

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.

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**ORDER**

This case comes before the Court without oral argument on the following matters:

- 1) Plaintiff Hill Dermaceuticals, Inc.'s Renewed Motion to Compel Documents Responsive to Plaintiff's July 27, 2016 and August 5, 2016 Requests For Production, Motion To Compel Documents Responsive To Plaintiff's August 19, 2016 Request For Production, and Request For Attorneys' Fees (Doc. 112), and Anthem, Inc.'s Response in opposition (Doc. 128);
- 2) Defendant Anthem's Motion for Protective Order (Doc. 123) and Hill's Response in opposition (Doc. 133); and
- 3). Anthem's Motion to Strike Plaintiff's Supplemental Filings (Docs. 57, 77, 81, 82, 84, And 108) For Violation Of Local Rules 3.01(A) and 3.01(C) (Doc. 117) and Hill's Response in Opposition (Doc. 132).

*Background*

As set forth in the pleadings and prior filings, actinic keratosis ("AK") is a precancerous skin condition that affects an estimated fifty-eight million people in the United States (Doc. 25, ¶ 14). Hill developed, manufactures and distributes Tolak®

(fluoracil) 4% Cream (“Tolak”) to treat AK (Id., ¶¶ 1, 14). It contends that Tolak is safer, as effective, and has a lower wholesale acquisition cost than the other existing brand name and generic AK drugs (Id., ¶¶ 16-19).

Anthem provides coverage to Medicare Part D participants (Id., ¶ 8). Hill asked Anthem to add Tolak to Anthem’s Medicare Part D formularies (Id., ¶ 22). Anthem denied the request, citing “insufficient evidence” to show the advantages of Tolak over the other AK drugs already included in its formularies (Id., ¶ 23). Hill alleges that it gave Anthem “overwhelming scientific evidence,” and that Anthem improperly rejected Tolak because it receives significant rebates from other drug manufacturers (Id., ¶ 45). Hill, which does not provide rebates on Tolak, alleges that Anthem’s decision not to include Tolak in its Medicare Part D formularies subjects “Medicare patients to drugs that cause more severe adverse effects, and are unnecessarily expensive to Medicare Part D participants and the federal government.” (Id., ¶ 27).

Anthem counters that the Medicare Prescription Drug Improvement and Modernization Act, which established the Part D benefit, contemplates the negotiation of prices between plan sponsors and pharmaceutical companies on behalf of Medicare beneficiaries (Doc. 110 at 5). Anthem also claims that “[r]ebates and discounts which are ‘properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity’ are protected under the discount exception and safe harbor provisions of the federal anti-kickback statute.” (Id.) (quoting 42 U.S.C. § 1320a-7b(b)(3)(A)). According to Anthem, before a drug can be included in its formularies, it must first be reviewed by the Clinical Review Committee (“CRC”) (Doc. 110 at 22). Anthem claims that the CRC is an independent committee charged with reviewing “drugs for efficacy, safety, effectiveness, and clinical aspects in comparison to similar drugs

within a therapeutic class or used to treat a particular condition.” (Id.). Anthem asserts that the CRC “may NOT include or consider the following: Rebates or potential rebates; Costs to the health plan, member or risk bearing entity; Economic outcomes; and/or Benefit types.” (Id. at 22-23). Anthem maintains that the Medicare Part D regulations require that clinical decisions be based “on the strength of scientific evidence and standards of practice, including assessing peer-reviewed outcomes research data, and other such information as it determines appropriate.” (Id. at 23) (quoting 42 C.F.R. § 423.120(b)(1)(v)).

Anthem explains that the insufficient evidence designation given to Tolak is used “when based upon the data available at the time of the review, the drug has an unclear treatment profile for the majority of individuals taking the product as compared to other available products within the therapeutic class of drugs or other available treatment options.” (Doc. 110 at 23, ¶ 9). Anthem maintains that when the CRC reviewed Tolak “there were no published scientific literature studies available relating to the risks/benefits of Tolak.” (Id. at 23). Anthem says its decision was “[b]ased upon the lack of published scientific literature available on Tolak.” (Id. at 24).

Hill’s amended complaint seeks a preliminary and permanent injunction compelling Anthem to withdraw or suspend its refusal to include Tolak in its Medicare Part D formularies (Doc. 25 at 15). Hill also prays for a declaratory judgment that Anthem’s decision not to list Tolak in its Medicare Part D formularies violates Federal regulations and Section 1860D-4(b) of the Social Security Act (Id., ¶ 36). Hill complains that Anthem has tortuously interfered with its customers (Id., ¶ 39), and that Anthem’s actions violate the Florida Deceptive and Unfair Trade Practices Act (Id., ¶ 42). Lastly, Hill alleges that

Anthem's actions constitute an unlawful restraint on trade in violation of 15 U.S.C. § 1 and FLA. STAT. § 542.18 (*Id.*, ¶¶ 47-61).

*The Discovery Motions*

The parties have wrestled with the appropriate scope of discovery in this case. The instant motions reflect concerns about production or disclosure of allegedly confidential materials, information concerning other drugs, and information regarding rebates, fees, discounts or other financial details. After these motions were filed,<sup>1</sup> the Court held a hearing (Docs. 124, 139) and issued several pertinent Orders (Docs. 125, 126, 127, 131 and 136) which address many of the same or similar matters raised in these motions.<sup>2</sup> And, as Anthem notes, it has already agreed to produce some of the documents and the Court assumes that has occurred. Thus, it is not clear which discovery requests, if any, remain legitimately at issue. As it is likely that subsequent events have rendered much of the discovery disputes moot, Hill's motion to compel (Doc. 112) and Anthem's motion for protective order (Doc. 123) are **DENIED, without prejudice** to renewal, if necessary, as to any *specific* matter that is still in dispute, despite a good faith conference under Local Rule 3.01(g).

*The Motion to Strike*

Anthem moves to strike multiple supplemental filings (Docs. 57, 77, 81, 82, 84, and 108) filed by Hill without leave of Court. Hill objects. Although motions to strike "are

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<sup>1</sup> Hill's motion was filed November 4, 2016 (Doc. 112) and Anthem's motion was filed November 15, 2016 (Doc. 123).

<sup>2</sup> The instant motions were not ripe at the time of the hearing, so they were not directly discussed. Nonetheless, Hill propounded similar discovery requests to Blue Cross Blue Shield of Florida, Inc., also Defendant in this consolidated case. The appropriate scope of discovery with respect to those requests was discussed at length at hearing, and an Order was subsequently entered (Doc. 136). To the extent Hill, through counsel, clarified the scope of its discovery requests as to Florida Blue, the Court assumes a similar stance with respect to Anthem. *See* Doc. 136 at 7. As no pertinent defenses unique to Anthem have been raised, it is safe to assume that conclusions similar to those set forth in that Order apply, as well.

generally disfavored by the Court and are often considered “time wasters,” Luxtottica Grp. S.P.A. v. Cash Am. E., Inc., No. 6:16CV728ORL31DAB, 2016 WL 4157211, at \*1 (M.D. Fla. Aug. 2, 2016), Anthem’s motion is well taken.

Local Rule 3.01(a) provides that in a motion or any other application for an order, a party shall file a single document containing a statement of the basis for the request and memorandum of legal authority. M.D. FLA. R. 3.01(a). Local Rule 3.01(b) requires that any response opposing a motion shall be filed in a single document. M.D. FLA. R. 3.01(b). Local Rule 3.01(c) provides that “[n]o party shall file any reply or further memorandum directed to the motion or response allowed in (a) and (b) unless the Court grants leave.” M.D. FLA. R. 3.01(c). These rules apply “as a basis to strike documents filed by [a party] that are frivolous, not filed in support of any motion, immaterial to any pleading or motion currently pending, or that fail to advance any aspect of litigation in [a] case ....” Farrell v. Florida Republicans, No. 2:13-CV-140-FTM-29, 2013 WL 5498277, at \*8 (M.D. Fla. Oct. 1, 2013).

a) Notice of Filing Declarations In Support of its Motion for Sanctions (Doc.57)

Hill filed its Declarations as a separate document, in violation of Local Rule 3.01(a). Although Hill contends that it made the decision to file the declarations separately “so [they] could be easily referenced in future filings” (Doc. 132 at 2), attaching the Declarations to the motion as an exhibit accomplishes the same thing and does not violate the rule. Now, docket entry 57 is **STRICKEN**.

b) Plaintiff’s Renewed Motion for Evidentiary Hearing (Doc. 77)

