



## **BACKGROUND**

This Hatch-Waxman case, commenced on July 31, 2015, relates to Defendants' separate efforts to obtain approval to market generic Abbreviated New Drug Application ("ANDA") products containing abiraterone acetate, the active ingredient in Janssen's ZYTIGA ®. The parties are currently litigating one patent in this case.<sup>1</sup> Plaintiffs allege that Defendants infringed their patent (U.S. Patent 8,822,438 – "the '438 patent") by filing ANDAs with the U.S. Food and Drug Administration ("FDA") seeking approval prior to the expiration of Plaintiffs' patent. [See Dkt. No. 204-1 at 5; Dkt. No. 274 at 3]. The '438 patent contains 20 claims covering methods for the treatment of prostate cancer by administering dosages of abiraterone acetate and prednisone, and it covers the FDA-approved method of using ZYTIGA ®. [See Dkt. No. 204-1 at 8; Dkt. No. 274-2 (Exhibit B)].

On September 28, 2015, prior to any defendant answering the original complaint, Plaintiffs filed an amended complaint naming Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc. as additional defendants. [See Dkt. No. 47]. On March 8, 2016, after a scheduling order had been entered in the case, Plaintiffs sought leave to file a second amended complaint in connection with a motion to correct inventorship of the '438 patent to add an additional named inventor (Dr. Johann de Bono) and to recognize BTG as a co-owner and co-plaintiff with respect to the '438 patent. [See Dkt. No. 176]. The Court granted Plaintiffs' request and the now-operative amended complaint was filed on January 30, 2017. [See Dkt. No. 274].

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<sup>1</sup> Plaintiffs' operative complaint includes claims against Actavis Laboratories FL, Inc. ("Actavis") for infringement of U.S. Patent 8,822,438 ("the '213 patent"). [See Dkt. No. 274 at 15, 71-73]. It appears that Actavis is no longer challenging the '213 patent and that the '213 patent has now expired. [See Dkt. No. 204-1 at 5 n.2].

While Plaintiffs' motion for leave to file a second amended complaint was still pending, Plaintiffs sought leave to file the present motion, which the Court granted on May 9, 2016. [*See* Dkt. Nos. 193, 201]. Plaintiffs' proposed third amended complaint seeks to add claims against certain defendants<sup>2</sup> for a declaratory judgment of infringement of two additional patents – U.S. Patent 8,236,946 (“the ’946 patent”) and U.S. Patent 8,389,714 (“the ’714 patent”). The ’964 and ’714 patents, owned by BTG and licensed to Janssen Oncology, Inc., relate to the processes used in the synthesis of abiraterone acetate, present in both Plaintiffs' ZYTIGA ® and Defendants' ANDA products. [*See* Dkt. No. 204-1 at 5-6].

The parties completed claim construction discovery and briefing on August 31, 2016, and the Court conducted a *Markman* hearing on October 25, 2016. [*See* Dkt. No. 236]. Thereafter, the parties jointly requested two extensions of fact and expert discovery deadlines, both of which the Court granted. [*See* Dkt. Nos. 251, 273]. Currently, fact discovery is set to close on February 14, 2017 and expert discovery is set to close on August 1, 2017. [*See id.*].

### **LEGAL STANDARD**

The decision of whether to grant leave to amend is within the sound discretion of the court. *Arab African Int'l Bank v. Epstein*, 10 F.3d 168, 174 (3d Cir.1993); *Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 230, 9 L. Ed. 2d 222 (1962); *Heyl & Patterson Int'l, Inc. v. F.D. Rich Housing of the Virgin Islands, Inc.*, 663 F.2d 419, 425 (3d Cir. 1981), *cert. denied*, 455 U.S. 1018, 102 S. Ct. 1714, 72 L. Ed. 2d 136 (1982)). The federal rules liberally allow for amendments in light of the “principle that the purpose of pleading is to facilitate a proper decision on the merits.” *Foman*, 371 U.S. at 182 (internal quotation marks omitted); *Alvin v.*

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<sup>2</sup> Plaintiffs do not seek a declaratory judgment of infringement with respect to the '946 and '714 patents against the following defendants named in their operative complaint: Wockhardt Bio AG, Wockhardt Ltd., and Wockhardt USA [*see* Dkt. No. 206 at 7], and Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., and Citron Pharma LLC (litigation has been stayed as to the Par and Citron defendants) [*see* Dkt. Nos. 103, 117].

*Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000). Notwithstanding this liberal standard, the Court may deny a motion to amend where there is “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment.” *Foman*, 371 U.S. at 182; *see Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006) (stating that “[l]eave to amend must generally be granted until equitable considerations render it otherwise unjust”). Stated differently, absent substantial or undue prejudice, an amendment should be allowed under Fed. R. Civ. P. 15 unless denial is based on bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiencies by amendments previously allowed, or futility of the proposed amendment(s). *See Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004); *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993) (citing *Heyl & Patterson Int’l, Inc.*, 663 F.2d at 425).

## **DISCUSSION**

Here, Defendants principally argue that they would face undue prejudice if Plaintiffs are permitted to amend their complaint and add two new patent claims. Defendants further argue that Plaintiffs acted with undue delay and dilatory motive, and that the proposed amendments are futile.<sup>3</sup> Defendants disagree that allowing Plaintiffs to join the additional patent claims would further judicial economy and efficiency, and instead contend that severing them from the present action is appropriate. Finally, Defendants argue that joinder under Fed. R. Civ. P. 18 is

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<sup>3</sup> Defendants believe that Plaintiffs’ motion is futile for failure to plead factual allegations plausible to suggest liability for infringement with respect to the ’964 and ’714 patents. [See Dkt. No. 205 at 22]. With regard to any futility analysis, Defendants’ arguments in opposition to Plaintiffs’ motion would overlap significantly with those made in support of a motion to dismiss. Notwithstanding the instant Opinion and Order, Plaintiffs still have the opportunity to file a new lawsuit with respect to the ’964 and ’714 patent claims. Accordingly, the Court, in its discretion, will not consider the futility arguments in connection with its review of Plaintiffs’ present motion. *See In re Aetna UCR Litig.*, No. 07-3541, 2015 WL 3970168, at \*8 (D.N.J. June 30, 2015); *Strategic Envtl. Partners, LLC v. Bucco*, No. 13-5032, 2014 WL 3817295, at \*2 (D.N.J. Aug. 1, 2014) (preserving futility argument for anticipated motions to dismiss).

inapplicable. As an analysis under *Foman* weighs against granting Plaintiffs' proposed amendments, the Court will focus its opinion accordingly. In its discretion, the Court finds that permitting an amendment to include the '964 and '714 patent claims would, on balance, be inequitable and undesirable, warranting denial of Plaintiffs' requested relief.

The Court finds that Defendants would face substantial prejudice if Plaintiffs are permitted to join the additional patents to the present litigation. In applying Fed. R. Civ. P. 15(a), the Third Circuit has established that prejudice to the non-moving party is the touchstone for the denial of an amendment. *Lorenz*, 1 F.3d at 1414 (quoting *Cornell & Co. v. Occupational Safety & Health Review Comm'n*, 573 F.2d 820, 823 (3d Cir. 1978) (internal citations omitted)). To establish prejudice, the non-moving party must demonstrate that allowing the amended pleading would: (1) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (2) significantly delay the resolution of the dispute; or (3) prevent the plaintiff from bringing a timely action in another jurisdiction. *See Long*, 393 F.3d at 400 (internal quotations and citations omitted).

Defendants argue that allowing Plaintiffs' proposed amendments would cause undue prejudice by increasing the complexity of a relatively streamlined litigation. Specifically, Defendants aver that adding the additional patent claims would invite "a host of complex scientific issues and new experts" unrelated to the '438 patent currently at issue. [Dkt. No. 205 at 15]. The Court agrees. The parties have invested extensive time and resources in discovery. The *Markman* hearing has already been conducted. Fact discovery is set to close in a matter of days and expert discovery in approximately five months' time.<sup>4</sup> Currently, only the '438 patent is at issue. Adding the '946 and '714 patents, at this juncture, would require Defendants to

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<sup>4</sup> As set forth in the amended scheduling order, fact discovery was to close on December 16, 2016 and expert discovery on June 16, 2017. [See Dkt. No. 164]. The Court thereafter granted two extensions of these deadlines upon the joint request of counsel. [See Dkt. Nos. 251, 273].

expend significant additional resources to conduct additional discovery and prepare for an October 2017 trial date.

