UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FORT LAUDERDALE DIVISION

APOTEX, INC. a Canadian Corporation and APOTEX CORP., a Delaware Corporation, **Plaintiffs,** **v.** **MYLAN PHARMACEUTICALS, INC., a Delaware Corporation** **Defendant.**	**CIVIL CASE NO. 0:12-cv-60704-PAS**

DEFENDANT, MYLAN PHARMACEUTICALS INC.'S
MOTION TO DISMISS PLAINTIFFS' COMPLAINT WITH PREJUDICE

Pursuant to Rule 12(b)(6), Federal Rules of Civil Procedure, Defendant Mylan Pharmaceuticals Inc. ("Mylan"), by and through its undersigned counsel, hereby moves to dismiss with prejudice the Complaint filed by Plaintiffs, Apotex, Inc. and Apotex Corp. (collectively, "Apotex" or "Plaintiffs"), for failure to state a claim upon which relief can be granted.

PRELIMINARY STATEMENT

Plaintiffs allege that two of Mylan's products infringe U.S. Patent No. 6,531,486 ("the '486 patent").[1] (D.E. 1.) However, Plaintiffs' Complaint is insufficient to maintain an

[1] On the same date, Plaintiffs filed two other effectively identical complaints, in this district, against pharmaceutical companies that, like Mylan, also sell quinapril hydrochloride products. *See* D.E. 1, *Apotex, Inc. et al. v. Pfizer, Inc. et al.*, Case No. 0:12-cv-60705-KMM (S.D. Fla.); D.E. 1, *Apotex, Inc. et al. v. Lupin Pharmaceuticals, Inc. et al.*, Case No. 0:12-cv-60708-DMM (S.D. Fla.). Plaintiffs' bare bones complaints against Mylan and the other pharmaceutical companies are virtually identical except for changing the defendants' names. Further, these complaints provide no more than generic and conclusory allegations against each defendant, notwithstanding the disparate nature of each of the defendants' respective businesses, products, and perhaps methods used to make said products. While this fact alone does not necessarily warrant dismissal, it is emblematic of Plaintiffs' wholesale litigation campaign which is

infringement charge of 16 method claims. While form does not trump substance, the absence of factual allegations is evidenced by the sheer brevity of Plaintiffs' purported support for their claims. For example, the Complaint is a mere five pages containing twenty-two paragraphs. Of those twenty-two paragraphs, only *two*—paragraphs 16 and 18—purport to provide any support for Mylan's alleged infringement.

More importantly, the substance of those two paragraphs is devoid of any plausible support that could lead to a reasonable inference of infringement. In fact, the most that is even provided is some form of "testing" allegedly performed on an unidentified dosage form of Mylan's "Quinapril Combination Product" line, coupled with Plaintiffs' "belief" that, "[a]fter an opportunity for discovery, there is likely to be evidence" that Mylan's process for making its product infringes the '486 patent. (D.E. 1 ¶ 16.) For Mylan's other accused product line, a non-combination "Quinapril Product," Apotex simply alleges 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.) Nowhere do Plaintiffs allege which of Mylan's dosage forms (of which there are seven) purportedly infringe Plaintiffs' patent.

Instead, Plaintiffs simply recite that Mylan's proprietary processes are not "publicly available." (D.E. 1 ¶¶ 16, 18.) As such, Plaintiffs claim that they must "resort[] to the judicial process and the aid of discovery…and confirm its belief that Mylan infringes." (D.E. 1 ¶ 18.) The fact that Mylan does not share its proprietary methods with competitors like Apotex, however, does not give Plaintiffs free reign to file a suit which is nothing more than a veiled fishing expedition. To the contrary, the law expressly prohibits Plaintiffs' self-professed

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unsubstantiated by any alleged fact except that these defendants, like Mylan, all sell quinapril products.

"resort[ing] to the judicial process" in the hopes of "confirm[ing] [Plaintiffs'] belief" that Mylan infringes. (D.E. 1 ¶ 18.); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2006).

While Rule 8(a)(2), Federal Rules of Civil Procedure, simply requires "a short and plain statement of the claim showing that the pleader is entitled to relief," Supreme Court precedent requires that the Complaint contain factual allegations, beyond conclusory legal conclusions, sufficient to demonstrate that the right to relief is beyond speculative. *Twombly*, 550 U.S. at 545. The Complaint, however, contains no such factual allegations, only Plaintiffs' "belief" and hopes for favorable fruits of discovery. It should be dismissed for several reasons.

