IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVERIO PHARMA GMBH, BAYER AG, and BAYER HEALTHCARE PHARMACEUTICALS INC.,	:	
Plaintiffs,	:	
v.	:	C. A. No. 18-73-LPS
ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, INC., and INC RESEARCH, LLC	:	
Defendants.	:	

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MEMORANDUM OPINION

February 13, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

Pending before the Court is Defendant INC Research, LLC's ("INC") motion to dismiss (D.I. 15) Plaintiffs Adverio Pharma GmbH, Bayer AG, and Bayer Healthcare Pharmaceuticals Inc.'s (collectively, "Adverio" or "Plaintiffs") complaint. (D.I. 1) Having considered the parties' submissions (D.I. 16, 20, 21, 22, 31) and heard oral argument (D.I. 32 ("Tr.")), the Court will grant the motion.

BACKGROUND

Plaintiffs have legal rights in relation to New Drug Application ("NDA") No. 204819, which covers their branded drug product Adempas®, indicated for the treatment of persistent/recurrent chronic thromboembolic pulmonary hypertension or pulmonary arterial hypertension. (D.I. 1 ¶ 32)[1] Plaintiffs also have legal rights in U.S. Patent No. 6,743,798 (the "'798 patent"), entitled "Substituted Pyrazole Derivatives Condensed with Six-Membered Heterocyclic Rings," which is listed in the "Orange Book" – i.e., "Approved Drug Products With Therapeutic Equivalence Evaluations" – as associated with Adempas®. (*Id.* ¶¶ 28, 33)[2]

Defendants Alembic Pharmaceuticals Limited ("APL") and its two wholly-owned subsidiaries, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc. (collectively, the three Alembic Defendants are referred to hereinafter as "Alembic"), seek to market a generic version of Adempas® (the "ANDA Product") prior to the expiration of the '798 patent. (*Id.* ¶¶ 1, 9, 10) Accordingly, Alembic has filed with the United States Food & Drug Administration

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[1]Bayer HealthCare is the holder of the NDA. (D.I. 1 ¶ 32)

[2]Adverio Pharma is the assignee of the '798 patent and Bayer AG is the exclusive licensee in the United States. (D.I. 1 ¶¶ 30-31)

("FDA") Abbreviated New Drug Application ("ANDA") No. 211127. (*Id.* ¶ 1) On December 1, 2017, Alembic provided notice to Plaintiffs "that Alembic had submitted ANDA No. 211127 seeking approval to commercially manufacture, use, import, offer for sale, and sell Defendants' ANDA Product." (*Id.* ¶ 25) Alembic certified its belief that its proposed generic drug product would not infringe the '798 patent and that the patent is invalid. (*Id.* ¶ 38; *see also* 21 U.S.C. § 255(j)(2)(B))

In response, Adverio filed its complaint on January 9, 2018, within the 45 days permitted for a patentee in this situation to obtain the benefit of an automatic 30-month stay of FDA approval of an ANDA. *See* 21 U.S.C. § 355(c)(3)(C); D.I. 1 ¶ 41. In its complaint (*see* D.I. 1 ¶ 45), Adverio alleges that Alembic's submission of its ANDA to the FDA is an act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A), which provides:

> It shall be an act of infringement to submit [to the FDA] an application [for approval of a drug product] if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent . . . .

Adverio further names INC as a Defendant. The complaint's allegations against INC are sparse. Other than statements relating to INC's connections to Delaware, the allegations against INC consist entirely of the following:

> 8. . . . On information and belief, INC Research is in the business of, among other things, performing contract research for pharmaceutical companies.
>
> . . .
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> 11. On information and belief, Alembic Pharma and/or INC Research are designated U.S. FDA agent(s) for APL.
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> 12. On information and belief, Defendants acted in concert to prepare

and submit ANDA No. 211127 to the FDA.

(D.I. 1 ¶¶ 8, 11, 12)

Other than the collective, generalized allegation "[o]n information and belief" that all Defendants, presumably including INC, "acted in concert to prepare and submit" the ANDA (*id.* ¶ 12), there is no specific, express allegation that INC played any role in the preparation of the ANDA. Nor is there any specific, express allegation that INC will benefit financially from the FDA's approval of the ANDA or that INC intends to (or will be) involved in the commercial manufacture, use, or sale of the proposed ANDA Product. The complaint does not seek any particular relief against INC, apart from the relief already sought from "Defendants" as a whole.

LEGAL STANDARDS

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

A well-pleaded complaint must contain more than mere labels and conclusions. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A plaintiff must plead facts sufficient to show that a claim has substantive plausibility.

See Johnson v. City of Shelby, 135 S. Ct. 346, 347 (2014). A complaint may not be dismissed, however, for imperfect statements of the legal theory supporting the claim asserted. *See id.* at 346.

"To survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). A claim is facially plausible "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. At bottom, "[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element" of a plaintiff's claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted).

The Court is not obligated to accept as true "bald assertions," *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are "self-evidently false," *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

DISCUSSION

It is undisputed that APL is an Indian corporation. (*See* D.I. 1 ¶ 5; D.I. 18 ¶ 5) When a foreign entity like APL seeks to file an ANDA, it must appoint "an attorney, agent, or other authorized official who resides or maintains a place of business within the United States" to sign the application. 21 C.F.R. § 314.50(a)(5). As INC asserts, the only substantive allegation

directly connecting INC to Alembic's ANDA is that INC was the U.S. FDA agent for Alembic. (*See* D.I. 16 at 2)[3] INC argues that it must be dismissed from this case because "[s]imply serving as a U.S. FDA agent for a foreign entity in connection with an ANDA filing does not create a basis for liability under 35 U.S.C. § 271(e)(2)." (*Id.*) Under the allegations pled here, the Court agrees with INC.

A. Relevant Case Law

"The Hatch-Waxman Act [21 U.S.C. § 355] does not provide a definition of 'submit.'" *In re Rosuvastatin Calcium Patent Litig.*, 2008 WL 5046424, at *10 (D. Del. Nov. 24, 2008) ("*Rosuvastatin I*"). Nor, as the parties agree, is there any binding decision that answers the question of what is required in order for an entity such as INC to be deemed to have "submitted" an ANDA to the FDA, and thus to be a proper defendant and potentially liable for infringement. The relevant case law, which includes a concurring opinion from the Court of Appeals for the Federal Circuit as well as several district court decisions, supports the conclusion that the allegations against INC are insufficient.

A decade ago, the undersigned Judge, then sitting as a Magistrate Judge, addressed a similar question. In *Rosuvastatin I*, the issue was whether two wholly-owned U.S. subsidiaries which signed an ANDA as U.S. agents for their foreign parent-applicant had "submitted" the ANDA. The Court concluded that the U.S. subsidiaries had "submitted" the ANDA, stating:

> [A] wholly-owned subsidiary of a foreign ANDA applicant, which signs an ANDA as the agent of its parent-applicant, and which intends to benefit directly if the ANDA is approved by

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[3]Alembic admits that APL appointed INC "to be the U.S. authorized agent to submit and receive all correspondence on technical and administrative matters pertaining to APL's submission" of ANDA No. 211127. (D.I. 18 ¶ 11)

> participating in the manufacture, importation, distribution, and/or sale of the generic drug [i]s subject to suit under § 271(e) as one who has "submitted" an ANDA.

Id. at *10. Accordingly, the Court recommended that the U.S. subsidiaries not be dismissed from the case.

In explaining its conclusion, the Court emphasized the gravity of the subsidiary having made representations as to the truth and accuracy of the information in the ANDA under threat of criminal prosecution, and of the subsidiary having undertaken the obligation to update the application with new safety information. *See id.* at *10-11. The Court distinguished the U.S. subsidiary defendants "from attorneys signing as mere agents" by noting that the subsidiary defendants (unlike attorneys):

> are alleged to be wholly-owned subsidiaries of the foreign "applicants," are alleged to have participated in the preparation of the ANDAs, and are alleged to be involved in "marketing, distributing, and selling generic pharmaceutical products within the United States" in concert with their foreign counterparts.

Id. at *11.

The *Rosuvastatin I* decision was in accord with other similar cases that predated it. *See id.* (citing *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 306-07 (D. Md. 2007) ("[W]hen a wholly-owned U.S. subsidiary of a foreign corporation exists to distribute foreign-produced generic drugs in the U.S. and is actively involved in the ANDA process, the subsidiary also 'submits' an ANDA application."); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 494 (E.D. Va. 2005) (refusing to dismiss wholly-owned U.S. subsidiary that "countersigned an ANDA application on its parent's behalf . . . where it appears to be the parent's marketing arm in

the United States")).[4]

After reviewing objections to the undersigned Judge's recommendation, Retired Judge Joseph J. Farnan, Jr. adopted the *Rosuvastatin I* position. *See Astrazeneca Pharm. LP v. Aurobindo Pharma Ltd.*, 2009 WL 483131, at *3 (D. Del. Feb. 25, 2009) ("*Rosuvastatin II*"). Later, in connection with a post-trial motion, Judge Farnan declined to reconsider his decision. *See In re Rosuvastatin Calcium Patent Litig.*, 719 F. Supp. 2d 388, 396-98 (D. Del. 2010) ("*Rosuvastatin III*"). With the benefit of a fully-developed record, Judge Farnan found that one of the U.S.-based signers ("Apotex USA") was not actually a wholly-owned subsidiary of the foreign parent-applicant ("Apotex Canada"), but he determined nonetheless that "the two companies are closely related" and "hold themselves out publicly and internally as part of the Apotex Group of companies." *Id.* at 397. Moreover, Judge Farnan found that Apotex USA "actively participated in activities related to the ANDA submission," including by assisting in the preparation of the ANDA, and that Apotex USA "intends to directly benefit from the approval of the ANDA" because, as the "marketing arm" of Apotex Canada, it intends "to market and sell" the generic product in the United States. *Id.*; *see also id.* at 396 (finding *Rosuvastatin III* decision supported by other post-*Rosuvastatin I* decisions, including *Cephalon, Inc. v. Watson Pharm., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009) (Robinson, J.) ("Parties 'actively involved' in preparing the ANDA are deemed to have 'submit[ted]' the ANDA, regardless of

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[4]Other cases that were distinguished in *Rosuvastatin*, *Wyeth,* and *Aventis* were *SmithKline Beecham Corp. v. Geneva Pharm., Inc.*, 287 F. Supp.2d 576, 584 (E.D. Pa. 2002), and *SmithKline Beecham Corp. v. Pentech Pharm., Inc.*, 2001 WL 184804, at *2 (N.D. Ill. Feb. 20, 2001). In those cases, courts held that third-party manufacturers of the active ingredient for proposed ANDA products, who were uninvolved in the submission of the ANDA, were ***not*** "submitters" within the meaning of the statute.

whether they are the named applicant, . . . especially . . . where the parties involved are in the same corporate family. . . . 'Active involvement' includes 'marketing and distributing the approved generic drugs in the United States.'") (quoting *Wyeth*, 505 F. Supp. 2d at 306-07); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 417 (D. Del. 2010) (Robinson, J.)).

On appeal, the Federal Circuit affirmed Judge Farnan's decision to hold Apotex USA liable as a "submitter" based on Apotex USA's admissions that it "participated in preparation of the ANDA" and "would sell the product in the United States." *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 529 (Fed. Cir. 2012) ("*Rosuvastatin IV*"). In a concurring opinion, Judge Plager addressed what he described as "a question of first impression." *Id.* at 529. Focusing on the language of 35 U.S.C. § 271(e)(2)(A) – which contains as a prerequisite to liability that "***the purpose*** of such [ANDA] submission is to obtain approval . . . ***to engage in the commercial manufacture, use, or sale*** of a drug" (emphasis added) – Judge Plager concluded, "[i]t would make little sense to read the statute as making such agents [i.e., attorneys or others acting as agents for the real party in interest] liable for the artificial 'act of infringement' created therein." *Id.* at 529-30. Thus, Judge Plager concluded that "[a]n agent who simply prepares and submits the application as such is not an applicant; it is the real party in interest – the commercial manufacturer – who is the statutory applicant who 'submit[s]' the application and commits the act of infringement." *Id.* at 530.

To Judge Plager, then, a prerequisite to being deemed to have "submit[ted]" an ANDA is to have "a financial interest beyond simply acting ***for*** the commercial manufacturer;" an interest in, for instance, "the manufacture or distribution of the drug that is the subject of the ANDA."

Id. at 529-30 (emphasis added). He added that "planning, preparation, and submission of the application . . . alone cannot create liability." *Id.* at 530. In *Rosuvastatin IV*, since Apotex USA had not only assisted Apotex Canada in preparing the application, but also clearly intended to sell the generic drug in the U.S., Judge Plager concluded that Apotex USA was a submitter under the statute. *See id.* at 530-31.

B. The Court's Understanding of "Submit" and "Submitter"

Consistent with Judge Plager's analysis in concurrence in *Rosuvastatin IV*, this Court understands that in order to be subject to liability for infringement, Section 271(e)(2)(A) requires that one "submit" an application ***for the purpose of*** "engag[ing] in the commercial manufacture, use, or sale" of the generic drug. In other words, the filing entity must intend to financially benefit, in a significant manner, from the FDA's ***approval*** of the application. An entity that signs an ANDA is a "submitter" if it intends to be financially compensated for active involvement in the commercial manufacture, use, or sale of the generic drug.

By contrast, an entity that merely assists in collecting materials for submission to the FDA, signs the ANDA, presents the ANDA to the FDA for approval, and acts in an ongoing manner as the liaison between the FDA and the applicant during the regulatory process, but will have no involvement with the ANDA product following FDA approval, is not a submitter.

As Judge Plager explained, these conclusions flow from the statutorily-defined act of infringement in an ANDA proceeding. Pursuant to § 271(e)(2)(A), "[i]t shall be an act of infringement" to submit an ANDA "***if***" (which the Court reads as "if but only if") "the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug" (emphasis added). If, instead, the "purpose of such submission" is merely to assist a

foreign entity to obtain a position by which that foreign entity may manufacture, use, or sell a drug, and the assisting entity will not be (and does not intend to be) involved in the commercial manufacture, use, or sale of the drug, then the assisting entity is not a "submitter" within the scope of § 271(e)(2)(A).

Other factors – such as the formal corporate relationship (e.g., parent-subsidiary), if any, between the "real filer in interest" and the entity filing the ANDA on the former's behalf; the entity's participation, or not, in preparation of the ANDA; and the financial compensation the assisting entity is receiving – are not dispositive, and, in most (maybe all) instances, will not even be pertinent to assessing whether the entity is a "submit[ter]." If the assisting entity is paid to assist with the preparation and filing of the ANDA, and is paid to interact with the FDA on behalf of the submitter throughout the review process, these payments do not transform the assisting entity into a submitter itself; whether the entity is a submitter depends on whether it is also going to engage in the commercial manufacture, use, or sale of the proposed generic drug product. This is so even if some or all of the assisting entity's compensation is contingent on the FDA approving the proposed generic drug product. What matters is the role, if any, the assisting entity will play after the proposed product receives FDA approval. If the assisting entity will not at that point be involved in the commercial manufacture, use, or sale of the drug, then it is not a submitter.

Under this reasoning, an attorney hired to represent a foreign entity submitter of an ANDA is not, herself, a submitter. Unless the attorney will be (or at least intends to be) involved in the "commercial manufacture, use, or sale of a drug," the attorney has not "submitted" the

ANDA as contemplated by the statute.[5]

C. Application to Pending Complaint

Turning to the facts alleged here, the only substantive, specific allegations concerning INC are that INC is "in the business of, among other things, performing contract research for pharmaceutical companies" and is a "designated U.S. FDA agent[] for APL." (D.I. 1 ¶¶ 8, 11) Although Adverio alleges that all defendants "acted in concert to prepare and submit ANDA No. 211127 to the FDA" and all "intend[] to engage in the marketing, commercial manufacture, use, offer for sale, sale, and/or importation" of the generic drug if approved (*id.* ¶¶ 12, 35; *see also id.* ¶¶ 13, 22, 43), allegations lumping multiple defendants together without providing allegations of individual conduct are frequently (as here) insufficient to satisfy the notice pleading standard. *See T-Jat Sys. 2006 Ltd. v. Expedia, Inc.*, 2017 WL 896988, at *7 (D. Del. Mar. 7, 2017).

Here, the group allegations, which are pled "on information and belief," are inadequate because they do not include a plausible allegation that INC will have a role in the commercial manufacture, use, or sale of Alembic's proposed ANDA Product. *See generally SCOMA Chiropractic, P.A. v. Jackson Hewitt Inc.*, 2017 WL 3149360, at *2 (M.D. Fla. July 25, 2017)

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[5]The Court recognizes that in *Rosuvastatin I* it emphasized the significant representations that are made regarding the truth and accuracy of the information in the ANDA when one, even an attorney, signs the application. *See* 2008 WL 5046424, at *10-11 ("Weighing heavily in favor of this holding are the representations the Submitter Defendants made by signing the ANDAs. . . . [T]he representations the Submitter Defendants made when signing the ANDAs are inconsistent with those that would be made by an unknowing agent, and [Plaintiff] was entitled to rely on these representations."). With the benefit of Judge Plager's analysis, the Court now believes that it placed too much weight on these representations as a factor in assessing whether an entity (or individual) has "submitted" an ANDA as that term is used in Section 271(e)(2)(A). One who makes false representations to the FDA should, and likely does, face significant consequences. Nevertheless, one who does so without any intent to be involved in the commercial manufacture, use, or sale of a proposed generic drug product is not liable as a "submitter" of an ANDA.

