**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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

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**MEMORANDUM OPINION**

November 22, 2024
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pending before the Court is Defendant Amgen Inc.'s ("Amgen") Motion for Summary Judgment and to Exclude Expert Testimony (D.I. 175), which has been fully briefed (D.I. 180; D.I. 209; D.I. 240). At issue in this case are Patents Nos. 8,709,421 (the "'421 patent") and 10,071,158 (the "'158 patent"). D.I. 157 Ex. 1. Amgen submitted four summary judgment motions and ranked them in the following order: 1) No Induced Infringement of the '421 Patent, 2) No Contributory Infringement of the '421 Patent, 3) Asserted Claims of the '158 Patent are Invalid for Lack of Written Description, and 4) No Induced Infringement of All Asserted Claims of both the '421 and '158 patents. D.I. 180 1–2.[1]

For the following reasons, the Court 1) GRANTS-IN-PART and DENIES-IN-PART Motion No. 1, 2) DENIES-AS-MOOT Motion No. 2, and DENIES Motions Nos. 3 and 4.

## I. BACKGROUND

On January 10, 2023, Plaintiff filed a complaint (D.I. 1) and, on April 4, 2024, Plaintiff filed the Amended Complaint ("AC") (D.I. 157). Defendant filed its Answer to First Amended Complaint, Affirmative Defenses, and Counterclaims on May 2, 2024. D.I. 166. Fact discovery closed on September 23, 2023. D.I. 57. On April 12, 2024, the parties deposed Lindis's expert Dr. Leslie Oleksowicz. D.I. 158. Expert discovery closed on April 19, 2024. D.I. 144 at 1. Defendant filed its Motions for Summary Judgment and to Exclude Expert Testimony on May 24, 2024.

[1] The Court will address and decide Amgen's Motion to Exclude Expert Testimony in a separate Memorandum Opinion to be entered. This Memorandum Opinion deals exclusively with Amgen's four summary judgment motions.

Plaintiff Lindis Biotech, GmbH ("Lindis") asserts that Amgen, *inter alia*, indirectly infringes two method patents, the '421 patent and the '158 patent (collectively, the "Asserted Patents"), by inducing or contributing to a medical practitioner's administration of glucocorticoids (steroids) with the life-saving cancer therapeutic drug BLINCYTO® in a manner that directly infringes the Asserted Patents. D.I. 180 at 1.

## II. LEGAL STANDARDS

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A genuine issue of material fact is one that could lead a reasonable jury to find in favor of the nonmoving party." *Bletz v. Corrie*, 974 F.3d 306, 308 (3d Cir. 2020). "The court must review the record as a whole, draw all reasonable inferences in favor of the nonmoving party, and must not 'weigh the evidence or make credibility determinations.'" *Id.* at 308 (quoting *Parkell v. Danberg*, 833 F.3d 313, 323 (3d Cir. 2016)).

## III. DISCUSSION

### A. Summary Judgment Motion 1: Amgen's Motion for Summary Judgment of No Induced Infringement of the '421 Patent is Granted-in-Part and Denied-in-Part

Amgen requests summary judgment of no induced infringement of all asserted claims of the '421 patent. D.I. 180 at 1. Lindis claims induced infringement by pointing to Amgen's FDA-required prescribing information (U.S. Label) and claiming that the U.S. Label specifically induces healthcare professionals to administer the glucocorticoids to adult patients "immediately before" administering BLINCYTO. D.I. 209 at 4. As a result, the administration of BLINCYTO would necessarily directly infringe the '421 patent. *Id.* In response, Amgen claims that the U.S. Label does not encourage, recommend, or promote administering glucocorticoids "immediately before," "immediately after," or "concurrently" with the recited antibody administration (as required by the

asserted claims of the '421 patent). D.I. 180 at 1. Amgen does not admit that BLINCYTO meets the limitation of a "recited antibody," but it argues that, if BLINCYTO did meet the limitation, Amgen would nonetheless be entitled to summary judgment on this issue. *Id.* at 6. Thus, for purposes of this motion alone, BLINCYTO is assumed to be a "recited antibody."

