IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH, *Plaintiffs*, v. **MODERNA, INC. and MODERNATX, INC.,** *Defendants*.	**Case No. 1:22-cv-00252-JDW**

MEMORANDUM

In Star Trek, members of Starfleet must observe the Prime Directive, even as they jump into or come out of warp speed. In this case, Arbutus Biopharma Corp. and Genevant Sciences GmbH (collectively, "Arbutus") claim that during the U.S. Government's own Operation Warp Speed to find a vaccine for Covid-19, Moderna Inc. and ModernaTX, Inc. (collectively, "Moderna") violated the Prime Directive of patent law: don't copy other people's inventions. Moderna asks me to hold as a matter of law that when it jumped to warp speed to make a Covid-19 vaccine, it did so for the Government, meaning the claims in this case belong in the Court Of Federal Claims. It also argues that Arbutus can't pursue claims under the doctrine of equivalents and that Arbutus's patents are invalid. For the reasons that follow, I conclude that most of this dispute belongs in this Court and that factual disputes require a jury to decide if the patents are invalid. But I also hold that the

prosecution history of some of Arbutus's patents forecloses Arbutus's doctrine-of-equivalents claims based on the molar ratios in Moderna's Covid-19 vaccine. For Arbutus to succeed on those claims, it will have to prove literal infringement.

I. BACKGROUND

A. LNP Technology

For many years, modern medicine fought viral infections with traditional vaccines, which work by introducing a weakened or inactive form of the virus into the body to teach the body's immune system how to recognize and attack the real virus. In recent years though, scientists have come up with a new class of vaccinations that introduce nucleic acids, such as DNA or RNA, into the body's cells to instruct them how to defend against a particular virus. Nucleic acids are fragile. They require some sort of protection for safe delivery into a person's body. It took years for scientists to develop a way to protect and transport nucleic acids across the cell membrane.

Liquid-nanoparticle ("LNP") technology provides a solution to that problem. It uses fat-like molecules known as lipids to encapsulate and protect the nucleic acids as they cross the cell membrane and consists of three components: (1) structural lipids, such as phospholipids and cholesterol; (2) cationic lipids, including ionizable lipids that have a positive charge at certain pH levels; and (3) conjugated lipids, which are lipids attached to a polymer such as polyethyleneglycol. Essentially, when one combines a nucleic acid with a particular ratio of structural, cationic, and conjugated lipids, an LNP forms. That LNP is

a lipid-based particle in which lipids surround the nucleic acid, so that the nucleic acid can safely cross the cell membrane into the cell. Once inside the cell, the lipids release the nucleic acid so that it can instruct the cell to fight a particular virus.

B. Arbutus's Patents

Arbutus claims that its scientists invented LNP technology and then applied for (and received) several patents. One category of patents, the "Molar Ratio Patents"[1] claims the particles comprising the nucleic acid and the various lipids in specific molar ratio amounts.[2] A separate patent, the '651 Patent,[3] claims a new method for developing LNPs involving continuously and rapidly mixing two solutions to form lipid vesicles that can encapsulate nucleic acids.

1. The Molar Ratio Patents

The Molar Ratio Patents are all part of one patent family in which the '069 Patent is the parent. The original '069 Patent application included the following claim:

> A nucleic acid-lipid particle comprising:
>
> (a) a nucleic acid;
>
> (b) a cationic lipid comprising from about 50 mol % to about 65 mol % of the total lipid present in the particle;
>
> (c) a non-cationic lipid comprising a mixture of a phospholipid and

[1] The Molar Ratio Patents include U.S. Patent Nos. 8,058,069; 8,492,359; 8,822,668; 9,364,435; and 11,141,378.

[2] On, May 29, 2025, Judge Goldberg ordered Arbutus to narrow the number of asserted patents to "no more than four." (D.I. 475 at 3.) As a result, Arbutus is no longer asserting claims based on the '069 Patent or the '668 Patent.

[3] U.S. Patent No. 9,504,651.

cholesterol or a derivative thereof, wherein the phospholipid comprises from about 4 mol % to about 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from about 30 mol % to about 40 mol % of the total lipid present in the particle; and

(d) a conjugated lipid that inhibits aggregation of particles comprising from about 0.5 mol % to about 2 mol % of the total lipid present in the particle.

