UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

APOTEX, INC., *et al.*,

Plaintiffs,

vs. Case No. 12-60704–CIV–SEITZ/SIMONTON

MYLAN PHARMACEUTICALS, INC.,

Defendant.
_____/

APOTEX, INC., *et al.*,

Plaintiffs,

vs. Case No. 12-60705–CIV–SEITZ/SIMONTON

PFIZER, INC., et al.,

Defendants.
_____/

APOTEX, INC., *et al.*,

Plaintiffs,

vs. Case No. 12-60708–CIV–SEITZ/SIMONTON

LUPIN PHARMACEUTICALS, INC., et al.,

Defendants.
_____/

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT, MYLAN PHARMACEUTICAL, INC.'S' MOTION TO DISMISS PLAINTIFFS' COMPLAINT PURSUANT TO FED. R. CIV. P. 12(B)(6)

Plaintiffs, Apotex, Inc. and Apotex Corp. (collectively, "Apotex"), submit this memorandum in opposition to Defendant's, Mylan Pharmaceuticals, Inc. ("Mylan"), Motion to Dismiss Plaintiffs' Complaint With Prejudice (D.E. 22 [1]).

[1] All citations to docket entries refer to Case No. 12-60704-CIV.

I. INTRODUCTION

What should a patentee with a process patent do when it suspects another company is secretly infringing that patent? The Federal Circuit answered that question in 2000 in what has become the leading case on the issue. *Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1364 (Fed. Cir. 2000). The patentee can conduct a reasonable investigation based on publicly available information, and if the results are consistent with infringement, he can utilize the judicial system to obtain the details of the secret infringement by filing a complaint for patent infringement. *See id.* The Federal Circuit later clarified that even after *Twombly* and *Iqbal*, the proper standard for pleading direct infringement are set forth in Fed. R. Civ. P. 84, Form 18. *In re Bill of Lading Transmission and Processing Sys. Patent Lit.*, 681 F.3d 1323, 1334 (Fed. Cir. 2012). Apotex meets those requirements: (1) Apotex conducted a pre-filing investigation including actual testing of a Mylan product that suggested infringement; and (2) Apotex pled direct infringement, including specific factual allegations mirroring those approved by the Court in *Hoffman-LaRoche*, and clearly met all of the elements of Form 18.

Not only has Apotex met the pleading requirements in its complaint, Apotex has requested that Mylan provide additional information on its secret process so that Apotex can definitively determine infringement as efficiently as possible. More reasonable defendants, like Pfizer, have accepted such a proposal. *See* D.E. 25. Instead, Mylan filed a baseless motion to dismiss that misstates the law, does not give effect to Apotex's well pled factual allegations, and fails to even cite *Hoffman-LaRoche* or *Bill of Lading*/Form 18, even thought the latter pair define the standard that controls the determination.

Because Apotex's Complaint has factual allegations that clearly satisfy all standards for stating a claim, Mylan's motion should be denied.

II. APOTEX'S COMPLAINT PROPERLY STATES A CLAIM OF DIRECT PATENT INFRINGEMENT UPON WHICH RELIEF CAN BE GRANTED

Rule 8(a) of the Federal Rules of Civil Procedure "requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief' in order to give the defendant fair notice of what the plaintiff's claim is ... and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting Fed. R. Civ. P. 8(a)(2)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). In other words, the Complaint should "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* When considering a motion to dismiss for failure to state a claim, the court must "accept[] the allegations in the complaint as true and construe[] them in the light most favorable to the plaintiff." *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1288 (11th Cir. 2010) (internal quotation marks omitted).[2]

A complaint for patent infringement under 35 U.S.C. §271(a) only needs to meet the requirements of Fed. R. Civ. P. 84, Form 18. *Bill of Lading*, 681 F.3d 1323, 1334 (Fed. Cir. 2012). The Complaint in this case includes every allegation required in Form 18:

(1)	jurisdiction	see *Compl.* at ¶ 7-8 (alleging jurisdiction)
(2)	patent ownership	see *Compl.* at ¶ 10 (alleging Apotex Inc. owns the '486 patent); *id.* at ¶¶ 5, 12 (alleging Apotex Corp. is exclusive licensee and exclusive distributor in U.S.)

