IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LINDIS BIOTECH, GMBH	)	
	)	
Plaintiff,	)	
v.	)	Case No. 22-35-GBW
	)	
AMGEN INC.	)	JURY TRIAL DEMANDED
	)	
Defendant.	)	

DEFENDANT'S AMGEN INC.'S RULE 50(a) MOTION FOR JUDGMENT AS A MATTER OF LAW AT THE CLOSE OF PLAINTIFF'S CASE-IN-CHIEF

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Rules

Defendant Amgen Inc. ("Amgen") respectfully moves for judgment as a matter of law. Plaintiff Lindis Biotech GmbH ("Lindis")'s case-in-chief is now closed, and there is no legally sufficient evidentiary basis for a reasonable jury to find for Lindis that Amgen induced infringement of the asserted claims of U.S. Patent Nos. 8,709,421 ("'421 patent") and 10,071,158 ("'157 patent"), that such infringement was willful, or that Lindis is entitled to damages. Consequently, this Court should grant judgment as a matter of law in favor of Amgen on those issues. *See, e.g.,* Fed. R. Civ. P. 50(a)(1).

I. LEGAL STANDARD

Under Rule 50(a), the Court may enter judgment as a matter of law (JMOL) "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a); *see also Rego v. ARC Water Treatment Co. of Pa.*, 181 F.3d 396, 400 (3d Cir. 1999).

JMOL is warranted on any issue where a jury's verdict in favor of the nonmovant would lack supporting substantial evidence or would be based on erroneous legal conclusions. *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1466 (Fed. Cir. 1997). "[C]onclusory testimony . . . does not constitute substantial evidence." *Sunoco Partners Mktg. & Terminals L.P. v. Powder Springs Logistics, LLC*, 624 F. Supp. 3d 473, 479 (D. Del. 2022) (citing *MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1172 (Fed. Cir. 2015)). Because no reasonable jury could find for Lindis based on this record, Amgen requests JMOL in its favor on Lindis's claims of infringement, willfulness, and damages.

II. THE COURT SHOULD GRANT JUDGMENT AS A MATTER OF LAW OF NO INFRINGEMENT

Lindis bears the burden of proving infringement by a preponderance of the evidence. *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1364 (Fed. Cir. 2000). Lindis

asserts only a theory of induced infringement in this case. "In order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement, and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002) (internal citation omitted). Lindis failed to adduce legally sufficient evidence to show either direct infringement or induced infringement of either of the two asserted patents.

A. No Reasonable Jury Could Find Direct Infringement

Lindis contends that doctors directly infringe the Asserted Claims by preadministering glucocorticoids before Blincyto, but has failed to adduce sufficient evidence from which a reasonable jury could conclude that at least two necessary elements of the asserted method claims are being practiced.

1. No non-specific cytokine release (both asserted patents)

Claims 3, 8, and 15 of the '421 patent and claims 1, 12, and 20 of the '158 patent ("Asserted Claims") are directed to a method of reducing non-specific cytokine release and require that a bispecific immunostimulatory antibody causes **non-specific cytokine release**. Day 2 Tr. at 176:3-14 (Dr. Leslie Oleksowicz, Lindis's sole technical expert, agreeing that "to meet every one of the asserted claims, [] the antibody that's being administered would have to be causing non-specific release of cytokines."). Lindis provided no reliable evidence from which a reasonable juror could conclude that Blincyto causes non-specific release of cytokines. Neither Lindis nor Dr. Oleksowicz tested Blincyto for non-specific release. *Id.* at 202:4-18 (Dr. Oleksowicz admitting that she has "never tested Blincyto to see if it caused non-specific release of cytokines"), 202:22-23 (Dr. Oleksowicz admitting she is "not aware of Lindis ever doing any testing with Blincyto to see if it caused non-specific release of cytokines"), 205:25-206:5 (Dr. Oleksowicz admitting that she is not relying on any direct testing of Blincyto by Lindis for her

infringement opinions). Instead, Lindis—through its direct examination of Dr. Oleksowicz—introduced four document exhibits in an attempt to support its unsubstantiated theory that Blincyto *may* cause nonspecific release of cytokines: (1) CDER Application (JTX079); (2) Klinger 2012 (JTX066); (3) Topp (DTX-300); and (4) Bargou 2008 Supplement (DTX-240). None of these references concludes this point, and Dr. Oleksowicz agrees.

CDER Application. Dr. Oleksowicz acknowledged that at least five scientists at the United States Food and Drug Agency ("FDA") reviewed the data in the CDER Application and concluded that "there's no T cell proliferation noted [absent the target with Blincyto]," *i.e.,* there is no non-specific release of cytokines caused by Blincyto. *See* Day 2 Tr. at 209:22-210:25, 211:4-10, 212:18-24, 213:3-8. Dr. Oleksowicz further testified that she "do[es] not disagree with the FDA." *See id.* at 211:7-10, 213:3-5.

Klinger 2012 and Topp 2011. Dr. Oleksowicz acknowledged that Klinger 2012 and Topp 2011—which describe the same study—both conclude that Blincyto cannot cause T cell activation and release of cytokines in the absence of target B cells. *See* Day 2 Tr. at 220:23-221:19, 224:4-18; *see also* JTX066_000008 ("[M]onovalent binding of blinatumomab does not activate T cells which is strictly dependent on the presence of target cells."); DTX-300.0005 ("[U]nivalent binding of blinatumomab to T cells in the absence of target cells does not induce cytokine release or proliferation."). Yet, Dr. Oleksowicz ignores that conclusion and reinterprets the data in Klinger 2012 and Topp 2011 to rationalize her theory that Blincyto causes non-specific release of cytokines. In particular, she argues that Figure 6A in Klinger 2012 and Figure 2A in Topp 2011 show T cell proliferation and release of cytokines in minimal residual disease (MRD) patients that have "zero" or "infinitesimally small number of" target B cells. Day 2 Trial Tr. at 99:4-100:25 (discussing Fig. 6A in Klinger 2012), 101:19-103:17 (discussing Fig. 2A in Topp 2011). But Dr.

Oleksowicz admitted during cross examination that the MRD patients in Klinger 2012 and Topp 2011 had approximately "375 million B cells . . . before they started the first round of treatment." *Id.* at 218:5-219:5. A reasonable juror would conclude that the T cell proliferation and release of cytokines in Klinger 2012 and Topp 2011 is caused by Blincyto not by non-specific release, but by *specific* release, i.e, when T cells were activated after binding to the Blincyto already bound to those 375 million B cell targets.

Bargou 2008. Similarly, Dr. Oleksowicz argued that Bargou 2008 shows that Blincyto causes non-specific release of cytokines because one cherry-picked mantle cell lymphoma patient had, in Dr. Oleksowicz's view, "zero or close to zero" target B cells and showed an "immediate rise of cytokines" after Blincyto administration. *Id.* at 104:3-105:23 (discussing Fig. S1 Patient 10 in Bargou 2008 Supplement), 225:13-20. However, during cross-examination, Dr. Oleksowicz admitted that that patient had approximately three billion target B cells at the start of the Blincyto administration. *Id.* 224:25-226:20. Further, nowhere does Bargou conclude that Blincyto causes non-specific release of cytokines. *See* DTX-240; JTX-067. A reasonable juror would again conclude that the "immediate rise of cytokines" described in Bargou 2008 is due to specific release, again when T cells were activated after binding to the Blincyto already bound to those three billion target B cells.

Lindis's four references fail to establish that Blincyto causes non-specific release of cytokines, and thus no reasonable jury could find for Lindis on direct infringement of either of the asserted patents.

