

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

HILL DERMACEUTICALS, INC.,

Plaintiff,

v.

Case No: 6:16-cv-833-Orl-40TBS

ANTHEM, INC.,

Defendant.

HILL DERMACEUTICALS, INC.,

Plaintiff,

v.

Case No: 6:16-cv-1282-Orl-40TBS

BLUE CROSS BLUE SHIELD OF
FLORIDA, INC.,

Defendant.

ORDER

These consolidated cases come before the Court on Defendants' respective motions to dismiss Plaintiff's complaints against them and Plaintiff's motions for preliminary injunctive relief. The parties have completed their briefing and the Court is otherwise fully advised on the premises. Upon consideration, Defendants' motions to dismiss will be granted, Plaintiff's motions for preliminary injunctions will be denied, and the cases will be dismissed.

I. BACKGROUND

A. Facts¹

Plaintiff, Hill Dermaceuticals, Inc. (“Hill”), is a developer, manufacturer, and distributor of dermatology products. One of those products—Tolak® (fluorouracil) 4% Cream (“Tolak”)—serves as the focal point of this lawsuit. Tolak is a patented and FDA-approved medicated cream used to treat actinic keratosis, a precancerous skin condition which causes rough, scaly lesions to develop on the skin. Hill touts Tolak as having three key benefits over its competitors. First, Tolak effectively treats actinic keratosis while producing less severe side effects in patients. Second, unlike most of the other medicated creams on the market, Tolak treats both clinical (visible) and subclinical (invisible) lesions, which is the preferred industry standard for treating actinic keratosis. Third, Tolak is substantially less expensive than its brand-name and generic competitors.

Tolak is additionally approved under Medicare Part D, which is a federal-government program designed to subsidize prescription drug costs and insurance premiums for Medicare recipients. This means that a Medicare recipient who has insurance with a Medicare Part D plan sponsor which covers Tolak will only pay a portion of Tolak’s retail price. To that end, Defendant, Blue Cross Blue Shield of Florida, Inc. (“Blue Cross”), is a Medicare Part D plan sponsor which provides benefits to its members who receive Medicare. Similarly, Defendant, Anthem, Inc. (“Anthem”), although not a Medicare Part D plan sponsor in its own right, owns and controls subsidiaries which are plan sponsors and provide benefits to Anthem’s Medicare recipients.

¹ This account of the facts is taken from Plaintiff’s Amended Complaints, the allegations of which the Court must accept as true when considering Defendants’ motions to dismiss. See *Linder v. Portocarrero*, 963 F.2d 332, 334 (11th Cir. 1992).

In early February 2016, Hill contacted Anthem and Blue Cross to request that Tolak be added to their Medicare Part D formularies so that Tolak could be available to Anthem's and Blue Cross's Medicare recipients. At the time Hill made its requests, the FDA had not yet published its research and conclusions regarding Tolak. Hill therefore provided Anthem and Blue Cross with Tolak's Formulary Monograph, which summarizes the scientific data supporting Hill's claim that Tolak provides unique therapeutic, safety, and price advantages over competing drugs. In March 2016, Anthem denied Hill's request to include Tolak in its formularies, citing "insufficient evidence" demonstrating the advantages Hill asserts. In July 2016, Blue Cross likewise denied Hill's request to add Tolak to its formularies. By not including Tolak in their formularies, Anthem and Blue Cross do not cover Tolak under Medicare Part D. As a result, Anthem's and Blue Cross's Medicare recipients must either pay out-of-pocket for Tolak, use a more expensive, less effective, and less safe alternative, or submit to an arduous procedure with the hope of obtaining an individual exception to use Tolak instead of another approved drug on Anthem's or Blue Cross's controlling formulary.