[2] In deciding a motion to dismiss in a patent case, the law of the regional circuit (here, the Eleventh circuit), and not the Federal Circuit, applies. *See, e.g., In re Bill of Lading Transmission and Processing System Patent Litigation*, 683 F.3d 1323, 1331 (Fed. Cir. 2012).

(3)	infringement	see *Compl.* at ¶¶ 7, 15-22 (alleging Mylan sells infringing tablets, identifying the brand names of those tablets and the ANDA's under which they were approved, as well as the testing Apotex conducted to determine infringement)
(4)	notice	inapplicable because only process claims asserted[3]
(5)	demand for relief	see *Compl.* at p.6.

Accordingly, Apotex's Complaint meets Form 18, and therefore states a claim on which relief can be granted. *Bill of Lading*, 681 F.3d at 1334; *see also Celorio v. Google Inc.*, No. 1:11-cv-79-SPM-GRJ, 2012 WL 2402833, *2-3 (N. D. Fla. May 23, 2012) (rejecting arguments identical to Mylan's that direct infringement claims should be analyzed under plausibility standard in *Iqbal*); *Minsurg Int'l Inc. v. Frontier Devices, Inc.*, No. 8:10-cv-1589-T-33EAJ, 2011 WL 1326863, *2 (M. D. Fla. Apr. 6, 2011) (finding Form 18 sufficient).

Because Apotex's complaint properly states a claim of direct infringement, Mylan's motion should be denied. *Id.*; *see also Aspex Eyewear, Inc., v. Hardy Life, LLC*, No. 09-61515-Civ., 2010 WL 2926511 (S.D. Fla. July 23, 2010) (denying 12(b)(6) motion reasoning "while the complaint is somewhat light on factual allegations, it meets the minimal 'short and plain statement' requirement"); *Automated Transaction Corp. v. Bill Me Later, Inc.*, No. 09-61903-CIV, 2010 WL 1882264 (S. D. Fla. May 11, 2010) (denying motion to dismiss stating "what is required in an infringement complaint is "notice of what the alleged infringer must defend.'" *quoting McZeal*, 501 F.3d at 1357); *Gelsomino v. Horizon Unlimited, Inc.*, No. 07-80697-CIV, 2008 WL 4194842, *3 (S.D. Fla. 2008) (denying 12(c) motion because complaint had required

[3] *See Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1316 (Fed. Cir. 2009) ("Infringement of method claims do not require notice.").

allegations of patent ownership; names of the individual defendants, the infringed patent, the means by which the defendants infringed, and the specific sections of patent law invoked); *cf. Doe v. Epstein*, 611 F. Supp. 2d 1339, 1343-44 (S. D. Fla. 2009) (denying motion because "*Twombly* did not alter the standard for dismissal under Rule 12(b)(6) in the typical case", *quoting CBT Flint*, 529 F. Supp. 2d. at 1379).[4]

In fact, Apotex's Complaint goes beyond the requirements of Form 18, and recites that Apotex conducted a test of Mylan's product, and that the results of that test indicate that Mylan's secret process is likely covered by the asserted claims of the '486 patent. *Compl.* at ¶¶ 7, 15-22. This is sufficient to state a claim. *Bill of Lading*, 681 F.3d at 1334; *see also McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1358 (Fed. Cir. 2007) (holding meeting Form 18's predecessor[5] is sufficient, and denying Rule 12(b)(6) motion under similar facts, while stating "the specifics of how [Defendant's] purportedly infringing device works is something to be determined through discovery.") *Cf. Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1364 (Fed. Cir. 2000) (stating that it is sufficient to rely on pre-filing testing even where further discovery is necessary to prove infringement, in Rule 11 context); *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1350 (Fed. Cir. 2009) (not a pleadings case, but holding "[a]n infringer does not escape liability merely by infringing in secret.").

