IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| ASTRAZENECA AB, ASTRAZENECA LP, and ASTRAZENECA PHARMACEUTICALS LP, | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civ. No. 15-988-SLR |
| DR. REDDY'S LABORATORIES, INC., | ) | |
| Defendant. | ) | |

**MEMORANDUM**

At Wilmington this 6th day of November, 2015, having reviewed the papers filed in connection with plaintiffs motion for a temporary restraining order, and having heard oral argument on same, the court issues its decision to grant the motion, for the reasons that follow:

1. **Background.**[1] Since 1989, the AstraZeneca plaintiffs ("AZ") have used the color purple to brand their gastrointestinal ("GI") products[2] for treating severe heartburn and acid reflux. The U.S. Patent and Trademark Office has confirmed the brand status of AZ's purple color by awarding AZ three federal trademark registrations covering the color purple for GI pharmaceuticals and one covering the phrase "THE PURPLE PILL®" for the same goods ("the Purple Marks"). (D.I. 5 at 10) None of AZ's competitors have

[1]The facts related to AZ are taken from the verified complaint filed in this litigation, and/or have not been disputed by DRL.

[2]Prilosec® and Nexium®.

challenged those registrations.

2. AZ has sold more than 7.1 billion purple Prilosec® capsules in the U.S. from 1989-2014, and more than 15.5 billion purple Nexium® capsules in the U.S. from 2001-2014, for a total of more than 22.6 billion purple capsules. On an average annual basis since 2001, AZ has sold over $3 billion of Prilosec® and Nexium® in purple capsules in the U.S. AZ has also provided hundreds of millions of purple Nexium® capsules as free samples over the years to doctors who, in turn, provide them to their patients at no cost.

3. The color purple has been used prominently by AZ in all of its efforts to promote Prilosec® and Nexium®, from the AZ website ("PURPLEPILL.COM") to advertising in many consumer publications that are widely distributed to the general U.S. public, to advertising on network and cable television, radio, and popular and highly trafficked websites.[3] According to AZ, such promotional materials have reached tens of millions of people each year. Between 1995 and 2014, AZ spent an average of over $250 million per year to build its purple brand as described above.

4. As a result of such promotional efforts, there is undisputed evidence that the media and the public associate the color purple with AZ and its Prilosec® and Nexium® products. (D.I. 5 at 8-9) Indeed, the FDA recognized the trademark significance of AZ's purple color as early as 2001 as part of an advertising review, finding that a television advertisement for Prilosec® (that did not mention Prilosec® by name) was nevertheless a "product-specific advertisement" because it discussed acid-reflux disease in

---

[3]Many examples of such are provided in D.I. 5 at 4-7.

conjunction with "the purple pill," and AZ's Prilosec® "[was] the only purple pill that treats heartburn due to acid-reflux disease." (*Id.* at 7)

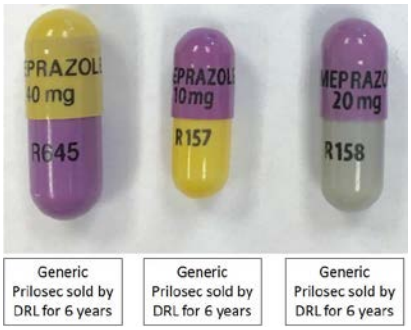
5. Nexium® is sold only in prescription form. In May 2014, Pfizer, under license from AZ, began selling an over-the-counter ("OTC") non-prescription 20 mg version of Nexium® called "Nexium24HR." Pfizer promotes the product on a predominantly purple website that prominently displays purple Nexium® capsules and AZ's trademark "The Purple Pill®." According to AZ, Pfizer paid an up-front fee of $250 million to gain access to exclusive global rights to sell OTC Nexium® and a license to use some of AZ's Purple Marks. Pfizer also agreed to pay AZ milestone and royalty payments based on product launches and sales. (D.I. 5 at 3)

6. Several companies have recently entered the market with generic versions of AZ's Nexium® esomeprazole magnesium compound. The first two companies permitted by the FDA to do so - Teva and Mylan - have used blue or white capsules. The second wave of generic companies entering the market have been more aggressive, choosing purple capsules for their generic Nexium®. More specifically, defendant Dr. Reddy's Laboratories, Inc. ("DRL"), a maker of generic drugs, launched its generic GI pharmaceutical (esomeprazole) in September 2015. AZ filed its verified complaint and motions for injunctive relief on October 28, 2015. (D.I. 1, 3, and 4)

7. All of the different iterations of the products at issue are shown below, in order to better illustrate the dispute at bar.

Prilosec® capsules

Nexium® capsules with either two or three gold-colored bands




Generic Prilosec® sold by DRL since 2009

Pfizer's Nexium® OTC capsules


First wave Nexium® generics


Second wave DRL Nexium® generic

8. **Standard of review.** As explained by the United States Court of Appeals for the Third Circuit,

> [p]reliminary injunctive relief is an "extraordinary remedy, which should be granted only in limited circumstances." . . . "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." . . . The "failure to establish any element . . . renders a preliminary injunction inappropriate." . . . The movant bears the burden of showing that these four factors weigh in favor of granting the injunction.

*Ferring Pharms., Inc. v. Watson Pharmaceuticals, Inc.*, 765 F.3d 205, 210 (3d Cir. 2014) (citations omitted). "'[O]ne of the goals of the preliminary injunction analysis is to maintain the status quo, defined as the last, peaceable, noncontested status of the parties.'" *Kos Pharms., Inc. v. Andrx Corp*, 369 F.3d 700, 708 (3d Cir. 2004) (citation omitted). In a trademark case, for example, "[it] is the situation prior to the time the junior user began use of its contested mark." *Id.* (citation omitted). "[T]he decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and . . . such discretion must be exercised consistent with traditional principles of equity." *eBay Inc. v. MercExchange, L.L.C.,* 547 U.S. 388, 394 (2006).[4]

9. **Likelihood of success on the merits - trademark infringement.** The Lanham Act defines trademark infringement as use of a mark so similar to that of a prior user as to be "likely to cause confusion, or to cause mistake, or to deceive." 15 U.S.C. § 1114(1). "Likelihood of confusion under the Lanham Act is not limited to

---

[4]There is no indication that the standard for issuance of a temporary restraining order is any different from that for issuance of a preliminary injunction. *See, e.g., Globus Medical, Inc. v. Vortex Spine, LLC*, 605 Fed. Appx. 126 (3d Cir. 2015); *Nutrasweet Co. v. Vit-Mar Enterprises, Inc.*, 112 F.3d 689 (3d Cir. 1997).

confusion of products[; c]onfusion as to source is also actionable." *Kos Pharms.*, 369 F.3d at 711. The Third Circuit has identified a number of factors to aid in determining likelihood of confusion. Those factors include:

> (1) the degree of similarity between the owner's mark and the alleged infringing mark; (2) the strength of the owner's mark; (3) the price of the goods and other factors indicative of the care and attention expected of consumers when making a purchase; (4) the length of time the defendant has used the mark without evidence of actual confusion arising; (5) the intent of the defendant in adopting the mark; (6) the evidence of actual confusion; (7) whether the goods, [even if] not competing, are marketed through the same channels of trade and advertised through the same media; (8) the extent to which the targets of the parties' sales efforts are the same; (9) the relationship of the goods in the minds of consumers because of the similarity of function; (10) other facts suggesting that the consuming public might expect the prior owner to manufacture a product in the defendant's market, or that he is unlikely to expand into that market.

*Interpace Corp. v. Lapp, Inc.*, 721 F.2d 460, 463 (3d Cir. 1983) ("the *Lapp* factors"). "'None of these factors is determinative in the likelihood of confusion analysis and each factor must be weighed and balanced one against the other.' . . . '[T]he different factors may properly be accorded different weights depending on the particular factual setting. A district court should utilize the factors that seem appropriate to a given situation.' . . ." *Kos Pharms.*, 369 F.3d at 709 (citations omitted). Where the marks are identical and/or used for competing goods, "the court need rarely look beyond the mark itself." *Opticians Ass'n of Am. v. Indep. Opticians of Am.,* 920 F.2d 187, 195 (3d Cir. 1990). "The *Lapp* factors are best understood as 'tools to guide a qualitative decision.'" *Kos Pharms.*, 369 F.3d at 709 (citation omitted).

10. **Degree of similarity** (*Lapp* #1)**.** DRL's generic capsule is purple, albeit two shades of purple. Although not identical to AZ's branded capsule, it does fit the

description of the mark, "purple." It has been recognized that a registration for a color covers all shades of that color. *See, e.g., Wolf Appliances, Inc. v. Viking Range Corp.*, 686 F. Supp. 2d 878 (W.D. Wis. 2010). It should be noted as well that the presence or absence of markings on DRL's capsules do not avoid a likelihood of confusion. As explained by the court in *Ciba-Geigy Corp. v. Bolar Pharm. Co.*, 547 F. Supp. 1095 (D.N.J. 1982), *aff'd*, 719 F.2d 56 (3d Cir. 1983), "[r]ealistically, the likelihood of confusion cannot be assessed by a side-by-side comparison of the plaintiff's and defendant's products. It is the overall physical appearance of defendant's trade dress which is critical. The vast majority of patients who take this type of medication do not or cannot identify their medication, or its source, by reference to the matter imprinted on the drug capsule of tablet." *Id.* at 1103. *See also Fisons Horticulture, Inc. v. Vigoro Indus., Inc.*, 30 F.3d 466, 477 (3d Cir. 1994) (the test for likelihood of confusion is whether the marks create the same overall impression when viewed separately). This factor weighs in favor of AZ.

11. **Strength of AZ mark** (*Lapp* #2). AZ has presented credible evidence that its Purple Marks branding is of long duration, of value, and strong.[5] This factor weighs strongly in favor of AZ.

12. **Consumer care in purchase** (*Lapp* #3). Given that the products in dispute

---

[5]In this regard, the court notes the following discussion in *Kos Pharmaceuticals* relating to the admissibility of a declaration (called a "certification") that contained hearsay: "It is well established that 'a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits.' . . . District courts must exercise their discretion in 'weighing all the attendant factors, including the need for expedition,' to assess whether, and to what extent, affidavits or other hearsay materials are 'appropriate given the character and objectives of the injunctive proceeding.'" 369 F.3d at 718-19.

are prescription (not OTC) drugs, the consumers are not necessarily involved in the decision to purchase one drug over another. Therefore, this factor weighs in favor of DRL.

13. **Defendant's use of mark** (*Lapp* #4). DRL introduced its generic product in September 2015. There has been no evidence presented of actual confusion. The court would not necessarily expect such, however, given the mere weeks that DRL's generic has been on the market; i.e., there has not been a meaningful opportunity for confusion. This factor is neutral.

14. **Defendant's intent** (*Lapp* #5). Given the totality of the circumstances, including the physical appearance of DRL's other generics (distinctive), the fact that DRL is a second wave generic in this market (and perhaps has to be more aggressive to get market share), and DRL's explanations for adopting an all-purple pill (which the court will discuss below), the court concludes that DRL intended to test AZ's trademark, rather than honor it. This factor weighs in favor of AZ.

15. **Evidence of actual confusion** (*Lapp #6)*. There is no evidence of record of actual confusion. Consistent with the discussion of *Lapp* factor #4, however, this factor is neutral.

16. **Competition and overlap** (*Lapp* # 7-10). Despite the fact that Nexium® is a branded product and DRL's generic is not, the court finds that AZ and DRL are still competing in the same market for the same consumers in the first instance, even if DRL is ultimately competing against other generics once the decision to buy a generic has been made. These factors weigh in favor of AZ.

17. The above analysis of the *Lapp* factors directs the conclusion that AZ has carried its burden to prove likelihood of success on the merits of its trademark infringement claim. For completeness, however, the court will address the remaining issues raised by the parties.

18. **Likelihood of success on the merits - dilution.** Liability for dilution occurs if, "at any time after the owner's mark has become famous, [defendant] commences use of a mark or trade name in commerce that is likely to cause dilution by blurring [. . .] regardless of the presence or absence of actual or likely confusion, of competition, or of actual economic injury." 15 U.S.C. § 1125(c)(1). Blurring "is association arising from the similarity [. . .] that impairs the distinctiveness of the famous mark." *Id.* § 1125(c)(2)(B). The statute characterizes a "famous" mark as one that is "widely recognized by the general consuming public of the United States as a designation of source." *Id.* § 1125(c)(2)(A). The Supreme Court has held that single-color marks are entitled to trademark protection, *see Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 163-64, 174 (1995), and also have been recognized as "famous" marks, *see, e.g., Binney & Smith v. Rose Art Indus.*, 2001 WL 910943 (E.D. Pa. Aug. 9, 2001) (finding Crayola's yellow and green color scheme famous).

