

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALNYLAM
PHARMACEUTICALS, INC.,

Plaintiff,

v.

PFIZER, INC., PHARMACIA &
UPJOHN CO. LLC, BIONTECH
SE, and BIONTECH
MANUFACTURING GMBH,

Defendants.

Civil Action No. 22-336-CFC
(consolidated)

MEMORANDUM ORDER

Alnylam has filed what it calls “Objections” to the Memorandum Opinion I issued on August 12, 2024. I explained in that Memorandum Opinion the reasons why I construed the disputed claim term “head group” to mean “a group that must be either permanently positively charged or protonatable.” D.I. 241 at 32.

Although I do not intend to make it a practice of responding to “objections” to my claim construction rulings, I thought it prudent to do so in this case because the “head group” term also appears in the patent asserted in *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al*, Civ. No. 23-580 and the parties in that case have agreed

that the record in this case “on the term ‘head group’ applies equally” to their dispute about the term, Civ. No. 23-580, D.I. 71 at 2.

Alnylam first objects to the statement in the Memorandum Opinion that “[i]t is [] undisputed that a head group consisting of a saturated aliphatic group and a hydroxyl group is not protonatable at any pH.” D.I. 243 at 1 (citing D.I. 241 at 27). Alnylam says that it “has disputed and continues to dispute this statement” and that it “has maintained in its expert declarations for claim construction that hydroxyl groups can be protonated at some pH—just not at physiological pH.” D.I. 243 at 1. In its briefing on the “head group” term, however, Alnylam itself equated “protonatable at physiological pH” with “protonatable.” *See, e.g.*, D.I. 184 at 13 (“Simply put, the dependent claim language expressly identifies a head group that a POSA would understand is not protonatable at physiological pH within the claimed cationic lipid, which, according to Defendants’ proposed construction, would be required to have a protonatable head group. Defendants’ proposed construction cannot be correct, as it would require the head group to be both protonatable and only composed of groups that are not protonatable.”); D.I. 184 at 53 (“It is without question each of the Patents-at-Issue include dependent claims in which the head groups are not positively charged or protonatable.”). And for that reason, I did the same in the Memorandum Opinion.

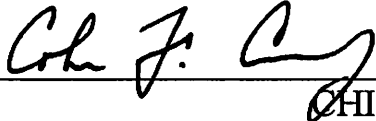
I will nonetheless revise the challenged sentence in the Memorandum Opinion to read: “It is also undisputed that an artisan of ordinary skill would not consider a head group consisting of a saturated aliphatic group and a hydroxyl group to be protonatable in a biological context.” Alnylam’s expert Dr. Kros expressly stated in his expert report that “[a] hydroxyl group [is] also known as an alcohol, D.I. 124-1 ¶ 76 (footnote omitted), and that “[w]hile alcohols may be protonated under very acidic conditions, they are considered non-protonatable in a biological context,” D.I. 124-1 ¶ 58 n.16. *See also* D.I. 124-1 ¶ 18 n.4 (“Some [groups], like water or alcohols, only accept protons in very acidic solutions (i.e., at very low pHs) . . . A POSA would not typically consider every such head group to be protonatable in the context of cationic lipid[s] for use in the lipid particles of the claims.”); D.I. 124-1 ¶ 66 n.19 (“[A] POSA typically does not consider such groups (hydroxyl or methoxy) to be protonatable in the context of the patented cationic lipids formulated into lipid particles carrying nucleic acids (*e.g.* RNA) for therapeutic purposes.”). Defendants, for their part, stated in their briefing that “[t]he [parties’] experts agree that in the relevant field of art, protonatability is limited to a biologically relevant pH range.” D.I. 184 at 63.

Alnylam next says that it “disputes the Court’s finding of ‘specific intent to ensnare Defendants’ mRNA vaccine products.” D.I. 243 at 2 (citing D.I. 241

at 32). It insists that its “issued claims are not improper under well-settled case law.” D.I. 243 at 2 (citations omitted).

I did not, however, find that Alnylam took an improper, illegal, or inequitable course of action when it added the dependent claims in question. I merely held, as the Federal Circuit did under similar circumstances presented in *Barrday, Inc. v. Lincoln Fabrics Inc.*, 2023 WL 7871688, at *7 (Fed. Cir. Nov. 16, 2023), that it was appropriate not to afford the dependent claims weight in construing the asserted and much older independent claims “because [the dependent] claims were added after the filing of the original patent application and because the motive for adding such claims appears to be litigation-driven.”

NOW THEREFORE at Wilmington on this Ninth day of September in 2024, it is **HEREBY ORDERED** that the Court will reissue its August 12, 2024 Memorandum Opinion.



CHIEF JUDGE