[4] Other District Court cases in this Circuit routinely deny motions to dismiss under similar circumstances. *See, e.g., Mesh Comm, LLC v. EKA Sys. Inc.*, No. 8:09-cv-1064-T-33TGW, 2010 WL 750337, *2 (M. D. Fla. Mar. 4, 2010); *Auburn Univ. v. Int'l Bus. Machines, Corp.*, No. 3:09-cv-694-MEF, 2012 WL 1986682, * 2-3 (M. D. Ala. June 4, 2012); *Iguana, LLC v. Lanham*, No. 7:08-CV-09(CDL), 2009 WL 1620586, *1-2 (M. D. Ga. June 9, 2009); *Ware v. Circuit City Stores, Inc.*, CA No. 4:05-CV-0156-RLV, 2010 WL 767094, *2 (N. D. Ga. Jan. 5, 2010); *Sikes Cookers & Grill, Inc. v. Vidalia Outdoor Prods., Inc.*, CA No. 1:08-CV-0750-JOF, 2009 WL 427227, *2-3 (N. D. Ga. Feb. 19, 2009); *CBT Flint Partners, LLC v. Goodmail Sys., Inc.*, 529 F. Supp. 2d 1376, 1378-82 (N. D. Ga. 2007).

[5] When *McZeal* was decided, the model patent infringement complaint was in Form 16, which has been subsequently renumbered as Form 18.

III. MYLAN ASSERTED IMPROPER STANDARDS AND MISSTATES THE LAW FOR PLEADING DIRECT PATENT INFRINGEMENT

In its brief, Mylan cites a multitude of cases – but conspicuously avoids mentioning Form 18 and *Bill of Lading*, which are controlling. In its brief, Mylan also fails to inform the Court of the numerous cases in this district and this Circuit that deny motions to dismiss on patent infringement complaints having less factual allegations than Apotex's. Instead, Mylan singles out a single case in this Circuit, *Ware v. Circuit City*. *See* D.E. 22 at 15 citing *Ware v. Circuit City Stores, Inc.*, CA No. 4:05-CV-0156-RLV, 2010 WL 767094, *2 (N. D. Ga. Jan. 5, 2010). *Ware* is distinguishable on its facts. In *Ware*, the plaintiffs "just inserted a defendant's name and paraphrased 35 U.S.C. §271(a)." In sharp contrast, the Complaint in this case alleges:

> [T]esting of Mylan's Quinapril Combination Product demonstrates that it contains quinapril magnesium, which is an indication that Mylan's Quinapril Combination Product is made by a process covered by claims 1-12 and 16-19 of the '486 patent. However, Mylan's exact process is not publicly available. After an opportunity for discovery, there is likely to be evidence that the process Mylan uses to manufacture its Quinapril Combination Product comprises reacting quinapril or an acid addition salt thereof with an alkaline magnesium compound in the presence of a solvent so as to convert the quinapril or quinapril acid addition salt to quinapril magnesium, which process is covered by the '486 patent.

Complaint ¶ 16. The Complaint further alleges that Mylan infringes "by using a process covered by [claims 1-12 and 16-19] to manufacture products, including" Mylan's Quinapril Combination Product and Mylan's Quinapril Product. *Id.*, ¶¶ 20, 22. These allegations meet the requirements of Form 18 and do not resemble the allegations that were the subject of the decision by the *Ware* court.