(D.I. 568 at 41–42.)

During patent prosecution, the patent examiner interpreted the use of the word "about" before each end of the molar ratio ranges listed for the lipid components as an ambiguous word that broadened the listed ranges by an amount of "+/- 10, 20, 30 mol % of [the] lipid component." (D.I. 568 at 46–48.) Given those broad ranges, the examiner rejected the claims of the '069 Patent as obvious and unpatentable, given the apparent overlap with a pending patent application 2006/0008910 ("MacLachlan"). According to the patent examiner, MacLachlan also taught a nucleic-acid-lipid particle with broad molar ratio ranges.

In response to the patent examiner's rejection, Arbutus amended its application to remove the word "about" before each end of the molar ratio ranges listed in the claim. The amended claim appeared as follows:

A nucleic acid-lipid particle comprising:

(a) a nucleic acid;

(b) a cationic lipid comprising from ~~about~~ 50 mol % to ~~about~~ 65 mol % of the total lipid present in the particle;

(c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from ~~about~~ 4 mol % to ~~about~~ 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from ~~about~~ 30 mol % to ~~about~~ 40 mol % of the total lipid present in the particle; and

(d) a conjugated lipid that inhibits aggregation of particles comprising from ~~about~~ 0.5 mol % to ~~about~~ 2 mol % of the total lipid present in the particle.

(D.I. 568 at 49–50.)

In connection with the amended application, the applicants submitted remarks explaining that they amended the claim "to delete 'about' from the ranges of lipid components" "[i]n an earnest effort to expedite prosecution, but without acquiescing on the merits of the rejection." (D.I. 568 at 50–51.) Their remarks recognized that the patent examiner's rejection of the application was based on "the term 'comprising from about' ... embrac[ing] a broad range of lipid components," and went on to "respectfully point[] out that [C]laim 1 as presently amended recites narrow ranges for each of the lipid components compared to the substantially broader ranges taught by MacLachlan." (D.I. 568 at 50–52.) The remarks even included a chart comparing the ranges of the various lipid components of Claim 1 of the '069 Patent Application as amended and the lipid ranges of MacLachlan:

Lipid Component	Claim 1 as Amended	US 2006/0008910[4]
Cationic Lipid	50–65 mol %	"2–60, 5–50, 10–45, 20–40, 30 mol %"
Phospholipid	4–10 mol %	"5–90 mol%"
Cholesterol	30–40 mol %	"20–55 mol %"
Conjugated Lipid	0.5–2 mol %	"1–20 mol %"

(D.I. 568 at 51–52.) The patent examiner approved the '069 application as amended. (*See* D.I. 568 at 54.) The '069 Patent issued with the narrower ranges that no longer included the word "about." (*See* D.I. 568 at 54.)

The applicants then filed applications for the other Molar Ratio Patents, each of which included claims with molar ratio range limitations. (*See* D.I. 568 at 54.) For two of the Molar Ratio Patents – the '359 Patent and the '435 Patent – the applicants included the word "about" in the molar ratio ranges but removed it in subsequent amendments. (*See* D.I. 568 at 55.) The applications for the other two Molar Ratio Patents – the '668 Patent and the '378 Patent – never included the word "about" before the listed molar ratio ranges. (*See* D.I. 568 at 54–55.)

2. The '651 Patent

The '651 Patent claims that "at least 70%," "at least 80%," and "about 90% of the mRNA in the [lipid vesicle] formulation is fully encapsulated in the lipid vesicles." (D.I. 568 at 71.) At the time of the application that led to the '651 Patent, there were several methods for analyzing encapsulation efficiency of oligonucleotides. In fact, at least one article listed various methods of measurement and concluded that the results for

[4] The ranges set forth in this column are reproduced from page 4 of the Office Action mailed by May 12, 2011.

measuring oligonucleotide encapsulation efficiency could differ from one quantification method to another. (*See* D.I. 568 at 96–97.)

B. The Covid-19 Pandemic And The Moderna Vaccine

After Arbutus's patents issued, Covid-19 arrived in the United States. On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency under 42 U.S.C. § 247(d). (*See* D.I. 568 at 2.) On May 15, 2020, the Trump Administration initiated Operation Warp Speed, through which the United States Government worked with private companies, including Moderna, to develop a Covid-19 vaccine.

