IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL CORPORATION, and DOW PHARMACEUTICAL SCIENCES, INC.,	)	
Plaintiffs,	)	
v.	)	Civ. Action No. 11-409-LPS-CJB
ACTAVIS MID ATLANTIC LLC,	)	
Defendant.	)	

ORDER

At Wilmington, Delaware this **30th day of April, 2012**,

IT IS ORDERED as follows:

A. Background and Procedural History

1. On April 16, 2012, Plaintiffs Medicis Pharmaceutical Corporation and Dow Pharmaceutical Sciences, Inc. ("Medicis") moved for an order compelling Defendant Actavis Mid Atlantic LLC ("Actavis") to provide all documents referring or relating to products that include hydroxyethyl cellulose ("HEC"), xanthum gum, and/or a polyacrylic acid polymer (collectively, "the ingredients"), and to supplement its responses to Medicis' Interrogatory Nos. 6 and 7. (D.I. 76 at 3) On April 17, 2012, Actavis responded to Medicis' motion, asserting that the minimal relevance of the requested documents was well outweighed by the significant burden that Actavis would face in producing them. (D.I. 79)

2. On April 18, 2012, the Court held a teleconference to discuss Medicis' motion, as well as another pending discovery dispute. (D.I. 93) At the end of the teleconference, the Court

ordered Medicis to produce the underlying document requests and interrogatories (and Actavis' responses thereto) that were related to Medicis' motion. The Court reserved decision on the motion, in order to provide the parties with additional time to attempt to resolve the dispute. (*Id.* at 44–45) Medicis produced the relevant documentation on April 19, 2012. (D.I. 83)

3. In accordance with the Court's directives, the parties continued to meet and confer in an attempt to reach agreement as to Medicis' requests. On April 26, 2012, the parties informed the Court that these efforts proved unsuccessful. Medicis' motion is therefore ripe for resolution.

B. Legal Standard

4. The Federal Rules of Civil Procedure generally allow for parties to "obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). However, a court must also "limit the . . . extent of discovery otherwise allowed by these rules" if it finds that "the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(2)(C).

C. Medicis' Document Requests

5. In this litigation, Medicis alleges, *inter alia*, that Actavis' generic Clindamycin Phosphate/Tretinoin topical gel product ("the ANDA product") infringes U.S. Patent No. 6,387,383 ("the patent-in-suit") under the doctrine of equivalents. (D.I. 76 at 1, 3) According to Medicis, this claim will require the Court to resolve whether Actavis' inclusion of xanthum gum or HEC as an ingredient in the ANDA product is equivalent to the inclusion of a polyacrylic acid polymer (or carbomer) in the composition claimed in the patent-in-suit. (*Id.*) Medicis asserts that information relating to Actavis' use of the ingredients in products other than the ANDA

product is relevant to Medicis' claim of infringement under the doctrine of equivalents. (*Id.*)

6. Actavis represents that it has 1,400 products currently on the market or under development, which include, *inter alia*, tablets, analgesic liquids, gels, and ointments. (D.I. 79 at 1–2; D.I. 93 at 34–36) It asserts that a significant number of these products contain xanthum gum, HEC, and polyacrylic acid polymers. (*Id.*) Actavis argues that records regarding any one of such products—"from toothpaste to suppositories"—could fall within the scope of Medicis' discovery requests, whether or not that product related in any way to the ANDA product. (D.I. 79 at 2) It is not possible to accurately estimate the number of products that Medicis' request, as currently formulated, would encompass, because Actavis has "no single database that has all of the formulations of all [Actavis] products." (D.I. 93 at 38)

7. Medicis claims that it is improper for Actavis to withhold discovery of products containing xanthum gum, HEC, and/or carbomers because "evidence that [Actavis] has substituted or interchanged these ingredients in its other products would demonstrate that they are equivalent in its proposed generic product." (D.I. 76 at 3) As an initial matter, Medicis cites no evidence that any such substitution has ever occurred, in either the ANDA product or in any other Actavis product.

