IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 17-663-VAC-SRF
	)	
TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC.,	)	**UNDER SEAL**
	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 25th day of **April, 2018**, the court having considered the parties' letter submissions regarding plaintiff Allergan, Inc.'s ("Allergan") request for documents relating to the generic 5% dapsone formulation of defendants Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc. (together, "Taro") in the above-captioned matter (D.I. 69; D.I. 70), IT IS HEREBY ORDERED THAT Allergan's narrowed request for documents[1] is GRANTED for the reasons set forth below.

1. **Background.** Allergan brought this civil action for patent infringement under the Hatch-Waxman Act on June 1, 2017, alleging a cause of action for infringement of United States Patent No. 9,517,219 ("the '219 patent"), which is entitled "Topical Dapsone and Dapsone/Adapalene Compositions and Methods for Use Thereof." (D.I. 1 at ¶ 18) The '219 patent encompasses the approved use of Allergan's Aczone® Gel, 7.5%, which contains dapsone

[1] The parameters of Allergan's narrowed request are set forth in its April 18, 2018 letter at footnote 6, which identifies the specific portions of Taro's 5% ANDA sought by Allergan. (D.I. 69 at 2 n.6) Allergan also includes "laboratory notebooks relating to the development of Taro's 5% product" in its narrowed request for documents. (D.I. 69 at 2)

as its active pharmaceutical ingredient ("API") and was approved for marketing by the Food and Drug Administration ("FDA") in Allergan's New Drug Application ("NDA") No. 207154. (*Id.* at ¶¶ 17, 19)

2. Taro submitted Abbreviated New Drug Application ("ANDA") No. 210191 to the FDA, seeking approval to market a generic version of Allergan's 7.5% Aczone® Gel prior to the expiration of the '219 patent. (D.I. 1 at ¶ 20) Allergan represents that Taro's generic 7.5% product contains the same API at the same concentrations, and uses a multi-component polymeric viscosity builder ("PVB"). (D.I. 69 at 1) According to Allergan, the court must ultimately determine whether Taro's inclusion of Carbopol 980 as an ingredient in the PVB of its 7.5% ANDA product is equivalent to the inclusion of acrylamide/sodium acryloyldimethyl taurate copolymer ("A/SA") in the PVB composition claimed in the '219 patent. (D.I. 70 at 1)

3. Taro previously developed a generic version of Allergan's earlier 5% dapsone formulation, which used Carbopol 980 as the exclusive PVB. (D.I. 69, Ex. A) By way of its motion to compel, Allergan seeks the production of portions of Taro's 5% ANDA, as well as laboratory notebooks relating to the development of Taro's 5% ANDA product. (D.I. 69 at 2 n.6) Allergan asserts that information relating to Taro's use of Carbopol 980 in products other than the 7.5% ANDA product is relevant to Allergan's claim of infringement pursuant to the doctrine of equivalents.

4. **Legal standard.** Pursuant to Rule 26,

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1). A party may move for an order compelling discovery pursuant to Rule 37. Generally, a party moving to compel discovery bears the burden of demonstrating the relevance of the requested information. *See Del. Display Grp. LLC v. Lenovo Grp. Ltd.*, C.A. Nos. 13-2108-RGA, 13-2109-RGA, 13-2122-RGA, 2016 WL 720977, at *2 (D. Del. Feb. 23, 2016) (citing *Inventio AG v. ThyssenKrupp Elevator Am. Corp.*, 662 F. Supp. 2d 375, 381 (D. Del. 2009)). However, "[t]he parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes." Fed. R. Civ. P. 26 advisory committee's note to 2015 amendment.

5. Analysis. Allergan's request for production of portions of Taro's 5% ANDA and associated laboratory notebooks is granted. The requested discovery is relevant to the litigation because Taro's 5% product and its 7.5% product have the same API and nearly identical inactive ingredients. In similar circumstances, discovery regarding a related ANDA product has been deemed relevant by the court:

> [T]he more similar or related that a product is to the ANDA product (particularly if the ingredients are used as viscosity-increasing agents), the more relevant the requested information about that product becomes to [the plaintiff's] infringement claims. Similarly, to the extent that document requests can be limited to certain narrow categories of [the defendant's] products, the burden on [the defendant] to search for responsive documents is reduced.

