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I. NATURE AND STAGE OF PROCEEDINGS

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

II. SUMMARY OF ARGUMENT

Alnylam’s theory under the doctrine of equivalents (“DOE”) would vitiate express claim limitations and applies the wrong analytical framework. Therefore, it raises no triable dispute, and the Court should grant summary judgment of noninfringement under DOE.

III. STATEMENT OF FACTS

All asserted claims require a “head group” that is “directly bonded” to a “central moiety.” UF 4. The Court construed “head group” as “a group that must be either permanently positively charged or protonatable.” D.I. 249.

Alnylam contends that ALC-0315’s single nitrogen atom literally satisfies the “central moiety” limitation. UF 7. Alnylam further contends that ALC-0315’s saturated aliphatic group and hydroxyl group literally satisfies the “head group” limitation. UF 6. Alternatively, Alnylam contends that to the extent ALC-0315’s alleged “head group” does not literally infringe the “head group” limitation, the

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

alleged *central moiety*—i.e., ALC-0315’s single nitrogen atom—*also* satisfies the “head group” limitation under DOE. UF 8.

IV. 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).

“[DOE] provides a limited exception to the principle that claim meaning defines the scope of the exclusivity right,” but infringement under DOE “is ‘exceptional.’” *NexStep, Inc. v. Comcast Cable Commc’ns, LLC*, 119 F.4th 1355, 1370 (Fed. Cir. 2024). “[P]roof under [DOE] must be on a limitation-by-limitation basis” (*id.* at 1370)—i.e., “applied to individual elements of the claim, not to the invention as a whole” (*Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997)). Where “a theory of equivalence would entirely vitiate a particular claim element,” “courts are obliged to grant partial or complete summary judgment.” *Id.* at 39 n.8.

V. ARGUMENT

The Court should enter summary judgment of noninfringement under DOE because Alynlam’s DOE theory fails to raise a triable dispute.

First, an alleged “head group” that is *not* permanently positively charged or protonatable (and thus does not literally infringe) cannot be equivalent to one that

“must be permanently positively charged or protonatable.” D.I. 284 at 32. A non-protonatable “head group” is the *antithesis* of one that “must be” protonatable; DOE cannot recapture “the very thing that the construction excludes.” *Southco, Inc. v. Fivetech Tech. Inc.*, 611 F. App’x 681, 686 (Fed. Cir. 2015); *see also Cook Biotech Inc. v. ACell, Inc.*, 460 F.3d 1365, 1379 (Fed. Cir. 2006) (“equivalency cannot embrace a structure that is specifically excluded from the scope of the claims”); *Planet Bingo, LLC v. GameTech Int’l, Inc.*, 472 F.3d 1338, 1345 (Fed. Cir. 2006) (“refus[ing] to apply [DOE] ... where the accused [product] contained the antithesis of the claimed structure”). Here, equivalency cannot be used to capture ALC-0315’s *non*-protonatable saturated aliphatic group and hydroxyl group as the alleged “head group” because that structure is *excluded* by the asserted claims. *See* D.I. 248 at 27.

Second, the testimony of Alnylam’s DOE expert, Dr. Kros, cannot raise a material factual dispute because he fails to apply DOE “on a limitation-by-limitation basis.” *NexStep*, 119 F.4th at 1370. Dr. Kros admits that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Dr. Kros’s opinion raises no triable question of fact because DOE must be “applied to individual elements of the claim, not to the invention as a whole.” *Warner-Jenkinson*, 520 U.S. at 29.

Third, Alnylam’s DOE theory impermissibly vitiates multiple limitations in all asserted claims, including the “head group” limitation and the limitation that the claimed “head group” structure and the separately claimed “central moiety” structure must be “directly bonded” to each other. UF 4. Under Alnylam’s theory, [REDACTED]

[REDACTED] But the alleged “central moiety” in ALC-0315 is a *single atom*. UF 7. Thus, Alnylam’s theory requires a single atom to satisfy *both* the “central moiety” limitation (literally) *and* the “head group” limitation (under DOE), *plus* the limitation that the central moiety and head group are “directly bonded” to each other. UF 4, 7, 8.

This theory fails as a matter of law and common sense: One atom cannot (1) satisfy two separately claimed structures or (2) be “directly bonded” to itself. *See TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1377 (Fed. Cir. 2008) (affirming summary judgment of noninfringement and rejecting DOE theory that the accused device’s “housing” was equivalent to the disputed “handle” limitation because “[t]he housing is a separately claimed element,” and “we cannot find that the housing in the accused device functions as an equivalent of the ‘handle’ ... without rendering the ‘housing’ limitation meaningless”).

There is no contrary evidence that could raise a triable dispute. Alnylam has no expert testimony or other evidence that ALC-0315’s single nitrogen atom is

“directly bonded” to itself. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Yet Dr. Kros does not—because he cannot—identify *any* physical, direct “bond[]” between the alleged “central moiety” and alleged “head group” equivalent, which are one and the same. UF 8. Thus, Alynlam’s DOE theory suffers from a complete failure of proof and logic.

VI. CONCLUSION

The Court should enter summary judgment that Defendants do not infringe the “head group” limitations under DOE.

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*

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/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)