On August 9, 2020, Moderna entered into a supply contract (the "C-100 Contract") with the Army Contracting Command of the United States Department of Defense. The C-100 Contract included two Federal Acquisition Regulation ("FAR") clauses: 52.227-1 and 52.227-1, Alternate I. Under Alternate I, which is the broader of the two clauses, "[t]he Government authorizes and consents to all use and manufacture of any invention described in and covered by a United States patent in the performance of this contract." (D.I. 568 at 18 (quoting 48 C.F.R. § 52.22701, Alt. I.).)

Moderna developed a nucleic acid vaccination using messenger RNA ("mRNA") to fight Covid-19. To ensure the fragile mRNA could cross the cellular membrane, Moderna used LNP technology with molar ratio ranges that differed slightly from those listed in Arbutus's Molar Ratio Patents, as follows:

Component	Moderna Vaccine	'359 Patent	'435 Patent	'378 Patent
Cationic Lipid	44.5–49 mol %	49.5–65.49 mol %	49.5–85.49 mol %	
Non-Cationic Lipid	50–53.5 mol %		12.5–49.549 mol %	
Conjugated Lipid	2.5–3.5 mol %	0.45–2.49 mol %	0.45–2.49 mol %	0.05–2.49 mol %

(D.I. 568 at 67–68.)

Moderna sold 500,001,540 doses of its Covid-19 vaccine under the C-100 Contact. (*See* D.I. 568 at 24.) The overwhelming number went to members of the general public, while the Government gave a small fraction to government employees.[5] The Government spent approximately $8.2 billion for Moderna's vaccine doses.

C. Procedural History

Arbutus filed this suit on February 28, 2022. Moderna moved to dismiss, alleging that 28 U.S.C. § 1498(a) bars Arbutus's claims. Judge Goldberg denied the motion to dismiss, reasoning that Moderna failed to show that its infringement was done "for the Government" and that it was done with the "authorization and consent" of the Government. The Government then filed a Statement of Interest arguing that it provided Moderna with its authorization and consent and that such infringement was done for the

[5] Arbutus argues that 98.75% of those doses went to the general public, but the Parties don't include that fact in their statement of facts, so I don't know whether it is undisputed. In preparing for trial, the Parties can determine which doses are part of this lawsuit and which are not, including whether there are factual disputes about those numbers.

Government. Multiple amici filed responses to the Government's Statement of Interest, all of which argued that Section 1498(a) does not apply in this case.

Judge Goldberg issued his claim construction opinion on April 3, 2024. In that opinion, among other things, he addressed several of the Parties' arguments. In response to Moderna's claim that removing the word "about" from the ranges in the Molar Ratio Patents limited its claim to just the recited amounts, Judge Goldberg stated that such removal "only clearly disclaimed the[] broader ranges" that resulted from the patent examiner's expansive interpretation of the word "about." (D.I. 266 at 21.) In connection with Arbutus's argument that a person skilled in the art would have understood the '651 Patent to identify fluorescent dyeing as the method used to measure whether the mRNA in an LNP was "fully encapsulated," Judge Goldberg noted that such "method necessarily counts" partially encapsulated mRNA. (D.I. 266 at 36–37.)

On August 1, 2025, Moderna moved for summary judgment on three issues. Moderna seeks summary judgment on its affirmative defense regarding 28 U.S.C. § 1498; its argument that prosecution history estoppel bars Arbutus from bringing its infringement claims under the doctrine of equivalents; and its argument that some of Arbutus's patent claims are indefinite as a matter of law. In connection with its motion for summary judgment, Moderna filed a motion to exclude expert testimony of Alex Brill and Peter Pitts concerning its Section 1498(a) defense.

Arbutus opposed both motions, filed a cross motion for summary judgment, and moved to exclude expert testimony offered by Dr. George Rutherford, Dr. Christopher Vellturo, and Dr. Robert Prud'homme related to Moderna's Section 1498(a) defense and indefiniteness arguments. In its cross motion for summary judgment, Arbutus requests that I find as a matter of law that Moderna's Section 1498 affirmative defense fails and that most of Arbutus's alleged claims are not indefinite. Moderna opposed Arbutus's motions and moved to exclude expert testimony offered by Dr. Michael Mitchell related to Arbutus's argument that Moderna fraudulently induced the Government into entering the C-100 Contract. All of those motions are ripe for disposition.

II. LEGAL STANDARD

A. Summary Judgment

A court must 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). When a party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," summary judgment must be entered against that party. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

B. *Daubert*

In a patent case, regional circuit law applies to issues concerning the admissibility of expert opinions unless those issues are unique to patent law. *See Micro Chem., Inc. v.*

Lextron, Inc., 317 F.3d 1387, 1390–91 (Fed. Cir. 2003). "Whether proffered evidence should be admitted in a trial is a procedural issue not unique to patent law," so Third Circuit law applies. *Id.* In the Third Circuit, the Federal Rules of Evidence "govern[] the admissibility of expert testimony." *Kannankeril v. Terminix Int'l., Inc.*, 128 F.3d 802, 806 (3d Cir. 1997). Federal Rule of Evidence 702 provides that "[a] witness who is qualified as an expert" may testify if the expert's testimony "will help the trier of fact to understand the evidence or to determine a fact in issue," "the testimony is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert's opinion reflects a reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702. But when no question of fact needs to be resolved, there is no need for expert testimony. *See id.*

III. ANALYSIS

A. Section 1498

Section 1498 provides that when an patented invention "is used or manufactured by or for the United States … the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture." 28 U.S.C. § 1498(a). The statute explains that the "use or manufacture of an invention described in and covered by a patent of the United States by a contractor … for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United

States." *Id*. The Federal Circuit has further explained that Section 1498 "provides a cause of action against the United States (waiving sovereign immunity) for a patent owner to recover damages for the unauthorized use or manufacture of a patented invention '*by or for* the United States.'" *Astornet Techs. Inc. v. BAE Sys., Inc.*, 802 F.3d 1271, 1277 (Fed. Cir. 2015) (emphasis in original).

A defendant can raise Section 1498 as an affirmative defense in private litigation. *See BAE Sys. Info. & Elec. Sys. Integration Inc. v. Aeroflex Inc.*, Case No. 09-769-LPS, 2011 WL 3474344, at *2 (D. Del. Aug. 2, 2011). Because Section 1498(a) serves as an affirmative defense, the defendant bears the burden of showing that each of the two prongs of Section 1498(a) is met. *See Sevenson Envt'l Servs., Inc. v. Shaw Envt'l, Inc.*, 477 F.3d 1361, 1365 (Fed. Cir. 2007). That means the defendant must establish (1) the infringing use was "for the Government" and (2) the infringing use was done "with the authorization and consent of the Government." *Id.*[6] In the C-100 Contract, the Government authorized and consented to any necessary infringement.[7] But that contractual language does not resolve the question of whether Moderna's manufacture was for the Government.

[6] Section 1498(a) initially uses the phrase "used or manufactured by or for **the United States**," but it then describes "use or manufacture … **for the Government**." 28 U.S.C. § 1498(a) (emphases added). From that, it appears that the statute uses the terms "United States" and "Government" synonymously.

[7] Arbutus argues that Moderna procured the C-100 Contract by fraud, which renders it void. Arbutus does not cite a single binding case where a court permitted a party faced with a Section 1498 defense to challenge the validity of the contract that provided the required authorization. In fact, the Federal Circuit case that Arbutus identifies to support

I must first determine what "for the Government" means before I can decide whether the C-100 Contract falls within the statute's scope. As in any statutory construction case, I must start with the statutory text and proceed from the understanding that, unless otherwise defined, I interpret statutory terms in accordance with their ordinary meaning. *Sebelius v. Cloer*, 569 U.S. 369, 376 (2013). In doing so, I must read the statutory text in context. *See Pulsifer v. United States*, 601 U.S. 124, 133 (2024).

Although Section 1498 uses the phrase "for the Government," it does not define the phrase or any of the words in it. When Congress enacted the predecessor to Section 1498(a), the term "for" "[i]ntroduc[ed] the intended recipient." *For*, A New English Dictionary on Historical Principles (1901). And the term "government" referred to "the system of polity in a state," "authority," "the administration," "a commonwealth," and "a state." *Government*, Webster's Practical Dictionary (1910). Taken together, then, the statute indicates that the Government, as an entity, must be the intended recipient of the infringing product, as opposed to the public that the Government represents.