2. No evidence that Blincyto is "trifunctional" ('421 patent)

The asserted claims of the '421 patent all require that the antibody be "trifunctional." To establish literal infringement, a patentee must prove "each and every limitation set forth in a claim" appears in the accused method. *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307,

1312 (Fed. Cir. 2005). The Court construed "trifunctional" as "a bispecific antibody having a function in addition to the two specific binding functions, namely (1) binding to a target antigen and (2) binding to a CD marker. Lindis did not present any evidence of a third function of Blincyto. Accordingly, for this additional reason, Lindis has failed to establish direct infringement with respect to the '421 patent.

B. No Reasonable Jury Could Find Induced Infringement

JMOL in favor of Amgen is independently warranted because Lindis failed to present legally sufficient evidence that Amgen has induced direct infringement. Indeed, even if health care providers' Blincyto administrations did directly infringe the Asserted Claims—they do not—no reasonable jury could find based on the record that Amgen induced such infringement.

"A person *induces* infringement under § 271(b) by actively and knowingly aiding and abetting another's direct infringement." *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 675 (Fed. Cir. 1990) (emphasis in original). Where 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). "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.

"The mere fact that the label may permit an infringing use is insufficient to show inducement, regardless of whether that fact is alleged in the complaint or stated later by an expert." *Ferring Pharms. Inc. v. Lupin Inc.*, 2020 WL 3414750, at *4 (D. Del. June 22, 2020); *see also Genentech, Inc. v. Sandoz, Inc.*, 592 F. Supp. 3d 355, 368 (D. Del. 2022) (no induced infringement where the "label merely provides physicians with multiple dose modification options, some covered by the Asserted Patents and some not, and leaves it to the physician's

clinical judgment to determine how to modify the patient's dosage."), *aff'd*, 55 F.4th 1368 (Fed. Cir. 2022).

To meet its burden, Lindis had to prove that Blincyto's label expressly "encourage[s], recommend[s], or promote[s] infringement." *HZNP Meds.*, 940 F.3d at 701-02. In other words, Lindis had to prove that the Blincyto's label induces physicians to administer glucocorticoids as a premedication to reduce non-specific release of cytokines caused by Blincyto. Lindis has failed to do so and has provided no other evidence of the alleged inducement.

Dr. Oleksowicz admitted that the Blincyto label **does not**:

- "mention non-specific [release of] cytokines," Day 2 Tr. 180:17;
- "say, in all of the scientific data that it provides, that Blincyto causes non-specific release of cytokines," *id.* at 180:14-17;
- "say anything about reducing non-specific release of cytokines," *id.* at 180:23-181:1;
- "say that premedication with glucocorticoids will reduce non-specific release of cytokines," *id.* at 181:8-11;
- "instruct physicians to administer glucocorticoids to reduce non-specific release of cytokines," *id.* at 181:17-20; or
- say "that cytokine release syndrome is caused by non-specific release of cytokines," *id.* at 183:14-17.

Because Lindis failed to adduce reliable evidence that Blincyto's label induces physicians to administer a glucocorticoid before Blincyto to reduce non-specific cytokine release, no reasonable jury could find that Amgen induces infringement.

Finally, JMOL is also appropriate because Lindis has made no showing that Amgen knew, or should have known, that the allegedly inducing acts constitute infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011).

III. THE COURT SHOULD GRANT JUDGMENT AS A MATTER OF LAW OF NO WILLFULNESS

No reasonable jury could find from the evidence presented at trial that Lindis's alleged infringement of the asserted claims was willful. To prove willful infringement, Lindis was required to show both that Amgen knew of the patents-in-suit and that it engaged in "deliberate or intentional infringement" of the patents. *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 988 (Fed. Cir. 2021). Further, "[t]o establish willfulness, the patentee must show the accused infringer had a specific intent to infringe at the time of the challenged conduct." *Id.* at 987-88.

