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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,	) C.A. No. 2:18-cv-03347-CCC-MF
Plaintiffs,	) **(RETURN DATE: JANUARY 7, 2019)**
v.	) **ORAL ARGUMENT IS REQUESTED**
ADELLO BIOLOGICS, LLC, AMNEAL PHARMACEUTICALS, LLC, and AMNEAL PHARMACEUTICALS, INC.	) **DEFENDANTS AMNEAL PHARMACEUTICALS LLC'S AND AMNEAL PHARMACEUTICALS, INC.'S NOTICE OF MOTION**
Defendants.	) **TO DISMISS THE CLAIMS AGAINST THEM IN PLAINTIFFS' FIRST AMENDED COMPLAINT**

TO: ALL COUNSEL

PLEASE TAKE NOTICE that on January 7, 2019 at 10:00 a.m. or as soon thereafter as counsel may be heard, Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals,

Inc. (collectively, "Amneal"), through their attorneys, will move before the Honorable Claire C. Cecchi, United States District Court Judge for the District of New Jersey, for an Order dismissing the claims against them in Plaintiffs' First Amended Complaint for Patent Infringement [Dkt. 50].

PLEASE TAKE FURTHER NOTICE that in support of this Motion, Amneal submits the accompanying Brief in Support of Amneal's Motion to Dismiss.

PLEASE TAKE FURTHER NOTICE that a proposed form of Order is also submitted herewith for the Court's consideration in accordance with Local Civil Rule 7.1(e).

Dated: December 5, 2018

By: *s/ Gregory D. Miller*
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IN THE UNITED STATES DISTRICT COURT
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AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. ADELLO BIOLOGICS, LLC, AMNEAL PHARMACEUTICALS, LLC, and AMNEAL PHARMACEUTICALS, INC. Defendants.	)	C.A. No. 2:18-cv-03347-CCC-MF (RETURN DATE: JANUARY 7, 2019) ORAL ARGUMENT IS REQUESTED

DEFENDANTS AMNEAL PHARMACEUTICALS LLC'S AND AMNEAL PHARMACEUTICALS, INC.'S BRIEF IN SUPPORT OF MOTION TO DISMISS THE CLAIMS AGAINST THEM IN FIRST AMENDED COMPLAINT

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I. PRELIMINARY STATEMENT

Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. (collectively, "Amneal" or "the Amneal Defendants") move to dismiss Plaintiffs' claims against them in Plaintiffs' First Amended Complaint for Patent Infringement [Dkt. 50] because they fail to state a claim under Rule 12(b)(6) and lack subject-matter jurisdiction under Rule 12(b)(1). Plaintiffs brought this action under the Biologics Price Competition and Innovation Act of 2009 (BPCIA) and the Declaratory Judgment Act, Amend. Compl. ¶7, but neither statute supports Plaintiffs' claims. The Supreme Court has explained that the BPCIA "sets forth a carefully calibrated scheme" for parties to adjudicate claims for BPCIA infringement. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017). Only specific entities are authorized to litigate BPCIA claims: "the manufacturer of a biosimilar (applicant)" and "the manufacturer (sponsor) of a previously licensed biologic"; and a specific act—the "submission of a biosimilar application" to the FDA—is an "artificial" act of infringement that entitles a patent owner to bring an infringement action against the applicant. *Id.*; 42 U.S.C. ¶ 262(l); 35 U.S.C. ¶ 271(e)(2)(C)(i)-(ii). Based on these requirements, the Amneal Defendants are not proper BPCIA defendants, and they are not alleged to have committed any acts of infringement under the BPCIA. As a result, Plaintiffs' BPCIA claims against Amneal must be dismissed.

