IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FORT LAUDERDALE DIVISION

APOTEX, INC. and APOTEX CORP.,

Plaintiffs,

v.

CIVIL CASE NO. 0:12-cv-60704-PAS
(Consolidated)

MYLAN PHARMACEUTICALS, INC., et al.

Defendants.
_____/

DEFENDANT MYLAN PHARMACEUTICALS INC.'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL DISCOVERY OF MYLAN'S QUINAPRIL ANDA PRODUCTS

Defendant, Mylan Pharmaceuticals Inc. ("Mylan"), by and through its undersigned counsel, hereby submits its response in opposition to Plaintiffs, Apotex, Inc.'s and Apotex Corp.'s (collectively "Apotex"), Motion to Compel Discovery of Mylan's Quinapril ANDA Products (the "Motion") [D.E. 88]. Submitted herewith in support of this motion are: (1) Mylan's Supplemental Responses to Apotex's Interrogatories ("Supp. Interrogs."), attached as Exhibit A; and (2) the Declaration of Brenda Dodd ("Dodd Dec."), attached as Exhibit B.

Apotex seeks discovery concerning products that are not the subject of this action and that Apotex itself omitted from the Amended Complaint in response to the Court's Order granting Mylan's Motion to Dismiss [D.E. 35]. Further, as set forth below, the discovery requested is irrelevant to the instant action, and the burden imposed on Mylan in producing this discovery would be immense. Accordingly, Apotex's Motion should be denied.

I. PROCEDURAL AND FACTUAL BACKGROUND

There are three Mylan-related ANDAs that are relevant to the instant dispute. Mylan has only marketed products under two of these ANDAs.

A. Mylan's Combination Product

ANDA No. 077-093 relates to tablets containing two active ingredients, quinapril hydrochloride and hydrochlorothiazide (the "Combination Product"). The Combination Product is available in three tablet strengths of quinapril/hydrochlorothiazide for oral administration: 10 mg/12.5 mg, 20 mg/22.5 mg and 20 mg/25 mg. Mylan initially submitted ANDA No. 077-093 to the Food and Drug Administration ("FDA") on March 17, 2004. The FDA approved ANDA No. 077-093 on March 28, 2005. Mylan launched the Combination Product covered by ANDA No. 077-093 on February 28, 2007 and continues to sell this product to this day. The Combination Product and ANDA No. 077-093 are the subject of Count I of both Apotex's original and Amended Complaints. (D.E. 1 ¶¶ 19-20; D.E. 39 ¶¶ 75-79.) Mylan has produced, and continues to produce, documents relating to this product and its ANDA. Thus, these documents are not subject to Plaintiffs' Motion to Compel.

B. The Genpharm ANDA

Genpharm ULC's ("Genpharm") ANDA No. 076-036 (the "Genpharm ANDA"), relating to quinapril tablets, was approved by the FDA on January 28, 2005. Genpharm transferred ownership of the Genpharm ANDA to Mylan in September 2009. Neither Genpharm nor Mylan ever marketed, sold, or offered for sale, a product covered by the Genpharm ANDA.

C. Mylan's Quinapril Only Product

On March 25, 2003, Mylan submitted ANDA No. 076-694 to the FDA, which was approved on December 23, 2004. ANDA No. 076-694 is directed to quinapril tablets containing 5 mg, 10 mg, 20 mg, and 40 mg of quinapril hydrochloride for oral administration ("Quinapril Only Product"). Presently, Mylan does not manufacture, market or sell the Quinapril Only Product.

D. Procedural History

The Genpharm ANDA was the subject of Count II of Apotex's original Complaint, which alleged that the Genpharm ANDA infringed Apotex's U.S. Patent No. 6,531,486 (the "'486 Patent"). (D.E. 1 ¶¶ 21-22.) In Count II, Apotex only alleged that "Apotex believes that Mylan is likely practicing processes covered by claims 1-12 and 16-19 of the '486 patent." (D.E. 1 ¶ 18.) Moreover, Apotex admitted that it was "presently not aware of any analytical technique which can be used to definitively establish that Mylan's Quinapril Product was made by use of one or more processes claimed in the '486 Patent," yet, it sought to employ the judicial process to aid in obtaining discovery to substantiate its beliefs. (*Id.* ¶¶ 18, 22.) Particularly as to Count II, Apotex failed to conduct any pre-suit investigation or allege any plausible facts that the Genpharm ANDA was infringing the '486 Patent. Accordingly, on July 2, 2012, Mylan moved to dismiss Count II for failure to state a claim because of the paucity of factual allegations relating to the alleged infringement. (D.E. 22.)

On September 6, 2012, during the Planning and Scheduling Conference, Judge Patricia A. Seitz, in ruling from the bench,[1] granted Mylan's Motion to Dismiss Plaintiffs' initial Complaint, which was later memorialized by written order. (D.E. 35; D.E. 36 4:22-25.) The Court made it clear that Count II had particular problems, stating in pertinent part:

> [W]hat I am concerned about is what I find the Complaint, especially as to Count 2 against Mylan, it doesn't reach the plausible statement of action if there is no allegations of even an attempt to test the product. But I also recognize the problems that the plaintiff has in providing greater specificity.

(D.E. 36 at 5:9-14.) The parties informed the Court that there was not one definitive process to make quinapril products. In light of that information, the Court stated:

[1] On the next day, the Court also entered a minute order memorializing the granting of Mylan's Motion to Dismiss during the hearing. (D.E. 34.)

> I got that point and I am satisfied that there is not one process. And so that's why I believe that the motion to dismiss is appropriate here, that there needs to be greater definition as to what are the facts that suggest that there is in fact a plausible claim for infringement.

(*Id.* at 35:20-24.) Counsel then had the following exchange with the Court:

> MR. MASAR: Your Honor, the issue with Mylan is that their refusal to provide even under attorney's eyes only information about the actual steps they take.
>
> THE COURT: But you need to know your process, you need to know your patent, and you need to look at your test results and come up with factual allegations that show that here is the unique process that you have and that based on your pre-test that the only way that they could end up with this result is if they used your process and facts that would show that that is the process that they used. It doesn't have to be an evidentiary brief, but there needs to be something more than what I have in this Complaint. And as to Count 2, and you have done no pre-test, you've got a problem there.
>
> MR. MASAR: That product is unavailable.
>
> MR. MUKERJEE: Your Honor, with respect to Count 2, could I just actually let you know about something? As I informed counsel for Apotex before this hearing, Mylan never marketed that product, Mylan never sold that product, Mylan doesn't even have any stock of that quin[a]pril-only product. And so I even informed them of that today, and I requested that before we knew what Your Honor's ruling was going to be I asked that they voluntary withdraw at least that count. So Count 2 is just --
>
> THE COURT: I think they got my message today, and you may see in the amended Complaint that one won't be in the Complaint.
>
> * * *
>
> I think they understand what I want from them, and I think we'll see different conduct going forward. But then I expect from you similar understanding that you have responsibilities as an officer of the court so that we can achieve the goals of Rule 1 [sic]. These cases are very expensive for your respective clients; maybe not much for the plaintiffs here since they are looking at this as a cash cow to help offset – I'm sorry. I don't mean to be so blunt. I'll be softer.

(*Id.* at 36:6-37:3.)

Following the hearing and the Court's Order dismissing the Complaint, on September 20, 2012, Apotex filed an Amended Complaint against Mylan, eliminating Count II from this action and reasserting a single Count alleging infringement based upon the Combination Product. (*See generally* D.E. 38.) As such, the Amended Complaint contains no assertion that any product relating to the Genpharm ANDA infringes or infringed the '486 patent. Moreover, Apotex never asserted a count of infringement in either the initial Complaint or the Amended Complaint directed to the Quinapril Only Product.

II. MEMORANDUM OF LAW

A. Apotex is seeking Discovery on Claims Dismissed by the Court

Plaintiffs' Motion amounts to an attempted end-run around this Court's prior ruling. As noted above, Count II of Apotex's original Complaint, which asserted infringement against the Genpharm ANDA, was dismissed and omitted from the Amended Complaint by Apotex. Nevertheless, Plaintiffs have relentlessly sought discovery on the unaccused ANDAs and products, treating them as if they are at issue in this case.

Apotex cites to *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340 (1978), *inter alia*, for the proposition that that Rule 26 discovery is broad and "not limited to the issues raised by the pleadings." (D.E. 88-1 at 5 (quoting *Oppenheimer*, 437 U.S. at 352).) While the scope of discovery is broad, that breadth is not without limits. *Oppenheimer* continues on to state that:

> Discovery of matter not "reasonably calculated to lead to the discovery of admissible evidence" is not within the scope of Rule 26(b)(1). Thus, *it is proper to deny discovery of matter that is relevant only to claims or defenses that have been stricken*, or to events that occurred before an applicable limitations period, unless the information sought is otherwise relevant to issues in the case.

Oppenheimer, 437 U.S. at 351 (internal footnotes omitted) (emphasis added).

Moreover, the Federal Rules of Civil Procedure were amended in 2000, with specific changes to Rule 26. Presently, Rule 26(b)(1) reads, in part: "Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense…"[2] Fed. R. Civ. P. 26(b)(1). "For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action." *Id.* Thus, the threshold contours of Rule 26 limit discovery to a party's claim or defense, *unless* the Court orders otherwise. Even then, the Advisory Committee notes to the 2000 Amendments to Rule 26(b)(1) are clear:

> The Committee intends that the parties and the court focus on the actual claims and defenses involved in the action.
>
> * * *
>
> The rule change signals to the court that it has the authority to confine discovery to the claims and defenses asserted in the pleadings, and signals to the parties that they have *no entitlement to discovery to develop new claims* or defenses *that are not already identified in the pleadings*.

Fed. R. Civ. P. 26 advisory committee's notes to 2000 Amendment (emphasis added). Apotex's avoidance of the current rule is telling.

Equally telling is Apotex's avoidance of the relevant portion of *Oppenheimer* and other decisions denying discovery relating to claims—like Count II—that have been stricken. *See U.S. v. 416.81 Acres of Land*, 514 F.2d 627, 632 (7th Cir. 1975) (upholding a court's striking of interrogatories where "most of the questions related to the various defenses and objections which had been stricken" from the case); *Bourget v. Gov't Employees Ins. Co.*, 313 F. Supp. 367, 372-73 (D. Conn. 1970) (defendants' motion for production was denied because it was based on two

[2] It may, at first, appear that, by promulgating the 2000 Amendments to Rule 26(1), the Supreme Court abrogated its ruling in *Oppenheimer*, as cited by Apotex. But that is not the case when one looks further in that opinion. The Supreme Court also stated that "[a] bare allegation of wrongdoing…is not a fair reason for requiring a defendant to undertake financial burdens and risks to further a plaintiff's case." *Oppenheimer*, 437 U.S. at 363.

defenses which had been stricken) *rev'd on other grounds* 456 F.2d 292 (2d Cir. 1972); *see also Lewis v. ACB Bus. Servs., Inc.*, 135 F.3d 389, 402 (6th Cir. 1998) (affirming denial of discovery regarding claims that were dismissed); *In re Merck & Co., Inc.*, No. 2:05–cv–02367–SRC–CLW, 2012 WL 4764589, at *7 (D.N.J. Oct. 5, 2012) (denying a motion to compel discovery of documents pertaining to issue that was dismissed and no longer before the court); *Breslin v. Dickinson Township*, No. 1:09-CV-1396, 2011 WL 3359638, at *2 (M.D. Pa. Aug. 3, 2011) (denying plaintiffs' motion to compel discovery "on proposed claims, issues and persons, which are not currently part of a lawsuit, solely on the basis of a speculative assertion that these claims and parties may someday become part of the pending litigation"). The scenarios found in the foregoing cases are directly analogous to what has happened in this action with respect to Count II; it was stricken and the discovery that would have been the subject matter thereof should now be denied.

B. Federal Circuit Precedent Prohibits Apotex's Tactics

Further, Apotex's true motivation for filing its Motion has nothing to do with obtaining meaningful discovery in furtherance of the issues in this case. Rather, as Apotex freely admits, it is hoping that discovery into these ANDAs and related materials will provide a sufficient basis to reassert a claim for infringement against Mylan's Quinapril Only Product. Apotex expressly states that "Apotex…now turns to discovery to establish infringement."[3] (D.E. 88-1 at 10-11 & n.4.) The Federal Circuit, however, has soundly rejected Plaintiffs' approach.[4]

[3] This is a familiar refrain. In its complaints, Apotex consistently admits that it "resorts to…the aid of discovery to determine…and confirm its *belief* that [Mylan] infringes one or more Claims of the '486 Patent." (*See, e.g.*, D.E. 38 ¶ 66 (emphasis added).)

[4] "Federal Circuit law applies when deciding whether particular written or other materials are discoverable in a patent case, because they relate to an issue of substantive law." *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 803 (Fed. Cir. 2000).

> The discovery rules are designed to assist a party to prove a claim it reasonably believes to be viable *without discovery*, not to find out if it has any basis for a claim. That the discovery might uncover evidence showing that a plaintiff has a legitimate claim does not justify the discovery request.

Micro Motion, Inc. v. Kane Steel Co., Inc., 894 F.2d 1318, 1327 (Fed. Cir. 1990) (internal citations omitted) (emphasis in original).

Accordingly, the Federal Circuit has expressly stated that a party like Apotex cannot be allowed to conduct discovery on unaccused products for the purposes of "find[ing] out if it has any basis for a claim." *See id.* The claim premised on the Genpharm ANDA was expressly dismissed from this lawsuit and not reasserted by Apotex. Further, the Quinapril Only Product is not the subject of the single count of infringement presently at issue in this case. Apotex should not be permitted to use the discovery process to place an undue burden on Mylan and attempt to find additional claims, when it presently has no basis for asserting them. On this basis alone, the Court should properly deny the instant Motion.

C. The Discovery Sought is Irrelevant

The discovery that Apotex demands also is not relevant to the sole count asserted in the Amended Complaint, which is directed to Mylan's Combination Product. Apotex has repeatedly stated that it suspects that the Quinapril Only Product infringes. But, as stated above, mere suspicion that an unaccused product infringes does not mean that discovery is relevant. As the Federal Circuit stated:

> Clearly discovery is allowed to flesh out a pattern of facts already known to a party relating to an issue necessarily in the case. At the other extreme, *requested information is not relevant* to "subject matter involved" in the pending action *if the inquiry is based on the party's mere suspicion or speculation*.

Micro Motion, 894 F.2d at 1326 (emphasis added). Moreover, discovery of unaccused products is only found to be "relevant" under Rule 26 when a plaintiff "articulate[s], in a focused

particularized manner, the characteristics or components that the unaccused products must have in order to suggest that they may infringe the patents-in-suit…" *Invensas Corp. v. Renesas Electronics Corp.*, No. 11-448-GMS-CJB, 2012 WL 6042605, at *6 (D. Del. Nov. 12, 2012). Here, Plaintiffs have simply identified the unaccused products by ANDA number. (D.E. 88-1 at 11) (stating that "Apotex has specifically identified [the unaccused products] by ANDA number.") That is not the type of specificity the courts require in the very cases cited by Plaintiffs.[5] And Plaintiffs' further arguments in support of the purported relevance of the requested discovery are equally flawed.

i. The Demanded Discovery is Not Relevant to Rebutting Mylan's Obviousness Defense

Apotex argues that the Genpharm ANDA and the Quinapril Only Product are relevant to rebut Mylan's defense that the '486 patent is obvious in light of the prior art. (D.E. 88-1 at 6-7, 9.) Apotex is wrong. At the outset, Mylan's obviousness arguments do not relate to, or depend upon, its Quinapril Only Product or related ANDAs. Rather, the obviousness arguments presented in this case are based on known prior art which pre-date the patent-in-suit.

Nonetheless, Apotex alleges that discovery into the unaccused ANDAs is necessary to support its "failure of others" argument in response to Mylan's obviousness defense. (D.E. 88-1 at 8-9.) Specifically, Plaintiffs argue that, because Mylan never marketed a product under the Genpharm ANDA, it must be evidence of Mylan's failure. This argument, however, is legally incorrect and is based on nothing more than Apotex's rank speculation.

[5] Rather, unlike *Invensas* and *Honeywell Intern. Inc. v. Audiovox Commc'ns Corp.*, No. Civ.A. 04-1337-KAJ, 2005 WL 3988905 (D. Del. Oct. 7, 2005), here, "the preferred bases for the discovery amounts to a broader, more generalized argument as to how the unaccused products may be similar to the accused products." *Invensas*, 2012 WL 6042605, at *6. Plaintiffs' request is clearly the result of Plaintiffs' "suspicion or speculation," and, therefore, should be denied. *See Micro Motion*, 894 F.2d at 1326.

In order for Apotex to rebut obviousness using the "failure of others," it must specifically show that others failed in attempting to follow the claimed *process* contemplated by the '486 patent. Setting aside the fact that Mylan does not practice the claimed process, the mere fact that Mylan submitted the ANDAs-at-issue to the FDA demonstrates that Mylan succeeded in making its (non-infringing) product, and, therefore such ANDAs cannot provide evidence to Apotex of "failure of others."

When a pharmaceutical company files an ANDA, it is attesting to the FDA that the filer has succeeded in making a drug product that works according to the requirements listed by the FDA. *See, e.g.*, 21 C.F.R. §§ 314.2 & 314.105. Thus, Mylan's and Genpharm's ANDA filings simply cannot evidence failures because submissions of the ANDAs, themselves, demonstrate success in making the product. Further, it bears noting that the FDA approved the Mylan Quinapril Only ANDA in 2004 and the Genpharm ANDA in 2005. Mylan respectfully submits that the FDA is not in the habit of approving failures. As such, Apotex's argument rings hollow.

Finally, Apotex has received and will continue to receive discovery related to Mylan's Combination Product, which is the only accused product in this action. Thus, Apotex will receive discovery that it can attempt to use in support of a "failure of others" argument. While Mylan believes that any such arguments would be specious at best,[6] the relevant inquiry for this Motion is whether Apotex will receive discovery on the accused product, which it has and will.

ii. The Demanded Discovery Is Not Relevant To Some Theoretical Damages Calculation

Apotex separately argues that the information sought is relevant to damages because Mylan's costs of development of a non-infringing method to make the Quinapril Only Product

[6] Of course, Mylan believes that nothing regarding its Combination Product will demonstrate any failure. To the contrary, Mylan believes that this "failure of others" argument is merely an attempt to provide some possible reason to authorize an end-run around this Court's prior ruling.

would have some impact on a reasonable royalty rate if the Combination Product was found to be infringing. (D.E. 88-1 at 8-9.) This argument is tenuous at best.

Apotex's entire argument is in the realm of hypotheticals. The argument depends upon the assumption that Mylan's Quinapril Only Product was developed involving extensive work to design around the '486 patent and that such information is relevant *if* the Combination Product infringes. But this simply cannot be. Mylan submitted the ANDA relating to the Quinapril Only Product to the FDA on March 23, 2003. As Mylan has informed Apotex through a response to an interrogatory, Mylan did not learn of the existence of the '486 patent until April 29, 2004. (*See* Supp. Interrogs. at 10-11 (response to Interrogatory No. 10).) Thus, Mylan developed the Quinapril Only Product and submitted the related ANDA to the FDA over a year before it even knew of the '486 patent. As such, Apotex's supposition that Mylan engaged in extensive work on its Quinapril Only Product to design around the '486 patent simply cannot be. The Quinapril Only Product does not have any relation to a theoretical damages calculation as Apotex hypothesizes.

Further, Apotex has provided no nexus between the discovery sought and the claims of the '486 patent. Rather, here as before, Apotex provides nothing more than speculation. The Federal Circuit has expressly stated that a plaintiff like Apotex seeking discovery has a "burden to show some relationship between the invention claimed in the [patent-at-issue] and [the discovery sought]." *American Standard, Inc. v. Pfizer Inc. et al.*, 828 F.2d 734, 742 (Fed. Cir. 1987). In that case, the Federal Circuit affirmed the denial of third-party discovery of sales data of an unaccused product where no nexus between that product and the claimed invention was shown. Similarly, Apotex demonstrated no such nexus here. To the contrary, Apotex has at most speculated that there is some connection.

However, speculation is not enough. As the Federal Circuit stated, while reflecting on *American Standard* in its *Micro Motion* opinion, "discovery may be denied where, in the court's judgment, the inquiry lies in a speculative area." *Micro Motion*, 894 F.2d at 1326-27 (finding discovery that was purportedly relevant to the plaintiff's damages theories "should have been denied as not relevant"). In this action, Apotex's musings that the unaccused ANDAs would have any impact on its theoretical damages calculation, in the words of the Federal Circuit, "lie in a speculative area."

In short, this Court asked Apotex for "a clear explanation of how exactly [it] think[s] these prior ANDAs are relevant to the claims concerning the present allegations of infringement." (D.E. 81 at 48:23-25.) Apotex was unable to provide the Court with such an explanation. Accordingly, Mylan respectfully submits that this Court should follow the lead of the Federal Circuit by not giving credence to Apotex's hypothetical support for its Motion.

iii. The Combination Product and the Products Covered by the ANDAs-at-Issue Cannot be One and the Same

Plaintiffs further allege that they are entitled to the demanded discovery because the Combination Product, the Genpharm ANDA, and the Quinapril Only Product and its ANDA are, in effect, all one and the same. (D.E. 88-1 at 7, 9-11.) Nothing could be further from the truth. It is undisputed that the Quinapril Only Product and the Combination Product are separate and distinct and, thus, so are their respective ANDAs, as required by the FDA. *See* 21 C.F.R. § 314.94. After all, if they *were* one and the same, this dispute would not even be before the Court. Plaintiffs' additional argument that the products contain "similar ingredients" is equally unavailing. (D.E. 88-1 at 10.) Curiously, Apotex never identifies what those similar ingredients might be. Moreover, Apotex's argument again casually ignores that the FDA requires that these products are separate and distinct. *See* 21 C.F.R. § 314.94.

FDA regulations aside, this Court stated:

> I am not persuaded that the mere fact that it is the same drug is sufficient, and I am not inclined to have you go on a fishing expedition to try to discover products that are not in suit.
>
> * * *
>
> I have just heard, "Well, it is the same product so they probably used the same process." But I think that has been squarely rejected.

(D.E. 81 at 49:1-4, 10-12.) Mylan agrees.

D. The Discovery Sought Would Impose an Undue Burden on Mylan

Quite simply, the difference in the burden and expense involved with producing all that Plaintiffs seek, instead of only discovery relating to the accused product, is immense. Several courts have held that discovery into unaccused products will not be allowed because of the sheer burden that it would impose to the responding party. *See, e.g., Bayer Healthcare LLC v. Norbrook Labs., Ltd.*, No. 08-C-953, 2011 WL 6046602, at *2-5 (E.D. Wis. Dec. 6, 2011) (denying patentee's motion to compel production of documents relating to formulations not directly at issue in the case, rejecting the patentee's contention that these formulations were relevant to an enablement defense, and also finding that the burden of producing the discovery outweighed any benefit); *Superior Commc'ns v. Earhugger, Inc.*, 257 F.R.D. 215, 219-20 (C.D. Cal. 2009) (denying motion to compel since request was overly broad and unduly burdensome where it sought discovery on all of the accused infringer's products and limiting required production to material relating to the accused products).

In this case, Brenda Dodd, Mylan's head e-discovery paralegal, conducted two electronic searches to determine the number of emails that would need to be produced. (Dodd Dec. at ¶¶ 6-14.) The first search was designed to determine how many emails would result in seeking documents responsive to only Count I of the Amended Complaint which accuses the Combination Product. (*Id.* ¶ 6.) To do so, Mylan searched emails for the term "quinapril"

combined with the terms "magnesium" and "hydrochlorothiazide" or "HCTZ." (*Id.*) That search resulted in approximately 100,000 emails. (*Id.* ¶ 7.)

Next, Mylan searched emails for the term "quinapril" only, in an effort to determine the scope of results that would be responsive to discovery sought on the accused product *and* the unaccused products and ANDAs. (*Id.* ¶ 10.) The result was over *1,000,000* emails. (*Id.* ¶ 11.) Thus, responding to Apotex's discovery demands would result in a burden and expense on Mylan that is at least *ten-fold* compared to providing discovery only regarding the accused product. Of note, these results do not include any email attachments or other documents that have been kept in electronic *or* non-electronic form. Mylan anticipates that a full search of the attachments to the emails, alone, would yield a number of documents to be reviewed and produced that "far exceeds one million." (*Id.* ¶ 12.) Overall, this email collection "would contain at least 800 GB to 1 terabyte ("TB") of data." (*Id.* ¶ 13.) Further, Ms. Dodd's time to process electronic emails on the currently-accused product alone would take approximately five (5) business days, as opposed to approximately twenty (20) business days to do the same for all of the emails sought by the Motion. (*Id.* ¶ 16.) Moreover, the processing and storage costs for the discovery sought by Plaintiffs would increase Mylan's costs by nearly seven-fold (from an upper limit of $75,000 to $512,000). (*Id.* ¶ 19-21.)

Nonetheless, Apotex has posited that Mylan can just "breeze through" the discovery. (D.E. 81 at 41:16-22.) As described above, that is simply not the case. Mylan first will have to internally review the documents for responsiveness. Mylan's outside counsel then will be required to review the records *de novo*, at significant additional expense to Mylan, for responsiveness and privilege. Lastly, counsel would have to produce the documents, the cost of which would be borne by Mylan.

Once those documents are produced, even Apotex will experience a significant burden when its counsel has to review such a potentially massive production, including the expanded burden and costs accompanying any depositions regarding such a production, or even follow-up discovery requests by Apotex.[7] In short, the burden and expense involved in this type discovery is well recognized by the courts. *See, e.g., Chudasama v. Mazda Motor Corp.*, 123 F.3d 1353, 1367-68 (11th Cir. 1997) (enumerating the many costs involved in discovery, as well as the burden that it places on the judicial system because of the need to resolve discovery disputes); *Rodriguez-Torres v. Gov't Dev. Bank of P.R.*, 265 F.R.D. 40, 44 (D.P.R. 2010) (considering the cost of privilege and confidentiality review in addition to the cost of production in finding that the ESI requested was not reasonably accessible because of undue burden and cost). Further, the Federal Rules explicitly allow the court to "limit the…extent of discovery," regardless of accessibility, whenever "the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(2)(C)(iii). Here, the burden and expense involved with the discovery requested far outweighs any scintilla of relevance that these unaccused ANDAs or related documents may have to this litigation. Mylan respectfully submits that this burden alone should result in a denial of Apotex's Motion.

Finally, Apotex implies that production will be easier because "[w]e have a protective order here," so Mylan need not spend time on redactions. (D.E. 88-1 at 12.) Mylan and its counsel would be remiss in their duties if they were to simply provide unresponsive and irrelevant, but nonetheless highly confidential information, to a competitor like Apotex. As

[7] Apotex states that it did not re-file Count II asserting infringement "against Mylan's Solo Products in the Amended Complaint" because it did not want to "waste the client's money on a pleading." (D.E. 88-1 at 11 n.4.) Mylan finds this assertion puzzling given the potential discovery avalanche that Apotex will have to endure if it has its way, not to mention the instant motion practice and its related expense.

such, Apotex's suggestion is simply unreasonable. Moreover, to the extent that Apotex was suggesting that the protective order "obviates [Mylan's] objections to discovery," Mylan cites to the Federal Circuit: "The protective order is not a substitute for establishing relevance or need." *Micro Motion*, 894 F.2d at 1325.

III. CONCLUSION

Apotex's Motion to Compel is without merit and is nothing more than an attempt to circumvent the Court's prior ruling and obtain discovery on products not at issue in this case in the hopes of potentially supporting another infringement claim. The requested discovery also is irrelevant to the products and claims at issue in this case. And, finally, the expense and burden Mylan would have to undertake in order to satisfy Apotex's improper discovery demand would be immense. Based on the foregoing, Mylan respectfully requests that the Court deny Plaintiff's Motion to Compel and award fees and costs pursuant to Rule 37, as deemed appropriate by the Court.

Dated: February 18, 2013

Respectfully submitted,

By: /s/Eric D. Isicoff

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 18th day of February 2013 I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record or pro se parties identified on the attached service list in the manner specified either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

/s/Susan V. Warner
Susan V. Warner

SERVICE LIST
APOTEX, INC. et al. vs. MYLAN PHARMACEUTICALS, INC.
CASE NO: 0:12-cv-60704-PAS
United States District Court, Southern District of Florida

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