Mylan's brief cites to a number of district court decisions outside of this Circuit that have been effectively superseded by *Bill of Lading* to the extent they hold that pleading direct infringement requires more than the specificity set forth in Form 18. *See* 681 F.3d at 1334 ("to

the extent the parties argue that *Twombly* and its progeny conflict with the Forms and create different pleadings requirements, the Forms control.").[6]

Additionally, there is no requirement in this Circuit that a Complaint "asserting infringement of a method patent *must* allege performance of each and every step of the claimed method" (D.E. 22 at 9 (emphasis in original); D.E. 22 at 10, 11, 13-16). Congress has acknowledged that a patented processes can be presumed to be infringed even if the plaintiff cannot actually determine that the process is used to make a product. 35 U.S.C. § 295[7]. In support of this argument, Mylan relies on *Canton Bio-Med., Inc. v. Integrated Liner Tech., Inc.*, 216 F.3d 1367, 1369-70 (Fed. Cir. 2000). D.E. at 9. *Canton Bio-Medical*, however, is not a decision on a motion to dismiss; it is a decision on a motion for summary judgment, where the Court found there was no infringement because of prosecution history estoppel. The other cases

[6] A number of cases cited by Mylan are either irrelevant or not controlling/persuasive. *See e.g.*, D.E. 22 at 16 citing *Driessen v. Sony Music Entm't*, No. 2:09-cv-0140-CW, 2012 WL 130412 (dismissing imprecise pleadings in the *joint infringement* context); *PageMelding, Inc. v. ESPN, Inc.*, No. C-11-06263 WHA, 2012 WL 851574, at *2 (N.D. Cal. Mar. 13, 2012) (holding *Iqbal* rejected Form 18); *Li Ming Tseng v. Marukai Corp.* U.S.A., No. SACV 09-0968 AG, 2009 WL 3841933 *1 (analyzing pleading of infringement under *Twombly/Iqbal* standard);*Gradient Enter., Inc. v. Skype Tech., Inc.*, No. 10-CV-6712L, 2012 WL 864804, at *2 (W.D.N.Y. Mar. 13, 2012) (holding "It is not clear, then, whether the Federal Circuit would, post- *Iqbal,* hold that a complaint for patent infringement that tracks Form 18 is necessarily sufficient to withstand a motion to dismiss"); *Lyda v. Fremantlemedia North Am., Inc.*, No. 10 Civ 4773, 2011 WL 2898313, at *2 (S.D.N.Y. July 14, 2011) (finding "In the wake of *Twombly* and *Iqbal,* several courts have questioned the continued viability of the traditional patent pleading standard and have required plaintiffs to make specific allegations about infringing products or methods in their complaints.")

[7] 35 U.S.C. §295 provides: In actions alleging infringement of a process patent based on the importation, sale, offered for sale, or use of a product which is made from a process patented in the United States, if the court finds-

(1) that a substantial likelihood exists that the product was made by the patented process, and

(2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

relied on by Mylan for this "requirement" are easily distinguished from the present facts. *See* D.E. 22 at 9-10 citing *Desenberg v. Google, Inc.*, 2009 WL 2337122 at *6, 8 (S.D.N.Y. 2009) (dismissing claim for infringement where a claimed method "clearly require[d] the participation of multiple parties" finding claimant had "not alleged that [infringer] acts as a "mastermind" directing or controlling the actions or participation of users"); *Palmetto Pharms. LLC v. Astrazeneca Pharms., LP*, 2012 WL 484907 at *5 (dismissing claim of patent infringement against a pharmaceutical company for a claim directed to a method of treating patients because "Plaintiff has failed to plead Defendant exercised direction and control over one or more third parties who actually performed all steps of the patented method."); *Ziptronix, Inc. v. Omnivision Techs., Inc.*, C.A. No. C 10-5525-SBA, 2011 WL 5416187 at 4 (dismissing counterclaim for patent infringement for lacking any allegation that all steps and stages of patented process were used by the sole alleged infringer).