Plaintiffs' Complaint makes it clear that Defendant Adello Biologics, not Amneal, is the only biosimilar manufacturer and applicant in this case, and the only party accused of committing acts of infringement under the BPCIA. Plaintiffs acknowledge that Adello "submit[ted] an abbreviated Biologics License Application (aBLA) to the FDA under [the BPCIA] seeking approval to market a biosimilar filgrastim product, and designating Amgen's Neupogen® as the reference product." Jt. Proposed Discovery Plan [Dkt. 37-1] at 2; *see* Amend. Compl. ¶ 14. Plaintiffs' Amended Complaint refers to the only aBLA in this case as "the *Adello* aBLA." Amend. Compl. ¶14 (emphasis added). Plaintiffs' Amended Complaint does not refer to any other aBLA or application, and does not refer to Amneal in connection with any aBLA or application. Moreover, Plaintiffs' Amended Complaint refers to Adello as the "biosimilar applicant." *Id.* ¶ 9 ("The [BPCIA] abbreviated pathway . . . allows ***a biosimilar applicant (here Adello)***. . ."") (emphasis added). Plaintiffs do not refer to Amneal or any other party as a biosimilar applicant. Finally, Plaintiffs' Amended Complaint states that Adello's submission of its aBLA "is an act (or acts) of infringement." *Id.* ¶ 22; *see also id.* ¶¶ 14, 17. Plaintiffs do not allege that Amneal submitted any application to the FDA, or that Amneal committed any acts of infringement under the BPCIA.

With respect to Plaintiffs' Declaratory Judgment claims, Plaintiffs have failed to allege that Amneal has done anything substantial enough to create a

current case or controversy "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment" and establish subject-matter jurisdiction. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). Plaintiffs' Amended Complaint does not allege that Amneal has done anything relating to the filgrastim biosimilar besides "enter[ing] into a license and commercialization agreement with Adello," which assigns Amneal responsibility for "marketing, selling and pricing the Adello Filgrastim Product" sometime in the future if and when FDA approval has been obtained. *Id.* ¶ 19. Plaintiffs do not allege that Amneal is doing anything currently to bring Adello's product to market – in fact, until FDA approval is obtained, it would be illegal for Amneal to market or sell the product. Moreover, even if the alleged facts were sufficient to create jurisdiction (which they are not), this Court should nevertheless decline to exercise declaratory jurisdiction because to do so would upend the carefully crafted BPCIA statutory scheme that Congress created.

II. THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2009

The BPCIA creates an abbreviated pathway to obtain FDA approval of a biological pharmaceutical product that is a biosimilar to a previously licensed product. *See* 42 U.S.C. § 262(k). As the Supreme Court has noted, "[t]he complex statutory scheme [of the BPCIA] establishes processes both for obtaining FDA approval of biosimilars and for resolving patent disputes *between manufacturers of*

licensed biologics and manufacturers of biosimilars." *Sandoz*, 137 S. Ct. at 1669 (emphasis added). In particular, the BPCIA "provides that the mere submission of a biosimilar application constitutes an act of infringement" under 35 U.S.C. § 271(e)(2)(C)(i)-(ii). *Id*. at 1670; *see also* 35 U.S.C. § 271(e)(2)(C)(ii) ("It shall be an act of infringement to submit . . . an application seeking approval of a biological product"). By creating a cause of action for "'artificial' infringement," the BPCIA allows the manufacturer of a licensed biologic product (the "sponsor") and the biosimilar manufacturer (the "applicant") to litigate any patent dispute before a traditional act of patent infringement occurs. *Sandoz*, 137 S. Ct. at 1670. The Supreme Court contrasted this "artificial infringement" with "act[s] that would traditionally constitute patent infringement" such as "making, using, offering to sell, or selling any patented invention within the United States without authority to do so." *Id*. at 1671.[1]

Upon submission of a biosimilar application, the "BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Id.* (citing 42 U.S.C. § 262(l)). If the biosimilar applicant

[1] *See generally* 35 U.S.C. § 271(a) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."); 35 U.S.C. § 271(g) ("Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.").

and sponsor of the previously-approved biological product comply with each of the detailed steps in the BPCIA, "they will have the opportunity to litigate the relevant patents before the biosimilar is marketed." *Id.* at 1672.

III. PLAINTIFFS' AMENDED COMPLAINT

According to Plaintiffs' Amended Complaint, on September 11, 2017, Adello informed Plaintiffs that it had submitted an application under subsection (k) of the BPCIA for abbreviated FDA approval of a biosimilar to Plaintiffs' previously-licensed filgrastim product, which is sold under the brand name Neupogen®. Amend. Compl. ¶14. Adello also notified Plaintiffs it would begin marketing its filgrastim product "upon receiving FDA approval and no earlier than 180 days from [September 11, 2017]." *Id*. (alteration in original). Plaintiffs specifically allege that by filing the subsection (k) application with the FDA, Adello committed an act of infringement under § 271(e)(2)(c)(ii). *Id*. ¶ 22, 73, 95, 117, 139. Plaintiffs do not accuse Amneal of having violated § 271(e) or committing any act of infringement. *Id*. at 34 (Prayer for Relief) ¶ D.

With respect to Amneal, the Amended Complaint also alleges that "Adello entered into a license and commercialization agreement with Amneal on October 1, 2017." *Id*. ¶ 19. Under the agreement, "Adello is responsible for development, regulatory filings, obtaining FDA approval, and manufacturing the Adello Filgrastim Product," while "Amneal is responsible for marketing, selling and

pricing the Adello Filgrastim Product." *Id*.

Plaintiffs do not allege (because they cannot) that the FDA has approved Adello's biosimilar application. Nor have Plaintiffs alleged any facts suggesting that Amneal has marketed Adello's filgrastim product (this would, of course, be unlawful in the absence of FDA approval). Rather, Plaintiffs' infringement claims concerning Amneal are based entirely on speculation about what Amneal may do sometime in the future. For example, Plaintiffs allege:

- "Defendants *intend to* and *will* make, use, offer to sell, or sell within the United States, or import into the United States the Adello Filgrastim Product, which is made by a process that falls within the scope of one or more claims of the [Asserted Patents], or has [sic] done so already, before the [Asserted Patents] expire[]." *Id*. ¶¶ 68, 90, 112, 134 (emphasis added).

- "Unless enjoined by this Court, upon information and belief, Defendants *will* infringe one or more claims of each of the Asserted Patents under 35 U.S.C. §§ 271(a) and 271(g) by making, using, offering to sell or selling within the United States, or importing into the United States the Adello Filgrastim Product which Adello makes by a process covered by each of the Asserted Patents, before the expiration of each of the Asserted Patents." *Id*. ¶ 23 (emphasis added).

These types of forward-facing allegations are the basis upon which Plaintiffs seek "a declaratory judgment that Amneal has infringed or will infringe one or more claims of the [Asserted Patents] by making, using, offering to sell, or selling within the United States, or importing into the United States the Adello Filgrastim Product before the expiration of the [Asserted Patents]." *Id.* ¶¶ 77, 99, 121, 143. In

their Prayer for Relief, Plaintiffs request a "judgment that Defendants have infringed or will infringe one or more claims of each of the Asserted Patents" under each of 35 U.S.C. §§ 271(a) and 271(g). *Id*. at 34 (Prayer for Relief) ¶¶ A, C. Plaintiffs seek judgment of infringement under §§ 271(b) (induced infringement) and 271(e)(2)(c)(ii) (artificial infringement) only as to Adello, not as to Amneal. *Id*. at 34 (Prayer for Relief) ¶¶ B, D.

IV. THE MOTION TO DISMISS STANDARD

A. Rule 12(b)(6)

A motion to dismiss under Rule 12(b)(6) challenges whether the complaint states a claim for which relief can be granted. Fed. R. Civ. P. 12(b)(6). In analyzing a 12(b)(6) motion, a court "must accept all factual allegations in the complaint as true, construe the complaint in the light favorable to the plaintiff, and ultimately determine whether plaintiff may be entitled to relief under any reasonable reading of the complaint." *Mayer v. Belichick*, 605 F.3d 223, 229 (3d Cir. 2010). "In order to withstand a motion to dismiss, 'a complaint's [f]actual allegations must be enough to raise a right to relief above the speculative level.'" *Id.* (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 230 (3d Cir. 2008)). This "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must contain "sufficient factual allegations so as to state a facially

plausible claim for relief," and the court is "not required to accept legal conclusions alleged in the complaint." *Belichick*, 605 F.3d at 229–30. "A claim possesses such 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.'" *Id.* (quoting *Gelman v. State Farm Mut. Auto Ins. Co.*, 583 F.3d 187, 190 (3d Cir. 2009)).