19. AZ has provided sufficient evidence to demonstrate that its trademarks are "famous." Specifically, it is evident that DRL, in its marketing of its GI generics, has progressed from using colors in its two-tone capsules that are not at all similar to AZ's purple pills, to a two-tone capsule that is (1) all purple and (2) uses AZ's shade of purple. This encroachment is likely to dilute AZ's Purple Marks.

20. **DRL's contract defense.** In its response to AZ's motion for a temporary restraining order, DRL raises several defenses, including a contract defense based on a settlement agreement ("the Agreement") entered into by, among others, the parties at bar in January 2011. The Agreement explains that AZ and DRL "are involved in litigation . . . concerning, inter alia, the validity of the [AZ Patents], as well as the alleged infringement by DRL of the [AZ Patents] resulting from DRL's requesting approval from the [FDA] for the distribution and sale of the DRL Product (as defined . . .) prior to expiry of the [AZ Patents]." (D.I. 17, ex. B at 2) The "DRL Product" was defined as "a Generic Esomeprazole product sold, offered for sale or distributed pursuant to ANDA No. 78-279, including any supplements or amendments to ANDA No. 78-279 that do not change the mode of administration. . . ." (*Id.* at 4) The "Mutual Release" referred to by DRL states that, "[i]n settlement of the disputed claims in the Actions," AZ releases DRL "from any and all claims, demands, damages, liabilities, obligations, and causes of action known or unknown, suspected or unsuspected, in law or equity, . . that were asserted, or that could have been asserted, by" AZ "in connection with the DRL Product . . . arising before the Effective Date of this Settlement Agreement." (*Id.* at 7) In ANDA litigation, of course, the only claims that are allowed to be presented before market entry of the generic in the artificial environment created by Congress under the Hatch-Waxman Act are those relating to patent infringement and validity.[6] The only context in

[6]DRL argues in this regard that the Agreement covered its right to use a purple capsule because its generic product was described as "purple opaque" in four sections of DRL's ANDA submission, which submission was made part of the litigation record before the Agreement was executed. DRL does not fully describe its ANDA submission for purposes of the record at bar. (D.I. 16 at 5-7) From the court's extensive ANDA litigation experience, however, the court takes judicial notice of the fact that such

which AZ's trademark rights are mentioned in the Agreement is in ¶ 9.13, in which DRL agrees that it "shall have no right, title or interest in or to (a) any trademark, trade dress, brand mark, service mark, trade name, brade name, logo or other similar business symbol of [AZ] . . ., including the trademark Nexium® or any trade dress of any Nexium® product . . . ." (*Id.* at 11)

21. Contract interpretation is usually a question of law in New Jersey. *Dome Petroleum Ltd. v. Employers Mut. Liab. Ins. Co.*, 767 F.2d 43, 47 (3d Cir. 1985) (citations omitted). Under New Jersey law, courts should interpret a contract considering "the objective intent [of the parties] manifested in the language of the contract in light of the circumstances surrounding the transaction." *Id.* (citations omitted). Although the New Jersey Supreme Court has "extolled the use of extrinsic evidence to aid in ascertaining the intent of the parties, even when the term of the instrument are otherwise unambiguous, it cautioned that such evidence may not be used 'for the purpose of modifying or enlarging or curtailing' the terms of the contract." *American Cyanamid Co. v. Fermenta Animal Health Co.*, 54 F.3d 177, 182 (3d Cir. 1995) (citing *Atlantic Northern Airlines, Inc. v. Schwimmer*, 96 A.2d 652, 656 (1953)).

22. The court concludes that the plain meaning of the Agreement, especially when viewed in the context of the ANDA litigation resolved by the Agreement, did not release DRL from any liability for selling its purple-colored generic product. If anything, the language of the Agreement specifically preserved AZ's trademark rights against the

---

submissions are voluminous by nature, and that the focus of ANDA litigation is on the formulation of the generic product for infringement purposes (not on the color of the proposed commercial product, which is not on the market as not even approved by the FDA yet).

very conduct in which DRL has engaged.

23. **DRL's acquiescence defense.** DRL asserts in this regard that its sale of the half-purple Prilosec generic capsules since 2005 demonstrates that "the market history of overlap between" the products undermines any argument for irreparable harm. (D.I. 16 at 13-14) As discussed above, the court rejects the notion that DRL's marketing strategies in the past excuse its encroachment now.