Unlike these cases, the asserted claims in the instant action are directed to processes of making pharmaceutical compositions comprising quinapril magnesium. Apotex's complaint alleges facts establishing that Mylan received approval from the FDA to market products containing quinapril magnesium in the United States. *See* Compl. at ¶¶ 16-18. Mylan has not denied that it manufactures such products. To the contrary, Mylan's brief identifies methods used to make these products by claiming them as "proprietary." *See* D.E. 22 at 2, 12 FN.5. Even cases cited by Mylan have held that allegations similar to those made by Apotex were sufficient to plead infringement. *See* D.E. 22 at 17 citing *Bender v. LG Elecs. U.S.A. Inc.*, No. C 09-02114-JF, 2010 WL 889541 at *6 (holding "Sufficient allegations would include, at a minimum, a brief description of what the patent at issue does, and an allegation that certain named and specifically identified products or product components also do what the patent does, thereby

raising a plausible claim that the named products are infringing."). Accordingly, Mylan's reliance on *Desenberg*, *Palmetto Pharms* and *Ziptronix*, is misplaced.

Mylan also argues that Apotex has not identified which dosage forms infringe. D.E. 22 at 2, 11. That argument is fatuous, since Apotex alleges that the process Mylan uses to manufacture tablets infringes its patents. Moreover, Form 18 requires only a general statement about the infringing products or processes. *See, e.g., Eon Corp.*, 802 F. Supp. 2d at 532 (". . . Form 18's . . . third element . . . identifies just a general category of products and provides no further details."). Other courts in this Circuit (and elsewhere) have "found complaints [that met Form 18] to sufficiently meet the notice pleading standard under Fed. R. Civ. P. 8(a) even if they did not allege the specific infringing item . . .." *Sikes Cookers*, 2009 WL 427227 at *2 (and cases cited therein) (emphasis added); *see also Mesh Comm*, 2010 WL 750337 at *1-2 (denying 12(b)(6) motion where the Complaint did not list the names of the specific products); *Auburn University*, 2012 WL 1986682 at *1, 3 (denying 12(c) motion where Complaint alleged infringement of "products, including without limitation, integrated circuits tested using the claimed methods . . . "). Apotex's identification of specific product names and the ANDAs under which they are sold meets all pleading standards. *See Compl.* at ¶¶ 7, 15-22.

Mylan's manufacturing process is a trade secret. Apotex has asked Mylan to provide documents that accurately and completely describe its manufacturing process for review under an attorneys' eyes only basis. Mylan has ignored such requests, opting instead to file the instant motion. *See* Ex. A.[8]

[8] As can be seen, Apotex has explained that it did not have access to Mylan's actual manufacturing method for its Quinapril Products. *See id.*, June 11, 2012 E-mail from M. Masar. Despite not receiving a response from Mylan's counsel, Apotex made four additional requests, even suggesting that any such disclosure be limited to an "Outside Counsel Eyes Only" basis. *See id.,* June 18, 22, 25 and 28 e-mails from M. Masar. After nearly a month of ignoring Apotex's requests, Mylan's responded by filing the instant motion and stating that "Mylan's

Under these circumstances, it is "difficult to imagine what else [Plaintiffs] could have done to obtain facts relating to [Defendant's] alleged infringement of their process patents." ; *Hoffmann-La Roche*, 213 F.3d at 1364; *See also, McZeal*, 501 F.3d at 1358 *Cambridge Prods., Ltd v. Penn Nutrients, Inc.*, 962 F.2d 1048, 1050 (Fed. Cir. 1992).[9] Mylan cannot hide behind the fact that it treats the accused product as a trade secret. *See Ultimax Cement*, 587 F.3d at 1350 ("[a]n infringer does not escape liability merely by infringing in secret."). Where, as here, the patentee has conducted a reasonable pre-filing analysis, the patentee can resort to discovery to prove infringement.