B. Rule 12(b)(1)

A Rule 12(b)(1) motion challenges the existence of subject-matter jurisdiction. Fed. R. Civ. P. 12(b)(1). A Rule 12(b)(1) motion presents "a procedural question not unique to patent law," and therefore is governed by regional circuit law. *Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1380 (Fed. Cir. 2002). A Rule 12(b)(1) motion can either present a facial or factual attack on the existence of subject-matter jurisdiction. *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). A facial attack contests the sufficiency of the pleadings, whereas a factual attack contests jurisdictional facts. *Lincoln Benefit Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). "In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." *Id.* (quoting *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000)). The party asserting subject-matter jurisdiction— here, ***Plaintiffs***—bears the burden

of proof as to its existence. *Id.*

V. PLAINTIFFS' AMENDED COMPLAINT SHOULD BE DISMISSED AS TO AMNEAL

A. Plaintiffs' Amended Complaint Does Not State a Claim for Which Relief Can Be Granted Because Plaintiffs Do Not Allege Any Facts Indicating Amneal Has Infringed.

To the extent Plaintiffs' Amended Complaint could be read as asserting claims of past infringement against Amneal, it must be dismissed for failure to state a claim upon which relief could be granted. Fed. R. Civ. P. 12(b)(6). Although the Amended Complaint includes the formulaic recitation that all defendants "have infringed or will infringe," Amend. Compl. ¶¶ 77, 99, 121, 143 & at 34 (Prayer for Relief) ¶¶ A, C, Plaintiffs have not pleaded any factual basis for the assertion that the Amneal Defendants "have infringed." Plaintiffs' conclusory allegation is insufficient to state a claim. *Belichick*, 605 F.3d at 229–30 (stating that the court is not required to accept legal conclusions alleged in the complaint).

It is undisputed that Adello, not Amneal, is the BPCIA applicant here, and Plaintiffs accuse only Adello of having committed an artificial act of infringement under 35 U.S.C § 271(e) by filing a biosimilar application with the FDA. *See, e.g.*, *id*. ¶¶ 9, 17 & at 34 (Prayer for Relief) ¶ D. As to actual infringement under Sections 271(a) and (g), Plaintiffs never allege that Amneal has *already* made, used, offered to sell, sold or imported the Adello filgrastim product. Plaintiffs at most allege that Amneal *intends* to do so *if* Adello obtains FDA approval in the

future and moves to launch its filgrastim product. *Id.* ¶¶ 21, 23, 68, 90, 112, 134. Pleading that Amneal has a contract that assigns it responsibility for "marketing, selling, and pricing" Adello's filgrastim product, *id.* ¶ 19, or broadly suggesting that all named defendants purportedly "intend[]" to take certain action if FDA approval is ultimately received, is not an allegation that either Amneal Defendant has infringed.

Therefore, Plaintiffs' Amended Complaint fails to state a claim for patent infringement against Amneal, and any such claims should be dismissed under Rule 12(b)(6). *See Twombly*, 550 U.S. 555 ("a formulaic recitation of the elements of a cause of action will not do"); *Belichick*, 605 F.3d at 229–30 (complaint must contain "sufficient factual allegations so as to state a facially plausible claim for relief").

B. This Court Lacks Subject-Matter Jurisdiction Because Plaintiffs' Assertion that Amneal Might Someday Infringe Does Not Create an Actual Controversy of Sufficient Immediacy to Warrant Declaratory Relief.

Plaintiffs' claims against Amneal also should be dismissed under Rule 12(b)(1) because Plaintiffs have not pleaded facts giving rise to an actual controversy involving Amneal such that the Court has jurisdiction to grant the requested declaratory and injunctive relief. Fed. R. Civ. P. 12(b)(1). It is not sufficient for Plaintiffs to allege that Amneal might at some point in the future infringe Plaintiffs' patents. Moreover, even if subject-matter jurisdiction did exist,

this Court in its discretion should decline jurisdiction over Amneal. To exercise jurisdiction over Plaintiffs' declaratory judgement claims would upend the "complex statutory scheme" Congress established in the BPCIA for litigating biosimilar cases. *Sandoz*, 137 S. Ct. at 1669. Moreover, the exercise of jurisdiction would waste judicial resources because as a practical matter, any injunctive relief Plaintiffs might obtain against Amneal would be duplicative of the relief Plaintiffs would obtain from Adello, the actual biosimilar applicant.

1. There is no subject-matter jurisdiction over Plaintiffs' requests for declaratory relief.

A court may exercise jurisdiction under the Declaratory Judgment Act only where there is an "actual controversy." 28 U.S.C. § 2201(a); *see also* U.S. Const. art. III, § 2, cl. 1. "[T]he question in each case is whether the facts alleged, under all circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127. Immediacy is determined "by considering how far in the future the potential infringement is, whether the passage of time might eliminate or change any dispute, and how much if any harm the potential infringer is experiencing, at the time of suit, that an adjudication might redress." *AIDS Healthcare Found., Inc. v. Gilead Scis., Inc.*, 890 F.3d 986, 991 (Fed. Cir. 2018) (quoting *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1278 (Fed. Cir. 2014)); *see also MedImmune, Inc. v. Centocor, Inc.*, 409

F.3d 1376, 1378 (Fed. Cir. 2005) ("Whether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law."), *overruled on other grounds*, *MedImmune, Inc. v. Genentech, Inc*., 549 U.S. 118 (2007). "A plaintiff seeking a declaratory judgment bears the burden of demonstrating that a case of actual controversy existed at the time the declaratory action was filed." *AIDS Healthcare Found.*, 890 F.3d at 990.

This Court lacks subject-matter jurisdiction to grant declaratory relief because there is not an immediate and real controversy pleaded as to Amneal. All three factors in the immediacy analysis weigh against a finding of jurisdiction. First, Plaintiffs seek a declaratory judgment that Amneal will at some point in the future infringe their patents. Amend. Compl. ¶¶ 77, 99, 121, 143 & at 34 (Prayer for Relief) ¶¶ A, C (seeking judgment that defendants "will infringe"). Plaintiffs recognize that Adello's biosimilar application is still pending before the FDA, *id*. at ¶¶ 15, 36, but they have pleaded no facts that final FDA approval of the Adello filgrastim product is imminent, much less that the product is about to be commercially launched. Thus, there is no basis to conclude that "future [] potential infringement" is imminent. *AIDS Healthcare Found.*, 890 F.3d at 991; *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1330 (Fed. Cir. 2012) (although "a showing of actual infringement is not required for a case or controversy to

exist[,] . . . [if] it is unclear when any even arguably infringing activity will occur, a dispute will lack the immediacy necessary to support the exercise of declaratory judgment jurisdiction"); *Abbott Diabetes Care, Inc. v. DexCom, Inc*., No. 05-590, 2006 WL 2375035, at *3 (D. Del. Aug. 16, 2006) (finding an intent to market a generic drug did not create declaratory judgment jurisdiction where, like here, it was not pleaded that FDA approval had occurred or that it would occur, and the defendant had not "distributed sales literature, prepared to solicit orders, or engaged in any sales or marketing activity with regard to" the alleged infringing drug).

Second, whether Adello and Amneal will ever be in a position to commercially market Adello's filgrastim product is contingent upon FDA approval. Amend. Compl. ¶ 21. If the FDA were to reject Adello's application, this would eliminate any potential dispute between Plaintiffs and Amneal. Thus, future events may remove the purported basis of Plaintiffs' claims. *See Sandoz Inc. v. Amgen Inc*., 773 F.3d at 1278 (discussing the importance of contingency in determining whether there is an actual controversy under the standard because ripeness is a constitutional minimum for a justiciable controversy).