First, Plaintiffs' allegations, at best, provide conclusory speculation of possible infringement, contrary to Supreme Court requirements. Second, Plaintiffs fail to specify how Mylan purportedly infringes the '486 patent's many methods. Third, devoid of factual allegations, the Complaint fails to provide the required "fair notice" under both current Supreme Court precedent as well as the former, more permissive, pleading standard. Lastly, the lack of plausible factual allegations strongly suggests that Plaintiffs failed in their duty to conduct due diligence by way of a pre-filing investigation. Mylan respectfully submits that this raft of failures should not be permitted and that Plaintiffs' Complaint be dismissed with prejudice.

I. BACKGROUND AND PLAINTIFFS' COMPLAINT

On April 20, 2012, Plaintiffs initiated a wholesale litigation campaign against anyone who happens to market a quinapril-containing product. Plaintiffs filed with this Court at least three separate but virtually identical complaints against three distinct but competing pharmaceutical companies (including Mylan) for infringement of the '486 patent.[2] Notably, and

[2] *See* D.E. 1, *Apotex, Inc. et al. v. Pfizer, Inc. et al.*, Case No. 0:12-cv-60705-KMM; D.E. 1 (the "Pfizer Action"), *Apotex, Inc. et al. v. Lupin Pharmaceuticals, Inc. et al.*, Case No. 0:12-cv-60708-DMM (the "Lupin Action"). Mylan is aware that the parties are discussing a potential consolidation motion for pre-trial purposes. While Mylan does not oppose such a motion for

except for changing the names, identical paragraphs are pleaded against each defendant. Yet, the only thing defendants (including Mylan) share is that they have been sued by Plaintiffs.

According to this series of complaints, Apotex, Inc. is the alleged lawful owner of the '486 patent. Plaintiffs allege that "[each defendant, including Mylan], directly or by and/or through its agents, manufactures, imports, offers for sale, sells, and/or uses tablets [containing quinapril magnesium][3] made by a process that is covered by [the method claims] of the '486 patent." (D.E. 1 ¶ 15.)[4] Further, Plaintiffs allege that, while the labels of each of the at least seven different accused products claim to contain *quinapril hydrochloride*, Plaintiffs' undisclosed so-called "testing" for the combination products suggests these products contain *quinapril magnesium*. (D.E. 1 ¶ 16.) And, as such, Plaintiffs allege each defendant (including Mylan) must necessarily be using Plaintiffs' process of converting quinapril or quinapril acid into quinapril magnesium. (*Id.*) Curiously, for at least one of the accused Mylan products, Plaintiffs cannot point to any analytical technique showing there is any quinapril magnesium in the product. (D.E. ¶ 18.) Nonetheless, Plaintiffs allege that even this product is made using the patented method.

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procedural efficiencies should the Court deem consolidation appropriate, Mylan submits that Apotex does not have a valid cause of action against Mylan.

[3] Plaintiffs allege that the following Mylan products are made using the methods claimed in the '486 patent. Mylan's accused products include Mylan's generic quinapril hydrochloride and hydrochlorothiazide product covered by Abbreviated New Drug Application No. 07-7093 (Mylan's "Quinapril Combination Product"); and Mylan's generic quinapril hydrochloride and hydrochlorothiazide product (Mylan's "Quinapril Product") covered by Abbreviated New Drug Application No. 07-6036. (D.E. 1 ¶¶ 16-17.)

[4] The specific references to the "Complaint" in this memorandum are to the Complaint in this Action; however, identical language is found in the complaints for the Pfizer Action and Lupin Action.

II. ARGUMENT

A. Legal Standard

Rule 8(a)(2) requires a plaintiff to set forth in its complaint a "'short and plain statement of the claim showing that the pleader is entitled to relief.'" *Harrison v. Benchmark Elec. Huntsville, Inc.*, 593 F.3d 1206, 1214 (11th Cir. 2010) (citing Fed. R. Civ. P. 8(a)(2)). If a complaint fails to satisfy Rule 8, it "must be dismissed" under Rule 12(b)(6) for failure to state a claim upon which relief can be granted. *Twombly*, 550 U.S. at 570.

The Supreme Court has explained that Rule 8(a)(2) "requires more than labels and conclusions" or "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 545; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (explaining Rule 8(a)(2) "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation"). Rather, the complaint must include sufficient factual allegations "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 545. That is, a plaintiff must allege "enough facts to state a claim that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678; *see also Phillips v. County of Allegheny*, 515 F.3d 224, 235 (3d Cir. 2008) (holding that plaintiff must allege "factual matter (taken as true) to suggest the required elements of [plaintiff's] claims").