8. But even assuming that such substitution has occurred, the Court is not persuaded that the theoretical interchangeability of xanthum gum and HEC for carbomers in products such as cough syrup or cosmetics would be of significant relevance to the question of whether those ingredients are interchangeable in a topical gel for the treatment of skin conditions, like the ANDA product. Whether Medicis' claims in this case are couched in terms of literal or equivalent infringement, the Court's inquiry as to the appropriateness of discovery must be

focused on the specific ANDA product at issue. *See, e.g.*, *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) ("Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of a drug, an ANDA specification . . . *will control the infringement inquiry*.") (emphasis added); *cf. Novartis Pharms. Corp. v. Eon Labs Mfg., Inc.*, 206 F.R.D. 392, 394 (D. Del. 2002) (denying plaintiff's request for documents relating to defendant's "consideration of possible alternatives in a business context" to the allegedly infringing products at issue in a patent litigation matter, because such documents related to products other than those at issue in the litigation). In this case, the doctrine of equivalents analysis is not an abstract biochemical examination of the similarities and differences among the ingredients. Instead, that analysis must be grounded in the particular context of the patent-in-suit and the ANDA product. Medicis' requests are not focused on the ANDA product or similar products, but instead seek a company-wide survey into products that are unrelated to even the field of use of the ANDA product. Moreover, Medicis' requests fail to reflect that although the ingredients have many uses, in the context of the products-at-issue they are used as "viscosity-increasing agents." (D.I. 79, ex. 2 at Actavis 0000192)

9. As the foregoing discussion illustrates, Medicis' current requests are substantially overbroad. The requests would implicate any documents referring or relating to the "development, formulation and design" of any product that happens to contain one of the ingredients—regardless of whether the document had anything do with the ingredients or their interchangeability as viscosity-increasing agents. During the Court's teleconference with the parties, even Medicis' counsel appeared to acknowledge the overbreadth of such requests. (D.I. 93 at 30–31)

10. Even if the requests were focused solely on documents relating to the ingredients or their interchangeability, the relevance of such documents would be circumscribed for the reasons set forth above. Moreover, such requests would, at a minimum, likely require Actavis to search through every document in its possession relating to products containing one or more of the ingredients. The burden and expense associated with such an open-ended search cannot be justified in light of the limited relevance of such documents to Medicis' infringement claims.

11. With that said, the 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 Medicis' infringement claims.[1] Similarly, to the extent that document requests can be limited to certain narrow categories of Actavis' products, the burden on Actavis to search for responsive documents is reduced. Thus, the Court finds that Medicis' requests must be limited to: (1) documents relating to topical gels that (like the ANDA product) are used to treat skin conditions; and (2) only insofar as those documents 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). The Court's Order below takes these conclusions into account.

D. Medicis' Interrogatories

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[1] *Cf. Pennwalt Corp. v. Plough, Inc.*, 85 F.R.D. 257, 261-63 (D. Del. 1979) (permitting discovery, in case involving allegations of false advertising regarding certain athlete's foot medications, of (1) results of test comparisons between plaintiff's product-at-issue, Desenex, and products other than those at issue in lawsuit, because such documents also had relevance to the efficacy of plaintiff's testing results comparing Desenex with defendant's product-at-issue; and (2) test results in which the active ingredients found in Desenex were applied independently of other Desenex ingredients, so long as the results related to the treatment of athlete's foot).

12. In addition to documents relating to products that include at least one of the ingredients, Medicis also requests that Actavis be compelled to supplement its responses to Interrogatory Nos. 6 and 7 to "include information pertaining to its other products." (D.I. 76 at 3) Those interrogatories request identification of documents that relate to the ANDA product, clindamycin phosphate and tretinoin gels, and/or the Ziana® product. Medicis now appears to ask the Court to redraft these interrogatories to request that Actavis "identify all documents and communications, whether written or oral" that relate to any product that may use the ingredients. For the reasons discussed above, such redrafting would create interrogatories of unduly broad and impermissible scope. *See, e.g.*, *Willemijn Houdstermaatschaapij BV v. Apollo Computer Inc.*, 707 F. Supp. 1429, 1441 (D. Del. 1989) (refusing to compel responses to interrogatories that sought information that did not "pertain to th[at] litigation"). The Court therefore declines to rewrite these interrogatories as Medicis requests or to order Actavis to supplement its responses to those interrogatories beyond what is required below.

E. Conclusion

13. For the foregoing reasons, absent further Order of the Court or agreement of the parties, by no later than **June 1, 2012**, Actavis shall produce: (i) any documents that refer or relate to the substitution of HEC, xanthum gum, and/or a polyacrylic acid polymer for each other as a viscosity-increasing agent in the ANDA product, or in any of Actavis' other topical gel products used to treat skin conditions; and (ii) any documents that refer or relate to the interchangeability of HEC, xanthum gum, and/or a polyacrylic acid polymer as a viscosity-increasing agent in the ANDA product, or in any of Actavis' other topical gel products used to treat skin conditions.

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE