IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LINDIS BIOTECH, GMBH, Plaintiff, v. AMGEN, INC., Defendant.	C.A. No. 22-35-GBW

MEMORANDUM ORDER

Pending before the Court is Defendant Amgen Inc.'s ("Defendant" or "Amgen") Motion to Dismiss Plaintiff Lindis Biotech, GMBH's ("Plaintiff" or "Lindis") Complaint under F.R.C.P. 12(b)(6) (the "Motion"). D.I. 13. Defendant's Motion raises several grounds challenging each of the following counts of the Complaint: (1) Count I, which asserts direct and indirect infringement of U.S. Patent No. 8,709,421 (the "'421 Patent") (D.I. 1, ¶¶ 69-72); (2) Count II, which asserts direct and indirect infringement of U.S. Patent No. 10,071,158 (the "'158 Patent") (D.I. 1, ¶¶ 75-78); and (3) Count III, which asserts direct and indirect infringement of U.S. Patent No. 10,576,149 (the "'149 Patent") (D.I. 1, ¶¶ 81-84). Having considered Defendant's Motion and all related briefing (D.I. 14, D.I. 23, D.I. 25), the Court finds that the Motion is GRANTED-IN-PART and DENIED-IN-PART. Defendant's Motion to Dismiss is GRANTED as to any contributory infringement claims alleged in Counts I and II, with leave for Plaintiff to amend. With respect to Count III, Defendant's Motion to Dismiss is GRANTED with prejudice. The Motion is otherwise DENIED.

I. LEGAL STANDARDS

To state a claim on which relief can be granted, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief . . . ." Fed. R. Civ. P. 8(a)(2). Such a claim must plausibly suggest "facts sufficient to 'draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). "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.'" *Klotz v. Celentano Stadtmauer & Walentowicz LLP*, 991 F.3d 458, 462 (3d Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). But the Court will "'disregard legal conclusions and recitals of the elements of a cause of action supported by mere conclusory statements.'" *Princeton Univ.*, 30 F.4th at 342 (quoting *Davis v. Wells Fargo*, 824 F.3d 333, 341 (3d Cir. 2016)). Under Rule 12(b)(6), the Court must accept as true all factual allegations in the Complaint and view those facts in the light most favorable to the plaintiff. *See Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327, 351 (3d Cir. 2020).

"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 Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 804 F.3d 633, 638 (3d Cir. 2015) (internal citation omitted). "A motion to dismiss [under Rule 12(b)(6)] 'may be granted only if, 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.'" *McCrone v. Acme Markets*, 561 F. App'x 169, 172 (3d Cir. 2014) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)).

II. DISCUSSION

Amgen presents five (5) grounds for dismissal:

(1) Count I should be dismissed in its entirety because "the Complaint does not allege that Blincyto® is a 'trifunctional, bispecific immunostimulatory antibody' as recited in all claims of the '421 [P]atent." D.I. 14 at 1.

(2) Count III should be dismissed in its entirety because "the Complaint does not allege that Blincyto® is used or directed for use to treat subjects with 'lymphoma' as recited in all claims of the '149 [P]atent." *Id.*

(3) All claims of direct infringement in Counts I-III should be dismissed because "the Complaint does not allege that Amgen itself performs any of the claimed methods of the Asserted Patents." *Id.*

(4) All claims of contributory infringement in Counts II-III should be dismissed because "the Complaint concedes that Blincyto® is suitable for a substantial non-infringing use." *Id.*

(5) To the extent that Counts I-III assert infringement based on the purported performance of methods outside of the United States, Amgen argues they should be dismissed because "such acts neither constitute infringement nor serve as a basis for indirect infringement." *Id.*

The Court will review each argument in turn.

A. Trifunctional, bispecific immunostimulatory antibody (Count I, the '421 Patent)

Amgen contends that Count I of the Complaint should be dismissed because, unlike the '421 Patent, the Complaint fails to allege that the accused product includes an antibody that is trifunctional. D.I. 14 at 8-9.

Count I asserts patent infringement of the '421 Patent. Independent claim 1 of the '421 Patent is representative:

> A method for reducing the non-specific release of a cytokine in a subject which is associated with a treatment of a cancer or tumor with an antibody comprising administering to the subject at least one glucocorticoid immediately before or immediately after administering at least one trifunctional, bispecific immunostimulating antibody directed against a tumor antigen and a CD marker, which glucocorticoid reduces the non-specific release of the cytokine associated with the treatment of the cancer or tumor, wherein the CD marker is selected from the group consisting of CD2, CD3, CD4, CD5, CD6, CD8, CD28, and CD44.

D.I. 1, Ex. A (the '421 Patent), claim 1.[1]

According to Amgen, Count I fails because the Complaint does not allege that the infringing product, Blincyto®, requires administration of a trifunctional, bispecific immunostimulating antibody. D.I. 14 at 8-9. In response, Lindis contends that it is only required to plead a "short and plain statement of the claim" to meet the *Iqbal/Twombly* pleading standard. D.I. 23 at 7. Lindis maintains that the Complaint satisfies this standard. *Id.* Amgen disagrees and argues that the complexity of the subject matter involved in this dispute requires Lindis to plead more than mere conclusory allegations of infringement. D.I. 25 at 2-3 ("Lindis cannot just 'flatly stat[e]—without more—that Defendants' accused products have or perform [every] limitation.'"). While the Court agrees that the Complaint must plead facts explaining how Amgen infringes the Asserted Patents, the Court finds that the Complaint meets the applicable pleading standard.

[1] Following a claim construction hearing, this Court construed "trifunctional, bispecific immunostimulating antibody" to mean "a bispecific antibody having a function in addition to two specific binding functions, namely 1) binding to a target antigen, and 2) binding to a CD marker." D.I. 95 ("Markman Order") at 2. With the benefit of claim construction, Plaintiff need only plead that the bispecific immunostimulating antibody contains some third function. *Id.* Thus, the Court will not address Amgen's arguments that are contrary to the Court's construction. *See* D.I. 14 at 5 ("Unlike typical antibodies and the "trifunctional, bispecific antibodies" recited in the claims, Blincyto® lacks an Fc region.").

1. Given the Complexity of the Technology Involved, Lindis Must Allege More than a Short and Plain Statement of the Claim.

Amgen correctly notes that the relevant pleading standard in an infringement claim depends, in part, on whether the Asserted Patents involve "simple" or "complex" technology. *Id.* In *Disc Disease Sols. Inc. v. VGH Sols., Inc.*, 888 F.3d 1256 (Fed. Cir. 2018), the Federal Circuit held that, in cases involving "simple technology," allegations are sufficient under the plausibility standard of *Iqbal/Twombly* if the complaint identifies the accused products, provides information "akin to including photos" of the products, and alleges that the accused products met "each and every element of at least one claim" of the Asserted Patents, either literally or equivalently. *Disc Disease*, 888 F.3d at 1260. However, in cases that do not involve such "simple technology," a plaintiff "must [] do more than assert that the product infringes the claim." *Bos. Sci. Corp. v. Nevro Corp.*, 415 F. Supp. 3d 482, 489 (D. Del. 2019).

In other words, in matters involving complex technology, the plaintiff "must show *how* the defendant plausibly infringes by alleging some facts connecting the allegedly infringing product to the claim elements." *Id.* (emphasis in original). To satisfy this standard, "[t]here needs to be something set out beyond a legal conclusion—i.e., some facts alleged that shows why it is plausible that the products infringe," and "[t]he patentee cannot meet its obligation to assert a plausible claim of direct infringement under the *Twombly/Iqbal* standard by merely copying the language of a claim limitation, and then flatly stating—without more—that Defendant['s] accused products have or perform such a limitation." *DIFF Scale Operation Rsch., LLC v. MaxLinear, Inc.*, C.A. No. 19-2109-LPS-CJB, 2020 WL 2220031, *2 (D. Del. May 7, 2020), *report and recommendation adopted*, 2020 WL 6867103 (D. Del. Nov. 23, 2020).

While the Court agrees that the asserted technology in this matter concerns subject matter that is more complex than *Disc Disease*, the Court finds that Count I is not, as Amgen claims,

"based solely on conclusory allegations." *See* D.I. 25 at 3. Rather, as discussed in more detail below, the Complaint properly pleads "some facts [] that show[] why it is *plausible* that the [accused] product[] infringe[s]." *DIFF*, 2020 WL 2220031, at *2.

2. The Complaint Meets the Heightened Pleading Standard.

"At the pleading stage, a plaintiff alleging patent infringement need not 'plead facts establishing that each element of an asserted claim is met . . . .'" *ID Image Sensing LLC v. OmniVision Techs., Inc.*, No. CV 20-136-RGA, 2020 WL 6888270, at *6 (D. Del. Nov. 24, 2020), *report and recommendation adopted*, No. CV 20-136-RGA, 2021 WL 602438 (D. Del. Feb. 16, 2021). Rather, as Amgen notes, the Complaint must only allege facts that *plausibly* indicate that Amgen's accused product infringes each limitation of the asserted claims. *Id.* The Court finds that Lindis has met this pleading standard.

Claim 1 of the '421 Patent discloses a method for administrating "at least one glucocorticoid" and "at least one trifunctional, bispecific immunostimulating antibody" to treat patients suffering from cancerous diseases. '421 Patent, claim 1. The patent specification notes that the intended goal of the invention is to "provide a new system for the most extensive possible alleviation of the side-effects" from immunotherapeutic cancer treatments. *Id.* at 2:20-25. According to the specification, immunostimulating antibodies are commonly used to target and treat tumor antigens and/or CD makers. *Id.* at 2:50-55. In many cases, however, the immunostimulating antibodies cause the cells of the body's immune system to over-secret a regulatory protein called cytokines, and these cytokines, in turn, cause patients to experience intense side-effects, including vomiting, allergic reactions, and even fatal circulatory failure. *See id.* at 1:41-58. Thus, to combat the side-effects, the invention discloses a method for administering a glucocorticoid alongside the immunostimulating antibodies to "reduce the non-specific release

of a cytokine." *Id.* at 3:27-44. The method disclosed in Claim 1 requires the use of an immunostimulating antibody that is trifunctional and bispecific. *Id.* at claim 1. Claim 1 further discloses that the trifunctional, bispecific immunostimulating antibody must be administered to the patient "immediately before or after" the glucocorticoid. *Id.*

In its Complaint, Lindis alleges that Amgen infringes the '421 Patent by manufacturing, selling, and marketing an immunotherapy drug, Blincyto®, both in and outside the United States, and instructing physicians to administer Blincyto® in a manner that mirrors the method disclosed in Claim 1. D.I. 1 ¶¶ 27-36. Specifically, Lindis alleges, that physicians are instructed by Amgen to administer Blincyto®, which Lindis contends is a bispecific recombinant antibody, in conjunction with a glucocorticoid (hereinafter, the "Amgen- Blincyto® Regimen"). *Id.* ¶ 46. Lindis claims that the instructions require that the patient be premedicated with glucocorticoid to reduce cytokine secretion. *Id.* ¶ 47.

When read as a whole, Lindis asserts sufficient facts to support its claim that the Amgen-Blincyto® Regimen plausibly infringes the '421 Patent. In fact, Lindis draws significant parallels between the elements of Claim 1 and the Amgen- Blincyto® Regimen. Lindis alleges, for instance that, like Claim 1, the Amgen- Blincyto® Regimen seeks to reduce the non-release of ctyokines in patients with Lymphoblastic Leukemia, a type of cancer, by instructing physicians to administer a glucocorticoid before they administer Blincyto®. *Id.* ¶¶ 47-49. Also like Claim 1, the Complaint reveals that Blincyto® is bispecific (i.e., it binds a cancer antigen to a T-Cell). *Id.* ¶ 28. Indeed, Lindis contends that Blincyto® "link[s] *the same specific cancer antigen* (CD19) *to the same type of T-cell* (CD3 positive) as does the [Claim 1] regimen." *Id.* (emphasis added).

While Lindis does not allege that Blincyto® is trifunctional, Amgen concedes that Lindis is not required to establish every element of Claim 1 to survive dismissal. D.I. 25 at 3. Further,

as noted above, the Complaint connects elements from the '421 Patent to elements of Amgen's accused product. The Court finds that, by doing so, the Complaint puts Amgen on notice as to what activity is being accused and how that activity infringes the '421 Patent. *Cf SIPCO, LLC v. Streetline, Inc.*, 230 F. Supp. 3d 351, 353 (D. Del. 2017). At this stage of the pleading, nothing more is required.

Accordingly, Amgen's Motion to Dismiss Count I on grounds that the Complaint fails to allege the tri-functionality of Blincyto® is DENIED.

B. Lymphoma (Count III, the '149 Patent)

The Court issued its Memorandum Opinion and corresponding order regarding claim construction on July 27, 2023. In its Opinion, the Court construed "lymphoma" to have its plain and ordinary meaning, which is a cancer of the lymphatic system. D.I. 94 at 21-25. The Court also found that the plain and ordinary meaning of lymphoma excluded leukemia. *Id.*

The '149 Patent expressly claims methods of treating lymphoma. *See* D.I. 1, Ex. C at claim 1 ("A method of using a bispecific antibody for treating lymphoma in a subject . . ."); claim 5 ("A method for administering a bispecific antibody to a subject having lymphoma . . .); claim 14 ("A method of antibody therapy for treating a subject having lymphoma. . ."). The parties agree that the claim preambles for claims 1, 5, and 14 of the '149 Patent were limiting. D.I. 86 at 7.

Following the entrance of this Court's Claim Construction Order, Plaintiff withdrew its opposition to Defendant Amgen's Motion to Dismiss Count III in its entirety. D.I. 98. Thus, the Motion to Dismiss Count III is GRANTED.[2]

[2] In granting the motion to dismiss Count III, the Court will not address the arguments made against Count III going forward.

C. Performance of Claimed Methods of Asserted Patents (All Counts)

Amgen contends that all allegations of direct infringement should be dismissed because "[t]he Complaint does not allege any facts to support claims that Amgen directly infringed the Asserted Patents by 'administering' certain therapeutic antibodies 'to [a] subject.'" D.I. 14 at 14 (internal citation omitted). Rather, Amgen argues that "Lindis solely relies on statements in the Complaint that Amgen . . . 'instructs' physicians by virtue of its FDA-approved prescribing information." *Id.* These instructions, according to Amgen, are "insufficient to show direction or control" as required under binding precedent to hold a third-party directly liable for the conduct of another. D.I. 25 at 7. While the Court agrees that "instructions" alone are generally insufficient to support a finding that a party directs or controls the infringing conduct of another, the Complaint alleges that Amgen provides physicians with more than mere "instruction."

"[F]or a party to be liable for direct patent infringement under 35 U.S.C. § 271(a), that party must commit all the acts necessary to infringe the patent, either personally or vicariously." *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1362 (Fed. Cir. 2013). Under the so-called "single actor" rule, "[d]irect infringement under § 271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015). "[A] defendant may be directly liable for infringing a claimed method where a third party carries out all steps of the method to obtain a benefit conditioned by the defendant and the defendant controls the manner or timing of that performance." *Sentius Int'l, LLC v. Apple Inc.*, No. 4:20-CV-00477-YGR, 2020 WL 6081775, at *4 (N.D. Cal. Oct. 15, 2020).

According to the Complaint, Amgen manufactures and sells the Accused Product, Blincyto®, D.I. 1 ¶ 27, provides prescribing information instructing physicians how to use Blincyto® in an infringing manner, *id.*, ¶¶ 29, 46, 57, and explains that performing the instructions will allow the user to receive the same treatment benefits as the Asserted Patents (i.e., the reduction of Cytokine secretion). *Id.*, ¶¶ 46-49, 57-60.

Additionally, the Complaint alleges that Amgen requires Blincyto® to be administered by a physician, not the patient, *id.* ¶ 36, and details the manner in which administration must occur. *See id.* ¶¶ 33 ("Amgen's prescribing information for Blincyto® instructs physicians to '[p]remedicate with prednisone or equivalent dexamethasone.'"); *Id.* ("For adult patients," physicians must "premedicate with 20 mg dexamethasone 1 hour prior to the first dose of [Blincyto®]"). The Complaint also alleges that Amgen places several visible warnings on the boxes and product labels for Blincyto® cautioning patients and physicians of "CYTOKINE RELEASE SYNDROM." *Id.* ¶ 29. The Complaint notes that the prescribing instructions similarly contain warnings that Cytokine Release Syndrome may be "life-threatening or fatal" to patients taking Blincyto® and inform patients that, "[b]efore [they] receive BLINCYTO, [they] will be given a corticosteroid medicine to help reduce infusion reactions." *Id.* ¶ 33.

When viewed in the light most favorable to Lindis, the alleged facts support a claim that Amgen intended to control and direct the method in which Blincyto® is administered. In fact, requiring Blincyto® to be administered by physicians supports a finding that Amgen does not offer the prescribing instructions as mere guidance. Because of their training and the duties that they have to their patients, physicians are more likely to understand and appreciate the need to administer Blincyto® as instructed and approved by the FDA. When coupled with detailed instructions specifying exactly when and how Blincyto® should be administered and the

inconspicuous warnings highlighting the fatal risks of Cytokine Release Syndrome in patients taking Blincyto®, the asserted facts "support a finding that [Amgen] cross[es] the line from merely guiding or instructing . . . to conditioning treatment" on abiding by the prescribing instructions. *See Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1366 (Fed. Cir. 2017). Thus, Amgen's Motion to Dismiss Counts I and II on grounds that "[t]he Complaint does not allege any facts to support claims that Amgen directly infringed the Asserted Patents" is DENIED.

D. Non-infringing Use (Counts I-II, the '421 and '158 Patents)

Amgen argues that Counts I and II should be dismissed for the additional reason that "the Complaint itself identifies a substantial non-infringing use for Blincyto®: its co-administration with prednisone" instead of Dexamethasone. D.I. 14 at 16. Specifically, Amgen contends that "[t]he Complaint expressly concedes that Blincyto® may be administered with the glucocorticoid 'prednisone' instead of 'dexamethasone' as follows: "Amgen's prescribing information for Blincyto® gives the instruction to '[p]remedicate with prednisone or equivalent dexamethasone.'" *Id.* (quoting D.I. 1 ¶¶ 29, 46). Thus, Amgen argues that the Complaint, on its face, precludes Lindis from alleging contributory infringement. *Id.* The Court agrees.

To state a claim for contributory infringement, the Complaint must "plead facts that allow an inference that the components sold or offered for sale have no substantial non-infringing uses." *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1337 (Fed. Cir. 2012). "Where the product is equally capable of, and interchangeably capable of both infringing and substantial non-infringing uses, a claim for contributory infringement does not lie." *Id.* at 1338. As the Supreme Court has recognized, this limitation on contributory infringement is of "critical importance" given that "a finding of contributory infringement is normally the functional equivalent of holding that the disputed article is within the monopoly granted to the patentee."

Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 441 (1984). Thus, to prevent a patentee from "extend[ing] his monopoly beyond the limits of his specific grant," the Supreme Court warned that a claim of contributory infringement would not survive unless the patentee can show that the unpatented articles are "'unsuited for any commercial noninfringing use.'" *Id.* (citing *Dawson Chemical Co. v. Rohm & Hass Co.*, 448 U.S. 176, 198, (1980)). By alleging that Blincyto® can be co-administered with prednisone, the Complaint fails to meet this standard.

While Lindis cites *Sanofi-Aventis U.S., LLC v. Watson Labs. Inc.*, 875 F.3d 636 (Fed. Cir. 2017), for the proposition that there is "liab[ility] for inducing an infringing use of a product even if the product has substantial noninfringing uses," D.I. 23 at 14, the language highlighted by Lindis concerned an infringement claim for inducement and thus is inapplicable to claims for contributory infringement. In fact, in finding that a non-conforming use would not defeat liability under an inducement theory, the Court in *Sanofi* explained that its holding was consistent with the Patent statute, since "Section 271(b), on inducement, does not contain the 'substantial noninfringing use' restriction of section 271(c), *on contributory infringement*." *Id.* at 646 (emphasis added).

Additionally, Lindis argues that "Amgen's use of Blincyto® also infringes under the doctrine of equivalents." D.I. 23 at 15. Lindis is barred, however, from raising the doctrine of equivalents in support of its contributory infringement claims because "Lindis dedicated co-administration with equivalent prednisone to the public." D.I. 25 at 8. That is, the disclosure-dedication doctrine holds that, "when a patent drafter discloses but declines to claim subject matter, ... this action dedicates the unclaimed subject matter to the public." *Eagle Pharms. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1175 (Fed. Cir. 2020) (internal citation omitted). "To determine whether the disclosure-dedication doctrine applies in a given case, we ask whether the specification discloses unclaimed subject matter with 'such specificity that one of ordinary skill in

the art could identify the subject matter that had been disclosed and not claimed.'" *Id.* (citing *PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004)). Here, Lindis does not dispute that the '421 and '158 Patents teach prednisone as an equivalent of dexamethasone. *See, e.g.*, '158 Patent, 2:47-52. Because prednisone is disclosed by both patent specifications, the disclosure-dedication doctrine holds that Lindis cannot assert a claim for contributory infringement which relies on an equivalency argument.

Finally, Lindis contends that "Amgen's argument is factually wrong, because its prescribing information for adults does not provide the option to premedicate with prednisone." D.I. 23 at 14. The relevant provision of the Complaint asserts:

> Amgen's prescribing information for Blincyto® instructs physicians to "[p]remedicate with prednisone or equivalent dexamethasone. (2.1)." In addition, the prescribing information states "[p]remedicate with dexamethasone: *For adult patients, premedicate with 20 mg dexamethasone 1 hour prior to the first dose of BLINCYTO®.*"

D.I. 1 ¶ 29 (emphasis added). While the Complaint highlights the dexamethasone instruction "[f]or adult patients," the language disclosing from the adult instruction does not, on its face, "discourage" or "foreclose" the use of prednisone for adults. *See Sanofi v. Glenmark Pharms. Inc.*, USA, 204 F. Supp. 3d 665, 684 (D. Del. 2016), *aff'd sub nom. Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636 (Fed. Cir. 2017) ("The proposed labels are written broadly enough so as to arguably render on-label uses in accordance with the E/A trials and certainly do not discourage such a use in any way. Numerous pieces of evidence also demonstrate that Sanofi advertises uses of Multaq® based upon the results of the E/A studies."). In fact, the Complaint introduces the adult instruction only after recognizing that physicians are instructed to premedicate with "prednisone or equivalent dexamethasone." D.I. 1 ¶ 29. The Complaint does not allege that the instruction to "premedicate with 20 mg dexamethasone" is a requirement rather than a preferred method of treatment or a mere

example. *See In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1338 (Fed. Cir. 2012) (internal citation omitted) ("That practicing the patented method may be the most logical or useful purpose for Appellees' products does not render the alternative uses 'unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.'"). Thus, the Court cannot find that the prescribing information, as pled in the Complaint, reveals that "the option to premedicate with prednisone" is not available for adults. *See* D.I. 23 at 14.

Accordingly, Amgen's Motion to Dismiss Counts I and II on grounds that "the Complaint itself identifies a substantial non-infringing use for Blincyto®" is GRANTED. Because an amendment clarifying the adult instruction may not be futile, the Court dismisses the contributory infringement claims of Counts I and II without prejudice and with leave for Lindis to amend. *See EIS, Inc. v. WOW Tech Int'l GmbH*, C.A. No. 19-1227-LPS/GBW, 2020 WL 7027528, at *13 (D. Del. Nov. 30, 2020).

E. Purported Performance of Methods Outside of the U.S. (All Counts)

Amgen also contends that the Complaint incorrectly claims infringement based on the use of Blincyto® by, or sale of Blincyto® to, third parties outside of the U.S. D.I. 14 at 17-18. Amgen thus argues that "those portions of Counts I, II, and III that seek relief based on the alleged use of Blincyto® outside the U.S." must be dismissed. *Id.* While the Court agrees that infringement of a method claim under §§ 271(a)-(c) requires that each infringing step occur in the United States, the Court finds that foreign sales or distribution of Blincyto® to foreign users are relevant to damages calculations.

A party directly infringes a patent when it "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." 35 U.S.C. § 271(a). Direct infringement of a method patent in particular

requires that the infringer utilize and complete all steps of the method. *NTP, Inc. v. Rsch. In Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) ("A method or process consists of one or more operative steps, and, accordingly, it is well established that a patent for a method or process is not infringed unless all steps or stages of the claimed process are utilized.") (internal citation omitted). Further, "[t]he use of a patented method does not infringe unless 'each of the steps is performed within this country.'" *F45 Training Pty Ltd. v. Body Fit Training USA Inc.*, No. CV 20-1194-WCB, 2022 WL 17177621, at *16 (D. Del. Nov. 17, 2022), dismissed, No. 2023-1304, 2023 WL 2965590 (Fed. Cir. Apr. 17, 2023) (citing *NTP*, 418 F.3d at 1318). Thus, to prove its infringement claims, Lindis must show that each step of the Asserted Patents was practiced in the U.S. *Id.*

The Complaint asserts that Amgen infringes the Asserted Patents by "manufacturing, marketing, distributing and selling the immunotherapy drug Blincyto® in the United States" and, in some instances, either "selling Blincyto® outside of the United States" or "ship[ping] Blincyto® from the US to other countries for distribution, sale and use, together with the prescribing information for Blincyto®." D.I. 1 at ¶¶ 70, 76, 82. Because the Complaint pleads that Blincyto® is, at times, sold and distributed in the United States and that "Amgen has induced and continues to induce infringement in this district and elsewhere in the United States," the Court finds that Lindis pleads sufficient facts to support a claim that, in some instances, each step of the infringing method is practiced within the United States.

While Lindis cannot rely on foreign uses of the patented method to prove infringement, the use and sale of Blincyto® to parties outside of the United States is relevant to patent damages. That is, a patentee who proves infringement may recover against "whoever without authority makes, uses, offers to sell, ***or*** sells any patented invention, within the United States." 35 U.S.C. § 271(a) (emphasis added). Because § 271(a)'s use of the disjunctive "or," courts have recognized

that "the sales of products that use the methods to foreign users can be used to measure damages for acts of infringement in the United States." *See Archerdx, LLC v. QIAGEN Scis., LLC,* No. CV 18-1019 (MN), 2021 WL 3857460, at *1 (D. Del. Aug. 30, 2021). In *Carnegie Mellon University v. Marvell Technology Group, Ltd.*, the Federal Circuit found that foreign sales could be used in calculating the royalty base of a damages award where the patentee demonstrates (1) an infringing act occurred within the United States (i.e., making, using, or selling), and (2) a substantial connection exists between the domestic infringing act and the foreign sale. 807 F.3d 1283, 1306–08 (Fed. Cir. 2015). When "a physical product is being employed to measure damages for infringing use of patented methods," for instance, the patentee may recover for foreign sales "only when any one of those domestic actions for that unit (e.g., sale) is proved to be present, even if others of the listed activities for that unit (e.g., making, using) take place abroad." *Carnegie Mellon Univ.,* 807 F.3d at 1306; *Cal. Inst. of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 992 (Fed. Cir. 2022).

Thus, while Lindis alleges that, in some instances, the accused products are practiced by users outside of the United States, these foreign uses or sales may be relevant to a royalty rate calculation.[3] To recover for foreign sales, however, Lindis will be required to show a substantial connection between a domestic action (e.g., the production of Blincyto®) and the alleged infringing act (e.g., the sale or use of Blincyto® abroad). *See Carnegie Mellon Univ.,* 807 F.3d at

[3] Of course, to be entitled to damages, Lindis must first prove infringement, and as the Court noted, infringement of a method patent requires that all infringing steps occur in the United States. Nothing in this opinion shall be read as "expanding the statutory requirement for infringement." *See Archerdx*, 2021 WL 3857460, at *2 (instructing the jury that, "[d]amages . . . may [] be awarded on sales of products that practice the patented methods in their normal intended use outside of the United States if, for those products, you find that (1) QIAGEN's infringement in the United States was a substantial cause of the sale of that product, and (2) QIAGEN made or sold the product within the United States").

1306. Because the foreign sales may be relevant to damages, Amgen's Motion to Dismiss Counts I and II on grounds that Lindis cannot recover for "infringement based on the purported performance of methods outside of the United States" is DENIED.

III. CONCLUSION

For the foregoing reasons, the Motion to Dismiss is granted-in-part and denied-in-part.

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WHEREFORE, at Wilmington this **27th** day of March, 2024, **IT IS HEREBY ORDERED** that:

1. Amgen's Motion to Dismiss Count I and Count II of Plaintiff Lindis' Complaint for Failure to State a Claim (D.I. 13) is **GRANTED-IN-PART** and **DENIED-IN-PART**. The Court grants dismissal of all claims of contributory infringement in Count I and Count II, with leave for Lindis to Amend. Amgen's Motion to Dismiss Count I and Count II is otherwise denied.
2. Amgen's Motion to Dismiss Count III of Plaintiff Lindis' Complaint for Failure to State a Claim (D.I. 13) is **GRANTED.**

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE