

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)

Ethan H. Townsend, MCDERMOTT WILL & EMERY LLP, Wilmington, Delaware; William G. Gaede, III, Anisa Noorassa, MCDERMOTT WILL & EMERY LLP, San Francisco, California; Sarah Chapin Columbia, Sarah J. Fischer, MCDERMOTT WILL & EMERY LLP, Boston, Massachusetts; Ian B. Brooks, Timothy Dunker, MCDERMOTT WILL & EMERY LLP, Washington, D.C.; Bhanu K. Sadasivan, MCDERMOTT WILL & EMERY LLP, Menlo Park, California; Mandy H. Him, MCDERMOTT WILL & EMERY LLP, Irvine, California

Counsel for Plaintiffs

Arthur G. Connolly, III, Alan R. Silverstein, CONNOLLY GALLAGHER LLP, Wilmington, Delaware; Sara Tonnie Horton, WILLKIE FARR & GALLAGHER LLP, Chicago, Illinois; Michael W. Johnson, Daniel Constantinescu, Brian W. Frino, WILLKIE FARR & GALLAGHER LLP, New York, New York

Counsel for Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC

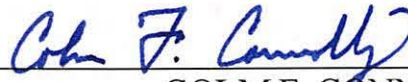
Jack B. Blumenfeld, Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT &

TUNNELL LLP, Wilmington, Delaware; Charles B. Klein, Jovial Wong, Claire A. Fundakowski, WINSTON & STRAWN LLP, Washington, D.C.; Katherine L. Kyman, Brian L. O’Gara, WINSTON & STRAWN LLP, Chicago, IL; Ashley Graham, WINSTON & STRAWN LLP, New York, New York

Counsel for Defendants BioNTech SE, BioNTech Manufacturing GmbH

MEMORANDUM OPINION

August 9, 2024
Wilmington, Delaware



COLM F. CONNOLLY
CHIEF JUDGE

In these consolidated actions, Plaintiff Alnylam Pharmaceuticals, Inc. alleges that COVID-19 vaccines manufactured by Defendants Pfizer, Inc, Pharmacia & Upjohn Co. LLC, BioNTech SE, and BioNTech Manufacturing GmbH infringe claims of six Alnylam patents, including U.S. Patent No. 11,590,229 B2 (the #229 patent). Pending before me is the parties' claim construction dispute regarding claims 27 and 28 of the #229 patent.

I.

A patent gives its owner the right to exclude others from making, using, selling, or importing the inventions covered by the patent. *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1379 (Fed. Cir. 2000). An inventor puts the public on notice of the bounds of her invention by writing “one or more claims” in the patent that “point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention.” 35. U.S.C. § 112(b). “It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005).

“[T]he construction of a patent, including terms of art within its claim[s], is exclusively within the province of the court.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). In the Federal Circuit’s words, the court not only has “[t]he duty . . . to determine the meaning of the claims at issue,” but “[i]n the exercise of that duty, [it] has an independent obligation to determine the meaning of the claims, notwithstanding the views asserted by the adversary parties.” *Exxon Chem. Pats., Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995). In fulfilling this independent obligation, the court is to construe each claim at issue “with an eye toward giving effect to all terms in the claim.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006); *see also Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so”).

II.

Before setting forth the claims at issue here, a word to the wise. When reading the claims, don’t be intimidated by or worry about understanding the chemical names and symbols in the claims. For each claim, two words—which are readily understandable—are really all that is necessary to resolve the dispute at hand.

So, with that in mind, claim 27 of the #229 patent reads:

What is claimed is . . .

[a] vaccine comprising a lipid particle and a pharmaceutically acceptable diluent, excipient, or carrier, wherein the lipid particle comprises:

(i) a nucleic acid, wherein the nucleic acid comprises RNA,

(ii) 35-65 mol % of a protonatable lipid compound,

(iii) 3-12 mol % distearoylphosphatidylcholine (DSPC),

(iv) 15-45 mol % cholesterol, and

(v) 0.5-10 mol % of a PEG-modified lipid,

wherein the mol % is based on 100% total moles of lipids in the lipid particle,

wherein the protonatable lipid compound comprises a head group, hydrophobic tails, and a central moiety to which the head group and the hydrophobic tails are directly bonded, wherein:

the central moiety is a nitrogen atom;

the hydrophobic tails consist of two hydrophobic tails;

each of the two hydrophobic tails has the formula — R^{12} — M^1 — R^{13} , wherein:

R^{12} is a C_4 - C_{14} alkyl group, M^1 is —OC(O)—, and R^{13} is a C_{10} - C_{20} branched alkyl, wherein R^{13} is branched at the alpha position relative to the —OC(O)— group;

the chain length of formula $\text{—R}^{12}\text{—M}^1\text{—R}^{13}$ is 17 atoms;
and

the total carbon atom content of each hydrophobic tail is
21 to 26 carbon atoms.

#229 patent at 493:43; 497:18–498:19 (emphasis added). Claim 28 reads: “What is claimed is . . . [*t*]he vaccine of claim 27, wherein the head group consists of a saturated aliphatic group and a hydroxyl group. #229 patent at 493:43; 498:20–21 (emphasis added).

III.

The parties’ claim construction dispute is not about the meaning of “vaccine.” The parties agree that I should construe “vaccine” to mean “a preparation that is used to stimulate the body’s immune response and protects against disease.” D.I. 191 at 8.

What the parties dispute is whether the term “vaccine” is “limiting” in claims 27 and 28. “Limiting” is patent-speak for “is an element of the claim.” In patent law, each substantive element in a claim is referred to as a “limitation.” *See* Manual of Patent Examining Procedure § 2103 (9th ed., Rev. 07.2022) (2023) (“For processes, the claim limitations will define steps or acts to be performed. For products, the claim limitations will define discrete physical structures or materials.”). To prove that a process or product infringes a patent’s claims, the

patent owner “must show that the accused [process or product] contains every limitation in the asserted claims.” *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998).

Notwithstanding the fact that claim 27 explicitly states that “[w]hat is claimed is . . . a vaccine” and claim 28 explicitly states that “what is claimed is . . . the vaccine of claim 27,” Alnylam says in its briefing that “[n]othing about [claims 27 and 28] suggests that the term ‘vaccine’ is meant to be a limitation.” D.I. 184 at 64. Its counsel steadfastly and without any hint of irony maintained this position at oral argument:

THE COURT: Just let’s be really clear. So Claim 27 provides, quote, a vaccine, right, and then words that follow. And your position is that – I just want to get this exactly right -- vaccine is not a limitation of the claim, right, that’s your –

[COUNSEL]: Correct, correct.

THE COURT: So you want me to read a claim which literally says that it’s claiming a vaccine, and you’re telling me it doesn’t have to claim -- or what is accused of infringing it doesn’t have to be a vaccine; right? That’s your position?

[COUNSEL]: That’s absolutely right, Your Honor.

D.I. 236 at 181:9–20.

To be clear, I do not fault Alnylam’s counsel for making this argument, even though it made me think at the time that I was in a nonsensical wonderland. *See* ALICE IN WONDERLAND (Walt Disney Productions 1951) (Alice saying, “If I had a world of my own, everything would be nonsense. Nothing would be what it is, because everything would be what it isn’t. And contrary wise, what it is, it wouldn’t be. And what it wouldn’t be, it would. You see?”). For starters, his logic was largely embraced by Defendants’ counsel. At no point during the claim construction oral argument or in the 33 pages of the Joint Claim Construction Brief (D.I. 184) devoted to the “vaccine” claim term did Defendants’ counsel ever say words to the effect, “Of course ‘vaccine’ is a limitation of the claims. The claims explicitly claim ‘a vaccine!’” According to Defendants, “vaccine” is a limitation in claims 27 and 28 not because the claims explicitly claim a vaccine but rather because (1) “‘vaccine’ does not merely recite the intended use of the claimed composition, but provides structural limitations with respect to the types of RNA that can be used,” D.I. 184 at 71; (2) “‘vaccine’ in the preamble of independent claim 27 provides the necessary antecedent basis for ‘[t]he vaccine’ in dependent claim 28, D.I. 184 at 71 (brackets in the original); and (3) “had the inventors not intended to limit claim 27 of the #229 to a ‘vaccine,’ they would have simply recited a ‘pharmaceutical composition’ like they did for claims 1 to 20 of the

[#]229 patent,” D.I. 184 at 71. Thus, Defendants accepted the fundamental premise of Alnylam’s argument—namely, that a patent does not necessarily claim what it claims if what it claims is set forth in the claim’s introductory words (i.e., the claim’s preamble).

Second, and in fairness to both sides’ counsel, the real culprit here is a long line of binding Federal Circuit case law that has endorsed the Mad Hatter logic of that premise. The Federal Circuit has expressly held on numerous occasions that “[g]enerally, the preamble [of a claim] does not limit the claim[.]” *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002); *see also, e.g., Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1236 (Fed. Cir. 2017) (“Generally, the preamble does not limit the claims.”); *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1347 (Fed. Cir. 2012) (“As a general rule[,] preamble language is not treated as limiting.” (citing *Allen Eng’g*, 299 F.3d at 1346 (Fed. Cir. 2002)); *DeGeorge v. Bernier*, 768 F.2d 1318, 1322 n.3 (Fed. Cir. 1985) (“Generally, and in this case, the preamble does not limit the claims.”). And it has expressly held on numerous occasions that “[p]reamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim.” *Bicon*, 441 F.3d at 952; *see also, e.g., Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010) (same) *Pitney Bowes, Inc. v.*

Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999) (where the preamble “merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.”). In *Marrin*, the court went so far as to refer to this latter general rule as “*the presumption* against reading a statement of purpose in the preamble as a claim limitation.” 599 F.3d at 1294–95 (emphasis added). In this case, Alnylam has seized on this legal presumption. It argues that “vaccine” is not a limitation of claims 27 and 28 because it is found in the claims’ preambles and “simply provides the ‘intended use’ for the invention.” D.I. 184 at 65.

The Federal Circuit, however, has also repeatedly held that “[t]he preamble limits the claimed invention if it is ‘necessary to give life, meaning, and vitality to the claim.’” *Marrin*, 599 F.3d at 1296. *See also, e.g., Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330 (Fed. Cir. 2007); *Rotatable Techs. LLC v. Motorola Mobility LLC*, 567 F. App’x 941, 943 (Fed. Cir. 2014); *Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1369 (Fed. Cir. 2020). And as I, for one, do not understand how the purpose or intended use of a claimed invention would not give meaning or vitality to that invention, the parties’ dispute before me

presents a conundrum. The purpose or intended use of something is the very reason for which that something is made or done. What could say more about the life, meaning, and vitality of a claimed invention than the claimed purpose or intended use of the invention?

I am unable to resolve in an intellectually honest way the conundrum before me. It is undisputed that the term “vaccine” is found in the preamble of independent claim 27, from which claim 28 depends. *See* D.I. 184 at 64, 69, 92–93.¹ It is undisputed that “vaccine” describes the intended use of the claimed invention. *See* D.I. 184 at 65, 70. And I do not think it can be reasonably disputed that the term “vaccine” gives life, meaning, and vitality to the claims. Indeed, “[w]hat is claimed” *first and foremost* in the claims—literally—is a “vaccine.”

¹ Black’s Law Dictionary defines “preamble” generally as “[a]n introductory statement in a constitution, statute, or other document explaining the document’s basis and objective; esp[ecially] a statutory recital of the inconveniences for which the statute is designed to provide a remedy.” *Preamble*, BLACK’S LAW DICTIONARY (12th ed. 2024). Black’s Law Dictionary defines “preamble” for “patents” as “[t]he first words of a patent claim, often a single phrase indicating the field of art.” *Id.* Consistent with this latter definition, the Federal Circuit treats a claim’s first words as its preamble. Thus, for example, and consistent with Alnylam’s insistence that “vaccine” is in the asserted claims’ preambles here and is non-limiting, the Federal Circuit held in *Arctic Cat Inc. v. GEP Power Prod., Inc.*, 919 F.3d 1320, 1322 (Fed. Cir. 2019), that the term “[a] personal recreational vehicle” in a claim that began with the words “[w]hat is claimed is . . . [a] personal recreational vehicle comprising” was in the claim’s preamble and non-limiting.

In the end, I will construe the term “vaccine” as a limitation in the asserted claims because that construction comports with common sense, the very notion of “a claim,” and the fundamental canon that a claim should be construed to give effect to all its terms. This construction will also preserve the credibility of the Court, the law, and the patent system in the eyes of the jury that will ultimately decide the outcome of this case. Under Federal Circuit law, “[t]he terms [of a patent], as construed by the court, must ensure that the jury fully understands the court’s claim construction rulings and what the patentee covered by the claims.” *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1348 (Fed. Cir. 2010) (internal quotation marks and citation omitted). I think it fair to say that rational jurors would find it confusing, question my competency, and perhaps even laugh out loud were I to instruct them that claims 27 and 28 do not claim what they explicitly claim and that to establish infringement of the claims Alnylam need not prove that the accused products are vaccines.

IV.

I conclude with the observation that this case well illustrates the need for the Federal Circuit to jettison its rulings that treat language in the preamble of a patent claim as not limiting the scope of the claim. I am not alone in this view. One prominent scholar has written:

The Federal Circuit's rules for interpreting the preambles of patent claims are an incoherent mess. They aren't justified by history, logic, or policy. They hurt both patent owners and accused infringers in individual cases, and they hurt everyone by making it hard to understand what a patent covers. The Supreme Court (or the en banc Federal Circuit) should get rid of all these doctrines and simply hold that all the words of a patent claim matter.

Mark A. Lemley, *Without Preamble*, 100 B.U. L. REV. 357, 388 (2020). And a prominent member of the Federal Circuit itself has stated:

Over the years our court has struggled to make sense of when a preamble should be construed as limiting.

. . . [W]e have not succeeded in articulating a clear and simple rule. As a result of the lack of clarity as to whether a preamble should be construed as limiting, our case law has become rife with inconsistency, both in result and in the articulation of the test. As the leading treatise on patent law observes, "the decisions are difficult to reconcile." 3 Donald S. Chisum, *Chisum on Patents* § 8.06[1][d] (2010).

It seems to me, a rule recognizing that all preambles are limiting would make better sense and would better serve the interests of all concerned. There is, after all, little to be said in favor of allowing an applicant, in the claim drafting process, to include material in the claims that is not binding. If patentees are allowed to include material in the claim definitions that is not binding, patentees can suggest or imply one position before the U.S. Patent & Trademark Office ("PTO") to secure allowance of the patent on the theory that the preamble is limiting and another, inconsistent position in infringement litigation on the theory that it is not limiting. Principles of fairness thus dictate that the patentee should be required to clearly

define the claimed invention's scope. By creating a uniform rule that all preambles are limiting, we would ensure the patentee has the burden of drafting a patent that avoids confusion as to the scope of the claims. As the Supreme Court concluded in *Merrill v. Yeomans*, 94 U.S. 568, 573–74, 24 L.Ed. 235 (1876), “nothing can be more just and fair, both to the patentee and to the public, than that the former should understand, and correctly describe, just what he has invented, and for what he claims a patent.”

Neither the Supreme Court nor our court sitting en banc has ever addressed the preamble limitation issue. I think the time may have come for us to eliminate this vague and confusing rule.

Am. Med. Sys., Inc. v. Biolitec, Inc., 618 F.3d 1354, 1364 (Fed. Cir. 2010) (Dyk, J., dissenting) (some citations omitted).

If this case is appealed, I hope the Federal Circuit will view it as an opportunity to clarify its jurisprudence in this area. All the words of a patent claim should matter. The purpose and intended use (and meaning and vitality) of a patent claim as well as common sense call for a simple rule of law: A claim claims what it claims, nothing more and nothing less.

* * * *

The Court will enter an Order consistent with this Memorandum Opinion.