



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 INVALIDITY UNDER 35 U.S.C. § 112 (SUMMARY JUDGMENT MOTION NO. 2)

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I. NATURE AND STAGE OF PROCEEDINGS

Alnylam presently asserts the following claims:

- US 11,246,933 claims 22, 24–26
- US 11,382,979 claims 2, 4, 13, 17
- US 11,590,229 claims 27, 28
- US 11,612,657 claims 5, 19
- US 11,633,479 claim 12

UF¹ 1. The Court construed claim terms, expert discovery is complete, and trial begins July 7, 2025.

II. SUMMARY OF ARGUMENT

All asserted claims are invalid pursuant to 35 U.S.C. § 112 under the Court’s “head group” claim-construction decision (D.I. 248).

The Court “effectively nullif[ied]” all claims reciting a “head group” that “consists of a saturated aliphatic group and a hydroxyl group”—the alleged “head group” in ALC-0315. *Id.* at 27; UF 10. Alnylam continues asserting three such claims: US 11,590,229 claim 28; US 11,612,657 claim 19; and US 11,633,479 claim 12 (the “Nullified Claims”). The Court should enforce its claim-construction ruling by entering summary judgment that these claims are invalid for improper dependency under 35 U.S.C. § 112(d).

The Nullified Claims are also invalid for lacking written description under § 112(a). In construing “head group,” the Court analyzed the asserted patents’

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

shared written description and found it does not describe a “head group” consisting of a saturated aliphatic group and hydroxyl group. *Id.* at 14–16. The Nullified Claims are thus invalid under both §§ 112(d) and (a).²

Under Alnylam’s contention that ALC-0315 literally infringes, the remaining claims necessarily would be invalid under § 112(a) for the same reason as the Nullified Claims—ALC-0315 has the same alleged “head group” recited in the Nullified Claims that lacks written description. *Vanmoor v. Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366 (Fed. Cir. 2000) (affirming summary judgment of invalidity where defendants denied infringement but “pled in the alternative” that plaintiff’s theory rendered claims invalid). The Court should thus enter summary judgment that any asserted claim found to cover ALC-0315 is necessarily invalid under § 112(a).

III. STATEMENT OF FACTS

All the presently asserted claims require a “head group.” UF 5. The Nullified Claims limit the “head group” of the claims from which they depend to those “consisting of a saturated aliphatic group and a hydroxyl group.” UF 6.

² Defendants also seek judgment under § 112(a) because Alnylam continues prosecuting claims in this patent family to ensnare ALC-0315 without using the “head group” or “cationic lipid” terms—a prosecution strategy designed to circumvent this Court’s rulings. *See* D.I. 248 at 32. Such gamesmanship will end if the Court enters judgment under § 112(a) confirming its finding that the written description does not support head groups consisting of a saturated aliphatic group and a hydroxyl group.

After twice hearing expert testimony and making credibility determinations, the Court construed “head group” as “a group that must be either permanently positively charged or protonatable.” D.I. 249. The Court reached that conclusion after analyzing the specification, which “spans more than 250 pages and contains 1,021 drawn embodiments of complete cationic lipids.” D.I. 248 at 12, 32. Despite its length, the specification discloses no drawn-out head group without a nitrogen/amine. UF 11. In reaching its claim construction, the Court also found the written description (including the disclosure in column 32 relied on by Alnylam) does not support “a non-protonatable head group that has a hydroxyl ... group on its own.” D.I. 248 at 15–16.

The Court further 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 this alleged “head group.” *Id.*

The purported “head group” in ALC-0315 consists only of a saturated aliphatic group and a hydroxyl group—no nitrogen. UF 9.

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. Improper dependency

“[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed.” 35 U.S.C. § 112(d). “A dependent claim that contradicts, rather than narrows, the claim from which it depends is invalid.” *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1362 (Fed. Cir. 2016).

C. Written description

Under 35 U.S.C. § 112(a), a patent’s written description must “reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Because “the test requires an objective inquiry into the four corners of the specification” (*id.*), courts may invalidate claims on summary judgment “for failure to meet the written description requirement, based solely on the language of the patent specification.” *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004).

V. ARGUMENT

A. The Court’s “head group” claim-construction decision renders the Nullified Claims invalid under 35 U.S.C. §§ 112(d) and (a).

1. The Nullified Claims are invalid for improper dependency.

Under the Court’s revised claim-construction decision, the Nullified Claims are invalid under § 112(d). 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). Consequently, the Court “effectively nullif[ied]” all dependent claims reciting this alleged “head group” for contradicting the Court’s construction. *Id.* In “effectively nullify[ing]” these claims, the Court cited *Multilayer* (D.I. 248 at 27–29), which invalidated a dependent claim under § 112(d) that “contradicts, rather than narrows, the claim from which it depends.” 831 F.3d at 1362.

The Court’s construction requires a head group that “must be ... protonatable” (*id.* at 32), whereas the Nullified Claims—in Alnylam’s words—are “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”).

Thus, the Nullified Claims contradict the Court’s head group construction—rendering them invalid under § 112(d).

2. The Nullified Claims are also invalid for lacking written-description support.

The Court’s reasoning underlying its construction—i.e., that the written description does not support a “head group” construction broad enough to capture the Nullified Claims’ “head group” (D.I. 248 at 12–18)—necessarily renders those claims invalid under § 112(a) as well.

The only alleged written-description support Alnylam cited for a “head group” having a hydroxyl group without an amine is column 32. *Id.* at 14. The Court rejected Alnylam’s argument, finding column 32 “does not teach that the claimed head group can be only a hydroxyl group,” as it only “discloses a head group that has an amine.” *Id.* at 15. “Accordingly, an artisan of ordinary skill would not understand [column 32] to disclose a non-protonatable head group that has a hydroxyl ... group on its own.” *Id.* at 15–16.

Despite the Court’s finding, Alnylam’s written-description expert relies solely on column 32 to support the Nullified Claims. [REDACTED]

[REDACTED] This testimony raises no triable dispute. It directly contradicts the Court’s factual finding, which is the law of the case. *See*

Del Mar Avionics, Inc. v. Quinton Instrument Co., 836 F.2d 1320, 1324 (Fed. Cir. 1987) (“Claim construction is a question of law that may require determination of underlying facts. To the extent that the underlying facts are based on identical premises, as is here the case, the prior findings and the claim construction based thereon are the law of the case. They are not available for redetermination.”) (citation omitted).

Alnylam’s nonobviousness expert, Dr. Scheidt, confirms invalidity under § 112(a). He opines that [REDACTED]

[REDACTED]

[REDACTED]

UF 18, 19. This further confirms that column 32 is insufficient to describe the Nullified Claims: “[A] description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.... Thus, *a fortiori*, a description that does *not* render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112.” *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997).

The Court should thus invalidate the Nullified Claims under § 112(a).

B. The remaining asserted claims are invalid for lacking written description under Alnylam’s literal infringement theory.

Under Alnylam’s literal infringement theory, the remaining asserted claims necessarily lack written-description support for the same reason as the Nullified

Claims. It is undisputed that the alleged “head group” in ALC-0315 is the same “head group” in the Nullified Claims—i.e., a saturated aliphatic group and a hydroxyl group. UF 10. Thus, any asserted claims found to cover the “head group” of ALC-0315 necessarily lack written description for the same reasons the Nullified Claims lack written-description support. The specification must—but does not—support “the full scope” of the claims, which are invalid if broad enough to cover the alleged “head group” in ALC-0315. *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1336 (Fed. Cir. 2021); *see also Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005) (§ 112(a) precludes claims that “overreach the scope of the ... descri[ption] in the patent specification”).

VI. CONCLUSION

The Court should enter summary judgment that the Nullified Claims are invalid under §§ 112(a) and (d). The Court should also enter summary judgment that all other asserted claims are invalid pursuant to § 112(a) under Alnylam’s literal infringement theory.

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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.

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