The statute's context reinforces this interpretation. The statute requires both the Government's authorization and that the use be for the Government. Those are separate

---

its voidability argument involves a voidability challenge that the Government made, not a non-contracting third party. *See Long Island Sav. Bank, FSB v. United States*, 503 F.3d 1234, 1246 (Fed. Cir. 2007). But in this case, the Government never claimed that the C-100 Contract is void. In fact, as demonstrated by its Statement of Interest, the Government insists that the contract is valid.

requirements. But, if all it took to invoke Section 1498 were a public benefit, then the Government's authorization alone would be enough because one could infer from the Government's authorization that the Government perceives a public benefit. Congress didn't write the statute that broadly, though. Even if the Government authorizes the manufacture or use of a patented product, it must do so for its own benefit. That additional requirement reinforces that the Government must receive the benefit itself.

Cases interpreting Section 1498 reinforce this conclusion. Courts have held that the benefit to the Government must be material and direct; it cannot be merely incidental or "too remote." *Sheridan v. United States*, 120 Fed. Cl. 127, 131 (2015). The Government's interest can be too remote even if it just has an "interest in [a] program generally[] or funds or reimburses all or part of [the program's] costs." *Larson v. United States*, 26 Cl. Ct. 365, 369 (1992).

The Court Of Claims' decision in *Larson* is particularly instructive. In *Larson*, the Court Of Claims refused to approve a Section 1498 defense where the Government paid for medical splints and casts for patients participating in certain government programs. Rejecting the argument that the use of infringing splints and casts to treat patients was for the Government, the Court Of Claims stated that "[m]edical care is provided for the benefit of the patient, not the [G]overnment." *Id.*

In this case, the C-100 Contract, for the most part, did not authorize the manufacture or use of vaccines for the Government. Instead, it authorized their

manufacture and use for residents of the United States. As Judge Goldberg pointed out at the motion to dismiss stage, "medical care is provided for the benefit of the patient, not the [G]overnment." (D.I. 31 at 3 (quoting *Larson*, 26 Cl. Ct. at 369).) This case is indistinguishable from *Larson*. Like the patients receiving splints and casts in *Larson*, the patients receiving Moderna's mRNA vaccines were the beneficiaries. That is true regardless of whether the Government "funds or reimburses all or part of [the] costs" for them. *Id.*

Moderna points to the language of the C-100 Contract and its proposed expert testimony to argue that its infringement was "for the Government." But that too is not enough. In fact, language of the C-100 Contract arguably supports the holding that the vaccines were not for the Government. It states that the vaccine was to be developed to "improve **patient** care, thereby mitigating the impact of Covid-19 on the nation and **its people**." (D.I. 17–1 at 20 (emphases added).)

While Section 1498 does not apply to the infringement claims related to the vaccine doses that went to the general public, it does apply to the claims of direct infringement for the vaccine doses that the Government acquired and distributed to its own employees. For those doses, the Government was a direct beneficiary because it distributed the vaccines itself to its employees to ensure that it could continue to function. In that sense, the vaccine doses that the Government provided to its employees are not materially different from cellphones, paper, or staples that the Government acquires for

its employees to enable them to perform the work that the Government hires them to do. Those claims belong before the Court Of Federal Claims.

However, even for those doses, only the direct infringement claims must go before the Court Of Claims. Section 1498 does not apply to claims of indirect infringement. The Federal Circuit has recognized that Section 1498(a) does "not waive the Government's sovereign immunity for indirect infringement." *Zoltek v. United States*, 672 F.3d 1309, 1320 (Fed. Cir. 2012). It based that statement on a Court Of Claims decision that held that "the Government is not liable ... for what, but for [S]ection 1498, would be contributory (rather than direct) infringement of its suppliers." *Decca Ltd. V. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980). Thus, Arbutus can pursue its indirect infringement claims even for the vaccine doses that the Government acquired and distributed to its employees.

Moderna argues that a plaintiff cannot pursue an indirect infringement claim in district court if the direct infringement claims belong in the Court Of Federal Claims. But the cases that Moderna cites for that proposition address what happens if a third party manufactures a product and then induces the Government to use it in a way that infringes a patent. *See, e.g., Astornet Techs. Inc.*, 802 F.3d at 1277–78; *Morpho Detection, Inc. v. Smiths Detection Inc.*, Case No. 2:11-cv-498, 2013 WL 5701522, at *4–6 (E.D. Va. Oct. 17, 2013). Arbutus, however, asserts that non-governmental third parties infringed and that Moderna contributed to or induced that infringement. Moderna has not pointed me to anything suggesting Congress intended to waive sovereign immunity for claims

concerning the actions of third parties and therefore channel such claims to the Court Of Federal Claims under Section 1498.

Finally, because I can resolve the meaning of the statutory phrase "for the Government" through traditional tools of statutory construction, I do not need expert testimony on what actions were, and were not, for the Government. The facts are not in dispute, and expert testimony is never necessary to shed light on the interpretation of a statute. I will therefore grant the various motions to preclude each side's experts on this issue (*i.e.*, Alex Brill, Peter Pitts, George Rutherford, Chrisopher Vellturo, and Michael Mitchell[8]).

B. Prosecution History Estoppel

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997). Recognizing that this doctrine could apply "broadly"

[8] Dr. Mitchell's opinions go to Arbutus's fraud-in-the-inducement theory, which I have rejected, so they are irrelevant. Dr. Mitchell also offers some opinions that relate to prosecution history estoppel. Moderna seeks to exclude those opinions solely based on its supposition that Dr. Mitchell couldn't have done all the work that he claims to have done in the time available to him. But Moderna offers no convincing evidence to support that theory, and I will not credit its unsupported speculation. In any event, I do not rely on Dr. Mitchell's opinions in resolving the prosecution history estoppel arguments, so none of this matters.

and "take on a life of its own, unbounded by the patent claims," courts have imposed limits on a patent holder's ability to bring infringement claims pursuant to it. *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1329–30 (Fed. Cir. 2019) (alterations accepted and quotations omitted).

Prosecution history estoppel is one such limit. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733–34 (2002). Under it, a patent holder cannot claim under the doctrine of equivalents subject matter that the patent holder disclaimed during prosecution of the patent. *See id.* In practice, a patent holder can disclaim subject matter in one of two ways: (1) "by making a narrowing amendment to [a] claim" (referred to as "amendment-based estoppel") or (2) "by surrendering claim scope through argument to the patent examiner" (referred to as "argument-based estoppel"). *Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1159 (Fed. Cir. 2019). Whether amendment-based or argument-based estoppel bars a doctrine of equivalents claim is a question of law. *See Regents of Univ of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1371 (Fed. Cir. 2008).

Amendment-based estoppel applies when a patent applicant narrows a claim during patent prosecution by submitting an amended application. *See Festo Corp.*, 535 U.S. at 738. For example, if an examiner rejects a patent application due to the existence of prior art, an applicant may amend his application and remove the subject matter that overlapped with the prior art. *See id.* at 737. "Such a narrowing amendment is presumed to be a surrender of all equivalents within the territory between the original claim and the

amended claim." *Eli Lilly & Co.*, 933 F.3d at 1330 (quotation omitted). That presumption, however, is rebuttable. *See id.*

A patent holder can rebut the presumption by showing that his reason for amending his patent application "bear[s] no more than a tangential relation to the equivalent in question." *Festo Corp.*, 535 U.S. at 740. "The tangential relation criterion for overcoming the … presumption is very narrow." *Honeywell Intern. Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1315 (Fed. Cir. 2008). It focuses "on the patentee's objectively apparent reason for the narrowing amendment" and requires a showing that the "narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Id.* (quotation omitted). The reason for the narrowing amendment "should be discernable from the prosecution history record." *Id.* (quotation omitted). To make this tangentiality determination, courts do not apply a "bright-line" test; instead, the inquiry must "be decided in the context of the invention disclosed in the patent and the prosecution history." *Eli Lilly & Co.*, 933 F.3d at 1333. Courts conduct this analysis on a case-by-case basis. *See Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1366 (Fed. Cir. 2020).

