UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FORT LAUDERDALE DIVISION

APOTEX, INC. and APOTEX CORP., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	CIVIL CASE NO. 0:12-cv-60704-SEITZ/SIMONTON
APOTEX, INC. a Canadian Corporation and APOTEX CORP., a Delaware Corporation, Plaintiffs, v. PFIZER, INC., *et al.*, Defendant.	CIVIL CASE NO. 0:12-cv-60705-SEITZ/SIMONTON
APOTEX, INC. a Canadian Corporation and APOTEX CORP., a Delaware Corporation, Plaintiffs, v. LUPIN PHARMACEUTICALS, INC., *et al.*, Defendant.	CIVIL CASE NO. 0:12-cv-60708-SEITZ/SIMONTON

DEFENDANT MYLAN PHARMACEUTICALS INC.'S
REPLY IN SUPPORT OF ITS MOTION TO DISMISS

Defendant, Mylan Pharmaceuticals Inc. ("Mylan") submits this Reply in support of its Motion to Dismiss with prejudice the Complaint filed by Plaintiffs, Apotex, Inc. and Apotex Corp. (collectively, "Apotex") for failure to state a claim upon which relief can be granted.

PRELIMINARY STATEMENT

Unable to salvage its deficient Complaint, Apotex resorts to mischaracterizations of the law. Every case relied upon is either inapplicable or distinguishable, or both. For instance, Apotex relies heavily on *In re Bill of Lading Transmission & Processing Sys. Patent Litig*., 681 F.3d 1323 (Fed. Cir. 2012). But, there, the relevant complaint contained numerous factual allegations and 10 exhibits, all of which provided specific details as to the activities that constituted the alleged infringement. *See generally* Complaint, *In re Bill of Lading Transmissions & Processing Sys. Patent Litig.*, Case No. 1:09-md-2050 (S.D. Ohio Apr. 6, 2010) (D.I. 123). Here, Apotex offers a bare bones Complaint with only *one* alleged fact—that Apotex purportedly conducted some type of testing on a Mylan Combination Quinapril product. Yet Apotex failed to provide any of the pertinent details with respect to such testing. Apotex did not state which Mylan's Combination Quinapril product was tested, what type of testing was done, how that testing was conducted, what the results actually were, or how such testing implicates that Mylan infringes. Moreover, this so-called testing had nothing to do with Mylan's *non*-combination Quinapril product which is also accused. This singular purported fact is insufficient to state a claim.

Further, Apotex refuses to address several of Mylan's arguments with respect to the Complaint's substantive deficiencies. Apotex is simply silent as to the Complaint's omission of any fact supporting its allegation that Mylan's products infringe the asserted method claims. Apotex is also silent on the *Papst* case, which most closely resembles the Complaint at issue. And, Apotex completely sidesteps the fact that its allegations concerning Mylan's non-combination product have no support. Instead, Apotex resorts to repeating the conclusory mantra that the Complaint "clearly satisfy[ies] all standards for stating a claim." Thus, Apotex's

Response mirrors its Complaint; both are rife with legal conclusions devoid of factual support. Such conclusions are neither sufficient to state a claim, nor sufficient to oppose this Motion.

ARGUMENT

I. APOTEX'S COMPLAINT FAILS TO STATE A CLAIM OR SATISFY FORM 18 REQUIREMENTS

Apotex alleges that its Complaint states a claim and further satisfies the requirements of Rule 84, Form 18, Federal Rules of Civil Procedure. As this Court is aware, Form 18 requires an allegation of infringement, among others. Apotex argues that, in paragraphs 7 and 15-22 of its Complaint, it alleges that Mylan sells infringing tablets as well as "the testing Apotex conducted to determine infringement." (D.E. 29 at 4.) Out of these nine paragraphs, only one, paragraph 16, contains a semblance of an alleged fact. There, Apotex refers to the supposed testing of an unidentified Mylan Combination Quinapril product. But Apotex did not see fit to attach a copy of the so-called testing results to its Complaint. Nor did Apotex provide any information about the testing or what the results actually were. For this reason alone, that allegation is insufficient to carry the Complaint or satisfy even the minimal Form 18 requirements.

Moreover, as noted in Mylan's Motion to Dismiss, this so-called testing is used to make an unjustifiable leap of logic—*i.e.*, that the mere presence of quinapril magnesium in Mylan's product makes it "likely" that it was made using a claimed process. (D.E. 22 at 11; D.E. 1 ¶ 16.) As Apotex well knows, Form 18 requires an allegation that a defendant *is* infringing, not that it is *likely* to infringe. As such, this allegation is nothing more than a fishing expedition into Mylan's proprietary process. It is not a fact upon which an infringement claim can be maintained.

Lastly, Apotex makes passing reference to an e-mail to Mylan's counsel requesting that Mylan simply turn over proprietary information with respect to its manufacturing processes for quinapril products. (D.E. 29 at 9 n.8.) However, Apotex's e-mails were sent at least two months

after having filed suit. (D.E. 29, Ex. A (e-mail M. Masar to T.J. Parker, dated June 11, 2012).) The fact that Apotex is even requesting such information two months after the filing of the Complaint shows the deficiency of the Complaint itself. Such an investigation should have been completed by Apotex prior to filing suit. But it was not. And, Apotex cannot now attempt to cure that deficiency.[1]

II. APOTEX'S RELIANCE ON CASELAW IS MISPLACED

Apotex's relies on *Bill of Lading* for the conclusory assertion that its Complaint meets or even goes beyond the requirements of Form 18. (D.E. 29 at 2, 5.) In that regard, Apotex effectively argues that *Bill of Lading* dispensed with the plausibility standard enunciated by the Supreme Court. Not so. *Bill of Lading* did not dispense with the requirement of pleading "*sufficient factual allegations*." *Bill of Lading*, 681 F.3d at 1336 (emphasis added). Further, as the Federal Circuit noted, the decision in that case was driven, in part, by the fact that the complaints there had detailed factual allegations of infringement. *Id.* at 1335. That type of factual specificity is not here.

For example, one of the amended complaints in *Bill of Lading* was 33 pages long, contained 161 paragraphs, and included 10 exhibits, all of which detailed activities that constituted the alleged infringement. *See generally* Complaint, *Bill of Lading*, Case No. 1:09-md-2050 (D.I. 123). That complaint not only pled specific facts but also outlined the reasonable inferences from those facts. The court found that those allegations went "beyond what is required by Form 18." *Bill of Lading*, 681 F.3d at 1335. Here, Apotex's allegations do not even come close to *Bill of Lading*. In the entirety of the Complaint, at best, there are only *two* paragraphs

[1] Mylan has no obligation to share its proprietary manufacturing process with a direct competitor. Further, Apotex's counsel never even offered to obtain such information under any confidentiality provisions until after Mylan filed the instant motion. Even then, counsel was simply willing to discuss the "possibility" of keeping it attorney's eyes only. In addition, Mylan has serious concerns in providing any of its proprietary information to Apotex.

(out of only 22 paragraphs spanning a mere five pages) that purport to provide any support for the alleged infringement.[2] (D.E. 1 ¶¶ 16, 18.) But those two paragraphs fail to actually provide any account of Mylan's purported acts of infringement. Thus, contrary to Apotex's assertions, the Complaint is hardly comparable to the one at issue in *Bill of Lading*.

Further, cases subsequent to *Bill of Lading* have not dispensed with the requirement of pleading sufficient facts. To the contrary, courts have continued granting motions to dismiss. For example, in *Via Vadis, LLC v. Skype, Inc.*, Case No. 22-507-RGA, 2012 WL 2789733 (D. Del. July 6, 2012), the District of Delaware granted defendant's motion to dismiss because there was "sufficient ambiguity" in plaintiffs' Complaint about a third-party's role in the alleged infringement even though the complaint had other detailed allegations. Here, there are no such details.

Similarly, the District of Colorado recently invoked *Bill of Lading* and granted plaintiff's motion for leave to amend because the complaint failed Form 18 requirements as it did not "identify with any specificity Defendant's product, service or type of product or services . . . ." *Zvelo, Inc. v. Sonicwall, Inc.*, Case No. 06-cv-00445-PAB-KLM, 2012 WL 2872115, at *5 (D. Colo. July 12, 2012). Apotex's Complaint likewise provides no such specificity. Thus, *Bill of Lading* does not lead to a whole sale denial of motions to dismiss as Apotex would have this Court believe.

Nor can Apotex draw much value from its self-proclaimed "leading case" of *Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359 (Fed. Cir. 2000).[3] In *Hoffman-LaRoche*, plaintiffs

[2] As noted above, only one of those two, *i.e.*, D.E. 1 ¶ 16, alleges any fact in support of their claims.

[3] Plaintiffs' reliance on *McZeal v Sprint Nextel Corp.*, 501 F. 3d 1354 (Fed. Cir. 2007), is equally unavailing. *McZeal* is inapposite. The court in *McZeal* considered a *pro se* complaint and employed the deferential standards that apply to such pleadings. *McZeal*, 501 F.3d at 1356

dismissed their complaint as part of a settlement of a patent infringement action. Defendant then moved for the imposition of Rule 11 sanctions claiming that plaintiffs had filed a baseless suit without proper investigation. In denying sanctions, the district court ruled that plaintiffs conducted an "extensive" pre-filing investigation. *Id.* at 1364-65. The plaintiffs investigated the manufacturing processes at issue and obtained samples of the generic drug *before* filing suit. *Id.* at 1361-62. Here, there was no such pre-suit investigation.

Plaintiffs' reliance on *Cambridge Prod., Ltd v. Penn Nutrients, Inc.*, 962 F.2d 1048 (Fed. Cir. 1992), is equally misplaced. In *Cambridge*, the plaintiff performed an independent chemical analysis of the allegedly infringing product. The plaintiff went even further and commissioned additional chemical studies and gathered necessary documentation *before* filing suit. *Id* at 1050. Apotex has not come close to such pre-filing conduct.

The balance of Apotex's opposition rests on a myriad of cases that bear no relationship to this action. Apotex makes a token attempt to address *Celorio v. Google, Inc.*, No. 1:11-cv-79-SPM-GRJ, 2012 WL 2402833 (N.D. Fla. May 23, 2012). Apotex alleges that the court in *Celorio* rejected that direct infringement claims should be analyzed under the plausibility standard. (D.E. 29 at 4.) But *Celorio* did not eradicate the plausibility standard. Also, Apotex fails to apprise this Court of the facts in *Celorio*. There, the *pro se* plaintiff actually complied with Form 18 and specifically alleged that the defendant infringed the patent at issue by *particular activities, i.e.*, "by installing and using an Espresso Book Machine in its California offices, by selling and offering to sell books printed on demand, and by providing electronic books to be printed on

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("Where, as here, a party appeared *pro se* before the trial court, the reviewing court may grant the pro se litigant leeway on procedural matters, such as pleading requirements."). Here, Plaintiffs are represented by counsel and no deferential standard applies. Moreover, the *pro se* plaintiff in *McZeal* specifically identified the purportedly infringing product. *Id.* at 1355. Thus, Plaintiffs here have failed to even match the specificity that the *pro se* plaintiff in *McZeal* mustered.

Espresso Book Machine." *Celorio*, 2012 WL 2402833, at *3. Here, Apotex has not specified the minimum purportedly infringing conduct that the plaintiff in *Celorio* provided.

The *Minsurg* case cited in a string cite with *Celorio* is equally distinguishable as the complaint at issue in *Minsurg* also described "*how*" defendants allegedly infringe the patents at issue. (D.E. 29 at 4.) The remaining cases cited by Apotex are also factually distinct.[4] *None* of them stand for the proposition that a plaintiff may file suit and only allege that it believes an infringement has occurred and that it intends to rely on the discovery process to confirm those beliefs. Instead, in those cases, *actual* infringement had been pled with factual support. Here, there is no allegation of actual infringement with factual support—just an unsubstantiated belief that infringement may be discovered. That is not enough to withstand a motion to dismiss.

Finally, Apotex's utter silence with respect to *In re Papst Licensing GMBH & Co., KG Litig.*, 585 F. Supp. 2d 32 (D.D.C. 2008), is far more instructive than all of the cases it cites. As noted in Mylan's Motion to Dismiss, the facts of this case most closely resemble those in *Papst*. (D.E. 22 at 6-8.) The *Papst* court clearly articulated that, hoping for an opportunity to investigate liability is not reason to file a complaint. Apotex's disregard of *Papst* is a tacit admission that its Complaint is deficient.

[4] Plaintiffs make no attempt to distinguish the facts of *Aspex Eyewear, Inc., v. Hardy Life, LLC*, No. 09-61515-Civ., 2010 WL 2926511 (S.D. Fla. July 23, 2010). The Complaint in *Aspex Eyewear* is far more detailed than the Complaint at issue here. First, the *Aspex Eyewear* complaint actually alleges that defendant "has infringed and continues to infringe" because its accused product incorporates "an auxiliary spectacle frame having arms for securing magnetic member" that satisfies each and every element of the claims at issue. The other cases cited by plaintiffs are equally distinguishable. Plaintiffs misread *Automated Transaction* and *Gelsomino*. As in *Aspex Eyewear*, the complaints in those cases contained "sufficient factual allegations" to support the direct infringement claim. (D.E. 29 at 4.)

III. APOTEX'S COMPLAINT FAILS TO SATISFY THE SUPREME COURT'S *TWOMBLY/IQBAL* STANDARD

Apotex cites no relevant authority to support its proposition that its Complaint meets the pleading standards of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). *Cf. Twombly*, 550 U.S. at 555 (setting forth pleading standard); *Iqbal*, 556 U.S. at 678 (same). Further, Apotex does not cite a single case in which a court has found a Complaint sufficient under the *Twombly* and *Iqbal* pleading requirements where the patentee has merely alleged "likel[ihood]" of a possible infringement and resorted to the discovery process to prove infringement. This is hardly surprising, as there is no such case.

Nevertheless, Apotex asserts that *Twombly/Iqbal* "simply call[] for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." (D.E. 29 at 10.) Apotex is wrong. *Twombly* cautioned against the very pleading that Apotex provides. The Court noted that allegations simply "suggesting" liability should be rejected in light of the "potentially enormous expense of discovery." *Twombly*, 550 U.S. at 559. That is precisely what Apotex's Complaint is: suggestions of liability which Apotex itself concedes may or may not be confirmed after the "enormous expense of discovery."

Apotex also misapplies the *Twombly/Iqbal* "plausibility" standard. Under this standard, the Complaint must include "*enough facts* to state a claim to relief that is *plausible* on its face." *Twombly*, 550 U.S. at 570 (emphasis added). Apotex has provided no facts, let alone enough facts to state a claim to relief that is plausible on its face. Instead, Apotex suggests that there is no "plausible factual allegations" standard. *Twombly* is clear: facts require facial plausibility. *Twombly*, 550 U.S. at 570; *Iqbal*, 556 U.S. at 678.

Mylan is not holding Apotex to a heightened standard of pleading detailed factual allegations. Mylan is simply asking for the minimum required by the Supreme Court—"enough

facts" so that this Court can draw reasonable inferences and Mylan may be properly put on notice. Apotex has provided none.[5] Thus, Apotex's Complaint falls far short of the *Twombly/Iqbal* standard and must be dismissed.

IV. APOTEX DOES NOT ADDRESS COUNT II'S DEFICIENCY

Count II of Apotex's Complaint alleges that it has a "belief" that Mylan's non-combination quinapril product "is likely practicing" claimed processes. (D.E. 1 ¶ 18, 22.) As noted above Apotex repeatedly alludes to a purported testing of Mylan's combination product which is accused in Count I. But that "testing"—to the extent it was even done and the details of which are unknown—was purportedly performed on Mylan's combination quinapril product, not Mylan's *non*-combination product accused in Count II. Thus, for Count II, Apotex does not have a scintilla of factual support for any of its allegations—not even the so-called testing. Yet Apotex never makes this distinction to the Court. As Count II is utterly without any arguable or factual support it should be dismissed.[6]

V. APOTEX'S ARGUMENTS AND EXHIBITS WHICH ARE OUTSIDE THE FOUR CORNERS OF THE COMPLAINT SHOULD BE DISREGARDED

Recognizing its failings, Apotex attempts to rescue its Complaint by submitting numerous exhibits and materials which were not part of the original filing. For example, Apotex's Response contained exhibits and emails that were not within the four corners of the Complaint. (D.E. 29-1; D.E. 29-2; D.E. 29-3.) Apotex's submission of these materials was improper.

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[5] Apotex also alleges that Mylan is requiring it to adhere to a heightened standard wherein Apotex must plead every fact with respect to how Mylan purportedly infringes the asserted method claims. (D.E. 29 at 3-5.) That is not true. Mylan is not asking that Apotex's Complaint be akin to infringement contentions. But, Mylan submits that some plausible factual support for the allegations made with respect to the method claims must be pled. And Apotex's Complaint is bereft of any such support.

[6] Apotex's Response failed to even address Mylan's arguments with respect to Count II's deficiencies.

In considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), "[t]he scope of the review must be limited to the four corners of the complaint." *St. George v. Pinellas County.*, 285 F.3d 1334, 1337 (11th Cir. 2002); *see also Bruhl v. Pricewaterhousecoopers Int'l*, No. 03-23044-Civ-MARRA, 2007 WL 997362, at *4 (S.D. Fla. Mar. 27, 2007). Thus, the exhibits and additional allegations sprinkled throughout Apotex's response, as well as any arguments stemming from them, must be disregarded. *Masacz v. Corr. Med. Servs., Inc.*, No. 09-80350-Civ, 2009 WL 3232008, at *2 (S.D. Fla. Oct. 2, 2009) (striking attachments to a motion-to-dismiss response and "ignor[ing] arguments based upon deposition testimony that is beyond the allegations of the complaint"); *Moore v. Miami-Dade County*, 502 F. Supp. 2d 1224, 1229 n.1 (S.D. Fla. 2007) ("declin[ing] to address" "additional allegations Plaintiff included in his Response"); *Brown v. J.P. Turner & Co.*, No. 1:09-CV-2649-JEC, 2011 WL 1882522, at *5 (N.D. Ga. May 17, 2011) ("[s]uch an allegation, made for first the [sic] time in response to a motion to dismiss, is plainly inappropriate." (citing *Milburn v. United States*, 734 F.2d 762, 765 (11th Cir. 1984)); *see also Mapp v. Ga. Dep't of Corr.*, No. 6:10-cv-90, 2011 WL 2462094, at *3 (S.D. Ga. June 20, 2011) ("[T]he Court will not allow Plaintiff to make an additional claim for relief in response to a dispositive motion.") *Fin. Sec. Assurance, Inc. v. Stephens, Inc.*, 500 F.3d 1276, 1284-85 (11th Cir. 2007); *Fed. Ins. Co. v. Bonded Lightning Protection Sys., Inc.*, No. 07-80767-CIV, 2008 WL 5111260, at *2-4 (S.D. Fla. Dec. 3, 2008) (excluding materials filed with an opposition to a motion to dismiss and information from those materials). Mylan respectfully requests that the Court disregard the newly submitted materials during its consideration of the instant Motion.

VI. CONCLUSION

For the foregoing reasons, and as set forth in Mylan's Motion to Dismiss, Counts I and II of the Complaint should be dismissed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 30th day of July, 2012 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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