Defendants proposed a stipulation to

add the new patents to this existing lawsuit. (D.I. 119, Ex. A.) The court notes that adding the new patents to this case will conserve judicial and party resources, because the alternative would require the parties to initiate a new lawsuit. (D.I. 109 at 8.) The court does not find any inference of bad faith on the part of the Plaintiffs.

The Defendants also assert that amending the counterclaims to include new patents on the INOmax listing serves the purposes of the Hatch-Waxman Act. (D.I. 109 at 7–8.) They contend that allowing adjudication of only some of a patentee's Orange Book patents essentially insulates the non-asserted patents from suit, which frustrates the purposes of the Hatch-Waxman Act. *See Teva Pharm. USA v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1343–44 (Fed. Cir. 2007). Congress enacted the declaratory judgment provisions to establish certainty about an ANDA filer's legal rights. *Teva*, 482 F.3d at 1345. ANDA filers have a legitimate interest in settling whether patents challenged through a Paragraph IV certification are invalid or not infringed so they can manufacture their own drug without fear of patent liability. *See Teva*, 482 F.3d at 1343. Therefore, the Defendants have a legitimate interest in adding the new patents to this litigation.

Accordingly, the court concludes this consideration favors granting leave to amend.

B. Undue Prejudice to Non-Movant

The Plaintiffs claim that adding the new patents to this case will cause them undue prejudice because fact discovery closes on August 29, 2016. (D.I. 109 at 4.) The Plaintiffs cite concerns of additional claim construction arising from the addition of the new patents (D.I. 117 at 12), but present no evidence of any disputed claim terms. (D.I. 119 at 7.)

The court finds that the Plaintiffs will not be prejudiced by the addition of the new patents. First, the new patents bear close relation to the asserted patents: the '911 patent is a continuation of the '209 patent already in suit, and the '802 patent is a continuation of the '911 patent. (D.I.

109 at 4.) Second, the Plaintiffs cannot claim surprise or lack of notice, as the Defendants notified them of their intent to add the new patents to the suit nearly two weeks before filing an expedited Paragraph IV certification for the new patents and over two weeks before seeking leave to amend. (D.I. 109, Ex. A.) Accordingly, this consideration favors granting leave to amend.

C. Futility of Amendment

The Plaintiffs argue that the Defendants' motion should be denied because the amendment would be futile, as the court lacks subject matter jurisdiction over the new patents. They charge that since the Defendants' Motion to Amend was filed four days after the Defendants' expedited Paragraph IV certification and lacked an offer of confidential access to the ANDA, it fails the provisions of § 355(j)(5)(C)(i)(I) and must be denied. (D.I. 117 at 7, 9.)

"The requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and this threshold jurisdictional determination does not depend on the ultimate merits of the claims." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012). A party creates "a present and actual controversy by choosing to sue under 35 U.S.C. § 271(e)(2)(A) on [an ANDA filer's] single act of infringement, thereby placing into actual dispute the soundness of . . . [the] ANDA and the [ANDA filer's] ability to secure approval of the ANDA." *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007). "This consideration occurs with the filing of an original complaint, not as of the filing of an amended complaint in a suit already in progress." *Torpharm, Inc. v. Pfizer, Inc.*, 2004 WL 1465756, at *8 (D. Del. June 28, 2004) (vacated on other grounds).

To seek declaratory judgment on its Paragraph IV certifications, the ANDA holder must give time and notice to the NDA holder to assess the ANDA and decide if it wishes to file a lawsuit

for infringement of its patents. Declaratory judgment claims cannot be filed unless: (1) the paragraph IV certification contains an offer for the NDA holder to confidentially inspect the ANDA so the NDA holder may decide whether to bring an action against them for infringement; (2) 45 days have elapsed since the filing of said Paragraph IV certification; and (3) no claims of infringement were raised by the NDA holder in that 45 day period. 21 U.S.C. § 355(j)(5)(C)(i)(I). These procedures are designed to provide notice of which patents could be implicated by the ANDA and therefore trigger a lawsuit. *See Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045 at * 5 (D. Del. March 1, 2012) ("the jurisdictional trigger was properly pulled by the filing of an ANDA and the initial Paragraph IV certification.").

The court declines to follow a form-over-function approach. Here, the Defendants have satisfied the purpose of the Hatch-Waxman declaratory judgment provisions. The Plaintiffs had access to the Defendants' ANDA for over a year before they added new patents to the INOmax Orange Book listing. The Plaintiffs chose to add the patents to the INOmax listing without adding them to their claims of infringement against the Defendants' ANDA. The Defendants notified the Plaintiffs on April 22, 2016 that they intended to seek declaratory judgment to settle the question of whether these new patents conflicted with their ANDA. (D.I. 109, Ex. A.) Over forty-five days have elapsed since the Plaintiffs were first made aware of the Defendants' desire to seek declaratory judgment. As a result, the purpose of the statute is satisfied and subject matter jurisdiction is established over the new patents for this case under the first Paragraph IV certification. *See Torpharm, Inc. v. Pfizer, Inc.*, 2004 WL 1465756, at *8 (D. Del. June 28, 2004) (declining to dismiss a declaratory judgment action on procedural grounds when the amended complaint was filed only 20 days after offering confidential ANDA access). Accordingly, amendment of the counterclaims would not be futile. The court will grant the Defendants' Motion.

V. CONCLUSION

For the foregoing reasons, the Defendants' Motion for Leave to Amend Counterclaims is granted. The Plaintiffs' Motion for Leave to File for Sur-reply is denied.

August 2, 2016

UNITED STATES DISTRICT COURT JUDGE

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ORDER

At Wilmington, this 2nd day of August 2016, consistent with the court's Memorandum of the same date; IT IS HEREBY ORDERED that:

1. The Plaintiffs' Motion for Leave to Amend Counterclaims (D.I. 109) is GRANTED;

2. The Defendants' Motion for Leave to File Sur-reply (D.I. 121) is DENIED.

August 2, 2016

UNITED STATES DISTRICT COURT JUDGE