UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

HILL DERMACEUTICALS, INC.,

Plaintiff,

-vs- **Case No. 6:11-cv-1827-Orl-28DAB**

AMNEAL PHARMACEUTICALS, LLC,
AND IDENTI PHARMACEUTICALS, LLC

Defendants.

ORDER

Plaintiff manufactures three brand-name topical drugs that treat certain skin diseases ("Plaintiff's drugs"). Defendant Identi Pharmaceuticals, LLC ("Identi") developed generic versions of Plaintiff's drugs, and Defendant Amneal Pharmaceuticals, LLC ("Amneal") manufactures and distributes those generic drugs. This cause is before the Court on Plaintiff's Motion for Preliminary Injunction (Doc. 5), in which Plaintiff asks this Court to enjoin Defendants from producing and distributing their generic drugs while this suit is pending.[1] Defendants have filed Responses (Docs. 18 & 22), and oral argument was heard on December 12, 2011. For the reasons set forth below, Plaintiff's motion shall be denied.

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[1] Plaintiff also filed a Motion to Compel (Doc. 28), requesting the Court to compel Defendants to provide exemplars of each of the three generic drugs to Plaintiff for testing to support Plaintiff's Motion for Preliminary Injunction. As discussed below, however, even if Plaintiff demonstrated that Defendants' drugs are not bioequivalent to Plaintiff's drugs, Plaintiff has not shown that it has a likelihood of success on the merits. Additionally, in its previous Order (Doc. 9), this Court denied Plaintiff's request for an evidentiary hearing. Accordingly, Plaintiff's Motion to Compel (Doc. 28) shall be denied.

In order to obtain a preliminary injunction, a plaintiff must show that "(1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." Siegel v. LePore, 234 F.3d 1163, 1176 (11th Cir. 2000). The Court need not address all of these factors because Plaintiff has failed to show a likelihood of success on the merits.

Plaintiff's drugs contain peanut oil, and Plaintiff developed a test to ensure that the oil was made up of 0.5 ppm or less of peanut protein so that it would not cause an allergic reaction in patients with a peanut allergy. In 2004, Plaintiff submitted a citizen petition to the Food and Drug Administration ("FDA") requesting that the FDA deny approval of any Abbreviated New Drug Application ("ANDA") for a generic version of Plaintiff's drugs unless the applicants undertook clinical trials and safety testing.[2] The FDA denied Plaintiff's Citizen Petition.

Thereafter, Identi submitted ANDAs for its generic versions of Plaintiff's drugs, and in 2011 the FDA approved all three of Identi's generic drugs. In response, Plaintiff filed suit in the U.S. District Court for the District of Columbia against the FDA and other related government officials ("the D.C. Action"), seeking "to enjoin the FDA to withdraw or suspend its approval of the three [ANDAs] submitted by Identi on the basis that the approval

[2]Generally, ANDA applicants need not submit new clinical evidence on drug safety because the proposed generic drug must be bioequivalent to an approved drug, and therefore, the applicant is able to rely on the FDA's findings for the brand name drug. See generally 21 U.S.C. § 355(j).

contravenes the sameness requirements, the misbranding restrictions, and the bioequivalence requirements of the Food, Drug, and Cosmetic Act and its implementing regulations." Hill Dermaceuticals, Inc. v. U.S. Food & Drug Admin., No. 11-1950 (RCL), 2011 WL 6005195, at *1 (D.D.C. Dec. 2, 2011). On December 11, 2011, the D.C. Court denied Plaintiff's motion for preliminary injunction. Id. at 10.

The crux of Plaintiff's claims in this case is that Defendants' generic drugs are not biologically equivalent to Plaintiff's drugs and therefore "are illegal in the State of Florida" pursuant to section 465.025, Florida Statutes. (Mot.Prelim. Inj., Doc. 5, at 3). Plaintiff asserts that under section 465.025 the State of Florida undertakes its own, distinct inquiry into whether or not a generic drug is the bioequivalent of the brand name drug; therefore, Plaintiff argues this suit is not duplicative of the D.C. action.

Section 465.025 provides in relevant part that "[a] pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product that is . . . [l]isted in the formulary of generic and brand name drug products . . . for the brand name drug prescribed" unless the prescriber provides otherwise. § 465.025(2), Fla Stat. Section 465.025(5) then requires "[e]ach community pharmacy" to establish its own "formulary of generic and brand name drug products which, if selected as the drug product of choice, would not pose a threat to the health and safety of patients receiving prescription medication" based on "drug product research, testing, information, and formularies compiled by other pharmacies, by states, by the United States Department of Health, Education, and Welfare, by the United States Department of Health and Human Services, or by any other source which the

pharmacist deems reliable." Furthermore, the drugs on the formulary must be "obtained from manufacturers or distributors holding an approved new drug application or abbreviated new drug application issued by the [FDA] permitting that manufacturer or distributor to market those medicinal drugs or when the former is non-applicable, those manufacturers or distributors supplying those medicinal drugs must show compliance with other applicable [FDA] marketing requirements." Fla. Admin. Code R. 64B16-27.520.

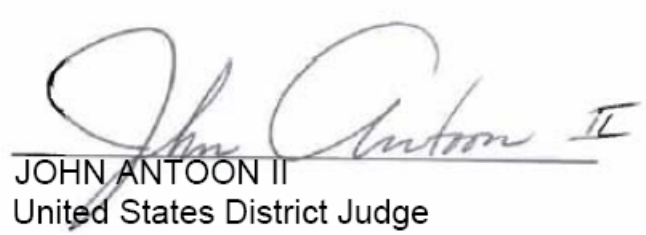
Contrary to Plaintiff's contention, section 465.025 does not provide for a separate state determination as to whether a generic drug is bioequivalent to the name brand, nor does it provide for a private right of action. Rather, section 465.025 contemplates a state administrative scheme, under which the state uses FDA determinations to further its policy of providing more affordable drugs to its citizens. See Abbott Labs. v. Mylan Pharms., Inc., 15 So. 3d 642, 646 (Fla. 1st DCA 2009) (noting that "[u]ntil the mid-1970s, nearly all states required pharmacists to dispense the exact drug specified by the prescribing physician, even if equivalent generic products were available" but that "with the advent of strict federal drug laws, most states more freely allow substitution in order to contain the high cost of drugs"). As such, it is unlikely that Plaintiff will prevail on the merits of this case.[3]

In accordance with the foregoing, Plaintiff's Motion for Preliminary Injunction (Doc. 5) and Plaintiff's Motion to Compel (Doc. 28) are **DENIED**. Plaintiff's Motion for Use of

[3] In its Complaint, Plaintiff also asserts violations of the Uniform Trade Secrets Act, section 688.001, et. seq., Fla. Stat. and the Sherman Antitrust Act, 15 U.S.C. § 1, but Plaintiff did not assert that either of these claims constituted a basis for this Court to enter a preliminary injunction.

Electronic Equipment at Hearing (Doc. 24) and Plaintiff's Motion to File Reply Memorandum (Doc. 30) are **moot**.

DONE and **ORDERED** in Chambers, Orlando, Florida this 13th day of December, 2011.



JOHN ANTOON II
United States District Judge

Copies furnished to:
Counsel of Record