(finding allegations "on information and belief" to be "insufficient to state a plausible claim against multiple defendants"); *see also Robbins v. Oklahoma*, 519 F.3d 1242, 1249-50 (10th Cir. 2008) ("Fair notice under Rule 8(a)(2) depends on the type of case . . . . [I]t is particularly important in [some] circumstances that the complaint make clear exactly ***who*** is alleged to have done ***what*** to ***whom***, to provide each individual with fair notice as to the basis of the claims against him or her, as distinguished from collective allegations against the state.").

As counsel for INC pointed out during the hearing, the complaint contains no allegations that INC "was the ANDA applicant or that [it is] corporately related to the ANDA applicant." (Tr. at 20) Further, there are no allegations that INC "was actively involved in the preparation of the ANDA application . . . [and] no allegation [is] made in the complaint that INC Research intends to benefit down the road through the commercial manufacture, sale or distribution of the drug at issue." (*Id.* at 21) Although Adverio argued at the hearing that its allegations against INC would satisfy Judge Plager's requirement of "receiving a financial benefit" (*id.* at 33), the Court disagrees. The financial benefit INC is receiving is not, based on the current complaint, "a financial interest in the manufacture or distribution of the drug that is the subject of the ANDA." *Rosuvastatin IV*, 703 F.3d at 530.

Finally, and notably, the Court can provide complete relief to Adverio, consistent with the purposes of the Hatch-Waxman Act, even without entering an order directed to INC. There is no basis to conclude that retention of INC as a defendant is necessary in order to achieve the timely, pre-launch resolution of patent disputes between the parties with interests in the patents protecting a branded drug and the parties who will be involved in the commercial manufacture, use, and sale of a potential generic competitor drug. Adverio has pointed out that INC, as agent,

is responsible for notifying the FDA of any judgment the Court might enter in this action. (*See* Tr. at 32-33) Should this case result in entry of judgment against Alembic, and should INC continue not to be a party, Adverio may ask the Court to exercise whatever authority it has over Alembic to ensure that the FDA receives the required notice of judgment.

D. Leave to Amend

Adverio requests leave to amend its complaint to add allegations that "part of INC's business model is to serve as the FDA agent for foreign ANDA filers." (D.I. 20 at 8) Given the Court's analysis, the addition of such allegations, without more, would be futile. The amended complaint could not withstand a renewed motion to dismiss. In order for INC to be liable as a "submitter" of the ANDA, Adverio will need to allege (and ultimately prove) that INC intends to be and/or will be involved in the future commercial manufacture, use, or sale of the ANDA Product. To date, Adverio has not alleged that such intent or involvement is part of INC's "business model."[6]

Nevertheless, should Adverio have or develop a good faith basis to allege that INC intends to be or will be involved in the commercial manufacture, use, and/or sale of Alembic's ANDA Product, at that point Adverio may seek leave to file an amended complaint.

CONCLUSION

At the hearing, counsel for Adverio acknowledged that, at this point, "we don't know what exactly the relationship between INC and Alembic is with respect to the financial benefits flowing to INC." (Tr. at 29) While it is understandable that Adverio does not know, without

[6]Nor does it appear that Adverio, which has had a copy of the agreement controlling the relationship between INC and Alembic since last June (*see* D.I. 31), believes such a role is part of INC's business model.

discovery, "what the relationship is between INC and Alembic" and how much, and on what terms, INC is being compensated (*id.* at 29-30), it is also true that there is no allegation (or reasonable basis to infer) that INC will be involved in the commercial manufacture, use, or sale of Alembic's proposed ANDA Product after FDA approval. Therefore, while it was entirely appropriate for Adverio to rely on INC's signature on the ANDA as a basis to sue INC (particularly within the relatively short 45-day period given to the patentee to file suit and obtain the benefit of the 30-month automatic stay of regulatory approval of an ANDA), at this point it is appropriate to dismiss INC as a defendant.

Accordingly, INC's motion to dismiss (D.I. 15) will be GRANTED. Adverio's request for leave to file an amended complaint is denied.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVERIO PHARMA GMBH, BAYER AG, and BAYER HEALTHCARE PHARMACEUTICALS INC.,	:	
Plaintiffs,	:	
v.	:	C. A. No. 18-73-LPS
ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, INC., and INC RESEARCH, LLC	:	
Defendants.	:	

ORDER

At Wilmington this **13th** day of **February 2019**:

For the reasons stated in the Memorandum Opinion issued this same date, **IT IS HEREBY ORDERED** that INC Research, LLC's motion to dismiss (D.I. 15) is **GRANTED**.

UNITED STATES DISTRICT COURT