24. **Irreparable harm.** "Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of good will," intangible harms for which "it is virtually impossible to ascertain the precise economic consequences." *Kos Pharms.*, 369 F.3d at 726 (citation omitted); *Ferring Pharms.*, 765 F.3d at 211 (citation omitted). By using AZ's Purple Marks, it is likely that DRL will create (and intended to create) the false impression that its generic esomeprazole magnesium capsules are identical to Nexium®, not merely bioequivalent, and may be an "authorized generic," that is, a generic drug made or authorized by the brand name company, i.e., by AZ. Such identity of source, sponsorship or affiliation with AZ not only dilutes AZ's Purple Marks, but puts at risk AZ's reputation in the event of quality or safety issues with DRL's generic. The court concludes that AZ has demonstrated a likelihood of irreparable harm.

25. **Balance of harms.** The question to be addressed is whether, and to what extent, DRL will suffer irreparable harm if injunctive relief is granted. Such irreparable harm "must be of a peculiar nature, so that compensation in money alone cannot atone for it." *Kos Pharms.,* 369 F.3d at 727. As noted by the Third Circuit in this regard,

"[i]njury to goodwill does constitute irreparable harm. . . . But, when the potential harm to each party is weighed, a party 'can hardly claim to be harmed [where] it brought any and all difficulties occasioned by the issuance of an injunction upon itself.'" *Id.* at 728 (citation omitted). The court recognizes that imposing injunctive relief on DRL (i.e., forcing DRL to take its generic off the market) will be costly, both monetarily (*see* D.I. 30) and in terms of such intangibles as market share and loss of good will. The court nevertheless concludes that DRL engaged in the conduct at issue fully aware of such consequences and, therefore, cannot be heard to complain that the risks it took did not pay off.

26. **Public interest.** "The most basic public interest at stake in all Lanham Act cases [is] the interest in prevention of confusion, particularly as it affects the public interest in truth and accuracy." *Kos Pharms.*, 369 F.3d at 730. Although the public certainly has an interest in having access to less expensive drugs, there are other generics on the market that did not test AZ's trademarks, a risk that DRL took and lost (at least momentarily).

27. **Conclusion.** Weighing all of the factors discussed above in the "totality of the circumstances," *Kos Pharms.*, 369 F.3d at 711, the court concludes that AZ has carried its burden to prove that it is likely to succeed on the merits of its case, that it is likely to suffer irreparable harm if the requested relief is not granted, that the balance of hardships and the public interest weigh in its favor. If DRL's arguments were carried to their logical end, the loss of a branded company's patent monopoly would inevitably result in a loss of its trademark rights, a result not consistent with the law or the market

place. Moreover, so long as injunctive relief is available to prevent harm, the court declines to force such plaintiffs such as AZ to actually incur harm that is likely, but not provable, at the outset. Therefore, AZ's motion for a temporary restraining order will be granted. An order shall issue.

United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| ASTRAZENECA AB, ASTRAZENECA LP. and ASTRAZENECA PHARMACEUTICALS LP, | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civ. No. 15-988-SLR |
| DR. REDDY'S LABORATORIES, INC., | ) | |
| Defendant. | ) | |

**ORDER**

At Wilmington this 6th day of November, 2015, consistent with the memorandum issued this same date;

IT IS ORDERED that:

1. Plaintiffs' motion for a temporary restraining order (D.I. 3) is granted.

2. Defendant Dr. Reddy's Laboratories, Inc. and all others, including without limitation, its employees, agents, partners, officers, directors, owners, shareholders, principals, parents, subsidiaries, related companies, affiliates, distributors, wholesalers, repackagers, retailers, and all person in active concert or participation with any of them (collectively, "defendant"), shall immediately stop the sale, delivery, transfer, or other disposition of its generic esomeprazole product that is the subject of this litigation, pending further hearing or trial of this action.

3. The parties shall confer on a more complete form of order, as well as on a

proposed schedule for the next stage of the litigation. If the parties cannot agree to such, they shall submit their competing proposals to the court on or before Wednesday, November 11, 2015. The court shall conduct a telephonic status conference on **Thursday, November 12, 2015 at 1:00 p.m.**, if needed, with plaintiffs' counsel initiating the call.

United States District Judge