Moreover, the fact that Adello and Amneal may intend to commercially launch a product *if* the FDA gives approval at some point in the future does not create a controversy of sufficient immediacy to establish declaratory judgment

jurisdiction. A case involving Amgen itself is instructive. *Genentech, Inc. v. Amgen Inc.*, 310 F. Supp. 3d 467 (D. Del. 2018) was a BPCIA case in which Amgen was the biosimilar applicant, and sought dismissal of Genentech's declaratory judgment claims under Rules 12(b)(1) and 12(b)(6). *Id.* at 468. Amgen asserted that Genentech's claims against Amgen lacked immediacy, and the court therefore lacked subject-matter jurisdiction, because it was unclear whether Amgen would actually launch its biosimilar before a particular date, and Genentech's only evidence of an actual controversy was a 180-day notice of commercial marketing that Amgen had previously provided under the BPCIA. *Id*. at 468–70. The district court agreed with Amgen, and ruled that "to exercise jurisdiction under the Declaratory Judgment Act [requires] . . . an 'actual controversy' . . . 'of sufficient immediacy and reality to warrant the issuance of a declaratory judgment,'" and that Genentech's "commercial marketing claim [was] not of 'sufficient immediacy'" to satisfy this standard. *Id.* at 470. Similarly, in this case, Adello's notice of an intent to commercially market its biosimilar upon FDA approval is not sufficient to give rise to declaratory judgment jurisdiction, particularly not against third-party Amneal.

In re Rosuvastatin Calcium Production Litigation is also instructive. *See* No. 08–1949, 2008 WL 5046424, at *12–13 (D. Del. Nov. 24, 2008). There the plaintiffs brought claims for artificial infringement under the Hatch-Waxman Act

pursuant to Section 271(e)[2] and claims for traditional infringement pursuant to Section 271(a). *Id*. at *12. The court found that it lacked declaratory judgment jurisdiction as to the § 271(a) claims because the defendants could not "manufacture, import, market, or sell their proposed generic drug in the United States without FDA approval," and the plaintiffs failed to show that such approval was imminent. *Id*. Therefore, there was no immediate controversy. *Id*.

Courts in other Hatch-Waxman cases have reached similar results. *See, e.g.*, *Eisai Co. v. Mut. Pharm. Co., Inc.*, No. 06-3613, 2007 WL 4556958, at *18 (D.N.J. Dec. 20, 2007) (dismissing declaratory judgment claims because prior to FDA approval of a generic drug application and a decision to market the generic drug after approval "the controversy is not sufficiently immediate"); *Reckitt Benckiser Pharm., Inc. v. Biodelivery Scis. Int'l, Inc*., No. 5:13–CV–760–BO, 2014 WL 2119822, at *2–3 (E.D.N.C. May 20, 2014) (finding no declaratory judgment jurisdiction where a defendant announced the intent to market a generic drug because any actual future infringement was contingent on both FDA approval and a decision to market the generic drug upon approval); *Abbott Labs. v. Zenith Labs., Inc*., 934 F. Supp. 925, 938 (N.D. Ill. 1995) (finding no controversy under pre-

[2] Similar to the BPCIA, the Hatch-Waxman Act facilitates early resolution of patent disputes between reference listed drug manufacturers and generic drug manufacturers by making the filing of an Abbreviated New Drug Application (ANDA) with the FDA an act of artificial infringement. *See generally* 35 U.S.C. § 271(e)(2)(A).

MedImmune standards where an application for FDA approval of a generic drug had been filed, because there was no guarantee of FDA approval, the requested FDA approval did not guarantee the generic drug would be brought to market upon approval, and defending the lawsuit did not definitively show intent to market the generic drug upon approval).

Third, Plaintiffs do not allege facts showing they are currently being harmed by the possibility that Amneal could work with Adello to market Adello's biosimilar product if and when Adello receives FDA approval. Plaintiffs may be concerned about the possibility of future harm, but the mere possibility of future events does not create current harm, or a current cause of action. *AIDS Healthcare Found.*, 890 F.3d at 991. The mere pendency of Adello's application does not create declaratory judgment jurisdiction. *See Eisai*, 2007 WL 4556958, at *18 (dismissing for lack of jurisdiction with Hatch-Waxman application pending); *Abbott*, 934 F. Supp. at 938 (same).

For these reasons, this Court should dismiss Plaintiffs' claims against Amneal because it lacks subject-matter jurisdiction to determine whether patent infringement might occur in the future.

2. Even if subject-matter jurisdiction were found to exist, this Court should decline to exercise jurisdiction.

Even if this Court were to determine that Plaintiffs have sufficiently pleaded a current case or controversy involving Amneal—which they have not—this Court

should exercise its discretion to decline jurisdiction. "The Declaratory Judgment Act provides that a court 'may declare the rights and other legal relations of any interested party,' not that it *must* do so." *MedImmune*, 549 U.S. at 136 (quoting 28 U.S.C. § 2201(a)) (emphasis in original). Even where declaratory judgment jurisdiction exists, a court may exercise its discretion to decline jurisdiction. *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008); *see also Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995) (holding a district court "possess[es] discretion in deciding whether and when to entertain an action under the Declaratory Judgment Act"). A court should exercise its discretion to issue a declaratory judgment when: (1) "the judgment will serve a useful purpose in clarifying and settling the legal relations in issue"; and (2) "it will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding." *Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673 (Fed. Cir. 1991). This discretion allows the court to "to make a reasoned judgment whether the investment of judicial time and resources in a declaratory action will prove worthwhile in resolving a justiciable dispute." *Id.* at 672.

Here, this Court should decline to exercise jurisdiction over Plaintiffs' claims against Amneal for at least two reasons. First, third parties like Amneal that are neither a biologics sponsor nor a biosimilar applicant have no role as a party to litigation under the "complex" and "carefully crafted" statutory scheme of the

BPCIA. *Sandoz*, 137 S. Ct. at 1669, 1675. The BPCIA's extensive procedures provide a detailed process for the exchange of information and the resolution of disputes between the biosimilar applicant and the sponsor of the reference product—and only between them. 42 U.S.C. § 262(l). Congress did not provide a role for other parties in what the Supreme Court described as a "carefully calibrated scheme." *Sandoz*, 137 S. Ct. at 1670. And, critically, the BPCIA creates an artificial act of infringement only as to a biosimilar applicant. *Id*. at 1670; 35 U.S.C. § 271(e)(2)(C)(ii) ("It shall be an act of infringement *to submit* . . . an application seeking approval of a biological product") (emphasis added). When Congress created a cause of action against the applicant based on the filing of a biosimilar application, it pointedly did not create a cause of action against anyone else.

In addition, Congress's decision to create a cause of action for "artificial infringement" based on the filing of a biosimilar application strongly suggests that Congress believed reference product sponsors like Plaintiffs did not already have a cause of action for patent infringement that arose whenever a biosimilar application is filed. For example, the *Rosuvastatin* court noted it would be inconsistent with Congress's intent to allow pre-product launch actions under both Sections 271(e) and 271(a) to proceed simultaneously because there would have been no need for Congress to create a Section 271(e) cause of action if relief under

Section 271(a) had already been available. 2008 WL 5046424, at *13. The reasoning that Congress would not have created a Hatch-Waxman cause of action under Section 271(e) if declaratory relief had already been available under Section 271(a) applies equally in the BPCIA context. Congress would never have felt the need to create the BPCIA in order to provide a unique cause of action against biosimilar applicants if these applicants could already be sued under the Declaratory Judgment Act; moreover, if declaratory judgment relief is not available against biosimilar applicants, there would be no basis for it to be available against biosimilar applicants' marketing partners.

To allow Plaintiffs to proceed in a declaratory judgment action against parties like Amneal, that are not contemplated by the BPCIA, would provide an end run around the limited jurisdiction Congress created in the BPCIA based on an artificial act of infringement. It would both upset Congress's evident belief that no such action would be available outside the special provisions of the BPCIA, and its judgment that any such litigation should only occur between the sponsor and the biosimilar applicant.

Second, litigation between Plaintiffs and Amneal would serve no useful purpose, and would not resolve any issue that Plaintiffs' litigation of their claims against Adello will not resolve. Plaintiffs seek a declaratory judgment that Amneal will infringe its patents by commercially marketing Adello's biosimilar and, of

course, whether or not Adello's biosimilar product will infringe any valid claim of the patents-in-suit is exactly the issue currently being litigated by Plaintiffs against Adello. If Adello's filgrastim product is found to infringe, Plaintiffs have requested injunctive relief to prevent the commercial sale of that product—relief which, if granted, would prohibit the sale of Adello's filgrastim product by Adello, Amneal, or anyone else. This also weighs strongly against the exercise of declaratory judgment jurisdiction in these circumstances. *See Takeda Pharm. Co., Ltd. v. Mylan, Inc.*, 62 F. Supp. 3d 1115, 1126–27 (N.D. Cal. 2014) (noting in Hatch-Waxman case that the existence of declaratory judgment jurisdiction was unsettled, and declining to exercise that jurisdiction even if it existed because the relief sought would be duplicative of other available relief).

Because any declaratory judgment relief as to Amneal will be redundant of the relief already authorized under the BPCIA as against Adello, and will frustrate Congress's purpose in creating a limited act of artificial infringement in the BPCIA, this Court should decline to exercise jurisdiction over Plaintiffs' Declaratory Judgment Act claims.

VI. CONCLUSION

For these reasons, the Amneal Defendants request that this Court dismiss Plaintiffs' claims against them in the First Amended Complaint.

Dated: December 5, 2018

s/ Gregory D. Miller

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. ADELLO BIOLOGICS, LLC, AMNEAL PHARMACEUTICALS, LLC, and AMNEAL PHARMACEUTICALS, INC. Defendants.	)	C.A. No. 2:18-cv-03347-CCC-MF **ORDER DISMISSING PLAINTIFFS' FIRST AMENDED COMPLAINT AGAINST AMNEAL PHARMACEUTICALS LLC AND AMNEAL PHARMACEUTICALS, INC.**

THIS MATTER having come before the Court by way of the motion of Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. for an order dismissing the claims against them in Plaintiffs' First Amended Complaint; and the Court having considered the submissions of the parties; and for good cause having been shown;

IT IS on this _____ day of _____, 2019;

ORDERED that the Motion to Dismiss of Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. is hereby **GRANTED**; and it is

FURTHER ORDERED that the claims against Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. in Plaintiffs' First Amended Complaint for Patent Infringement are hereby dismissed with prejudice.

_____
Hon. Claire C. Cecchi, U.S.D.J.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. ADELLO BIOLOGICS, LLC, AMNEAL PHARMACEUTICALS, LLC, and AMNEAL PHARMACEUTICALS, INC. Defendants.	C.A. No. 2:18-cv-03347-CCC-MF **CERTIFICATE OF SERVICE**

I certify that on this day I caused to be filed with the Court and served upon all counsel of record via the ECF System the following:

a. Defendants Amneal Pharmaceuticals LLC's and Amneal Pharmaceuticals, Inc.'s Notice of Motion to Dismiss the Claims Against Them in Plaintiffs' First Amended Complaint;

b. Defendants Amneal Pharmaceuticals LLC's and Amneal Pharmaceuticals, Inc.'s Brief in Support of Motion to Dismiss the Claims Against Them in First Amended Complaint;

c. Proposed Form of Order Dismissing Plaintiffs' First Amended Complaint Against Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc.; and

d. Certificate of Service.

Dated: December 5, 2018

By: *s/ Gregory D. Miller*
Gregory D. Miller