Medicis Pharm. Corp. v. Actavis Mid Atl. LLC, 282 F.R.D. 395, 398 (D. Del. 2012) (ordering production of documents that "relate to or discuss the substitution or interchangeability of the ingredients as viscosity-increasing agents (i.e., the manner in which the ingredients are utilized in the ANDA product).").

6. Taro alleges that Allergan does not need Taro's development documents regarding the 5% product because Allergan's 5% product is identical to Taro's generic version,

and information is available from other sources regarding the state of the prior art at the time of the invention. However, Taro's 5% ANDA and corresponding laboratory notebooks are undisputedly not available to Allergan from any other source.

7. Moreover, the requested documents are likely to reveal Taro's observations regarding the state of the prior art, the results of product testing, reports on problems, and the consideration of alternative ingredients that led Taro to ultimately select the inactive ingredients in its 5% ANDA product. Due to the similarities in the overall composition of Taro's 5% product and its 7.5% formulation, information regarding Taro's 5% product could reasonably shed light on its choice of PVB in its 7.5% product. *See* Fed. R. Civ. P. 26 ("Information within this scope of discovery need not be admissible in evidence to be discoverable."); *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) (observing that federal courts broadly construe the relevance standard under Rule 26).

8. Taro further contends that differences between a single-component and multi-component PVB are irrelevant to Allergan's ultimate infringement claim under the doctrine of equivalents. According to Taro, problems regarding the use of Carbopol 980 as the sole PVB arose only in conjunction with the increased concentration of dapsone, and were not discussed in connection with the development of its 5% ANDA product. Allergan should be permitted to test Taro's assertions by reviewing the documents produced in response to its narrowly-tailored request.

9. The documents requested by Allergan are relevant to questions of invalidity as well as infringement. As indicated by Allergan, discovery regarding the properties of Taro's 5% product formulation may shed light on why Taro "reverse engineered" Aczone® 7.5% to develop its own multi-component PVB used in the generic 7.5% product. (D.I. 69 at 2)

Allergan anticipates that the requested discovery will refute Taro's claims that there were no objective indicia of non-obviousness by "provid[ing] an objective baseline for comparing the two Taro products" and "show[ing] whether . . . Taro's 7.5% product benefits from unexpected comparative advantages associated with the use of a multi-component PVB, including smaller particle size, improved product appearance, less grittiness, and better stability." (*Id.* at 4) Courts have held that, even where discovery regarding unaccused predecessor products is not sufficiently relevant to the infringement inquiry, the production of the discovery may be warranted as it relates to invalidity contentions. *See CooperVision, Inc. v. CIBA Vision Corp.*, 2007 WL 2264848, at *3 (E.D. Tex. Aug. 6, 2007) (concluding that discovery relating to the predecessor product was relevant to the defendant's invalidity argument).

10. Taro's offer to produce documents relating to its 7.5% ANDA product that also refer to its 5% ANDA product does not adequately satisfy Allergan's request. Allergan has explained that this offer would likely exclude documents revealing problems observed in the development of Taro's 5% product. According to Allergan, Taro's 7.5% ANDA does not address why Taro selected a different PVB for its 7.5% product than the PVB used in its 5% product. Taro's discussion of product testing, identification of problems associated with the product, and consideration of alternative PVB formulations relating specifically to the 5% generic product are broadly relevant to the issue of how Taro selected its PVB in connection with its 7.5% ANDA product.

11. The court further concludes that Allergan's narrowed request, limited specifically to Taro's 5% ANDA and corresponding laboratory notebooks, is not unduly burdensome to Taro. *See Medicis*, 282 F.R.D. at 398 ("[T]o the extent that document requests can be limited to

certain narrow categories of [the defendant's] products, the burden on [the defendant] to search for responsive documents is reduced.").

12. Conclusion. In view of the foregoing analysis, Allergan's narrowed request for production of portions of Taro's 5% ANDA and corresponding laboratory notebooks is granted. Taro shall produce the requested discovery in accordance with this Memorandum Order on or before **May 7, 2018.**

13. Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Order under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Order should be redacted, the parties should jointly submit a proposed redacted version by no later than **May 7, 2018**. The court will subsequently issue a publicly available version of its Memorandum Order.

14. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to ten (10) pages each.

15. The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, www.ded.uscourts.gov.

Sherry R. Fallon
United States Magistrate Judge