IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INC. and BIOGEN MA INC.,

Plaintiffs,

v.

SANDOZ INC. and POLPHARMA BIOLOGICS S.A.,

Defendants.

REDACTED - PUBLIC VERSION
(Filed March 10, 2023)

C.A. No. 22-1190-GBW

[redacted]

POLPHARMA BIOLOGICS S.A.'S OPENING BRIEF IN SUPPORT OF ITS RULE 12(B)(6) MOTION TO DISMISS BIOGEN'S SECOND AMENDED COMPLAINT

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I. PRELIMINARY STATEMENT

Defendant Polpharma Biologics S.A. ("Polpharma") moves to dismiss Plaintiffs Biogen Inc. and Biogen MA Inc.'s ("Biogen") claims against it in the Second Amended Complaint ("SAC") (D.I. 98). Biogen fails to state a claim for patent infringement against Polpharma.

Biogen's First Amended Complaint ("FAC") (D.I. 51) alleged that Sandoz submitted an application to sell and market a biosimilar to Biogen's Tysabri product (using the now off-patent active pharmaceutical ingredient natalizumab). FAC ¶¶ 18-20, 72, 73. The FAC also alleged that Sandoz will infringe under 35 U.S.C. § 271(a), (b), or (g). Polpharma moved to dismiss because Biogen has no plausible infringement position as to Polpharma. D.I. 71.

Rather than respond to the motion, Biogen filed the SAC, but the new allegations cannot manufacture facts plausibly suggesting that Biogen is entitled to any relief as to Polpharma. If the FDA approves Sandoz's application, Polpharma will not make, use, sell, offer to sell or import biosimilar natalizumab in the United States. Thus, Sandoz, not Polpharma, is the only proper defendant for Biogen's patent infringement claims.[1]

Of course, to this day Sandoz's conduct (and Polpharma's conduct to the extent relevant) falls within a statutory safe harbor that protects the manufacture, sale, use or importation of a biosimilar for "uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1). Biogen filed its complaint based on an exception to that safe harbor, which permits a declaratory judgment against a person who "submit[s] . . . an application seeking approval of a biological product" to the FDA. 35 U.S.C. § 271(e)(2)(C)(i); *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674 (2017). This exception, where it applies at all, does not apply to Polpharma as it did not submit an

[1] Nor does Polpharma concede that personal jurisdiction is properly exercised over it.

application to FDA. Unlike the FAC, the SAC does now state that Polpharma "submitted" an application seeking approval of a natalizumab biosimilar. But this is simply a legal conclusion, and the facts that Biogen added to the SAC are no different in kind than those in the FAC. In both complaints, the facts pled as to Polpharma's involvement in Sandoz's application for natalizumab fall squarely within the Federal Circuit's *Celgene Corp. v. Mylan Pharmaceuticals Inc.* decision and do not plausibly suggest that Polpharma submitted Sandoz's BLA. Sandoz, not Polpharma, is the only proper defendant in this action. Thus, Polpharma should be dismissed under Rule 12(b)(6) for failure to state a claim upon which relief can be granted.

II. NATURE AND STAGE OF PROCEEDINGS

On [redacted], Sandoz submitted to the FDA an abbreviated biologics license application (BLA) for a proposed natalizumab biosimilar, which the FDA subsequently accepted. SAC ¶¶ 19, 97-98. [redacted], Sandoz intends to market and sell its biosimilar natalizumab in the United States. *Id.* ¶¶ 19, 20.

Pursuant to the Biologics Price Competition and Innovation Act (BPCIA), Biogen filed this action on September 9, 2022, naming as defendants Sandoz Inc. ("Sandoz"), Sandoz International GmBH, Sandoz GmBH, and Polpharma Biologics S.A. D.I. 2. After counsel for Sandoz agreed to accept service of the complaint on behalf of Sandoz by email, Biogen and Sandoz stipulated to the dismissal of defendants Sandoz International GmBH and Sandoz GmBH, but not Polpharma. D.I. 11. Polpharma and Biogen reached a stipulation and agreement on the date for service and the date for Polpharma's response to the FAC, which was submitted to the Court. D.I. 70.

Polpharma filed its Motion to Dismiss the FAC on January 20, 2023. D.I. 71. And Biogen filed its SAC on February 8, 2023. D.I. 98.

III. SUMMARY OF ARGUMENT

1. Biogen has not alleged facts to show that Polpharma is properly named as a defendant pursuant to 35 U.S.C. § 271(e)(2)(C)(i) because Polpharma did not submit an application to FDA seeking approval for natalizumab biosimilar. *See Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1129 (Fed. Cir. 2021).

2. Biogen has not alleged facts to show that Polpharma will make, use, sell, offer to sell or import the proposed natalizumab biosimilar (or a JCV assay) in the United States and thus, Polpharma does not infringe under 35 U.S.C. § 271(a) or (g). Biogen has not alleged that Polpharma will market or promote the biosimilar to healthcare professionals in the United States and thus, Polpharma does not infringe under 35 U.S.C. § 271(b).

3. Biogen has not alleged facts to show that Polpharma is liable for any alleged past or present infringing acts because any Polpharma acts specified in the SAC fall within the scope of a statutory safe harbor protecting acts in support of a FDA filing. *Shire LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1309-10 (Fed. Cir. 2015).

IV. STATEMENT OF FACTS

Polpharma is a Polish company that has no U.S. presence, sales, or operations. SAC ¶¶ 16, 27. [redacted].

Polpharma has reached an agreement with Sandoz in which Sandoz will market the biosimilar worldwide. As a result, in [redacted], Sandoz—not Polpharma—filed an application with FDA seeking marketing approval for the natalizumab biosimilar in the United States. SAC ¶¶ 19, 97-98. Upon approval, only Sandoz will be authorized to market and sell the natalizumab biosimilar in the United States.

After approval, only Sandoz will import, market, offer to sell and sell the biosimilar product in the United States. Polpharma will do none of those things. As Biogen concedes, "Polpharma

[is] responsible for developing, manufacturing, and supplying the proposed biosimilar natalizumab and Sandoz would be responsible for commercializing and distributing it in all markets upon approval, through an exclusive global license." SAC ¶ 22. [2]

V. LEGAL STANDARD

The Court should dismiss a complaint that does not allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 663-64 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "[A] court need not accept as true allegations that contradict matters properly subject to judicial notice or by exhibit." *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 913 (Fed. Cir. 2017) (internal quotations omitted).

VI. ARGUMENT: BIOGEN FAILS TO STATE A CLAIM AGAINST POLPHARMA FOR WHICH RELIEF CAN BE GRANTED

A. The SAC Does Not Allege that Polpharma Submitted the BLA for a Natalizumab Biosimilar.

Biogen fails to plead that Polpharma is a proper defendant for a declaratory judgment claim under the statutory exception to the safe harbor in § 271(e)(2)(C)(i). Section 271(e)(2)(C)(i) applies only to a defendant that "submits" an application to market a biosimilar. In both the Original Complaint and the FAC, Biogen correctly alleged that Sandoz—not Polpharma—submitted the application. *See, e.g.*, SAC ¶¶ 18-20, 96, 97 ("Sandoz Inc. filed aBLA (Application Number 761322) with the FDA seeking approval of a proposed biosimilar natalizumab, referred to in the aBLA as "PB006."'); D.I. 14 ¶ 23. Biogen's opening brief in support of its motion for a

[2] Polpharma disputes a number of these allegations from the SAC. [redacted]

preliminary injunction says the same thing, confirming that Sandoz (not Polpharma) submitted the application. D.I. 75 at 6 ("Thereafter, [redacted], Sandoz submitted an abbreviated Biologics License Application ([redacted] "BLA" or] "aBLA") seeking FDA approval to market Defendants' natalizumab biosimilar [redacted] in the United States." (citing Sandoz's [redacted]) (D.I. 76-1, Ex. V)). Sandoz has indicated that [redacted], Sandoz intends to market, distribute, and sell its biosimilar natalizumab in the United States." D.I. 14 ¶ 23.

Faced with Polpharma's motion to dismiss the FAC, Biogen's SAC for the first time states the Polpharma "is a submitter of the aBLA." SAC ¶ 26. But this is a legal conclusion which the Court need not, and should not, accept as true. *See Secured Mail*, 873 F.3d at 913. And the underlying facts added to the SAC do not plausibly suggest that Biogen's legal conclusion is correct.

Section 271(e)(2)(C)(i) provides a unique and limited exception to a statutory safe harbor that protects activity associated with efforts to develop an application for the FDA. The exception to the safe harbor is limited to the person who "***submit[s]*** . . . an application seeking approval of a biological product." § 271(e)(2)(C) (emphasis added); *Warner–Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003) (submitting an application is "an 'artificial' act of infringement that creates case-or-controversy jurisdiction"). Section 271(e)(2) unambiguously limits liability for infringement to the party that submits an BLA to the FDA. *See Bausch Health Ir. Ltd. v. Mylan Lab'ys Ltd.*, C.A. No. 21-10403 (SRC) (JSA), 2022 WL 683084, at *6 (D.N.J. Mar. 8, 2022); *Smithkline Beecham Corp. v. Pentech Pharms., Inc.*, No. 00 C 2855, 2001 WL 184804, at *2 (N.D. Ill. Feb. 20, 2001) ("Section 271(e)(2)(A) unambiguously refers only to persons who submit ANDAs.").

Because Sandoz, an unrelated company, indisputably signed and physically submitted the BLA, Biogen must plead sufficient facts that Polpharma "was actively involved in and directly benefited from the [BLA] (including in the agent-principal sense)." *Celgene*, 17 F.4th at 1128-29 (holding that conclusory allegations that the defendants "work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products" do not state a plausible claim under § 271(e)(2)). Stating a claim on which relief can be granted requires allegations that the accused submitter will engage in and "directly" benefit from the activities subject to the application and that will give rise to the alleged infringement if the application is approved. *Id.* at 1129 (explaining that selling the generic drug is the type of direct benefit that supports finding that a party is a submitter).

Applying *Celgene*, the court's opinion in *Bausch Health Ireland Ltd. v. Mylan Laboratories Ltd.*, is instructive. 2022 WL 683084, at *10. *Bausch* held that even the following specific alleged conduct did not transform a *direct corporate affiliate* of an ANDA filer into a "submitter":

> (i) appointed MPI as a U.S. agent for Drug Master File ("DMF") No. 34227; (ii) provides quality assurance and testing of the final drug substance and may manufacture the drug; and (iii) communicated with the FDA New Jersey Division regarding inspections of the facilities for manufacturing and testing of plecanatide in connection with ANDA No. 215686.

Id. Biogen's allegations here resemble the plaintiff's claims against Mylan in *Bausch*:

- Polpharma collaborated extensively with Sandoz to develop, manufacture, and submit the BLA for PB006. SAC ¶ 27.
- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

None of these, even if true, would transform Polpharma into the entity that submitted the application to the FDA. "[T]he Federal Circuit emphasized, 'it is the *submission* that infringes,' not an act 'merely' 'related to' [the submission] in some broader sense." *Bausch Health Ir.*, 2022 WL 683084, at *10 (quoting *Celgene*, 17 F.4th at 1121) (emphasis in original). Providing information for a BLA, even "tak[ing] certain steps with respect to the manufacturing, packaging, labeling, release, and stability testing" does not subject a party to a claim under § 271(e)(1)(C)(i). *See id.* (first citing *SmithKline Beecham Corp. v. Geneva Pharm., Inc.*, 287 F. Supp. 2d 576, 584 (E.D. Pa. 2002), and then citing *Smithkline Beecham Corp. v. Pentech Pharms., Inc.*, No. 00 C 2855, 2001 WL 184804, at *2 ("There is no reference in section 271(e)(2)(A) to suppliers of ingredients of generic drug products or preparers of DMFs relied on by ANDA filers. Section

271(e)(2)(A) unambiguously refers only to persons who submit ANDAs.")); *United Therapeutics Corp. v. Sandoz, Inc.*, C.A. No. 12-CV-1617, 2014 U.S. Dist. LEXIS 206939, at *8-9 (D.N.J. Mar. 10, 2014) (finding API supplier that had provided information and technical assistance had not submitted the ANDA).

The SAC's allegations that [redacted] falls short of alleging the direct benefit required by *Celgene*. SAC ¶¶ 27, 83-86 ([redacted]). If the BLA is approved only Sandoz will import, market, offer for sale, and sell the natalizumab biosimilar in the United States. [redacted] These are the only activities alleged to infringe the asserted patents, and as explained in further detail below, the SAC does not allege that Polpharma will do any of them. [redacted]. *See* SAC ¶ 22. Based on the allegations in the SAC, Polpharma is [redacted]. Also, the SAC relates [redacted]. As such, the SAC does not adequately allege that Polpharma will directly benefit from approval of the BLA.

Having failed to allege any facts plausibly suggesting that Polpharma submitted the relevant BLA, the SAC fails to allege the existence of a case or controversy with respect to patent infringement by Polpharma. *See Warner–Lambert*, 316 F.3d at 1365 (explaining that submission creates exception to statutory safe harbor and gives rise to case or controversy).

Before the Federal Circuit's *Celgene* decision, some Delaware decisions held that "[p]arties 'actively involved' in preparing the [application] are deemed to have 'submit[ted]' the [application], regardless of whether they are the named applicant." *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009) (explaining that "'[a]ctive involvement' includes 'marketing and distributing the approved generic drugs in the United States'" (quoting *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 306 (D. Md. 2007)). But importantly, no published Delaware decision has held that an entity that has not filed an application constitutes a "submitter" in the absence of a "formal corporate relationship (e.g., parent-subsidiary) . . . between the 'real filer in interest' and the entity filing the [application] on the former's behalf." *See, e.g.*, *Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, C.A. No. 18-73-LPS, 2019 WL 581618, at *5 (D. Del. Feb. 13, 2019) (finding that the defendant's third-party FDA consultant who acted as its agent was not a "submitter"). These decisions emphasize the importance of interlocking corporate relationships between multiple defendants, i.e. circumstances in which "the parties involved are in the same corporate family." *Cephalon, Inc.*, 629 F. Supp. 2d at 349 (noting that "this is especially true where the parties involved are in the same corporate family"); *Novartis Pharms. Corp. v. Handa Neuroscience, LLC*, C.A. No. 21-645-LPS, 2022 WL 610771, at *5 (D. Del. Mar. 1, 2022) (finding corporate affiliates were "submitter[s]" where there was "ample evidence that they [were] all part of the same corporate family as [the filer]"); *Endo Pharms. Inc. v. Actavis Inc.*, C.A. No. 14-1381-RGA, 2017 WL 522825, at *1 (D. Del. Feb. 8, 2017) (denying motion to dismiss where the movant was "the corporate parent of the current defendants and intend[ed] to manufacture, market, and sell the infringing drug itself"); *Otsuka Pharm. Co. v. Hetero USA, Inc.*, C.A. No. 19-1954-LPS, 2020 WL 6822971, at *2-3 (D. Del. Nov. 20, 2020) (denying motion to dismiss "vertically integrated" non-filer that "share[d] one or more common corporate directors" with filer,

operated as "a unitary entity and . . . single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products," and would "work[ ] in unison" with filer, including after FDA approval).

Courts outside Delaware have also emphasized the corporate connection between defendants where they have permitted a patent holder to sue an entity that did not sign the FDA application. *See, e.g.*, *AbbVie Inc. v. Alvotech hf.*, No. 21 C 2258, 2021 WL 3737733, at *3 (N.D. Ill. Aug. 23, 2021) (denying motion to dismiss claims against parent of unnamed wholly owned subsidiary who filed BLA because the parent was the entity that would engage in the manufacture, commercialization, marketing, and sale); *Helsinn Healthcare S.A. v. Hospira, Inc.*, C.A. No. 15-2077 (MLC), 2016 WL 1338601, at *7 (D.N.J. Apr. 5, 2016) (applying "rationale . . . that an entity that does not sign the ANDA but intends to benefit from it is possibly liable for infringement . . . because Hospira and Worldwide function together in the 'same corporate family,' as parent and subsidiary looking to distribute and market their generic Aloxi® product"); *Wyeth*, 505 F. Supp. 2d at 306-07 ("[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.").

Here, the SAC recognizes that Polpharma and Sandoz are not corporate affiliates, but *entirely separate entities*. Unlike the entities found to be submitters in those decisions, the SAC does not allege that Polpharma will market the biosimilar or benefit from its sale as a member of a vertically integrated corporate structure. *See Celgene*, 17 F.4th at 1129 (upholding dismissal where allegations "amount[ed] to legal conclusions as to the defendants as a group—not to facts showing a plausible inference of liability as to Mylan N.V."). Moreover, *Celgene* has cautioned against holding non-signers liable under § 271(e)(2) and stated that the Federal Circuit's earlier

opinion in *Rosuvastatin* "did not hold a non-signer liable or provide that benefiting from the [application] was enough to be deemed to have 'submitted' it." *Id.*; *see also In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 527-29 (Fed. Cir. 2012) (finding that U.S. subsidiary of Canadian real party in interest that signed and filed the application had "submitted" the ANDA).

The lone example finding an unrelated, non-filing entity a "submitter," of which Polpharma is aware, involves readily distinguishable facts that are absent here. *See Purdue Pharma L.P. v. Varam, Inc. (In re OxyContin Antitrust Litig.)*, No. 04-MD-1603 (SHS), 2012 WL 5184949, at *5-6 (S.D.N.Y. Oct. 19, 2012). The court in *Purdue* denied a motion from a pharmaceutical company that had developed a generic for extended-release oxycodone and prepared an ANDA but assigned the ANDA before filing it. *Id.* at *2. It "gave . . . the draft ANDA free of charge" and "promised to perform all the work necessary to complete the ANDA process." *Id.* The assignee had a single "shareholder, director, officer and employee" with "no scientific or technical expertise" to whom the pharmaceutical company provided shared office space. *Id.* This, coupled with the fact that the pharmaceutical company had "taken every relevant action except the final formalities," led the court to hold that not deeming the company to have "'submit[ted]' the ANDA pursuant to section 271(e)(2) would be to elevate form over substance." *Id.* at *6. Unlike the individual that signed and physically submitted the ANDA in *Purdue*, Sandoz is a large company and it, not Polpharma, will actually import, market, and sell the biosimilar at issue here.

Sandoz submitted the FDA application that gives rise to the declaratory judgment claim that is permitted by the carve out from the safe harbor. Polpharma should be dismissed.

B. The SAC Does Not Allege that Polpharma Infringes Under 35 U.S.C. § 271(a), (b), or (g).

Biogen initiated this claim based on a limited exception to a statutory safe harbor that protects a pharmaceutical company's efforts to apply for FDA approval of a biosimilar. Biogen

has conceded that the active pharmaceutical ingredient in Sandoz's proposed product (a biosimilar for natalizumab) does not infringe any unexpired patent, but in the SAC, Biogen asserts several secondary and tertiary patents related to tests, uses, and general manufacturing methods that Biogen alleges will be infringed by Sandoz once it starts marketing the biosimilar.

Although, § 271(e)(2) creates an artificial act of infringement upon submission of an BLA to the FDA for approval of a biosimilar, to obtain relief, the patent holder must prove that the conduct of the submitter would later infringe the asserted patent(s) if the FDA approves the application. *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.,* 731 F.3d 1271, 1278-79 (Fed. Cir. 2013) (question is whether the conduct for which filer seeks approval would infringe); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (holding that § 271(e)(2)'s "act of infringement . . . consists of submitting an ANDA . . . containing . . . [a] certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent"). Thus, even assuming the SAC adequately alleges that Polpharma is a submitter—it does not—Polpharma should still be dismissed because the SAC does not allege that any Polpharma commercial activity will infringe the Asserted Patents if the FDA approves Sandoz's BLA. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 693 F. Supp. 2d 409, 418 (D. Del. 2010) (dismissing claims for "fail[ure] to allege any future acts" that would induce infringement upon approval of the ANDA).

A critically important question to Biogen's requested relief in this action is what entity Biogen alleges will, [redacted], make, use, sell, offer to sell, or import the approved biosimilar in the United States. *See* 35 U.S.C. § 271(a). Similarly, at issue is what entity Biogen alleges will indirectly infringe by inducing others to infringe in the United States. *See* 35 U.S.C. § 271(b). Finally, a critical question is what entity Biogen alleges will "import[] into the United

States or offer[] to sell, sells, or uses within the United States a product which is made by a process patented in the United States." *See* 35 U.S.C. § 271(g). Biogen's SAC alleges it is Sandoz, not Polpharma, that will engage in these acts.

Specific to importation, the SAC pleads facts establishing that Sandoz, not Polpharma, will import [redacted] into the United States. The SAC specifically quotes Sandoz's development agreement with Polpharma, which grants [redacted] The SAC's unsupported allegations on information and belief that Polpharma will "collaborat[e]" or "participate" in the importation of [redacted] SAC ¶¶ 27, 75, do not plausibly suggest that Polpharma will import [redacted] as required to state a claim under § 271(g). Nor is the allegation consistent with the Original Complaint, the FAC or the motion for a preliminary injunction, the last of which states, "[redacted], and Sandoz plans to import and sell the product as [redacted] in the U.S." D.I. 75 at 19.

Pfizer Inc. v. Aceto Corp. is instructive. There, the court dismissed a § 271(g) claim against a foreign manufacturer because, though the foreign manufacturer knowingly sold to an importer, it never "itself import[ed] the infringing product into the United States." 853 F. Supp. 104, 105-06 (S.D.N.Y. 1994) (noting that dismissal of the foreign manufacturer did not leave the plaintiff without remedy because the actual importer was subject to liability under § 271(g)); *Anvik Corp. v. Sharp Corp.*, No. 07 Civ. 0825 (SCR), 2010 U.S. Dist. LEXIS 146677, at *20 (S.D.N.Y. Aug. 11, 2010) (adopting *Pfizer*). Biogen has not only *not* alleged that Polpharma will be an importer,

it has affirmatively alleged that Polpharma [redacted]. Accordingly, Biogen has failed to plead importation claims under § 271(a) or (g).

As to the remaining claims against Polpharma under § 271(a) and (b), Biogen does not allege that Polpharma will participate in any marketing or other commercial activity in the United States. Rather, the SAC concedes that Sandoz is solely responsible for that conduct. *See* SAC ¶ 72; *id.* ¶ 22 (linking to a press release stating that "Sandoz will commercialize and distribute the medicine in all markets upon approval, through an exclusive global license"). Polpharma will [redacted], but all post-approval importation, marketing and sales activities in the United States will be conducted by Sandoz. *Compare id.* ¶¶ 16 (alleging that Polpharma is a Polish corporation), 27 (alleging that Polpharma will manufacture [redacted] *with id.* ¶¶ 18-20 (alleging Sandoz's intended post-approval importation, marketing, and sales activities in the United States). Thus, Sandoz, not Polpharma, is the proper defendant in connection with the SAC's allegations under § 271(a) and (b).

Biogen's only allegations specific to Polpharma reflect that Polpharma is responsible for the *overseas* manufacture of the biosimilar. *See* SAC ¶¶ 22 ("Under the agreement, Polpharma was responsible for developing, manufacturing, and supplying the proposed biosimilar natalizumab . . . ."), 27 ("[redacted]"). That, however, is not infringement. Overseas manufacturing cannot infringe a United States patent under § 271(a), which only applies to manufacture "within the United States." 35 U.S.C. § 271(a). Pursuant to the SAC, Sandoz, not Polpharma, is subject to a claim under § 271(g) because Biogen alleges that Sandoz will import the natalizumab biosimilar into the

United States. SAC ¶ 22. Finally, the SAC concedes that only Sandoz will be licensed to market in the United States, and thus only Sandoz would be subject to a claim under § 271(b).

Finally, any alleged acts by Polpharma to assist Sandoz's preparation of an application for the FDA do not reflect infringement under § 271(a), (b), or (g). *See Pfizer Inc. v. Ranbaxy Lab'ys Ltd.*, 321 F. Supp. 2d 612, 618 (D. Del. 2004) (dismissing induced infringement claims "based solely on activities related to the preparation of the ANDA filing"); *In re Cyclobenzaprine*, 693 F. Supp. 2d at 418 (dismissing claims for "fail[ure] to allege any future acts" that would induce infringement upon approval of the ANDA). Biogen's allegations of infringement under these sections are legally inadequate and should be dismissed.

C. Section 271(e)(1)'s Regulatory Safe Harbor Bars Any Claims for Infringement Based on Past or Present Conduct by Polpharma.

Outside of the question whether Polpharma submitted the FDA application, Polpharma is not liable for any alleged past or present infringing acts pleaded in Biogen's SAC because acts by Polpharma "in support of the filing of an [application]" fall within the safe harbor. *Shire*, 802 F.3d at 1309-10. Section 271(e)(1) provides that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). "Section 271(e)(1)'s exemption from infringement 'extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.'" *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1338 (Fed. Cir. 2019) (applying safe harbor defense to substance subject to a biologics license application) (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005)).

Biogen's SAC added several paragraphs directed to Polpharma's [redacted] In *AbTox, Inc. v. Exitron Corp.*, the Federal Circuit confirmed that § 271(e)(1)'s safe harbor protects any act performed "solely for uses reasonably related to" FDA approval of any medical device, [redacted]. 122 F.3d 1019, 1029-30 (Fed. Cir. 1997); *OrthoPediatrics Corp. v. Wishbone Med., Inc.*, No. 3:20-CV-929-JD-MGG, 2022 WL 4529382, at *11 (N.D. Ind. Sept. 28, 2022) (denying motion to strike safe harbor defense where defendant "alleged that the accused system obtained 510(k) clearance from the FDA and that any activities reasonably related to development and submission of the accused system to the FDA fall under § 271(e)(1)"); *Carl Zeiss Meditec, Inc. v. Topcon Med. Sys., Inc.*, No. 19-4162-SBA, D.I. 285, at 14-16 (N.D. Cal. Oct. 7, 2020) (granting a motion to dismiss under the safe harbor because the infringement claims were based on activity surrounding 510(k) notification). [redacted] *See Eli Lilly*, 496 U.S. at 676-78 (explaining how filing only certain drug applications constitutes infringement under § 271(e)(2) and (4) yet acts in support of filing for FDA approval of medical devices are nevertheless protected under § 271(e)(1)'s safe harbor).

Similarly, Polpharma's [redacted] is a non-issue due to the safe harbor. That conduct relates to the development and submission of information to the FDA. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). The same holds true for any conduct by Polpharma [redacted]

clinical trials in the United States or any work overseas designed to aid in Sandoz's submission of the FDA application to market the biosimilar.

Biogen's SAC is properly focused on the future, but, to the extent that Biogen asserts that Polpharma's past or present conduct is an alleged infringement of any patent, the § 271(e)(1) safe harbor legally insulates Polpharma from any potential liability.

The SAC's failure to state a claim for patent infringement against Polpharma is further confirmed because Biogen will obtain complete relief on every claim in the SAC if it prevails against Sandoz. Sandoz alone is seeking authorization to market and sell a natalizumab biosimilar. Sandoz alone will use, sell, offer to sell, or import that product within the United States. [redacted] A judgment against Sandoz fully addresses the harm that Biogen alleges, and the SAC fails to state any claim against Polpharma.

VII. CONCLUSION

For the foregoing reasons, Polpharma respectfully requests that the Court grant Polpharma's motion to dismiss.

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CERTIFICATE OF SERVICE

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