NOT FOR PUBLICATION

IN THE UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

FERRING PHARMACEUTICALS INC.,

Plaintiff,

Civil Action No. 2:12-cv-05824 (DMC) (JAD)

v.

WATSON PHARMACEUTICALS, INC.,

Defendant.

OPINION

JOSEPH A. DICKSON, U.S.M.J.

This matter comes before this Court upon motion by plaintiff Ferring Pharmaceuticals Inc. ("Plaintiff" or "Ferring") for leave to file an amended complaint pursuant to Fed. R. Civ. P. 15(a) (the "Motion to Amend") to add two defendants: (1.) Watson Pharma, Inc., a/k/a Actavis Pharma, Inc.¹ ("Watson Pharma"); and (2.) Watson Laboratories, Inc. ("Watson Labs"). Pursuant to Rule 78 of the Federal Rules of Civil Procedure, no oral argument was heard. Upon consideration of the parties' submissions, and for the reasons stated below, Plaintiff's motion to amend is **granted** in its entirety.

¹ Watson represents that Watson Pharma has changed its name to Actavis Pharma, Inc., and remains a Delaware Corporation. Watson does not object to the Motion to Amend on this ground, and if the motion is granted does not object to substituting the correct identifying information. (Def.'s Br. 2, ECF No. 70).

I. BACKGROUND.

Ferring and Watson Pharmaceuticals² ("Defendant" or "Watson") are companies that market competing products used for in vitro fertilization in a process referred to as assisted reproductive technology. Plaintiff brought section 43(a) Lanham Act false-advertising and related state law claims against Watson alleging that several of Watson's advertising materials promoting Crinone are false and misleading. Plaintiff's Complaint alleged that the advertisements "in effect" paint Endometrin as "dangerous, not effective and disliked by consumers." (Compl. ¶ 1, ECF No. 1). Plaintiff further alleged that Watson's marketing materials improperly state or imply that Crinone is superior to other products, including Plaintiff's Endometrin. As a result, Plaintiff, as a direct competitor of Defendant, claimed it has lost sales to Watson and suffered "lessening of goodwill associated with [Plaintiff] and its products. (Id. at ¶ 212).

A. <u>Procedural History.</u>

On September 17, 2012, Plaintiff filed a lengthy Complaint asserting four counts against Watson based on allegations that Defendant made false and misleading statements that compare the Crinone product and the Endometrin product in their advertising material and in promotion of their Crinone product. Based on these allegations, Plaintiff asserted: (1) statutory claims arising under section 43(a) of the Lanham Act, 15 U.S.C § 1125(a); (2) unfair competition under N.J.S.A. § 56:8-1 et seq, governing unconscionable trade practices; as well as (3) common law claims of unfair competition; and (4) defamation. Two days later, Plaintiff moved for an

² In or around November 2012, Watson announced that it would change its name to Actavis, Inc. (Am. Compl. ¶ 4, ECF No. 68-3).

expedited discovery schedule in support of its Motion for Preliminary Injunction. (Pl.'s Ltr., ECF No. 6).³

A review of the record before this Court reveals that the parties discussed the issue of Ferring's proposed amendment of its Complaint to include additional claims against Watson affiliates as earlier as January 29, 2013. (Pl.'s Ltr., ECF No. 48). On that date, Ferring submitted a letter to this Court expressing concern for delay by Watson in refusing to provide initial disclosures pursuant to Fed. R. Civ. P. 26(a) concerning the identification and naming of the proper parties to the lawsuit. (Id.). This Court then set a schedule for discovery by Order dated February 21, 2013. (Scheduling Order ECF No. 53).

B. <u>The Proposed Defendants.</u>

The Court's February 21, 2013 Scheduling Order set June 21, 2013 as the deadline to file any motions to amend the pleadings or join parties. (Scheduling Order at ¶ 13, ECF No. 53). Plaintiff timely filed the instant motion on June 21, 2013, seeking leave to file an Amended Complaint to name Watson Pharma, and Watson Labs as defendants.

By way of its present Motion to Amend, Plaintiff argued that the Proposed Amended Complaint is necessary to assert claims against additional corporate entities with direct involvement in the marketing, sale and distribution of Crinione. Watson has a complex corporate structure consisting of multiple subsidiaries and related companies. (Pl.'s Br. 2, ECF No. 68-1). For instance, despite the name "Watson Pharmaceuticals, Inc." appearing on much of the allegedly offending advertising material, counsel for Watson claimed that another Watson entity – Watson Pharma – markets, sells and distributes Crinone. (Id.) Further, Watson Labs

³ Plaintiff moved for a preliminary injunction against Defendant on November 9, 2012. The District Court entered an Order on April 4, 2013 denying Plaintiff's Motion for Preliminary Injunction. (ECF No. 55).

owns the New Drug Application ("NDA") for Crinone. (<u>Id</u>.). Plaintiff therefore seeks to amend the causes of action as follows:

- Count I continues to allege unfair competition under section 43(a) of the Lanham Act, but adds Watson Pharma and Watson Labs as Defendants;
- Count II continues to allege unfair competition under N.J.S.A. § 56:8-1 et seq, but adds Watson Pharma and Watson Labs as Defendants;
- Count III continues to allege common law unfair competition, but adds Watson Pharma and Watson Labs as Defendants;
- Count IV continues to allege defamation, but adds Watson Pharma and Watson Labs as Defendants;

Specifically as to Watson Pharma, Plaintiff's Amended Complaint also alleges that:

• Watson Pharma "markets, sells, and distributes Crinone." (Am. Compl. ¶ 33, ECF No. 68-3).

Specifically as to Watson Labs, Plaintiff's Amended Complaint also alleges that:

- Watson Labs is a wholly owned subsidiary of Watson; (Id. at ¶ 6).
- Watson Labs owns the NDA for Crinone; (Id. at ¶ 34).
- "Upon information and belief, Watson Labs derives financial benefit from the marketing, sale, and distribution of Crinone." (Id. at ¶ 37).

II. STANDARD OF REVIEW.

Rule 15(a) provides that after a responsive pleading has been filed:

[A] party may amend its pleading only with the opposing party's written consent or the courts leave. The court should freely give leave when justice so requires.

Fed. R. Civ. P. 15(a)(2).

The grant or denial of leave to amend under Rule 15(a) is a matter "committed to the sound discretion of the district court." <u>Arab African Int'l Bank v. Epstein</u>, 10 F.3d 168, 174 (3d Cir. 1993). The Third Circuit adopted a liberal approach to the amendment of pleadings under

Rule 15 to ensure that "a particular claim will be decided on the merits rather than on technicalities." <u>Dole v. Arco Chem. Co.</u>, 921 F.2d 484, 487 (3d Cir. 1990) (internal citation omitted). The burden is generally on the party opposing the amendment to demonstrate why the amendment should not be permitted. <u>Foman v. Davis</u>, 371 U.S. 178 (1962).

Leave to amend a pleading may be denied where the court finds: (1) undue delay; (2) undue prejudice to the non-moving party; (3) bad faith or dilatory motive; or (4) futility of amendment. Shane v. Fauver, 213 F.3d 113, 115 (3d Cir. 2000). Unfair prejudice is the most common factor cited by courts to deny leave. Unfair prejudice is usually found when there has been a significant unjustified delay in moving to amend that creates an unfair disadvantage for the defendant. However, delay alone will not justify denying a motion to amend. See Cureton v. Nat'l Collegiate Athletic Ass'n, 252 F.3d 267, 273 (3d Cir. 2001) (holding that mere passage of time does not require that a motion to amend a complaint be denied on grounds of delay). Only where delay becomes 'undue', i.e., placing an unwarranted burden on the court, or 'prejudicial', i.e., placing an unfair burden on the opposing party, is denial of a motion to amend appropriate. Adams v. Gould Inc., 739 F.2d 858, 868 (3d Cir.1984) ("The question of undue delay, as well as the question of bad faith, requires that [the Court] focus on the plaintiff['s] motives for lot amending [its] complaint to assert [the] claim[s] earlier; the issue of prejudice requires that [the Court] focus on the effect on the [defendant]."). Delay may become undue when there has been previous opportunity to amend the complaint. See Lorenz v. CSX Corp., 1 F.3d 1406, 1414 (Bd Cir.1993) (finding that a three-year lapse between the filing of the complaint and the proposed amendment was "unreasonable" delay when plaintiff had previous opportunities to amend). In such cases, the Court must focus on the moving party's reasons for not amending the pleading sooner. USX Corp. v. Barnhart, 395 F.3d 161, 168 (3d Cir. 2004).

A proposed amendment may also be denied based on futility if it "would fail to state a claim upon which relief could be granted." Shane v. Fauver, 213 F.3d at 115. Thus, "[In assessing 'futility' the District Court applies the same standard of legal sufficiency as applies under Rule 12(b)(6)." Id. To survive dismissal under Rule 12(b)(6), a complaint "must contain sufficient factual matter accepted as true to 'state a claim to relief that is plausible on its face" Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009).

III. <u>DISCUSSION</u>.

As an initial matter, Defendant does not object to the addition of Watson Pharma as defendant (Def.'s Br. 1, ECF No. 70), therefore the Motion to Amend as to that aspect of the Proposed Amended Complaint is granted.

A. Whether Plaintiff Has Demonstrated Undue Delay, Bad Faith, or Dilatory Motives.

Defendant first argues that Plaintiff's Proposed Amended Complaint is nothing more than a delayed assertion of claims that could have been brought at the time of the original Complaint. (Def.'s Br. 2-3, ECF No. 70).

In the Third Circuit, delay alone does not justify denying a motion to amend. <u>Cureton v. Nat'l Collegiate Athletic Ass'n</u>, 252 F.3d 267, 273 (3d Cir.2001). Rather, it is only where delay becomes "undue", i.e., placing an unwarranted burden on the court, or "prejudicial", i.e., placing an unfair burden on the opposing party, is denial of a motion to amend appropriate. <u>Adams v. Gould Inc.</u>, 739 F.2d 858, 868 (3d Cir.1984). "Implicit in the concept of 'undue delay' is the premise that Plaintiffs, in the exercise of due diligence, could have sought relief from the court earlier." <u>In re Pressure Sensitive Labelstock Antitrust Litig.</u>, No. MDL.03–1556, 2006 VIL 433891, at *1 (M.D.Pa. Feb. 21, 2006).

Upon reviewing the procedural history of this case, this Court declines to find that Plaintiff engaged in any undue delay or dilatory tactics. The Federal Rules of Civil Procedure require that a party have a proper legal and factual foundation before initiating a lawsuit or filing a claim against a party. Fed.R.Civ.P. 11(b). Plaintiff plausibly alleged that although it had reason to suspect the participation of the additional defendants, it did not have sufficient support for adding such defendants until Watson confirmed that its answer to Plaintiff's Interrogatory 9 requesting the names of Watson corporate entities involved in the marketing, sale, and distribution of Crinone was complete. Specifically, it did not become clear to Plaintiff that Watson Pharma and Watson Labs were the proper parties to add to the Complaint until it received Watson's May 14, 2013 e-mail stating that "Watson Pharma[] is the sole marketer of Crinone. Watson Labs[], only owns the NDA, and does not do the selling, marketing or distribution of Crinone." (Def.'s Br.2, ECF No. 70). Shortly after receiving that e-mail, Plaint ff filed its Motion to Amend.