There is no evidence from which a reasonable jury could find that Amgen knew that the allegedly inducing acts constitute infringement, let alone that Amgen had a specific intent to infringe. As discussed with respect to induced infringement, neither the Blincyto label nor any other evidence in the record suffices to show that Amgen knew that pre-administration of glucocorticoids before Blincyto met the "non-specific release of cytokines" claim limitations of both patents. Nor is there evidence that, with respect to the '421 patent, Amgen knew that Blincyto was a "trifunctional" antibody. On the contrary, Lindis's main fact witness, Dr. Lindhofer, testified that Amgen expressly stated its belief that Blincyto was not covered by Lindis's patent because it lacks an Fc region. Day 1 Tr. at 209:12-20. Lindis also presented no evidence that Amgen became aware of Lindis's infringement theory before Lindis filed its complaint in January 2022. This Court has previously ruled that "[t]he complaint itself cannot serve as the basis for a defendant's actionable knowledge for a willful infringement claim." *Cleveland Med. Devices Inc. v. ResMed Inc.*, 696 F. Supp. 3d 4, 14 (D. Del. 2023) (Williams, J.)

On this sparse record, JMOL of no willfulness is warranted.

IV. THE COURT SHOULD GRANT JUDGMENT AS A MATTER OF LAW OF NO DAMAGES

"The burden of proving damages falls on the patentee." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009). Even if Amgen is found to have induced infringement of valid claims of the '421 or '158 patents, Lindis has failed to show an adequate basis for reasonable royalty damages for at least the reasons below. Lindis's proposed damages should therefore be rejected as a matter of law.

A. Lindis Failed to Present Evidence to Support Ex-U.S. Damages

Preliminarily, Amgen reiterates and preserves the arguments made in support of its Motion to Preclude Lindis's Damages Expert from Opining that Lindis Should Receive Reasonable Royalty Damages on Amgen's Ex-U.S. Sales of Blincyto, D.I. 175. Because Mr. Schoettelkotte's legally and factually flawed opinions are the sole basis for Lindis's request for ex-U.S. damages, that testimony should not have been admitted, and the Court should rule that Lindis is entitled to no damages on ex-U.S. sales. *See, e.g., Uniloc USA Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1315 (Fed. Cir. 2011).

Lindis did not present evidence from which a reasonable jury could find entitlement to damages based on Blincyto sales outside the United States. To recover such damages, Lindis had to show, by a preponderance of the evidence, a causal relationship between the accused infringing conduct and Amgen's foreign Blincyto sales. *See Brumfield, Tr. for Ascent Tr. v. IBG LLC*, 97 F.4th 854, 878-79 (Fed. Cir. 2024) ("[T]he infringement [must] have the needed causal relationship to the foreign conduct for which recovery is sought.") The only conduct accused of infringing the asserted method claims is Amgen's alleged inducement of healthcare providers to pre-administer a glucocorticoid before Blincyto in the United States. Dr. Oleksowicz, Lindis's

technical expert, provided no opinion on whether any conduct outside the United States infringes.

Because Blincyto sales abroad cannot infringe, Lindis had to, as a "minimum requirement," "show why that foreign conduct increases the value of the domestic infringement itself—because, e.g., the domestic infringement enables and is needed to enable otherwise-unavailable profits from conduct abroad." *Id.* at 877. Lindis did not present any evidence that could satisfy this "minimum requirement." *Id.* No facts were introduced to establish a causal link between the alleged domestic infringement—Amgen's alleged inducement of healthcare providers in the U.S.—and Blincyto's sales abroad. Nor did Lindis present any testimony or other evidence providing any connection between Blincyto's U.S. FDA label and Amgen's sales of Blincyto abroad. Mr. Schoettelkotte merely applied his royalty rate to ex-U.S. sales, but admitted he did not offer any opinion on whether those sales *should* be included in the first place. Day 3 Tr. at 297:2-4.

Given the absence of *any* facts from which a reasonable jury could determine a causal nexus between the activity accused of infringement—Amgen's alleged inducement of health care providers' direct infringement in the U.S.—and the Blincyto sales abroad, JMOL should be granted with respect to any damages based on ex-U.S. Blincyto sales.

B. Lindis's Damages Evidence Is Impermissibly Based on Non-Infringing Activities

The patentee must show its damages "by evidence," and damages "must not be left to conjecture by the jury. They must be proved, not guessed at." *Promega Corp. v. Life Techs. Corp.*, 875 F.3d 651, 660 (Fed. Cir. 2017). The Federal Circuit has repeatedly granted JMOL of no damages when a patentee's damages theory is untethered from its infringement theory such that the damages theory includes non-infringing acts. "The royalty base for reasonable royalty

damages cannot include activities that do not constitute patent infringement, as patent damages are limited to those 'adequate to compensate for the infringement.'" *Enplas Display Device Corp. v. Seoul Semiconductor Co., Ltd.*, 909 F.3d 398, 411 (Fed. Cir. 2018) (quoting *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1343 (Fed. Cir. 2015)). In *Enplas*, the defendant moved for JMOL that the jury's damages award was not supported by substantial evidence because "the only evidence supporting the jury's award was based, in part, on non-infringing sales." *Id.* The Federal Circuit agreed and vacated the award, holding that damages cannot be based on "activities that do not constitute patent infringement." *Id.*

Here, the trial record unambiguously shows that Mr. Schoettelkotte's damages calculations, which use as a royalty base all Blincyto revenue, are impermissibly based, in part, on non-infringing activities—namely, frontline and pediatric uses of Blincyto.

1. Lindis seeks damages that improperly include non-infringing frontline, off-label Blincyto administration

As this Court recently emphasized, "[a] label cannot induce infringement if a drug is used in a way the label does not prescribe, *i.e.*, 'off-label use.'" D.I. 310 at 7 (citing *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1322 (Fed. Cir. 2012)). Lindis's damages expert, Mr. Schoettelkotte, acknowledged being aware of evidence showing that Blincyto is prescribed for off-label frontline (or "first-line") use about 15% of the time. Day 3 Tr. at 286:15-19. He also conceded that the Blincyto label does not specify such frontline or first-line use of Blincyto. *Id.* at 284:2-12. Finally, he admitted that "to the extent [off-label frontline use] was determined not to be infringing, it would need to be removed" from his royalty calculation. *Id.* 286:25-287:1. Lindis presented no evidence from which a reasonable juror could find that Amgen induces off-label, frontline use of Blincyto. Because Mr. Schoettelkotte did not exclude such non-infringing

use, his damages opinion cannot stand. *See Enplas*, 909 F.3d at 412 ("[Section] 284 and our precedent proscribe awarding damages for non-infringing activity.").

2. Lindis seeks damages that improperly include non-infringing pediatric use of Blincyto

Mr. Schoettelkotte's damages opinion further runs afoul of apportionment law because it also includes royalties for non-infringing, pediatric use of Blincyto. As the Court stated in its Memorandum Opinion on Amgen's Motions for Summary Judgment, Lindis does not accuse pediatric Blincyto administration of infringing the '421 patent. D.I. 292 at 4. Mr. Schoettelkotte readily acknowledged this fact (Day 3 Tr. at 279:5-12), and yet admitted that his damages calculation nonetheless *does include* such non-infringing pediatric use. *Id.* at 280:22-281:3. Mr. Schoettelkotte's calculated damages span from January 11, 2016, six years before Lindis's complaint, to June 30, 2024. *Id.* at 159:19-160:3. Thus for at least the period from January 11, 2016, to September 11, 2018 (when the '158 patent was granted, JTX-2 at Cover), there can be no dispute that Mr. Schoettelkotte's damages "include activities that do not constitute patent infringement." *AstraZeneca*, 782 F.3d at 1343. JMOL of no damages is thus warranted for this additional reason.

V. CONCLUSION

Because no reasonable jury could find for Lindis on these issues, Amgen respectfully requests that the Court grant judgment as a matter of law in favor of Amgen on (1) non-infringement; (2) lack of willfulness; and (3) damages.

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