When Hill confronted Anthem about the decision not to cover Tolak, an Anthem representative stated that Anthem bases its formulary decisions in part on whether a drug manufacturer provides financial incentives for covering its drug. The Anthem representative further illuminated that Anthem receives "huge discounts" in the form of rebates from Hill's competitors. Since Hill does not offer rebates or other financial incentives for covering Tolak, Hill infers that Anthem's refusal to include Tolak in its formularies was driven primarily, if not exclusively, by financial considerations. Hill has

reason to believe that Blue Cross employed the same calculus in reaching its decision not to cover Tolak.

B. Procedural History

Hill initiated these lawsuits against Anthem and Blue Cross on May 17, and July 18, 2016, respectively. Hill has since amended its complaints against both Defendants, and these Amended Complaints remain Hill's operative pleadings. Hill sues Anthem and Blue Cross for declaratory and injunctive relief. Specifically, Hill asks the Court to declare that Anthem and Blue Cross violated the Social Security Act and the federal regulations governing Medicare Part D when they refused to cover Tolak, and to compel Anthem and Blue Cross to add Tolak to their formularies. Hill additionally sues Anthem and Blue Cross for tortiously interfering with its business relationships, for engaging in deceptive and unfair trade practices, and for unlawfully restraining trade. Lastly, Hill sues Blue Cross for product disparagement. Anthem and Blue Cross now move to dismiss Hill's Amended Complaints pursuant to Federal Rule of Civil Procedure 12(b)(6).²

II. STANDARDS OF REVIEW

A motion to dismiss made pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of a plaintiff's complaint. In order to survive a Rule 12(b)(6) motion, the complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible on its face when the plaintiff alleges enough facts to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678

² On September 27, 2016, the Court consolidated Hill's lawsuits for discovery and trial.

(2009). The mere recitation of the elements of a claim is not enough, and the district court need not give any credence to legal conclusions that are not supported by sufficient factual material. *Id.* District courts must accept all well-pleaded allegations within the complaint and any documents attached thereto as true and must read the complaint in the light most favorable to the plaintiff. *Hunnings v. Texaco, Inc.*, 29 F.3d 1480, 1484 (11th Cir. 1994) (per curiam).

Additionally, federal courts are courts of limited jurisdiction, meaning that they are conscribed to hearing only those types of cases and controversies specifically enumerated by Article III of the United States Constitution or otherwise granted to them by the United States Congress. *Smith v. GTE Corp.*, 236 F.3d 1292, 1299 (11th Cir. 2001). As such, a federal court is obligated to ensure that it has subject matter jurisdiction at all times during the proceedings, and the court may examine its jurisdiction with or without a party's urging. *Id.* “[O]nce a federal court determines that it is without subject matter jurisdiction, the court is powerless to continue.” *Univ. of S. Ala. v. Am. Tobacco Co.*, 168 F.3d 405, 410 (11th Cir. 1999).

III. DISCUSSION

Anthem and Blue Cross move to dismiss all of Hill's claims against them for various reasons, which the Court discusses in the most logical order.

A. The Court Lacks Subject Matter Jurisdiction Over Hill's Declaratory Judgment Claims

In Count II of each Amended Complaint, Hill seeks declaratory relief pursuant to the Declaratory Judgment Act and Federal Rule of Civil Procedure 57. As described above, Hill asks the Court to declare that Anthem and Blue Cross violated the Social Security Act and Medicare Part D's regulations when they denied Hill's requests to include

Tolak in their formularies. Anthem and Blue Cross move to dismiss these counts on the ground that Hill cannot state a claim for relief, as no cause of action exists to prosecute the violations Hill alleges. Although closely related to Defendants' argument, the Court resolves the issue on the basis of subject matter jurisdiction.

The Declaratory Judgment Act grants to the federal courts the power to “declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.” 28 U.S.C. § 2201(a). In short, the Declaratory Judgment Act serves as a vehicle to afford relief where “there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

However, “the operation of the Declaratory Judgment Act is procedural only,” *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 238 (1937), and “it is well established that the Declaratory Judgment Act does not, of itself, confer jurisdiction upon federal courts,” *Stuart Weitzman, LLC v. Microcomputer Res., Inc.*, 542 F.3d 859, 861–62 (11th Cir. 2008). As a result, a plaintiff who seeks relief under the Declaratory Judgment Act must invoke the court’s subject matter jurisdiction by demonstrating that, “absent the availability of declaratory relief, the instant case could nonetheless have been brought in federal court.” *Id.* at 862. Because the role of plaintiff and defendant are essentially reversed in a declaratory judgment action, the plaintiff will satisfy this requirement (and therefore invoke the court’s jurisdiction) by alleging sufficient factual material in its complaint indicating that the *defendant* could have brought a coercive action

against the plaintiff to vindicate its rights, and that this action would lie within the court's original jurisdiction. *Id.*

Indeed, the entire purpose of the Declaratory Judgment Act is to provide a means for the plaintiff to precipitate a lawsuit which would otherwise wait until a cause of action accrued to the defendant. *Gulf States Paper Corp. v. Ingram*, 811 F.2d 1464, 1467 (11th Cir. 1987), *abrogated on other grounds by King v. St. Vincent's Hosp.*, 502 U.S. 215 (1991). For example, an insurer might file a lawsuit against its insured seeking a declaration that it has no duty to indemnify the insured under the parties' insurance contract. *See, e.g., First Mercury Ins. v. Excellent Computing Distribs., Inc.*, 648 F. App'x 861, 862 (11th Cir. 2016) (per curiam). Had the insurer not sued for declaratory relief, it would have been forced to breach the insurance contract and wait for the insured to sue to settle its rights and obligations. Or a business that uses potentially copyrighted material might file a lawsuit against the owner of the copyright seeking a declaration that it did not infringe the copyright by using the material. *See, e.g., LaJoie v. Pavcon, Inc.*, 146 F. Supp. 2d 1240, 1242–45 (M.D. Fla. 2000). Had the business not sued for declaratory relief, it would have needed to wait for the copyright owner to sue to settle its rights and obligations. In other words, "the declaratory judgment device allows a party 'to bootstrap its way into federal court' by bringing a federal suit that corresponds to one the opposing party might have brought." *Gulf States Paper*, 811 F.2d at 1467 (quoting *Superior Oil Co. v. Pioneer Corp.*, 706 F.2d 603, 607 (5th Cir. 1983)).

Here, Hill alleges no facts which would lead the Court to conclude that either Anthem or Blue Cross could have instituted a federal lawsuit against Hill concerning the conduct at issue in the Amended Complaints. It bears emphasizing that Hill does not

assert claims against Anthem and Blue Cross for the violation of any statutory or regulatory provision. And while Hill contends in its responses to Defendants' motions to dismiss that it can maintain an implied cause of action under the Social Security Act and Medicare Part D, Hill has not alleged any such implied cause of action in its pleadings.

Rather, Hill seeks a declaration pursuant to the Declaratory Judgment Act that Anthem and Blue Cross violated section 1860D-4(b) of the Social Security Act, 42 U.S.C. § 1395w-104(b), and 42 C.F.R. § 423.120 regulating Medicare Part D. In pertinent part, these provisions require Medicare Part D plan sponsors like Anthem and Blue Cross to base their decisions on whether to include a drug in their formularies “on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as [they] determine[] to be appropriate.” 42 U.S.C. § 1395w-104(b)(3)(B)(i); *accord* 42 C.F.R. § 423.120(b)(1)(v). Hill takes the position that Anthem and Blue Cross failed to adequately consider the strength of the scientific evidence when they denied Hill's requests to include Tolak in their formularies.

However, the Court is unable to discern in these provisions any corresponding coercive lawsuit Anthem or Blue Cross could bring in federal court to vindicate their rights against Hill. Neither 42 U.S.C. § 1395w-104 nor 42 C.F.R. § 423.120 provide a cause of action—express or implied—which would allow a Medicare Part D plan sponsor like Anthem or Blue Cross to sue a pharmaceutical manufacturer like Hill for damages or injunctive relief relating to the manufacturer's request that a product be included in the plan sponsor's formularies. Because no corresponding coercive action exists in these

cases, the Court lacks subject matter jurisdiction over Hill's declaratory judgment claims. The Court will consequently dismiss Count II of the Amended Complaints.

B. Hill Fails to State Claims for Unlawful Restraint of Trade

In Count V of each Amended Complaint, Hill asserts claims for unlawful restraint of trade in violation of the Sherman Antitrust Act, 15 U.S.C. § 1, and the Florida Antitrust Act, Fla. Stat. § 542.18. Anthem and Blue Cross move to dismiss these counts for failing to state claims for relief; Defendants contend that Hill does not allege a prohibited agreement.

To state a claim for unlawful restraint of trade,³ the plaintiff must allege "an agreement between two or more persons to restrain trade." *Levine v. Cent. Fla. Med. Affiliates, Inc.*, 72 F.3d 1538, 1545 (11th Cir. 1996). The plaintiff cannot rely on the bald assertion that the defendant agreed with other parties to restrain trade, but must identify the members to the agreement. *See Lombard's, Inc. v. Prince Mfg., Inc.*, 753 F.2d 974, 975 (11th Cir. 1985). Likewise, "[i]ndependent action is not proscribed," and no claim will lie where the plaintiff alleges that it is only the defendant who is restraining trade. *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984); *see also Am. Needle, Inc. v. Nat'l Football League*, 560 U.S. 183, 190 (2010) ("Section 1 [of the Sherman Antitrust Act] applies only to concerted action that restrains trade.").

Hill ultimately fails to allege the requisite agreement. While Hill offers the conclusory allegation that Anthem and Blue Cross entered into vertical conspiracies with

³ Because the Florida Legislature has indicated that courts should interpret the Florida Antitrust Act in the same manner as the Sherman Antitrust Act, *see MYD Marine Distrib., Inc. v. Int'l Paint Ltd.*, 76 So. 3d 42, 46 (Fla. Dist. Ct. App. 2011), the Court applies the same analysis to Hill's federal and state antitrust claims.

other parties and that these conspiracies have the effect of restraining trade, Hill does not identify the parties with whom Anthem and Blue Cross purportedly conspired. Further, Hill does not allege that these unnamed parties agreed with Anthem and Blue Cross to restrain trade; the only factual content Hill provides is that Anthem and Blue Cross required these parties to pay rebates in order for their medications to be included in Anthem's and Blue Cross's formularies. The most the Court can reasonably infer from these allegations is that Anthem and Blue Cross acted on their own in an effort to restrain trade. Since unilateral conduct is not enough to form an agreement, Hill fails to state claims for unlawful restraint of trade. The Court will therefore dismiss Count V of the Amended Complaints.

C. The Court Declines to Exercise Supplemental Jurisdiction Over Hill's State Law Claims Against Blue Cross

Title 28 U.S.C. § 1367 permits a district court to decline to exercise supplemental jurisdiction over pendent state law claims where the court "has dismissed all claims over which it has original jurisdiction." 28 U.S.C. § 1367(c)(3). Having dismissed Hill's claims under the Declaratory Judgment Act and the Sherman Antitrust Act, the Court no longer has original jurisdiction over Hill's lawsuit against Blue Cross.⁴ The Court declines to exercise supplemental jurisdiction over Hill's state law claims against Blue Cross and will therefore dismiss the remainder of Hill's Amended Complaint against Blue Cross.

⁴ The Court notes that Hill and Blue Cross are both Florida corporations and that, for this reason, they are not diverse.

D. Hill Fails to State a Claim Against Anthem for Tortious Interference With a Business Relationship

In Count III of its Amended Complaint against Anthem, Hill alleges that Anthem tortiously interfered with its business relationships with its customers by refusing to cover Tolak. Anthem moves to dismiss this count for failing to state a claim for relief.⁵ Specifically, Anthem submits that Hill does not allege a protected business relationship.

To state a claim under Florida law for tortious interference with a business relationship, the plaintiff must establish four elements: (1) the existence of a business relationship between the plaintiff and a third party, (2) the defendant's knowledge of the relationship, (3) the defendant's intentional and unjustified interference with the relationship, and (4) damages resulting from the defendant's interference. *Ethan Allen, Inc. v. Georgetown Manor, Inc.*, 647 So. 2d 812, 814 (Fla. 1994). As to the first element, "[a] protected business relationship need not be evidenced by an enforceable contract." *Id.* However, the business relationship must at least afford existing or prospective legal rights to the parties and embody "an actual and identifiable understanding" that the parties will do business together. *Id.* at 815. Accordingly, although a business's relationship with a past customer is not a protected relationship, an ongoing relationship with a current customer or a potential relationship with a future customer may be protected. See *id.* at 815 & n.1; *Magre v. Charles*, 729 So. 2d 440, 444 (Fla. Dist. Ct. App. 1999). Moreover, it is well-settled that a business's relationship with the general consuming public is not protected; instead the asserted relationship must be with an identifiable customer. *N.*

⁵ Anthem also moves to dismiss this count, along with all of Hill's state law claims, as preempted by federal law. Upon review of the controlling law, the Court finds that Hill's state law claims are not preempted by the federal statutes Anthem cites.

Am. Van Lines, Inc. v. Ferguson Transp., Inc., 639 So. 2d 32, 33 (Fla. Dist. Ct. App. 1994), *aff'd*, 687 So. 2d 821 (Fla. 1996).

Hill pleads no facts indicating the existence of a protected business relationship. While Hill alleges that it “sells, and has sold, TOLAK to consumers in this State and throughout the United States” and that Anthem has interfered with these consumers’ abilities to purchase Tolak, Hill fails to identify any current or prospective consumer with whom Hill has “an actual and identifiable understanding” regarding the sale and purchase of Tolak. In other words, Hill alleges nothing more than a relationship with the consuming public at-large. Since this relationship is insufficient to state a claim for tortious interference, the Court will dismiss Count III.

E. Hill Fails to State a Claim Against Anthem for Deceptive and Unfair Trade Practices

In Count IV of Hill’s Amended Complaint against Anthem, Hill asserts that Anthem violated the Florida Deceptive and Unfair Trade Practices Act (“FDUTPA”), Fla. Stat. §§ 501.201–.213, when it denied Hill’s request to include Tolak in its formularies. Anthem moves to dismiss this count for failing to state a claim for relief, as Hill does not allege a cognizable deceptive act or unfair practice.

“FDUTPA affords civil private causes of action for both declaratory and injunctive relief and for damages.” *Rollins, Inc. v. Butland*, 951 So. 2d 860, 869 (Fla. Dist. Ct. App. 2006). Regardless of the type of relief sought, the plaintiff must allege facts showing that the defendant committed a deceptive act or engaged in an unfair practice in order to state a claim. See *id.* A deceptive act is one which “is likely to mislead the consumer acting reasonably in the circumstances, to the consumer’s detriment.” *PNR, Inc. v. Beacon Prop. Mgmt., Inc.*, 842 So. 2d 773, 777 (Fla. 2003) (citation and internal quotation marks

omitted). And an unfair practice is one which causes substantial injury to a consumer which the consumer could not have reasonably avoided and which is not outweighed by countervailing benefits to the consumer or to competition. *Porsche Cars N. Am., Inc., v. Diamond*, 140 So. 3d 1090, 1096 (Fla. Dist. Ct. App. 2014), *review denied*, 157 So. 3d 1042 (Fla. 2014). Importantly, an act is not deceptive and a practice is not unfair unless a consumer was actually aggrieved by the act or practice. *Shibata v. Lim*, 133 F. Supp. 2d 1311, 1317 (M.D. Fla. 2000).

Here, Hill's theory is that Anthem deceived consumers—including pharmacists and physicians who prescribe Tolak—and acted unfairly by denying Hill's request to include Tolak in its formularies. Hill reasons that Anthem's denial implies to consumers that Tolak is either not effective at treating actinic keratosis, too dangerous, or too expensive, thus deceiving consumers as to the truth and subjecting them to less effective, more dangerous, and more expensive alternatives. However, by its own allegations, Hill fails to show that a consumer has actually been aggrieved by Anthem's conduct. The most Hill alleges is that Anthem's decision not to cover Tolak "*may lead physicians, pharmacists, and residents of the State of Florida to believe TOLAK lacks scientific evidence to prove its demonstrated safety benefits over other . . . medications.*" (emphasis added). Without a consumer who was actually aggrieved by Anthem's alleged misconduct, Hill fails to establish a deceptive act or unfair practice. The Court will therefore dismiss Count IV.

F. Hill is Not Entitled to Injunctive Relief

Finally, in Count I of Hill's Amended Complaint against Anthem, Hill seeks an injunction compelling Anthem to add Tolak to its formularies. Since Hill fails to state a

claim which would entitle it to such relief, the Court will dismiss this count as well. For the same reason, the Court will deny Hill's motion for a preliminary injunction against Anthem.

IV. CONCLUSION

For the aforementioned reasons, it is **ORDERED AND ADJUDGED** as follows:

1. Defendant Anthem, Inc.'s Motion to Dismiss Plaintiff's Amended Complaint (Case No. 6:16-cv-833-Orl-40TBS, Doc. 36) is **GRANTED**. Plaintiff's Amended Complaint against Defendant Anthem, Inc. is **DISMISSED**.
2. Plaintiff's Amended Motion for a Preliminary Injunction Against Defendant Anthem, Inc. (Case No. 6:16-cv-833-Orl-40TBS, Doc. 26) is **DENIED**.
3. Plaintiff's Omnibus Motion to Strike Defendant Anthem, Inc.'s Declarations and Enter a Preliminary Injunction or, in the Alternative, Renewed Request for an Evidentiary Hearing (Case No. 6:16-cv-833-Orl-40TBS, Doc. 82) is **DENIED AS MOOT**.
4. Defendant Blue Cross and Blue Shield of Florida, Inc.'s Motion to Dismiss (Case No. 6:16-cv-1282-Orl-40TBS, Doc. 14) is **GRANTED**. Plaintiff's Amended Complaint against Defendant Blue Cross and Blue Shield of Florida, Inc. is **DISMISSED**.
5. Plaintiff may assert its state law claims against Defendant Blue Cross and Blue Shield of Florida, Inc. in the proper state court within the time provided by 28 U.S.C. § 1367(d).
6. Plaintiff's Motion for a Preliminary Injunction Against Defendant Blue Cross and Blue Shield of Florida, Inc. (Case No. 6:16-cv-1282-Orl-40TBS, Doc. 10) is **DENIED AS MOOT**.

7. Plaintiff's Amended Motion for a Preliminary Injunction Against Defendant Blue Cross and Blue Shield of Florida, Inc. (Case No. 6:16-cv-833-Orl-40TBS, Doc. 107) is **DENIED AS MOOT**.
8. In *Hill Dermaceuticals, Inc. v. Anthem Inc.*, Case No. 6:16-cv-833-Orl-40TBS, the Clerk is **DIRECTED** to enter the Judgment of the Court that the case is dismissed.
9. In *Hill Dermaceuticals, Inc. v. Blue Cross Blue Shield of Florida, Inc.*, 6:16-cv-1282-Orl-40TBS, the Clerk is **DIRECTED** to enter the Judgment of the Court that the case is dismissed.
10. The Court retains jurisdiction to resolve any pending motions for sanctions.

DONE AND ORDERED in Orlando, Florida on January 18, 2017.


PAUL G. BYRON
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel of Record