Federal Circuit decisions on the tangentiality exception demonstrate that if an amendment cures an issue that is different in kind from the claim limit that is the subject of a claimed equivalent, then it can be tangential. But if the amendment is about the same claim limit, even though it is different in degree, then it is not tangential. Three decisions

illustrate situations where a difference in kind between the portion of the claim limit that the patentee amended and the portion subject to a claimed equivalent led the Federal Circuit to conclude that the tangential exception applied.

- In *Insituform Tech. Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1368 (Fed. Cir. 2004), an applicant amended a claim about a method of using a vacuum or multiple vacuums to fill a flexible tube with resin. A prior art reference disclosed a single vacuum far from the resin source, and the amended application overcame that reference by placing a single vacuum near the resin source. *See id.* at 1369–70. In a later suit, the patentee accused a method involving several vacuums of infringement based on the doctrine of equivalents. *See id.* at 1370. The Federal Circuit held that the tangential exception applied because the purpose of the amendment was to distinguish the distance from the vacuum to the resin source. It was not addressed to the number of vacuums. *See id.* at 1368-70.

- In *Regents of the Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1368 (Fed. Cir. 2008), an applicant amended a claim about a method used to detect chromosomal abnormalities. The original application involved a claim directed to general methods of disabling the hybridization capacity of repetitive DNA sequences and a claim that recited blocking nucleic acids. The patent prosecution history indicated that the examiner and inventors discussed ways to distinguish the invention from prior art by including "a proposed claim directed solely to the use of blocking nucleic acids to direct

probe hybridization to unique segments." *Id.* at 1378. The parties then limited the claim to a particular technique that used blocking nucleic acids. Then, in litigation, the patentee accused a blocking method that used synthetic nucleic acids instead of the human nucleic acids that the claim limit required. *See id.* The Federal Circuit concluded that the tangential exception applied because the purpose of the amendment was to overcome prior art on the method of blocking, not on the type of nucleic acid that the patented method would use. *See id.*

- In *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1284–85 (Fed. Cir. 2010), an applicant amended a claim about DNA sequences that encode a type of porcine circovirus, called "porcine circovirus II." The original claim recited DNA sequences consisting of a group of thirteen open reading frames, which are the portions of a gene that encode proteins. However, as originally written, the claim would have covered any sequence that included one of the thirteen open reading frames. The examiner rejected the original claim, noting that the claim as written could cover open reading frames from any organism. The applicants then amended the claim to require that the open reading frames be of porcine circovirus type II. In litigation, the patentee alleged that a DNA strain found in defendant's vaccine with over 99% nucleotide homology with porcine circovirus type II was an equivalent to porcine circovirus type II. Although the Federal Circuit recognized that there was a presumption that the patentees surrendered all equivalents outside of the open reading frames of porcine circovirus type II, the Court held that the

tangential exception applied because the "rationale for the amendment was to narrow the claimed universe of [open reading frames] down to those of [porcine circovirus type II], and bore only a tangential relation to the question of which DNA sequences are and are not properly characterized as" porcine circovirus type II. *Id.*

On the other hand, when a distinction is one of degree but still touches on the part of the claim limit that led to the amendment, the Federal Circuit has held that the tangential exception does not apply. For instance, in *Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296 (Fed. Cir. 2005), the examiner rejected claims about a buffered phosphorus fertilizer over a prior art reference that disclosed a fertilizer that buffered when diluted. The applicant amended the claims to distinguish them from the prior art by indicating the claimed fertilizer had to be concentrated rather than diluted. *See id.* at 1306. In particular, the applicant added a limitation that required the fertilizer to include certain components "in an amount of about 30 to about 40 weight percent." *Id.* at 1305–06. The patentee then claimed that a fertilizer with compounds between 59% and 62% was equivalent. *See id.* at 1301. The Federal Circuit held that the tangential relation exception did not apply because "both the reason for the amendment and the asserted equivalent relate to the concentration of the fertilizer." *Id.* at 1306.

In this case, Arbutus narrowed its original application for the '069 Patent to address the examiner's concern about the imprecision of the molar ratio ranges. Now, it asserts an equivalent based on the molar ratio ranges in Moderna's vaccine. Because the

amendment in the application was about the same issue as the equivalent, amendment-based estoppel bars Arbutus from asserting an equivalent because the difference between the purpose of the amendment and the equivalent is one of degree, not of kind.

