NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FERRING PHARMACEUTICALS INC.,	**Hon. Dennis M. Cavanaugh**
Plaintiff,	**OPINION**
v.	Civil Action No. 12-cv-05824 (DMC) (JAD)
WATSON PHARMACEUTICALS,	
Defendant.	

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon Motion for Preliminary Injunction by Plaintiff Ferring Pharmaceuticals Inc. ("Plaintiff" or "Ferring") to enjoin Defendant Watson Pharmaceuticals ("Defendant" or "Watson") from further statements and for corrective advertising. (Pl.'s Mot. for Prelim. Injunc., Nov. 9, 2012, ECF No. 29). Pursuant to FED. R. CIV. P. 78, no oral argument was heard. The Court has reviewed the submissions of the parties, and for the reasons set forth below, Plaintiff's request for relief is **denied.**

I. BACKGROUND[1]

A. THE PRODUCTS

Ferring and Watson are pharmaceutical companies that market competing products used for in vitro fertilization in a process referred to as assisted reproductive technology ("ART"). The reproductive products are used to assist woman in establishing and maintaining pregnancies

1 The facts contained herein have been adopted from the Parties' respective moving papers.

through progesterone supplementation. The traditional method for progesterone supplementation is through intramuscular injections. Ferring's product, Endometrin, and Watson's product, Crinone, are vaginal inserts of progesterone that supplement or replace daily intramuscular shots. Progesterone is a natural hormone often prescribed following ovulation and egg retrieval to help prepare the uterine lining to receive a fertilized egg after implantation. Ferring's Endometrin is delivered in capsule form and applied two or three times per day. Watson's Crinone product is a gel delivered via applicator and is applied once daily. There are currently no other vaginal inserts for ART approved by the Food and Drug Administration ("FDA").

B. SEPTEMBER 11, 2012 PRESENTATIONS AND WEBCASTS

Ferring has brought the instant Lanham Act false-advertising claim against Watson, alleging that several of Watson's advertising materials promoting Crinone are false or misleading. Ferring's Complaint alleges that the advertisements "in effect" paint Endometrin as "dangerous, not effective, and disliked by consumers." (Compl. ¶ 1). Ferring further alleges that Watson's marketing materials improperly state or imply that Crinone is superior to other products, including Ferring's Endometrin. Ferring states that Watson hosted and invited doctors and healthcare professionals to two events on September 11, 2012, at which Dr. Kaylen M. Silverberg detailed the qualities and success rates of Crinone in an effort to influence attendees to purchase the product. On that date, Dr. Silverberg, a paid consultant of Watson, made two presentations on Crinone, streamed at 7:30 p.m. and 9:00 p.m. throughout the United States and viewed medical professionals in-person and over the Internet via a password (individually "7:30 p.m. Webcast" and "9:00 p.m. Webcast" and collectively "Dr. Silverberg Webcasts"). During the Dr. Silverberg Webcasts, Ferring alleges several false statements were made about Endometrin, implying that

Endometrin is not effective and Crinone is the only proven and trustworthy product for progesterone delivery.

C. SUBSTANCE OF STATEMENTS

Three statements in particular made during Dr. Silverberg's Webcasts form the basis for Ferring's Motion for Preliminary Injunction. Ferring takes issue with: (1) Dr. Silverberg's reference to a "Black Box warning" on Endometrin; (2) Dr. Silverberg's claims of patient preference for Crinone; and (3) Dr. Silverberg's claims that Endometrin has not been proven effective for women over thirty-five years of age.

1. Black Box Claims

During the 7:30 p.m. Webcast, Dr. Silverberg indicated that "if you read the package insert[2] for Endometrin there is a Black Box warning showing the efficacy has not been demonstrated with [...] Endometrin for patients 35 years of age and older." (Michalek Decl., Exh. 5, Nov. 9, 2012, ECF No. 28-2). Ferring asserts that Endometrin does not now have, nor has it ever had, a Black Box warning. A Black Box warning is of special note to those in the medical community as it contains the strongest warnings required by the FDA, and signifies that medical studies indicate the drug carries a significant risk of serious, or in some cases, life-threatening adverse effects. (Beltsos Decl. ¶ 9, Nov. 9, 2012, ECF No. 28-1). Endometrin's packaging does in fact state, "[e]fficacy in women 35 years of age and older has not been clearly established." (Michalek Decl., Exh. 6). Ferring thus takes issue, not with the content of the statement itself, but the mistaken pronouncement that the wording is contained in a Black Box warning.

Dr. Silverberg was alerted to the inaccuracy of the statement after the 7:30 Webcast and the

2 A "package insert" is a document that accompanies a drug and contains prescribing information, describes side effects, and provides additional information about the medication.

9:00 p.m. Webcast did not contain such a statement. Dr. Silverberg has since certified to Ferring and this Court that, in the future, he will not repeat this statement. (Silverberg Cert., Dec. 3, 2012, ECF No. 34-3).

2. Crinone and Endometrin Comparisons

Ferring also objects to particular statements Dr. Silverberg made regarding patient preference for Crinone over Endometrin. Ferring asserts that there is no support whatsoever for the percentages utilized by Dr. Silverberg to support a patient preference for Crinone. The substance of the remarks in question, made during the 7:30 p.m. Webcast are contained in the transcript of the event. (Phillips Cert., Exh. 1, Dec. 3, 2012, ECF No. 35-2). They include Dr. Silverberg's statement that:

> When you look at Crinone compared to Endometrin, similar findings. 94 percent of patients thought that Crinone was easier to incorporate into their daily lifestyle, probably because it's given once a day compared to three times a day for Endometrin. 82 percent thought that it was more convenient, or I'm sorry, that may be 88 percent, 94 percent thought that it was more comfortable to use Crinone than the Endometrin.
>
> Now looking at Crinone compared to Endometrin, telephone survey, 94 percent of patients thought that Crinone was easier to incorporate into a daily lifestyle than the Endometrin given three times a day. 88 percent thought it was more convenient. 84 percent thought it was more comfortable to use.

(Michalek Decl., Exh. 5 at 20:12-20, Exh. 7 at 19:21-20:1). Ferring asserts that Watson did not produce the questions and answers to the survey, nor any evidence that the individual women being interviewed used both Crinone and Endometrin, and were therefore able to make a comparison between the two. The percentages utilized by Dr. Silverberg – 94%, 88%, and 84% – Ferring alleges, were not figures garnered from comparing the two products, but merely represented the percentage of women who liked Crinone. Ferring asserts that other women in the study were reported to like Endometrin, but that those statistics were not utilized. Ferring argues

Watson heralds the findings as a "comparative study," when it was in fact no such thing. Ferring cites to FDA requirements for maintaining the accuracy of preference claims about pharmaceuticals. (See e.g. Michalek Decl., Exh. 11) ("Patient preference claims should be supported by well-designed and controlled head-to-head studies using well-developed instruments that can evaluate all determinants of patient preference.). Ferring asserts Dr. Silverberg failed to meet these guidelines and thus the comparative statements contained in the presentation were improper. Watson concedes that the percentage figures used were inaccurate and the survey described ultimately found that 68.1% of the patients preferred Crinone over Endometrin. However, Watson asserts that the study was, in actuality, a survey of women who used both Crinone **and** Endometrin.

3. Age Restriction Claims

Ferring also finds fault with Dr. Silverberg's remarks concerning the efficacy of Crinone and Endometrin in women over thirty-five years and older. During the 7:30 p.m. presentation, Dr. Silverberg compared the efficacy of Crinone and Endometrin for women thirty-five and over and relied upon two relevant medical studies. In characterizing Crinone, Dr. Silverberg stated that it, unlike other products, had been established in women throughout the entire reproductive spectrum from twenty-two to forty-seven years of age, including women age thirty-five and older. Ferring asserts the studies cited to during the 7:30 p.m. Webcast did not stand for the asserted proposition. Furthermore, Dr. Silverberg stated during the same presentation that Endometrin "was not found to be efficacious for women over the age of 35." (Michalek Decl., Exh. 5 at 19:25-20:3) ("Webcast #1 Tr.). Ferring asserts that the studies relied upon and cited to by Dr. Silverberg say nothing about Endometrin and that Watson has produced no data to support its

claim that Endometrin does not work for women thirty-five years and older. Watson, through Dr. Silverberg, asserts that the data from the relevant study does in fact support the assertions contained in Dr. Silverberg's Webcasts. (Silverberg Cert. ¶¶ 17-21, Dec. 3, 2012, ECF No. 34-3).

II. LEGAL STANDARD

Injunctive relief is an "extraordinary remedy, which should be granted only in limited circumstances." Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Consumer Pharms. Co., 290 F.3d 578, 586 (3d Cir. 2002) (quotation and citation omitted); Kos Pharm. Inc. v. Andrx Corp., 369 F.3d 700, 708 (3d Cir. 2004); see also Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc., 42 F.3d 1421, 1427 (3d Cir.1994). "A decision to grant or deny a preliminary injunction is within the sound discretion of the district court." Sanofi–Aventis Deutschland GmbH v. Glenmark Pharms. Inc., 2010 WL 2428561 (D.N.J. June 9, 2010) (citing Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339 (Fed. Cir. 2003)); see also Spartacus, Inc. v. Borough of McKees Rocks, 694 F.2d 947, 949 (3d Cir. 1982). To determine whether a preliminary injunction should be granted, a district court must consider four factors:

(1) whether the movant has shown a reasonable probability of success on the merits; (2) whether the movant will be irreparably injured by denial of the relief; (3) whether granting preliminary relief will result in even greater harm to the nonmoving party; and (4) whether granting preliminary relief will be in the public interest. Gerardi v. Pelullo, 16 F.3d 1363, 1373 (3d Cir.1994); see also ACLU of N.J. v. Black Horse Pike Reg'l Bd. of Educ., 84 F.3d 1471, 1477 n. 2 (3d Cir. 1996); Opticians Ass'n of Am. v. Indep. Opticians of Am., 920 F.2d 187, 191–92 (3d Cir. 1990); CIBA–GEIGY Corp. v. Bolar Pharm. Co., Inc., 747 F.2d 844, 850 (3d Cir. 1984) cert. denied 471 U.S. 1137 (1985). The moving party bears the burden of showing that these factors

weigh in favor of granting the injunction. Kos Pharm. Inc., 369 F.3d at 708. "Only if the movant produces evidence sufficient to convince the [court] that all four factors favor preliminary relief should the injunction issue." Opticians Ass'n of Am., 920 F.2d at 192; see also Nutrasweet Co. v. Vit–Mar Enter. Inc., 176 F.3d 151, 153 (3d Cir.1999); Am. Tel. & Tel. Co., 42 F.3d at 1427 (citation omitted).

The Third Circuit has accorded particular weight to the first two of the injunction factors: irreparable harm and likelihood of success on the merits. Hoxworth v. Blinder, Robinson & Co., 903 F.2d 186, 197 (3d. Cir. 1990) (quoting In re Arthur Treacher's Franchisee Litig., 689 F.2d 1137, 1143 (3d Cir. 1982) ("[W]e cannot sustain a preliminary injunction ordered by the district court where either or both of these prerequisites are absent.")); see also Scholastic Funding Grp., LLC v. Kimble, Civ. No. 07-557, 2007 WL 1231795, at *28 (D.N.J. Apr. 24, 2007). Nonetheless, the district court should only award preliminary injunctive relief upon weighing all four factors. Am. Tel. & Tel. Co., 42 F.3d at 1427, (citing Duraco Prod, Inc. v. Joy Plastic Enter. Ltd., 40 F.3d 1431, 1438 (3d Cir.1994).)

III. DISCUSSION

A. IRREPARABLE HARM

This Court first addresses whether Plaintiff can demonstrate irreparable harm, since "[in] the absence of irreparable injury, no preliminary injunction would lie, even if the other three elements . . . were found." Nutrasweet Co. v. Vit-Mar Enterprises, Inc., 176 F.3d 151, 153 (3d Cir. 1999). "Establishing a risk of irreparable harm is not enough. A plaintiff has the burden of proving a 'clear showing of immediate irreparable harm' " absent injunctive relief. Hoxworth v. Blinder, Robinson & Co. Inc., 903 F.2d 186, 205 (3d Cir. 1990) (citing ECRI v. McGraw–Hill,

Inc., 809 F.2d 223, 225 (3d Cir.1987)). Irreparable harm cannot be presumed, and "must be established as a separate element, independent of any showing of likelihood of success." King Pharm. Inc. v. Sandoz, Inc., Civ. No. 08-5974, 2010 WL 1957640, at *5 (D.N.J. May 17, 2010) (citing Winter v. Natural Resources Defense Counsel, Inc., 555 U.S. 7, 21-22 (2008)). "In order to demonstrate irreparable harm the plaintiff must demonstrate potential harm which cannot be redressed by a legal or an equitable remedy following a trial." Instant Airfreight Co. v. C.F. Airfreight, Inc., 882 F.2d 797, 801 (3d Cir. 1989). Thus, the "preliminary injunction must be the only way of protecting the plaintiff from harm." Id. (emphasis added); see also Acierno v. New Castle County, 40 F.3d 645, 653 (3d Cir. 1994). Irreparable injury occurs when money damages are difficult to ascertain or would be inadequate. In re Arthur Treacher's Franchise Litig., 689 F.2d 1137, 1146 (3d Cir.1982). Failure to establish irreparable injury automatically results in denial of a preliminary injunction. Instant Airfreight Co., 882 F.2d at 800; see also Nutrasweet Co., 176 F.3d at 153.

Ferring asserts that, without injunctive relief, Ferring "will continue to suffer irreparable harm from Watson falsely informing the marketplace that Endometrin is dangerous, not effective, and disliked by women." (Pl.'s Mot. Br. 28). Watson, in turn, argues that Ferring has not and cannot meet its burden of demonstrating irreparable injury. (Def.'s Opp. Br. 21-22, Dec. 3, 2012, ECF No. 714). The Third Circuit has made clear that "the preliminary injunction device should not be exercised unless the moving party shows that it specifically and personally risks irreparable harm." Liberty Lincoln-Mercury, Inc. v. Ford Motor Co., 563 F. 3d 533, 557 (3d Cir. 2009) (citing Adams v. Freedom Forge Corp., 204 F.3d 475, 487 (3d Cir. 2000)).

Ferring must present evidence showing a likelihood of real irreparable harm and has not

sufficiently made that showing. Ferring asserts that Watson "falsely asserting that Endometrin is dangerous, ineffective, and disliked, relative to Crinone, 'necessarily diminishes' Endometrin's 'value in the minds of the consumer.'" (Pl.'s Mot. Br. 29, Nov. 9, 2012, ECF No. 29-1). Ferring further asserts that Watson deprived Ferring of a legitimate competitive interest and reduced consumers' incentive to select Endometrin. (Pl.'s Mot. Br. 29). To support these assertions, Ferring points to the propensity of false information promulgated on the Internet to "propage[], endure[], and continue to do harm." (Pl.'s Mot. Br. 29). However, Dr. Silverberg agreed he misstated the existence of a Black Box Warning on Endometrin during the 7:30 p.m. Webcast but removed the statement during the subsequent 9:00 p.m. Webcast. In his Certification to this Court, Dr. Silverberg has promised he will never state in the future that "[f]or Endometrin, there is a black box warning showing that efficacy has not been demonstrated with Endometrin for patients 35 years of age and older." (Silverberg Cert. ¶ 10, Dec. 3, 2012, ECF No. 34-3). Dr. Silverberg has further certified that, at the request of Watson, in future presentations concerning Crinone, he will make only specified statements as to the efficacy of Endometrin for women thirty-five (35) years or older in accordance with the statement contained on the product's package insert. (Silverberg Cert. ¶ 22). Furthermore, there has been no showing that the information contained in the Dr. Silverberg's Webcasts is still available online to be accessed by consumers.

Given that Ferring has not alleged facts sufficient to prove that it was harmed, or that the alleged harm was irreparable and could only be cured by a preliminary injunction, Ferring is unable to satisfy its burden of showing this factor weighs in favor of granting a preliminary injunction. Therefore, the Motion for a Preliminary Injunction must, by necessity, fail.

B. Likelihood of Success on the Merits

Although this Court has already determined that Ferring has not demonstrated irreparable harm, and is therefore not entitled injunctive relief, it will briefly address allegations regarding a likelihood of success on the merits in further support of denial of Ferring's motion. A "likelihood of success on the merits" for the purposes of a preliminary injunction analysis does not require "a moving party to demonstrate 'a certainty of prevailing, but rather . . . a reasonable probability of eventual success in the litigation." Assisted Living Assoc. of Moorestown, L.L.C. v. Moorestown Tp., 996 F. Supp. 409, 433 (D.N.J. 1998) (citation omitted). Ferring raises claims of, and seeks injunctive relief for, false advertising in violation of the Lanham Act. The Lanham Act prohibits any false or misleading description or representation of fact that "in commercial advertising or promotion, misrepresents that nature, characteristics, qualities, or geographic origin" of goods. 15 U.S.C. § 1125(a)(1)(B). A defendant violates the prohibition when: "1) the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will etc." Warner-Lambert Co. v. Breathasure, Inc., 204 F.3d 87, 91-92 (3d Cir. 2000).

Ferring asserts initially that Watson's advertisements are false because Watson's claims are unsubstantiated. (Pl.'s Mot. Br. 17). Ferring relies on the Third Circuit's acknowledgment that "although the plaintiff normally has the burden to demonstrate that the defendant's advertising is false, a court may find that a completely unsubstantiated advertising claim by defendant is *per se* false without additional evidence from the plaintiff to that effect." (Pl.'s Mot. Br. 17) (citing

Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 290 F.3d 578, 590 (3d Cir. 2002)). However, the Court does not agree that it is clear, at this stage, that the substance of the advertising claim was "completely unsubstantiated." Watson has demonstrated that at least some support exist to form the basis of the statements. In either case, the Court need not make a determination as to the likelihood of success of Ferring's claims, because, as mentioned above, Ferring has failed to demonstrate irreparable harm.

C. HARM TO DEFENDANTS AND PUBLIC INTEREST

The Third Circuit has "held that these latter two factors should be taken into account only when they are relevant." Am. Tel. and Tel. Co. v. Winback and Conserve Program, Inc., 42 F.3d 1421, 1427 n. 8 (3d Cir.1994); see also Hoxworth, 903 F.2d at 196. These factors are only relevant if Plaintiff has first established "both a likelihood of success on the merits and the probability of irreparable harm if relief is not granted" because a preliminary injunction cannot be sustained "where either or both of these prerequisites are absent." Id. (internal citations omitted). Since at least one of these prerequisites is absent, this Court need not address the potential harm to Defendants from or the public interest in granting a preliminary injunction.

IV. CONCLUSION

For the foregoing reasons, Ferring's Motion for Preliminary Injunction is **denied**. An appropriate Order accompanies this Opinion.

Dennis M. Cavanaugh, U.S.D.J.

Date: April 4, 2013
cc: All Counsel of Record
Joseph A. Dickson, U.S.M.J.