Since the Supreme Court's decision in *Iqbal*, district courts have required heightened fact pleading in actions for patent infringement. *See, e.g., Elan Microelec. Corp. v. Apple, Inc.*, No. C 09-01531 RS, 2009 WL 2972374, at *2 (N.D. Cal. Sept. 14, 2009) (granting motion to dismiss for failure to adequately plead induced infringement according to *Twombly* fact pleading standard); *Desenberg v. Google, Inc.*, No. 09 Civ. 10121 (GBD) (AJP), 2009 WL 2337122, at *7-10 (S.D.N.Y. July 30, 2009) (analyzing defendant's motion to dismiss under the "plausibility

standard" established in *Twombly* and *Iqbal*), *aff'd on other grounds*, 392 F. App'x 868, 870-871 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 962 (2011); *Sharafabadi v. Univ. of Idaho*, No. C09-1043JLR, 2009 WL 4432367, at *6-9 (W.D. Wash. Nov. 27, 2009) (analyzing defendant's motion to dismiss plaintiff's patent infringement claims under the plausibility standard set forth in *Twombly* and *Iqbal*).

B. Plaintiffs Fail To State a Claim for Patent Infringement

The Court should dismiss Plaintiffs' Complaint under Rule 12(b)(6) because it is insufficient under the Supreme Court's pleading standards. *Twombly*, 550 U.S. at 545; *Iqbal*, 556 U.S. at 678.

1. Plaintiffs' Allegations, at Best, Provide Mere Speculation of Infringement

Plaintiffs' allegation that, "[a]fter an opportunity for discovery, there is *likely* to be evidence" that Mylan uses the process claimed in the '486 patent simply does *not* state or substantiate a claim for infringement. (D.E. ¶¶ 16, 18 ("Apotex *believes* that Mylan is *likely* practicing processes covered by claims . . . of the '486 patent") (emphasis added). Belief, when not substantiated by plausible factual allegations, cannot lead to a reasonable inference that there is infringement. For this reason alone, the Complaint should be dismissed.

The two paragraphs cited above (*i.e.*, D.E. 1 ¶¶ 16 and 18) are the Complaint's only paragraphs that even attempt to provide any support for infringement. Even they, however, offer no such support. As such, Apotex's Complaint provides nothing more than speculation that Mylan *may* be infringing (which it is not).

Nonetheless, pleadings are required to contain something more than statements that simply create a suspicion of a legally cognizable right of action. *Twombly*, 550 U.S. at 545 ("[f]actual allegations must be enough to raise a right to relief above the speculative level").

While Plaintiffs need not prove infringement at the initial pleading stage, some threshold of plausibility must be crossed at the outset before a patent infringement case should enter the inevitably costly and protracted discovery phase. *Id.*; *Ryan v. Mary Immaculate Queen Ctr.*, 188 F.3d 857, 860 (7th Cir. 1999) (purpose of the notice pleading requirement is to allow the court "to determine at the outset of the litigation, before costly discovery is undertaken, whether the plaintiff has any tenable theory"); *In re Papst Licensing GMBH & Co., KG Litig.*, 585 F. Supp. 2d 32, 36 (D.D.C. 2008).

Indeed, since *Twombly* and *Iqbal*, district courts have consistently dismissed patent infringement claims based on pleadings similar to Plaintiffs' complaint. In *Papst*, the plaintiff alleged in its complaint that "[a] reasonable opportunity for further investigation or *discovery is likely to provide evidentiary support* the [defendants] have made, used, sold or offered to sell" products covered by the asserted patent. *Id.* at 33 (emphasis added). This is nearly identical to the Plaintiffs in this action essentially asking this Court to allow "an opportunity for discovery" after which "there is *likely* to be evidence" of infringement. (D.E. 1 ¶ 16 (emphasis added).) Mylan respectfully submits that the outcome here should be the same as in *Papst*. There, the court held that such allegations were insufficient to state a claim for relief.

> The Complaint merely speculates that [defendant] might have infringed or be infringing and notifies [defendant] and the Court that [plaintiff] intends to investigate whether [plaintiff] has an infringement claim against [defendant].

In re Papst, 585 F. Supp. 2d at 35, *aff'd and amended*, 602 F. Supp. 2d 17, 20-21 (D.D.C. 2009) (affirming dismissal of complaint). Hoping for an opportunity to investigate is not sufficient reason to file a complaint. Rather, as discussed below, plaintiffs have an affirmative duty to conduct their investigation *before* instituting litigation. That is exactly what the Plaintiffs, here, appear not to have done. Plaintiffs' Complaint is equally speculative in nature. *See Elan*

Microelec. Corp., 2009 WL 2972374, at *3-4 (dismissing counterclaims that merely alleged that "it is likely that reasonable opportunity for further investigation or discovery" will confirm infringement).

Plaintiffs' strategy of "sue first and ask questions later" does not comport with either the letter or the spirit of the Federal Rules of Civil Procedure or Supreme Court precedent. On this basis alone, Plaintiffs' Complaint should be dismissed.

