



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALNYLAM PHARMACEUTICALS, INC.,)	
)	
)	
Plaintiff,)	
)	C.A. No. 22-336 (CFC)
v.)	(CONSOLIDATED)
)	
PFIZER INC., PHARMACIA & UPJOHN CO. LLC, BIONTECH SE and BIONTECH MANUFACTURING GMBH,)	JURY TRIAL DEMANDED
)	
)	
)	
Defendants.)	REDACTED - PUBLIC VERSION

DEFENDANTS’ OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT OF LITERAL NONINFRINGEMENT FOR “HEAD GROUP” (SUMMARY JUDGMENT MOTION NO. 1)

CONNOLLY GALLAGHER, LLP
Arthur G. Connolly, III (#2667)
Alan R. Silverstein (#5066)
1201 North Market Street, 20th Floor
Wilmington, DE 19801
(302) 757-7300
aconnolly@connollygallagher.com
asilverstein@connollygallagher.com

*Attorneys for Defendants Pfizer Inc.
and Pharmacia & Upjohn Co. LLC*

December 20, 2024

MORRIS, NICHOLS, ARSHT, & TUNNEL LLP
Jeremy A. Tigan (#5239)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jtigan@morrisnichols.com
araucci@morrisnichols.com

*Attorneys for Defendants BioNTech SE
and BioNTech Manufacturing GmbH*

TABLE OF CONTENTS

	Page
I. NATURE AND STAGE OF PROCEEDINGS.....	1
II. SUMMARY OF ARGUMENT.....	1
III. STATEMENT OF FACTS	2
IV. LEGAL STANDARDS	2
A. Summary judgment	2
B. Literal infringement.....	2
V. ARGUMENT.....	3
VI. CONCLUSION.....	4

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Planet Bingo, LLC v. GameTech Int’l, Inc.</i> , 472 F.3d 1338 (Fed. Cir. 2006)	2
<i>SIMO Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.</i> , 983 F.3d 1367 (Fed. Cir. 2021)	3
Other Authorities	
Fed. R. Civ. P. 56(a).....	2

I. NATURE AND STAGE OF PROCEEDINGS

Alnylam contends ALC-0315—a component in Defendants’ vaccine products—infringes 13 claims across five patents. UF¹ 1. The Court construed claim terms, expert discovery is complete, and trial begins July 7, 2025.

II. SUMMARY OF ARGUMENT

In its revised claim construction decision, the Court construed the term “head group” and “effectively nullif[ied]” all asserted dependent claims reciting a “head group” that “consists of a saturated aliphatic group and a hydroxyl group,” as inconsistent with the Court’s claim construction for “head group.” D.I. 248 at 27; UF 8. Three such claims remain asserted: US 11,590,229 claim 28; US 11,612,657 claim 19; and US 11,633,479 claim 12 (the “Nullified Claims”).

Under a plain reading and logical application of the Court’s decision, all other remaining asserted claims—listed below—are not literally infringed:

- US 11,246,933 claims 22, 24–26
- US 11,382,979 claims 2, 4, 13, 17
- US 11,590,229 claims 27
- US 11,612,657 claims 5

(the “Challenged Claims”). UF 1. Because the alleged ALC-0315 “head group” is the same “head group” recited in the Nullified Claims, it is not covered by the

¹ “UF” refers to the accompanying concise statement of undisputed facts.

Court’s “head group” claim construction. Thus, ALC-0315 does not literally infringe the Challenged Claims.

III. STATEMENT OF FACTS

The Challenged Claims all recite a “head group.” UF 3. The Court construed “head group” as “a group that must be either permanently positively charged or protonatable.” D.I. 249. The Court found it “undisputed that an artisan of ordinary skill would not consider a head group consisting of a saturated aliphatic group and a hydroxyl group to be protonatable in a biological context.” *Id.* at 27. Consequently, the Court found that its construction “effectively nullif[ies]” all dependent claims reciting such purported head groups. The alleged “head group” of ALC-0315 is a saturated aliphatic group and a hydroxyl group—i.e., the same purported head group in the Nullified Claims. UF 7, 8.

IV. LEGAL STANDARDS

A. Summary judgment

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).

B. Literal infringement

“Infringement entails a two-step process: First, the court determines the scope and meaning of the patent claims asserted and second, the properly construed claims are compared to the allegedly infringing device.” *Planet Bingo*,

LLC v. GameTech Int'l, Inc., 472 F.3d 1338, 1341 (Fed. Cir. 2006) (cleaned up). “To prove literal infringement, the patentee must show that the accused [product] contains each and every limitation of the asserted claims.” *SIMO Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.*, 983 F.3d 1367, 1380 (Fed. Cir. 2021).

V. ARGUMENT

The Court construed “head group,” a term that appears in all asserted claims, as “a group that must be either permanently positively charged or protonatable.”

D.I. 249. In reaching that construction, the Court found it “undisputed that an artisan of ordinary skill would not consider a head group consisting of a saturated aliphatic group and a hydroxyl group to be protonatable in a biological context.”

D.I. 248 at 27 (citing, e.g., Alnylam’s expert, Dr. Kros, D.I. 124-1 ¶¶18 n.4, 58 n.16, 66 n.19)². As a result, the Court also found that its construction “effectively nullif[ies]” the Nullified Claims reciting this alleged “head group” as inconsistent with the Court’s claim construction for “head group.” *Id.*

² See also [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] D.I. 184 at 21 (Alnylam: claims recite “biological cationic lipid compounds”); D.I. 124-1 (Kros. Decl.) ¶16 (claims recite “biological cationic lipids”), 37 n.19 (the “patented cationic lipids” are “for therapeutic purposes”).