Defendant, moreover, does not challenge Plaintiff's representation that it repeatedly indicated its intent to amend its Complaint — both in letters to this Court dated January 29, 2013 (ECF No. 48) and May 16, 2013 (ECF No. 59) — but that its efforts were hampered by various factors, including active discussion of the many discovery disputes. Plaintiff has proffered a reasonable explanation for the delay and is not guilty of repeated failure to cure deficiencies by previous amendment since this is Plaintiff's first attempt to amend its Complaint. Therefore, the Motion to Amend will not be denied on the basis of undue delay or prejudice.

⁴ Plaintiff acknowledges that Watson, in its Answer, repeatedly answers with reference to "ts affiliate, Watson Pharma[]" (Pl.'s Ltr., ECF No. 48; Answer ¶¶ 1, 19, 22, 24, 26-27, 32-34, 36, ECF No. 33). Also, the fact that Watson Labs owns the New Drug Application for Crinone is public record. (Def.'s Br. 2, ECF No. 70). Thus, Defendant argues that it has not "refused to provide discovery, or hidden the names of any entity so they could not be named in an amended complaint." (Id. at 3).

Given the fact that Defendant has not established any undue delay, dilatory motive, undue prejudice or bad faith by the Plaintiff; (indeed, Defendant does not explicitly contend that Plaintiff's Motion to Amend should be denied on such grounds) and considering that this Cour's review of the record in this case has not revealed any such actions by Plaintiff, this Court must next consider Defendant's futility argument.

B. Whether the Proposed Amendment to Add Watson Labs is Futile.

In their second argument, Defendant contends that Plaintiff's Motion to Amend should be denied as futile on the grounds that Plaintiff "has not and cannot state a cause of action against Watson Labs[]" (Def.'s Br. 4, ECF No. 70). "Futility" means that the complaint, as amended, would fail to state a claim upon which relief could be granted. Holst v. Oxman, 290 Fed.Aprx. 508, 510 (3d Cir.2008). The futility analysis on a motion to amend is essentially the same as a Rule 12(b)(6) motion. Id. The trial court may thus deny leave to amend where the amendment would not withstand a motion to dismiss. Massarsky v. Gen. Motors Corp., 706 F.2d 111, 125 (3d Cir.1983). Given the liberal standard for the amendment of pleadings, however, "courts place a heavy burden on opponents who wish to declare a proposed amendment futile." Aruanno v. New Jersey, No. Civ.A.06–296, 2009 WL 114556, at *2 (D.N.J. Jan. 15, 2009).

Here, Plaintiff asserted claims arising under section 43(a) of the Lanham Act, in Count I of its Proposed Amended Complaint.⁵ Specifically, Plaintiff claimed that Watson Labs made false and misleading statements regarding its product, Crinone, and Plaintiff's product, Endometrin. (Am. Compl. ¶¶ 55-58). Plaintiff further alleged that it, as a competitor of

⁵ "[U]nfair competition claims under New Jersey statutory and common law generally parallel those under § 43(a) of the Lanham Act." <u>Bracco Diagnostics, Inc. v. Amersham Health, Inc.</u>, 627 F. Supp. 2d 384, 454 (D.N.J. 2009).

Defendant, suffered losses in the form of lost sales and by lessening of goodwill associated with Plaintiff and its products. (Am. Compl. ¶ 230, ECF No. 68-3).

In its Reply, Defendant argued that these allegations are insufficient to establish a claim under section 43(a) of the Lanham Act. In support of its argument, Defendant pointed out that Plaintiff's Proposed Amended Complaint failed to allege "that Watson Labs[] has made any false or misleading statements." (Def.'s Br. 4, ECF No. 70). Moreover, Defendant argued that, at most, Plaintiff can allege that Watson Labs "derives financial benefit from the marketing, sale and distribution of Crinone." (Id.) Defendant further claims that no cases exist that suggest that an entity can be held liable for false advertising for merely deriving financial benefit.