2. Plaintiffs Have Not Sufficiently Pled Infringement of the Method Patent-In-Suit

Given the purely speculative nature of Plaintiffs' infringement counts, it should come as no surprise that they have not sufficiently pled the factual allegations necessary to find even a reasonable inference of infringement. As set forth below, Plaintiffs' failure in this regard is manifest for several reasons: (a) the Complaint provides no allegations regarding the many methods of the claims of the patent, much less how Mylan purportedly practices *even one* of those many methods; (b) Plaintiffs' assertions that two of Mylan's product lines infringe the '486 patent are wholly conclusory; (c) Plaintiffs' "support" for Count I rests on one implausible, alleged fact; and (d) Plaintiffs' "support" for Count II rests on no fact but, rather, merely on "belief." For these reasons, the Complaint should be dismissed.

(a) No Aspect of The Many Methods of The Claims, or How Mylan Purportedly Practices Them, Has Been Pled

The '486 patent at issue here contains 16 method claims (*i.e.*, claims 1-12, 16-19) all of which are asserted in each of Counts I and II. *See* the '486 patent at col. 6, *l.* 46-col. 8, *l.* 4; and col. 8, *ll.* 25-41; D.E. 1 ¶¶ 15, 20, 22. Each of these patent claims contains one or more steps of the process or additional limitation, many of which compound each other. For example, independent claim 12, which has one limitation, depends on claim 8, which has four process steps and in-turn depends on claim 1, which recites yet another process step. As such, to allege

infringement of just claim 12, Plaintiffs need to plead some facts which show that Mylan infringes *at least* six separate limitations. Yet, Plaintiffs have provided Mylan with none.

But claim 12 is just one example. Depending on how one calculates the limitations from the dependent claims, there may be as many as 54 (or more) process limitations alleged to be infringed. And that is just for claims 1 through 12. Asserted claims 16 through 19 add at least another four limitations. And those numbers apply to two different types of Mylan quinapril product lines, themselves having multiple dosage forms.

Plaintiffs have neither set forth any of these limitations nor identified *even one* way in which *even one* of Mylan's products purportedly infringes *even one* of the limitations. Plaintiffs have not even come close to meeting their burden under *Twombly/Iqbal* to allow for a reasonable inference that even one of the '486 patent's method claims is infringed.

It is axiomatic that proof of patent infringement requires a showing that an accused party "perform[s] or use[s] each and every step or element of a claimed method or product." *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007). A method is a process, or series of steps or acts, for performing a function or accomplishing a result. *See Gottschalk v. Benson,* 409 U.S. 63, 70 (1972). "It consists of doing something, and therefore has to be carried out or performed." *In re Kollar,* 286 F.3d 1326, 1332 (Fed. Cir. 2002).

Indeed, in its complaint, a plaintiff asserting infringement of a method patent *must* allege performance of each and every step of the claimed method. *Canton Bio-Med., Inc. v. Integrated Liner Tech., Inc.*, 216 F.3d 1367, 1369-70 (Fed. Cir. 2000) (affirming dismissal of a claim for patent infringement under Rule 12(b)(6) based, *inter alia,* on failure to adequately allege that defendant carries out all the steps of the patented method); *see also Ziptronix, Inc. v. Omnivision Techs., Inc.*, C.A. No. C 10-5525-SBA, 2011 WL 5416187, at *3 (N.D. Cal. Nov. 8, 2011)

("[W]ith a method patent infringement claim, to properly allege 'use' of the patent, the patentee *must* identify the steps of the claimed infringing process that allegedly violated the protected method and must allege that *all* the protected steps have been used by the infringer.") (emphasis added).

Here, aside from broadly asserting infringement of 16 claims, Plaintiffs' Complaint does not allege that Mylan has performed *any* aspect of the patented methods of making products that contain quinapril magnesium, let alone allege facts plausibly demonstrating that *all* steps are directly infringed. *Desenberg*, 392 F. App'x at 870-71 (affirming the district court's Rule 12(b)(6) dismissal because the complaint failed to allege that the infringer performed all of the steps of the claimed method); *Ziptronix*, 2011 WL 5416187, at *3; *Palmetto Pharms. LLC v. Astrazeneca Pharms., LP*, No. 2:11-cv-00807-SB-JDA, 2012 WL 484907, at *5-6 (D.S.C. Jan. 4, 2012) (granting motion to dismiss where plaintiff failed to allege defendant performs every step of the patented method).