Lindis agrees to limit its claim for infringement of the '421 patent to administering glucocorticoids to adult patients "immediately before" administration of BLINCYTO. D.I. 209 at 3–4. Lindis does not pursue claims for induced infringement of the '421 patent based on the alternative requirements of administration of glucocorticoids "immediately after" or "concurrently with" a bi-specific antibody. In addition, Lindis does not pursue infringement based on administration of BLINCYTO to pediatric patients. *Id.* at 4 n.1. The court's analysis is thus limited to administering glucocorticoids to adult patients "immediately before" administration of BLINCYTO. For the following reasons, the Court grants Amgen's motion with respect to administration of glucocorticoids "immediately after" or "concurrently with" a bi-specific antibody and with respect to the administration of BLINCYTO to pediatric patients. The Court denies Amgen's motion with respect to administering glucocorticoids to adult patients "immediately before" administration of BLINCYTO.

**1. Inducement Legal Standard**

A patentee may only establish inducement under 35 U.S.C. § 271(b) if it can prove the accused "actively and knowingly aid[ed] and abett[ed] another's direct infringement." *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (emphasis and citation omitted). Where (as here) specific intent is based on a drug label, courts must determine whether the label "encourage[s], recommend[s], or promote[s] infringement." *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 701–02 (Fed. Cir. 2019) (citation omitted). "Merely describing the infringing use, or knowing of the possibility of infringement, will not suffice; specific intent and

action to induce infringement must be shown." *Id.* at 702 (citation omitted) (affirming summary judgment of no induced infringement where the drug label did not describe performing the patented method, even where plaintiffs otherwise showed that some users may infringe); *see also Warner–Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003) (citation omitted).

**2. Summary of Pertinent Facts**

Independent claim 1 of the '421 patent, and, by extension, its dependent claims, require "administering to the subject at least one glucocorticoid immediately before or immediately after administering at least one trifunctional, bispecific immunostimulating antibody." Independent claim 15 of the '421 patent requires "administering to the subject at least one glucocorticoid immediately before, concurrently or immediately after treatment with at least one trifunctional, bispecific immunostimulating antibody." These timing limitations were construed by the Court. "Immediately" means "without any intervening time." D.I. 180 at 6.

The U.S. Label provides BLINCYTO administration information to healthcare professionals. BLINCYTO is only approved for two indications: the treatment in adult and pediatric patients with (1) CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% or (2) relapsed or refractory CD19-positive B-cell precursor ALL. *Id.* at 6–7. For both approved indications, the U.S. Label states to "premedicate" patients with glucocorticoids (e.g., dexamethasone or prednisone). D.I. 176 ¶ 8. For adult patients under both approved indications, the U.S. Label states that premedication should occur "1 hour prior to the first dose of BLINCYTO in each cycle." *Id.* at ¶ 9.

Lindis's technical expert, oncologist Leslie Oleksowicz, M.D. ("Dr. Oleksowicz"), opined that, "as soon as the steroid [glucocorticoid] has finished infusing into the patient, the antibody infusion proceeds. . . . The antibody following the steroids is consistent with how oncologist [sic]

premedicate patients treated with therapeutic antibodies." D.I. 209 at 6. Dr. Oleksowicz further explained that the reason healthcare professionals would want to give BLINCYTO "without any intervening time" after infusion of glucocorticoids is because at that time patients will have the highest steroid levels in their body at the critical point when the need is the greatest to address cytokine release syndrome caused by the antibody: "the closer you give the steroid to the time that the antibody is started the higher the serum levels of dexamethasone will be when the patient starts having symptoms of [cytokine release syndrome]." *Id.* at 7.

At the same time, Dr. Oleksowicz testified that the U.S. Label does not expressly use the words "immediately before" in premedicating adult patients with glucocorticoids before administration of BLINCYTO. D.I. 210 ¶ 15. She further testified that the phrase "an hour before the first dose of Blincyto" in the U.S. Label provides "leeway in when exactly dexamethasone is stopped and Blincyto is begun." D.I. 176 ¶ 16. Lindis asserts that, during Dr. Oleksowicz's deposition, she explained that, because of the amount of time it takes to infuse a patient with a bag of glucocorticoid, there is no intervening time before the patient is administered BLINCYTO. D.I. 209 at 6 ("It's going to take at least 45 minutes, maybe even longer, for that bag to get into the patient and then next the patient is going to get the antibody. . . . [G]enerally the premeds are infused and after those are finished the antibody is infused.").

**3. Analysis**

Amgen asserts that Lindis's claim of inducement of the '421 patent fails as a matter of law and undisputed facts. First, Amgen asserts that inducement fails because the U.S. Label does not specify administering glucocorticoid "immediately before" administering BLINCYTO. D.I. 180 at 10. Second, Amgen asserts that, because the U.S. Label does not specify glucocorticoid administration "immediately before" BLINCYTO administration, inducement also fails as a

matter of law. Because this Court finds that there is a genuine issue of material fact concerning inducement of the '421 patent, this motion is denied.

Based on the record, there is "a genuine issue of material fact . . . that could lead a reasonable jury" to find for Lindis on this issue. *Bletz*, 974 F.3d at 308. In this case, a reasonable jury could find that Amgen specifically intended to premedicate adult patients with glucocorticoids "immediately before" BLINCYTO administration. *See DSU Med. Corp.*, 471 F.3d at 1306. A reasonable jury could reach this conclusion by finding that Amgen's prescribing information, recommending users premedicate adult patients with a glucocorticoid "1 hour prior" to administration of BLINCYTO, necessarily results in administration of the glucocorticoid "without any intervening time"—i.e., "immediately before"—administration of BLINCYTO. As Dr. Oleksowicz contends, instructing healthcare professionals to administer a glucocorticoid "1 hour prior" to administering BLINCYTO, necessarily results in administration of BLINCYTO without any intervening time after completion of the infusion of the glucocorticoid, given the amount of time it takes to infuse the patient with a bag of glucocorticoid.

Amgen bases its summary judgement motion on the difference between the phrases "immediately before" and "1 hour prior." In its view, because these phrases are literally different, there can be no inducement. D.I. 240 at 4. However, a reasonable jury could look at the facts and decide 1) administering glucocorticoid takes one hour and 2) a doctor would administer BLINCYTO immediately after completing the glucocorticoid administration. Indeed, Amgen's efforts to discredit both of these notions fall flat.

First, Amgen attempts to show that there is no factual basis for glucocorticoid administration taking one hour to complete. Amgen quotes portions of Dr. Oleksowicz's deposition to claim that the length of administration of glucocorticoid is "variable," not one hour.

D.I. 240 at 5. However, Dr. Oleksowicz asserted that it would "take at least 45 minutes, maybe even longer" to administer glucocorticoid. D.I. 209 at 6. The actual words of Dr. Oleksowicz provide enough of a basis for a reasonable jury to determine that the length of time to complete administration of glucocorticoid is one hour. Second, Amgen does not counter that a doctor could administer BLINCYTO "without intervening time" after the one-hour period of administering the glucocorticoid. Dr. Oleksowicz's testimony offers a rational explanation that "the closer you give the steroid to the time that the antibody is started the higher the serum levels of dexamethasone will be when the patient starts having symptoms of CRS." D.I. 209 at 10. Thus, there is a basis in the record to support the disputed fact that glucocorticoid administration takes 1 hour and results in the administration of BLINCYTO "without any intervening time."

Moreover, none of the cases cited by Amgen supports summary judgment on this issue. In *Grunethal GmbH v. Alkem Laboratories Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019) (cited by Amgen (D.I. 180 at 13)), the Federal Circuit concluded that an FDA label instructing treatment for "severe chronic pain" generally was insufficient to show induced infringement of claims requiring treatment of a specific type of pain ("polyneuropathic pain"). *Id.* at 1339-40. Severe chronic pain incudes polyneuropathic pain, as well as multiple other forms of severe chronic pain. *Id.* Thus, while treating "severe chronic pain" might treat some amount "polyneuropathic pain," it does not necessary result in such treatment. *Id.* Instructions for treating "severe chronic pain" could just as easily treat other forms of pain, including those falling outside the scope of the claims. *Id.*

In contrast to *Grunethal*, in this action, a reasonable jury could find that Amgen's prescribing information instructs healthcare professionals to give a glucocorticoid in a way that necessarily results in direct infringement of the '421 patent. As discussed above, instructing healthcare professionals to give adult patients a glucocorticoid "1 hour prior" to BLINCYTO could

necessarily cause healthcare professionals to administer BLICYTO "without any intervening time" after administration of the steroid (glucocorticoid), because of the time it takes to completely infuse the patient.

*Ferring Pharms v. Lupin, Inc.*, C.A. No. 19-913 (RGA), 2020 WL 3414750 (D. Del. June 22, 2020) (cited by Amgen (D.I. 180 at 14)) is similarly distinguishable. In *Ferring Pharms*, the court concluded that a regimen instructing patients to drink liquid "at least 2 hours before the colonoscopy," could not logically be interpreted as encouraging, recommending, or promoting consumption "less than 3 hours before the colonoscopy." *Id.* at *4. In contrast, in this action, Lindis offers admissible evidence to attempt to prove that, given the substantial amount of time it takes to completely infuse patients with a glucocorticoid, healthcare professionals necessarily will directly infringe the '421 patent, because BLINCYTO will be administered immediately after infusion, without any intervening time. Unlike the instructions in *Ferring Pharms*, a reasonable jury in this action could find that following Amgen's prescribing information could necessarily cause healthcare professionals to directly infringe when treating adult patients.

Further, Amgen fails to show how a reasonable jury could not find the requisite specific intent for induced infringement. Amgen cites cases where the court found no induced infringement where the drug label did not describe performing the patented method. D.I. 180 at 5 (citing *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019)). However, since the record shows that a reasonable jury in this action could find that the drug label does describe performing the patented method, Amgen's summary judgment argument with respect to specific intent fails.

### B. Summary Judgment Motion 2: Amgen's Summary Judgement Motion of No Contributory Infringement of the '421 Patent is Denied-as-Moot

Amgen's Summary Judgment Motion No. 2 requests summary judgment of no contributory infringement of all asserted claims of the '421 patent. D.I. 180 at 2. Lindis has voluntarily agreed not to pursue a claim for contributory infringement of the '421 patent. D.I. 209 at 1. Thus, Amgen's motion for summary judgment of no contributory infringement of the '421 patent is denied-as-moot.

### C. Amgen's Remaining Summary Judgment Motions Are Denied

Given the Court's denial-in-part of Amgen's first ranked summary judgment motion, the Court denies Amgen's summary judgment motion No. 3 (contending that all asserted claims of the '158 patent are invalid for lack of written description) and summary judgment No. 4 (no induced infringement of all asserted claims of both the '421 and '158 patents) in accordance with its ranking procedures.

## IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS-IN-PART** and **DENIES-IN-PART** Defendant Amgen's Summary Judgment Motion No. 1 as follows: 1) the Court grants Amgen's motion with respect to administration of a glucocorticoid "immediately after" or "concurrently with" a bi-specific antibody; 2) the Court grants Amgen's motion with respect to the administration of BLINCYTO to pediatric patients; and 3) the Court denies Amgen's motion with respect to administering a glucocorticoid to adult patients "immediately before" administration of BLINCYTO. The Court **DENIES-AS-MOOT** Defendant Amgen's Motion for Summary Judgment No. 2, and the Court **DENIES** Defendant Amgen's Motions for Summary Judgment Nos. 3 and 4. An Order consistent with this Memorandum Opinion will be entered.