IV. APOTEX'S COMPLAINT GOES BEYOND FORM 18 AND MEETS THE NOTICE AND PLEADING STANDARDS OF *TWOMBLY* AND *IQBAL*

As discussed above, Apotex's Complaint satisfies the requirements of Form 18. Apotex's Complaint even goes beyond those requirements, and thus is sufficient under the heightened standards of *Twombly* and *Iqbal*, assuming *arguendo* that the standard set forth in those cases is not met by Form 18. These cases "do[] not impose a probability requirement at the pleading stage," but instead "simply call[] for enough facts to raise a reasonable expectation that discovery will reveal evidence of" the necessary element. *Twombly*, 550 U.S. at 556 (underline added); *cf.* Adv.Comm. Note to Rule 11(b)(3) ("[S]ometimes a litigant may have a good reason to believe that a fact is true . . . but may need discovery, formal or informal, from opposing

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position on the matter is set forth in its motion to dismiss." *See id.,* July 6, 2012 e-mail from T. Parker.

In stark contrast, in a related suit, Apotex and Defendants Pfizer and Greenstone have been able to work out a stipulation that will allow for an early exchange of Apotex's testing documents for Pfizer & Greenstone's process documents. *See* D.E. 25.

[9] While *Hoffman LaRoche* and *Cambridge* are Rule 11 cases, they establish that conducting a pre-filing investigation is sufficient to develop a reasonable claim for infringement. Apotex's allegations in its complaint on its pre-filing investigation similarly show a claim for infringement.

parties or third persons to gather and confirm the evidentiary basis for the allegation.").[10] They "do not require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. Once facts have been plead and accepted as true, they are construed in the light most favorable to the plaintiff. *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1288 (11th Cir. 2010) (internal quotation marks omitted). Also, "a plaintiff 'receives the benefit of imagination, so long as the hypotheses are consistent with the complaint.'" *Twombly*, 550 U.S. at 563 (quoting *Sanjuan v. American Bd. Psychiatry and Neurology*, 40 F.3d 247, 251 (7th Cir. 1994)).

Apotex's complaint alleges the following facts – not the broad legal conclusions that were considered in *Twombly*:

- The '486 patent relates to, *inter alia*, "processes for making solid pharmaceutical compositions comprising quinapril magnesium made by reacting quinapril or an acid addition salt therof with an alkaline magnesium compound in the presence of a solvent so as to convert the quinapril or quinapril acid to quinapril magnesium." Compl. at ¶¶ 10, 16.
- Mylan, *inter alia*, manufactures and sells quinapril pharmaceutical products in the United States. *Id.* at ¶ 7. Mylan has FDA approval to market Quinapril and Quinapril Combination products ("Mylan's Products") under ANDA Nos. 07-6036 and 07-7093, respectively. *Id.* at ¶¶ 16, 17.
- The Product Labels (Attached herewith as Exs. B & C) indicate that Mylan's Products are made using, *inter alia*, quinapril hydrochloride, magnesium carbonate, and magnesium stearate. *Id*.

[10] This is directly in contradiction to Mylan's statement of the law that "the law expressly prohibits Plaintiffs' self-professed 'resort[ing] to the judicial process' in the hopes of 'confirm[ing] [Plaintiffs'] belief' that Mylan infringes." (D.E. 22 at 2; *see also id.* at 12, n. 2.) Also, Mylan's only citation is to the syllabus of *Twombly*, which "constitute no part of the opinion of the Court." 550 U.S. at 544. Mylan's inability to cite proper support for its positions is indicative of the frivolity of its motion.

- Testing of Mylan's Quinapril Combination Product demonstrates that it contains quinapril magnesium. *Id.* at ¶ 16.
- The exact manufacturing process for Mylan's Products is not publicly available. *Id.* at ¶¶ 16, 18. Further, Mylan's process can not be determined definitively from its Products or the publicly available information. *Id.*

None of these statements are legal conclusions or labels. They are not "a formulaic recitation of the elements of the cause of action." *See Twombly*, 550 U.S. at 545. Nor are they "naked assertion[s] devoid of 'further factual enhancement." *Id.* at 557. They are short and plain statements of fact. But their brevity is no cause for concern, as the Supreme Court has stated a complaint "does not need detailed factual allegations" under Rule 8(a). *See, e.g.*, *id.* at 555.