(b) Plaintiffs' Assertions in Counts I & II—That Mylan's Product Lines Infringe—Are Wholly Conclusory

Instead, Plaintiffs rest their theory of infringement on the allegations that Mylan markets and sells certain unidentified quinapril products. The entirety of Plaintiffs' patent infringement claim consists of the following bald assertion:

> *Upon information and belief, which is likely to be substantiated through discovery*, Mylan has infringed one or more of claims 1-12 and/or 16-19 of the '486 Patent by using a process covered by those claims to manufacture products, including Mylan's [quinapril products], and or [*sic*] by importing, selling, and/or offering for sale the product of such process into the United States in violation of 35 U.S.C. §271 (a) and/or (g).

(D.E. 1 ¶¶ 20, 22 (emphasis added).) In this conclusory fashion, Plaintiffs merely identify the patent-in-suit and allege on "information and belief" that Mylan's quinapril products infringe.

Plaintiffs make no allegations whatsoever as to *how* Mylan's quinapril products are made, and *how* or *why* such methods infringe. Thus, Plaintiffs' Complaint amounts to a claim that Mylan's quinapril products are necessarily infringing Plaintiffs' method patent by virtue of simply being a quinapril-containing product. (D.E. 1 ¶¶ 16, 18.) This cannot be. The Complaint is entirely deficient.

(c) Plaintiffs' "Support" For Count I of The Complaint Rests on One Implausible, Alleged Fact

Indeed, the only hint of an alleged fact—with respect to Mylan's Quinapril Combination Product—is some suggestion that Plaintiffs tested the combination product and found such quinapril magnesium. (D.E. 1 ¶ 16.) But, even then, the Complaint uses this trace "fact" to support an unjustifiable leap of logic: the "testing" purportedly found quinapril magnesium in Mylan's Combination Product and, *therefore*, that ingredient's presence "is an indication" that the product was made by a process claimed in the '486 patent. (*Id*.)

There is no assertion, much less allegation, that Plaintiffs' claimed methods are the *only* way to derive quinapril magnesium in such a product. As such, this so-called "testing," the details of which Plaintiffs keep secret, cannot be viewed as a plausible factual allegation. Further, Mylan notes that Plaintiffs have only cited to "testing" of *one* of Mylan's accused products without even mentioning the dosage form, of which there are at least seven. As such, Mylan has no understanding as to which dosage form or forms purportedly infringe. Thus, Mylan is left with no notice whatsoever.

(d) Plaintiffs' "Support" For Count II of the Complaint Rests Merely on "Belief"

For the other accused Mylan product type, of which no dosage forms are identified, Plaintiffs state that they are "not aware of any analytical technique which can be used to *definitively* establish that Mylan's Quinapril Product" infringes and that "Mylan's exact process

is not publicly available."[5] (D.E. 1 ¶ 18 (emphasis added).) But Plaintiffs then claim that "based on analytical studies available to it" (which are never identified) "Apotex *believes* that Mylan is *likely* practicing processes covered" by the asserted claims. (*Id*. (emphasis added).) Mylan submits that having a mere "belief" of some "likelihood" is neither sufficient to state a claim, nor sufficient to "resort[] to the judicial process and the aid of discovery" in order to "confirm its belief," as Apotex admits it is doing. (*Id*.)

The four points above demonstrate the Complaint's overall deficiency. Similar faulty pleadings have been rejected by many courts. In one example, the Eastern District of Michigan provided an instructive opinion in *Prestige Pet Prods., Inc. v. Pingyang Huaxing Leather & Plastic Co., Ltd.*, 767 F. Supp. 2d 806 (E.D. Mich. 2011), just last year. That court dismissed a patent infringement complaint under *Twombly/Iqbal* where the plaintiff provided no facts aside from the list of product lines allegedly infringing the method patent at issue.

> Although the assertion that products have been produced with a patented method in violation of U.S. patent law is *not inherently implausible*, neither is it sufficient to nudge allegations beyond "the mere possibility of misconduct."

Id. at 810 (quoting *Iqbal*, 129 S. Ct. at 1950) (emphasis added). Here, too, the identification of products that "*might* be made by infringing [the '486 patent], without more, states only a *possibility* of a claim." *Prestige Pet*, 767 F. Supp. 2d at 810 (emphasis added). In keeping with

[5] That Mylan does not make its proprietary processes known to potentially competitive entities such as Apotex is of no moment. If Plaintiffs have nothing more than a "belief" that an entity infringes their patent, Plaintiffs do not have a proper basis for filing suit. Mylan respectfully submits that it is not the Court's obligation to "confirm" Plaintiffs' unsubstantiated beliefs. Rather, it is Apotex's obligation. Mylan is left to surmise that Plaintiffs may have filed suit simply to have Mylan turn over its proprietary information to Apotex. Indeed, Apotex's counsel contacted Mylan's counsel by e-mail requesting exactly that — "to produce documents that completely and accurately describe [Mylan's] manufacturing processes." Mylan is not obligated to simply produce its proprietary information at Plaintiffs' behest. And Plaintiffs' e-mail evidences the lack of factual support for any of its allegations against Mylan. As noted, filing suit first and asking questions later is not appropriate.