As noted by Anthem, the Renewed Motion for Evidentiary Hearing is effectively supplemental briefing on a motion already filed and constitutes multiple filings seeking the same relief. The Court is not persuaded by Hill’s response that the renewed motion

pertains to an amended motion for preliminary injunction and, as such, was not duplicative. The Court had already addressed the issue of an evidentiary hearing on the amended motion. See Doc. 50 at 1 (“As discussed at the status conference, the Court will notify the parties by separate order should the Court require the benefit of oral argument on Plaintiff’s Amended Motion for Preliminary Injunction.”). Accordingly, docket entry 77 is **STRICKEN**.

c) Plaintiff’s Notice of Filing Articles (Doc.81)

The Notice of Filing Articles was filed as an unauthorized supplement to an already-filed response brief in violation of L.R.3.01 (b) and filed without leave of Court in violation of L. R. 3.01(c). Hill argues that “[t]his is a moot issue in light of the Court’s entry of a Protective Order on November 18, 2016. (Doc. 127).” While this filing may not be pertinent to any existing matter, in the interest of preserving the integrity of the docket, docket entry 81 is **STRICKEN**.

d) Plaintiff’s Motion to Strike Declarations and Enter a Preliminary Injunction, or, in the Alternative, Renewed Request for an Evidentiary Hearing (Doc. 82).

Anthem argues, correctly, that this filing seeks some of the same relief and includes the same arguments made in prior motions. Thus, Anthem seeks to strike the portions of the motion seeking a preliminary injunction and evidentiary hearing. Hill responds:

The purpose of Doc. 82, as the title suggests, was to request the Court strike Anthem’s declarations filed in support of Anthem’s opposition to Hill’s Amended Motion for a Preliminary Injunction (Doc. 53) and 8 of the 12 pages in the Motion are dedicated to that purpose. Further, the “Renewed Request for Evidentiary Hearing” was an alternative request should this Court deny Hill’s request to strike Anthem’s declarations, not a stand-alone motion. Because the primary purpose of this Motion was directed at striking Anthem’s

declarations (Doc. 53), striking the entire filing is not warranted.

(Doc. 132 at 5). Hill's argument does not address the merits of Anthem's position that the portions of the motion seeking a preliminary injunction and evidentiary hearing are duplicative of earlier motions. The portions of the filing related to seeking a preliminary injunction and evidentiary hearing are **STRICKEN**.

e) Plaintiff's Notice of Filing of Amended Declarations In Support of Motion for Sanctions (Doc. 84)

Anthem argues that this is an unauthorized supplement to Hill's already-filed Notice of Filing of Declarations In Support of Motion for Sanctions (Doc. 57). Hill counters that it filed this Amended Declaration to include new information from its declarant, Gerardo Mendez. By definition, every amended paper includes something "new." The difficulty with Hill's position is that Hill did not seek leave to introduce the new information. Absent such leave, the supplemented filing is unauthorized. Now, docket entry 84 is **STRICKEN**.

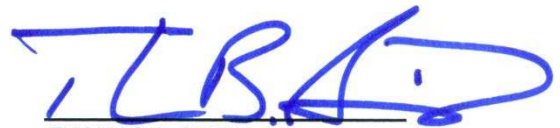
f) Plaintiff's Supplement to Amended Motion for Preliminary Injunction and Incorporated Memorandum of Law (Doc. 108)

Hill asserts that it filed this "supplemental authority to support the argument detailed extensively in its Amended Motion for Preliminary Injunction (Doc. 26)." It argues that a notice of filing supplemental authority does not fall within the purview of Local Rule 3.01(c), citing Williams v. Heritage Operating, L.P., 8:07CV977 T24MSS, 2007 WL 2302131, at \*1 (M.D. Fla. Aug. 8, 2007). The Court is not persuaded. Williams involved a notice of a recent *case* in support of arguments already raised. Id. The supplement at issue here is a seven page brief with attached *evidence*. It is not a "mere" notice of recent

case authority. Williams. As it was filed without permission, docket entry 108 is **STRICKEN**.

The Court recognizes that some of the objections here are technical and Hill is correct in its position that defects in form are not equal to defects in substance. But, there comes a point where failure to adhere to the rules renders the docket unmanageable. The Court acts now, to prevent that from occurring. To the extent Hill wishes the Court to consider any of the matters in the stricken documents, it must comply with the local rules (including Local Rule 3.01(g)) and file an appropriate motion setting forth sufficient grounds supporting each proposed filing.

**DONE and ORDERED** in Orlando, Florida on December 8, 2016.



THOMAS B. SMITH  
United States Magistrate Judge

Copies furnished to Counsel of Record