Whereas the Court’s construction requires a head group that “must be ... protonatable” (*id.* at 32), the “head group” in the Nullified Claims—in Alnylam’s words—is “only composed of groups that are not protonatable” and “not protonatable for the biological cationic lipid compounds claimed.” D.I. 184 at 13, 21. Citing the Nullified Claims, Alnylam made clear this is undisputed: “It is without question each of the Patents-at-Issue include dependent claims in which the head groups are not positively charged or protonatable.” *Id.* at 53; *see also* D.I. 86 at 56 n.26 (arguing these claims are “limited to non-protonatable head groups”).

It is undisputed that the alleged ALC-0315 “head group” is the *same* head group recited in the Nullified Claims—i.e., “a saturated aliphatic group and a hydroxyl group.” UF 7. Consequently, the Challenged Claims necessarily are not literally infringed for the same reason the Court’s construction “effectively nullif[ies]” the dependent claims reciting the same head group: The Court’s construction does not cover a purported head group consisting of “a saturated aliphatic group and a hydroxyl group.”

Thus, ALC-0315 does not meet the “head group” limitation as construed.

VI. CONCLUSION

The Court should enter summary judgment of no literal infringement for the Challenged Claims.

CONNOLLY GALLAGHER, LLP

/s/ Alan R. Silverstein

Arthur G. Connolly, III (#2667)
Alan R. Silverstein (#5066)
1201 North Market Street, 20th Floor
Wilmington, DE 19801
(302) 757-7300
aconnolly@connollygallagher.com
asilverstein@connollygallagher.com

OF COUNSEL:

Sara Tonnies Horton
WILLKIE FARR & GALLAGHER
300 North LaSalle Drive
Chicago, IL 60654
(312) 728-9040

Michael Johnson
Heather Schneider
Dan Constantinescu
WILLKIE FARR & GALLAGHER
787 Seventh Avenue
New York, NY 10019
(212) 728-8000

*Attorneys for Defendants and
Counterclaimants Pfizer Inc. and
Pharmacia & Upjohn Co. LLC*

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jtigan@morrisnichols.com
araucci@morrisnichols.com

OF COUNSEL:

Charles B. Klein
Jovial Wong
Claire A. Fundakowski
Sharon Lin
WINSTON & STRAWN LLP
1901 L Street, N.W.
Washington, DC 20036
(202) 282-5000

Eimeric Reig-Plessis
WINSTON & STRAWN LLP
101 California Street
San Francisco, CA 94111
(415) 591-1000

Brian L. O’Gara
WINSTON & STRAWN LLP
35 W. Wacker Dr.
Chicago, IL 60601
(312) 558-5600

Ashley Graham
WINSTON & STRAWN LLP
200 Park Avenue
New York, NY 10166
(212) 294-6700

*Attorneys for Defendants BioNTech SE
and BioNTech Manufacturing GmbH*

December 20, 2024

WORD COUNT CERTIFICATION

The undersigned counsel hereby certifies that the forgoing document contains 902 words, which were counted by using the word count feature in Microsoft Word, in 14-point Times New Roman font. The word count includes only the body of the brief. The word count does not include the cover page, tables of contents and authorities, or the counsel blocks.

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)

CERTIFICATE OF SERVICE

I hereby certify that on December 20, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 20, 2024, upon the following in the manner indicated:

Ethan H. Townsend, Esquire
MCDERMOTT WILL & EMERY LLP
The Brandywine Building
1000 N. West Street, Suite 1400
Wilmington, DE 19801
Attorneys for Plaintiff
Alnylam Pharmaceuticals, Inc.

VIA ELECTRONIC MAIL

William G. Gaede, III, Esquire
Anisa Noorassa, Esquire
MCDERMOTT WILL & EMERY LLP
415 Mission Street, Suite 5600
San Francisco, CA 94105
Attorneys for Plaintiff
Alnylam Pharmaceuticals, Inc.

VIA ELECTRONIC MAIL

Sarah Chapin Columbia, Esquire
Sarah J. Fischer, Esquire
MCDERMOTT WILL & EMERY LLP
200 Clarendon Street, Floor 58
Boston, MA 02116-5021
Attorneys for Plaintiff
Alnylam Pharmaceuticals, Inc.

VIA ELECTRONIC MAIL

Ian B. Brooks, Esquire
Timothy M. Dunker, Esquire
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street NW
Washington, DC 20003
Attorneys for Plaintiff
Alnylam Pharmaceuticals, Inc.

VIA ELECTRONIC MAIL

Bhanu K. Sadasivan, Ph.D.
MCDERMOTT WILL & EMERY LLP
650 Live Oak Avenue, Suite 300
Menlo Park, CA 94025-4885
Attorneys for Plaintiff
Alnylam Pharmaceuticals, Inc.

VIA ELECTRONIC MAIL

Mandy H. Kim, Esquire
MCDERMOTT WILL & EMERY LLP
18565 Jamboree Road, Suite 250
Irvine, CA 92612-2565
Attorneys for Plaintiff
Alnylam Pharmaceuticals, Inc.

VIA ELECTRONIC MAIL

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)