the *Prestige Pet* analysis, Plaintiffs' claims "that appear to embrace all [quinapril] products and allege that all such [products] are made using the method of the ['486 patent] are no more plausible than would be a claim that the ['486 patent] is infringed by the manufacture of tennis balls or bedroom slippers." *See id.*

Because Plaintiffs have pled no facts from which the Court may reasonably infer that Mylan's quinapril products are actually made using the steps claimed in Plaintiffs' patented method, the Complaint is not plausible and properly should be dismissed.

3. The Complaint Does Not Provide Mylan With The Required "Fair Notice," Thereby Failing That Lesser Standard

Plaintiffs' allegations are so bereft of factual content that the Court cannot draw any inference, let alone a reasonable one, that Mylan infringes the '486 patent. As noted above, by failing to identify the purportedly infringing method, how such a method is covered by the claims at issue and, most importantly, how Mylan practices the claimed methods, the Complaint fails to meet the *Twombly/Iqbal* standard. Even worse, the Complaint further fails to put Mylan on fair notice, as required. Thus, Plaintiffs' Complaint is even defective under the basic "fair notice" standard, articulated in *Conley v. Gibson*, 355 U.S. 41, 47 (1957).

Plaintiffs' infringement allegations in both counts of the Complaint simply paraphrase the words of the Patent Act and rely upon the plain assertion that Mylan's allegedly infringing method is a "process covered by…the '486 patent." (D.E. 1 ¶ 16; *see also id.* ¶¶ 20, 22.) These are mere legal conclusions, not alleged facts. "[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678.

As stated above, the Complaint fails to provide virtually *any* factual allegations in support of this legal conclusion. Such absence of factual allegations to support the legal conclusions

alleged mandate dismissal. *See, e.g.*, *PageMelding, Inc. v. ESPN, Inc.*, No. C-11-06263 WHA, 2012 WL 851574, at *2 (N.D. Cal. Mar. 13, 2012) (dismissing direct infringement claims where "claims are nothing more than legal conclusions couched as factual allegations."); *Pieczenik v. Bayer Corp.*, No. 2011-1385, 2012 WL 1177925, *1-2 (Fed. Cir. Mar. 22, 2012) (*non-precedential*) (affirming dismissal of infringement claims because the patentee failed to plead facts sufficient to show infringement); *Li Ming Tseng v. Marukai Corp.* U.S.A., No. SACV 09-0968 AG, 2009 WL 3841933, at *1 (C.D. Cal. Nov. 13, 2009) (granting defendant's motion to dismiss plaintiff's patent infringement claims where plaintiffs' allegations were "too conclusory to support a claim under *Twombly* and *Iqbal*"). Because of this failure to allege factual allegations, the Complaint fails the basic, more lenient "fair notice" standard.

The fair notice standard merely requires "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 claim is and the grounds upon which it rests." *Conley*, 355 U.S. at 47. As noted above, Plaintiffs' Complaint ostensibly claims infringement against two product lines of Mylan's quinapril-containing pharmaceuticals, implicitly including any and all dosage forms. Yet, Plaintiffs have not alleged any facts about Mylan's purportedly infringing method(s)-of-manufacture used to make these products or how such methods infringe those claimed by the '486 patent, or what specific products are included within the scope of the Complaint.

Fair notice, at a bare minimum, requires that Plaintiffs identify the specific methods alleged to infringe and why Plaintiffs believe they are infringed. Plaintiffs have failed to do so at even a general level. As such, it is impossible for Mylan to know how its processing method is accused of infringing the claimed methods. *Twombly*, 550 U.S. at 556 n.3 ("Without some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement

that he or she provide not only fair notice but also the grounds on which the claim rests.") (internal citations omitted); *Ware v. Circuit City Stores, Inc.*, No. 4:05-cv-0156-RL, 2010 WL 767094, at *2 (N.D. Ga. Jan. 5, 2010) (holding allegation that "apparatuses" infringe "does not provide the minimal factual pleading to put defendants on notice of the claims against them, which is what is required by Rule 8").

Because Plaintiffs have not specifically stated what the '486 patent protects and the grounds upon which Mylan's quinapril-containing products (and related processes) allegedly infringe, Mylan has not been given fair notice of the claims against which it must defend. *See, e.g., Enlink Geoenergy Serv., Inc. v. Jackson & Sons Drilling & Pump, Inc.*, No. C 09-03524-CW, 2010 WL 1221861, at *2-3 (N.D. Cal. Mar. 24, 2010) (dismissing complaint as failing to meet even the pre-*Iqbal*, minimalist approach because it did not notify defendant of the methods it was allegedly infringing). Thus, the Complaint is inadequate under even the minimalist, fair notice standard (or any standard, for that matter) and should be dismissed.

4. Plaintiffs' Complaint Evinces a Lack of Required Due Diligence and Pre-filing Investigation

As noted above, Plaintiffs are trying to improperly "resort[] to the judicial process and the aid of discovery" to support their claims, instead of substantiating their legal conclusions with factual allegations. (D.E. 1 ¶ 18.) The federal pleading standard, however, "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 556 U.S. at 678-679. Nor do the Patent Rules have tolerance for Plaintiffs' lack of due diligence in bringing suit. To the contrary, "[t]he Patent Rules demonstrate high expectations as to *plaintiffs' preparedness* before bringing suit." *Am. Video Graphics, L.P. v. Elec. Arts, Inc.*, 359 F. Supp. 2d 558, 560 (E.D. Tex. 2007) (emphasis added). Indeed, Plaintiffs' deficient pleading demonstrates their utter *lack* of preparedness.

In violation of *Twombly*, this lack of preparedness results in Mylan having no clear and fair notice as to the factual grounds on which the two Counts rest. *Twombly*, 550 U.S. at 556 n.3 ("Without some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement that he or she provide not only fair notice but also the grounds on which the claim rests.") (internal citations omitted); *see also Driessen v. Sony Music Entm't*, No. 2:09-cv-0140-CW, 2012 WL 130412, at *1 (D. Utah Jan. 17, 2012) (granting motion to dismiss where plaintiffs' "imprecise pleading…fails to give clear and fair notice to defendants and increases the expense of litigation").

Courts have repeatedly dismissed patent infringement claims akin to these for failure to identify the infringing method or conduct, or the accused product. *See, e.g., Gradient Enter., Inc. v. Skype Tech., Inc.*, No. 10-CV-6712L, 2012 WL 864804, at *3 (W.D.N.Y. Mar. 13, 2012) (granting motion to dismiss where complaint "simply alleges that defendants have infringed [the patent in suit]" by their systems and methods); *Lyda v. Fremantlemedia North Am., Inc.*, No. 10 Civ 4773, 2011 WL 2898313, at *3 (S.D.N.Y. July 14, 2011) (granting motion to dismiss where "Plaintiff fails to plead any information that identifies the infringing product or method"); *Enlink Geoenergy Serv., Inc.*, 2010 WL 1221861, at *1 (granting motion to dismiss where "Plaintiff has not identified the activity that [defendant] allegedly undertakes that infringes Plaintiff's patents.").

In addition to specifying the allegedly infringing method or process (which they did not), Plaintiffs must also identify *how* such methods meet the claim limitations of the '486 patent. Plaintiffs have failed to do so. Because they are wholly devoid of any allegations of what the '486 patent covers or how Mylan's allegedly infringing methods read on those claims, infringement Counts I and II must be dismissed. *Cal. Inst. of Computer Assisted Surgery, Inc. v.*

Med-Surgical Servs., Inc., No. 10-02042 CW, 2010 WL 3063132, at *2 (N.D. Cal. Aug. 3, 2010) (granting motion to dismiss infringement allegations because plaintiff "fails to allege with any specificity what [the allegedly infringing product] is and how it infringes upon any of its four patents"); *Bender v. LG Elecs. U.S.A. Inc.*, No. C 09-02114-JF, 2010 WL 889541, at *6 (N.D. Cal. March 11, 2010) (requiring sufficient infringement allegations to provide at least "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").

In fact, the Complaint is so devoid of factual allegations as to suggest that Plaintiffs failed to engage in the pre-filing investigation required by Rule 11(b)(3). Rule 11(b)(3) "requires an attorney who files a patent infringement action to compare the accused device with the construed patent claims…[and to] make a reasonable effort to determine whether the accused device satisfies each of the claim limitations." *Antonious v. Spalding & Evenflo Co.*, 275 F.3d 1066, 1073-1074 (Fed. Cir. 2002). "Simply guessing or speculating that there may be a claim is not enough." *Elan Microelec. Corp.*, 2009 WL 2972374, at *4. Instead, a plaintiff "should be able to articulate at least some facts as to why it is reasonable to believe there is infringement." *Id.* As the Federal Circuit has noted:

> [Rule 11] require[s] the law firm to, at a bare minimum, apply the claims of each and every patent that is being brought into the lawsuit to an accused device and conclude that there is a reasonable basis for a finding of infringement of at least one claim of each patent so asserted. The presence of an infringement analysis plays the key role in determining the reasonableness of the pre-filing inquiry made in a patent infringement case under Rule 11.

View Eng'g, Inc. v. Robotic Vision Sys., Inc., 208 F.3d 981, 985-86 (Fed. Cir. 2000) (affirming Rule 11 sanctions where the only basis for the filing was the belief that defendants "*probably infringed*" the patents) (emphasis added).

Plaintiffs' Complaint fails to meet the *Twombly/Iqbal* pleading standard because it does not identify the purportedly infringing method and how such unidentified method allegedly infringes the many methods of the '486 patent. Further, the Complaint fails to put Mylan on fair notice. Lastly, these failures suggest that Plaintiffs neglected to conduct the required pre-filing due diligence investigation to support their conclusory assertion of infringement. For all of the foregoing reasons, Mylan submits that the Complaint should be dismissed with prejudice.

C. Dismissal With Prejudice is Warranted

Although a plaintiff facing dismissal for failure to state a claim is often afforded an opportunity to amend a complaint, dismissal with prejudice and without leave to amend is warranted where "amendment would be inequitable or futile." *Phillips*, 515 F.3d at 245; *see also Riordan v. H.J. Heinz Co.*, No. 08-1122, 2009 WL 4782155, at *43 (W.D. Pa. Dec. 8, 2009) (dismissing complaint with prejudice where "Plaintiff has failed to set forth sufficient facts to demonstrate a plausible claim to relief" and "amendment cannot cure these deficiencies"). The Court should dismiss Plaintiffs' patent infringement claims with prejudice because it is not likely that Plaintiffs can re-plead sufficient facts to state a claim.

If Plaintiffs were aware of any activities by Mylan that allegedly infringe the '486 patent, they would have listed those activities in the Complaint. But they did not. Plaintiffs' failure to include any such activities shows that Plaintiffs are unaware of any infringement (because there is none). Moreover, as they admittedly have no knowledge of Mylan's methods of manufacture, it is impossible for Plaintiffs to be able to draft a sufficient complaint in the near future.

Under such circumstances, Plaintiffs should not be permitted to consume more of the Court's time and resources with attempts at re-pleading what appear to be baseless and frivolous allegations. *See Colida v. Nokia, Inc.*, 347 F. App'x 568, 569-570 (Fed. Cir. 2009) (affirming dismissal and imposition of anti-filing injunction against repeat patent infringement plaintiff

where complaint failed to specify key "facts relevant to the question of infringement" and where plaintiff was "no stranger to patent litigation"). Therefore, the Complaint should be dismissed with prejudice.

III. CONCLUSION

For all the foregoing reasons, Mylan respectfully requests that this Court dismiss with prejudice Plaintiffs' Complaint.

WHEREFORE, Defendant, Mylan Pharmaceuticals, Inc., respectfully requests that the Complaint filed against it by Plaintiffs, Apotex, Inc. and Apotex Corp., be dismissed with prejudice for the reasons set forth above and that Mylan be awarded its attorneys' fees and costs to the fullest extent permitted by law and any further relief that the Court deems appropriate.

Respectfully submitted,

By: s/ Eric D. Isicoff
Eric D. Isicoff
Florida Bar No.: 372201
Isicoff@irlaw.com
Susan Warner
Florida Bar No.: 38205
Warner@irlaw.com
ISICOFF, RAGATZ & KOENIGSBERG
1200 Brickell Avenue, Suite 1900
Miami, Florida 33131
Tel: (305) 373-3232
Fax: (305) 373-3233

OF COUNSEL:
Thomas J. Parker
thomas.parker@alston.com
Deepro R. Mukerjee
deepro.mukerjee@alston.com
Poopak Banky
paki.banky@alston.com
ALSTON & BIRD LLP
90 Park Avenue
New York, NY 10016-1387
Tel: 212-210-9400
Fax: 212-210-9444

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 2nd 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/ Eric D. Isicoff
Eric D. Isicoff

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

Matthew S. Nelles Broad and Cassel One Financial Plaza 100 S.E. Third Ave., Suite 2700 Fort Lauderdale, FL 33394 *Attorneys for Plaintiffs Apotex Corp. and Apotex Inc.* Service via CM/ECF	Robert B. Breisblatt Brian J. Sodikoff Christopher B. Ferenc Dennis C. Lee Eric C. Cohen Martin S. Masar, III Suresh B. Pillai Katten Muchin Rosenman LLP 525 West Monroe Street Chicago, IL 60661-3693 *Attorneys for Plaintiffs Apotex Corp. and Apotex Inc.* Service via CM/ECF