In order to prevail on a claim of false advertising pursuant to section 43(a) of the Lanham Act, a plaintiff must establish that: (1) the defendant made false or misleading statements about the plaintiff's or [defendant's] own product; (2) there is actual deception or a tendency to deceive a substantial portion of the intended audience; (3) the deception is material in that it is likely to influence purchasing decisions; (4) the advertised goods traveled in interstate commerce; and (5) there is a likelihood of injury to the plaintiff. Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, L.P., 292 F.Supp.2d 594, 598 (D.N.J.2003) (quoting Highmark, Inc. v. UPNC Health Plan, Inc., 276 F.3d 160, 171 (3d Cir.2001) (internal editing marks omitted)); 15 U.S.C. § 1125(a)(1)(B). However, if the plaintiff alleges literal falsity, he need not show that the audience was misled. Santana Prod., Inc. v. Bobrick Washroom Equip., Inc., 401 F.3d 123, 136 (3d Cir.2005).

Plaintiff argues that it sufficiently pleaded its Lanham Act false-advertising claim against Watson Labs. In support of its argument, Plaintiff alleged that when the term "Defendants" is used in its Proposed Amended Complaint, it refers to all Defendants, collectively. The added

language in the Proposed Amended Complaint is found in the Background and General Allegations portion. Accordingly, this Court finds that Plaintiff has sufficiently pleaded the first element of its Lanham Act claim because Plaintiff has asserted that Watson Labs, among others, has made false or misleading statements.

Furthermore, this Court finds that Plaintiff has sufficiently pleaded element five of its Lanham Act claim. To satisfy element five, Plaintiff must establish that there is a likelihood of injury to the plaintiff in terms of declining sales, and loss of good will. Defendant acknowledges that Watson Labs "derives financial benefit from the marketing, sale and distribution of Crinone." (Def.'s Br. 4, ECF No. 70). Moreover, Plaintiff is entitled to lost profits and disgorgement of all profits associated with the sale of Crinone. See Bracco Diagnostics, Inc. v. Amersham Heath, Inc., 627 F. Supp. 2d 384, 484 (D.N.J. 2009). This includes the financial benefit, if any, acquired by Watson Labs in association with the sale of Crinone.⁶

With respect to the remaining elements (two – four) of Plaintiff's Lanham Act claim, its lengthy Proposed Amended Complaint sufficiently details statements found in Defendans' advertising materials regarding both Crinone and Endometrin that it believes are false and misleading. Plaintiff also alleges that Defendants made allegedly misleading statements during webcasts. (Am. Compl. ¶¶ 55-118, ECF No. 68-3). Those allegations suggest that Defendans' alleged misstatements were made in interstate commerce. Taking these allegations as true, as

⁶ As noted above, courts within the Third Circuit favor a liberal policy in granting amendments to pleadings, including adding parent companies for their direct involvement. See Agere Sys. Guardian Corp. v. Proxim, Inc., 190 F. Supp. 2d 726, 736 (D. Del. 2002) (the court granted leave to add an alter-ego entity as a party because the court hesitates to foreclose potentially viable avenues for relief at this stage of the proceedings). Similarly, this Court is reluctant to foreclose Plaintiff's potential avenue for recovery against Watson Labs at this stage of the proceeding. As Plaintiff correctly noted, the "financial arrangement by, between or among Crinone, Watson, Watson Pharma and Watson Labs will be uncovered during discovery." (Pl.'s Reply Br. 4, ECF No. 71).

required by Federal Rule of Civil Procedure 12(b)(6), this Court finds it is plausible that Plaint ff will prevail on its Lanham Act and related state law claims. Plaintiff's Proposed Amended Complaint goes beyond mere legal conclusions and includes facts sufficient to put defendants on notice of the claims against them. Ultimately, the full scope of discovery may establish that the claims against Watson Labs are groundless. This Court cannot, however at this juncture, find that the addition of Watson Labs as a defendant is clearly futile. As such, and given the liberal standard to be afforded amendment applications under Rule 15, Plaintiff's application will be granted.

IV. CONCLUSION.

For the reasons set forth above, Plaintiff's Motion to Amend (ECF No. 68) is GRANTED.

SO ORDERED

JOSEPH A. DICKSON, U.S.M.J.