Plaintiffs contend that the additional patents share the same specification and cover the same subject matter (Janssen's ZYTIGA ®) as the '438 patent such that there is likely to be duplication of the claims and defenses related to them. [See Dkt. No. 204-1 at 6]. While this may be true, each new patent claim asserted will require a separate analysis for infringement and will require separate investigation into prior art and prosecution history for any invalidity defense. Adding two more patent claims is bound to needlessly strain an already tight schedule and significantly delay resolution of this matter. See *Sandisk Corp. v. ITE Technologies, Inc.*, 2010 WL 1410728, \*1-2 (W.D. Wis. 2010) (denying leave to amend and add additional patents that were continuations of the originally asserted patents, finding that permitting the new patents would overburden a lawsuit that was set for trial in less than one year); *Cont'l Wire Cloth, LLC v. Derrick Corp.*, No. 09- 474, 2012 WL 2359462, at \*2-3 (N.D. Okla. June 20, 2012) (denying leave to amend and add two new patent claims after a *Markman* hearing had been conducted).

Although Defendants argue otherwise, Plaintiffs' motion does not appear to be untimely or brought with dilatory motive. Plaintiffs filed the present motion after seeking leave from the Court and within the deadline set forth in the amended scheduling order. [See Dkt. Nos. 201, 164]. Nevertheless, the Court is not persuaded that the present matter should be expanded beyond its original boundaries. The parties have limited time in which to complete discovery with respect to the '438 patent. There appears to be no great need to include two additional patents, seemingly related to the processes used to synthesize abiraterone acetate, to a lawsuit focused on the methods of administering abiraterone acetate.

Unsurprisingly, the parties take opposing views as to whether this court should grant Plaintiffs' motion based on notions of justice and joinder under Fed. R. Civ. P. 18, and assert jurisdiction based on considerations of judicial economy, economy to the parties, and patent certainty. [*Compare* Dkt. No. 204-1 at 16-22 *with* Dkt. No. 205 at 22-30]. Without delving into a detailed analysis of these issues, the Court is not entirely convinced by Plaintiffs' proposition that justice requires amending their complaint or that one single trial on all three patents would be more efficient and provide patent certainty. [*See* Dkt. No. 204-1 at 6, 16; Dkt. No. 206 at 7]. While this may be the case, such a result is unclear. Plaintiff contends that the additional patents share the same specification and cover the same subject matter as the '438 patent such that there is likely to be much duplication of the claims and defenses related to them. [Dkt. No. 204-1 at 6, 14; Dkt. 206 at 7]. To the extent that issues do overlap, a resolution of the parties' disputes with respect to the '438 patent may well resolve issues in a subsequent case involving the '964 and '714 patents, or perhaps narrow the issues to be pursued.

Plaintiffs are not foreclosed from filing a new lawsuit with respect to the '964 and '714 patents. Consequently, Plaintiffs will not suffer grave prejudice if an amendment is disallowed. Accordingly, Plaintiffs' motion for leave to file a third amended complaint is **DENIED**.

**CONCLUSION**

The Court having considered the papers submitted pursuant to Fed. R. Civ. P. 78 and L. Civ. R. 78.1(b), and for the reasons set forth above;

**IT IS** on the 8th day of February, 2017,

**ORDERED** that Plaintiffs' Motion for Leave to File a Third Amended Complaint is **DENIED**; and it is further

**ORDERED** that the Clerk of the Court terminate the aforementioned motion [Docket Entry No. 204] accordingly.

s/James B. Clark, III  
**JAMES B. CLARK, III**  
**UNITED STATES MAGISTRATE JUDGE**