V. MYLAN'S OTHER ARGUMENTS ARE WITHOUT MERIT

Mylan argues that Apotex has provided no reasonable assertion of infringement. However, as discussed above, Apotex's asserted patent claims recite a process of making a composition comprising quinapril magnesium by reacting components found in Mylan's Products. Furthermore, Apotex plead that testing of Mylan's product demonstrates that it contains quinapril magnesium. The reasonable inference drawn from these facts is that Mylan's process infringes a claimed process of the asserted claims of the '486 patent.

Mylan argues that Apotex's the Complaint fails to provide the required 'fair notice' under both current Supreme Court precedent as well as the former, more permissive, pleading standard. D.E. 22 at 3, 13-14, and 16. But at the same time, Mylan admits "Plaintiffs' Complaint ostensibly claims infringement against two product lines of Mylan's quinapril-containing pharmaceuticals, implicitly including any and all dosage forms." D.E. 22 at 14. Thus, it is quite clear that Mylan knows what Apotex is claiming and their empty protestations otherwise should be ignored. None of the cases cited by Mylan find lack of notice where a specific product is identified in the complaint.

Mylan also makes a number of other misstatements on the law or the holdings of cases. For example, Mylan argues in relation to Apotex's well-pled testing that, "this so-called 'testing', the details of which Plaintiffs keep secret, cannot be viewed as a plausible factual allegation." D.E. 22 at 11; *see also* at 2. First, there is no "plausible factual allegation" standard – all facts specifically alleged are taken as true. The Supreme Court has made it clear that "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and **then** determine whether they plausibly give rise to entitlement to relief." *Iqbal*, 556 U.S. at 678; *see also Twombly,* 550 U.S. at 555-56 ("[A]ll the allegations in the complaint are true (even if doubtful in fact) . . .."); *Neitzke v. Williams*, 490 U.S. 319, 327 (1989) ("Rule 12(b)(6) does not countenance ... dismissals based on a judge's disbelief of a complaint's factual allegations.") (emphasis added for each). Second, Apotex has engaged Mylan in an effort to have it disclose under strict confidentiality its secret manufacturing process for its Quinapril Products – but Mylan has refused. Third, Apotex's testing must be assumed as accurate, and provides a reasonable basis for asserting infringement to be determined in discovery.

Mylan also suggests that Apotex did not conduct an adequate pre-filing investigation. *See* D.E. 22 at 2-3, 15-18. Notably, Mylan does not state what testing it would consider adequate. Further, Mylan completely ignores the Federal Circuit's holdings in *Cambridge* and *Hoffman LaRoche* which confirm the reasonableness of Apotex's pre-filing investigations. *Cambridge*, 962 F.2d at 1050; *Hoffmann-La Roche*, 213 F.3d at 1364 (stating that it is sufficient to rely on pre-filing testing even where further discovery is necessary to prove infringement, in context in Rule 11). In *Cambridge*, a secret method was also at issue. The Federal Circuit found the patentee's pre-filing inquiry was sufficient because:

> [the patentee] had tested a sample of the allegedly infringing product and had commissioned further chemical analyses and acquired documents that appeared to

> confirm that the product alleged to infringe fell within the chemical specifications of the patent method.

That is exactly what Apotex did here, and the results suggest infringement. Therefore, Mylan's motion should be denied.

CONCLUSION

For the reasons stated above, Apotex's Complaint states claims for infringement of the '486 patent on which relief can be granted based on the requirements proper requirements set forth in Fed. R. Civ. P. 84, Form 18. Furthermore, the legal assertions made by Mylan in support of its motion are improper and inaccurate. Therefore, Mylan's motion to dismiss under Fed. R. Civ. P. 12(b)(6) should be denied.

Dated: July 19, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 19th day of July 2012, I electronically filed the foregoing Memorandum of Law 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 on the service list below 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.

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