Arbutus argues that it only disclaimed the broader ranges in the original application to overcome MacLachlan, not the narrower ranges that it invokes against Moderna. However, that's not how amendment-based estoppel works. When an amendment touches on the same aspect of a claim limit as an alleged equivalent, the amendment bars it. Arbutus points to the Federal Circuit's decision in *Eli Lilly & Co.*, 933 F.3d at 1333, for the proposition that there is no "bright line rule" that requires application of amendment-based estoppel when the same claim limit is at issue in an amendment and a proposed equivalent. But that doesn't save Arbutus because the question is what aspect of the claim limit was at issue in the amendment. If, as in this case, it's the same limit as in the equivalent, then estoppel applies.

The Federal Circuit's decision in *Eli Lilly & Co.* does not counsel a different outcome. In that case, Lilly amended a patent claim to limit its claim to pemetrexed disodium, rather than antifolates generally. *See* 933 F.3d at 1326. In litigation, Eli Lilly then argued that a different form of pemetrexed salt was an equivalent. *See id.* at 1326–27. The Federal Circuit held that the narrowing amendment was designed to distinguish between antifolates generally and pemetrexed specifically, but that it did not necessarily limit the patent to a single type of pemetrexed salt. *See id.* at 1331. But the court also explained

that a party invoking the tangential exception must prove that the equivalent was "peripheral, or not directly relevant, to its amendment." *Id.* at 1332 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003)).

The decision in *Eli Lilly & Co.* is no different than the decision in *Intervet*. In both cases, the Federal Circuit held that an amendment to narrow a claim from a broad category to a specific type within that category did not estop the patentee from claiming that something was equivalent to the specific type of structure that it patented. But that's not this case. This case is about numerical ratios. Arbutus narrowed its claim to specify certain ratios, and now it claims ratios outside the claimed ranges are equivalent. But that imprecision is exactly what the examiner was worried about, and while the equivalent that Arbutus claims is narrower than the range about which the examiner expressed concern, the fact remains that Arbutus seeks to claim an equivalent that is about the very same issue that led to its amendment, not some tangential aspect. Because Arbutus has not shown that its amendment to limit the molar ratios that its patent covered was tangential to an equivalent with a molar ratio outside the range it claims, it has not satisfied its burden of proving that the exception applies.

Arbutus also argues that Judge Goldberg's claim construction ruling forecloses Moderna's argument, but I disagree. In construing the claims, Judge Goldberg determined that Arbutus had only "clearly disclaimed" the broader ranges as part of the amendment process. (D.I. 266 at 21.) But Judge Goldberg had no occasion as part of the claim

construction process to consider the application of amendment-based estoppel, so his ruling on a different issue does not require a different outcome.[9]

C. Invalidity

An alleged infringer may challenge a patent's validity by contending that it is indefinite. *See* 35 U.S.C. § 282. A patent is indefinite if it fails to "particularly point[] out and distinctly claim[] the subject matter which the [applicant] . . . regards as [his] invention." 35 U.S.C. § 112. Courts have interpreted this statutory language to require a claim to "reasonably apprise those skilled in the art of the scope of the invention." *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1378 (Fed. Cir. 2000) (quotation omitted).

[9] Moderna also makes an argument about argument-based estoppel. Argument-based estoppel can estop a patent holder from bringing an infringement claim under the doctrine of equivalents for subject matter that the applicant surrendered via argumentation before the patent examiner. *See Conoco, Inc. v. Energy & Environmental Intern., L.C.*, 460 F.3d 1349, 1364 (Fed. Cir. 2006). For this type of estoppel to apply, the applicant's argument before the patent examiner "must evince a clear and unmistakable surrender of subject matter." *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1326 (Fed. Cir. 2003) (quotation omitted). Because I conclude that Arbutus cannot rely on equivalents outside the claimed molar ratios in the Molar Ratio Patents, Moderna's argument-based estoppel argument is moot. However, I note that no competitor would reasonably believe that Arbutus surrendered the equivalents at issue. During prosecution, Arbutus emphasized to the examiner the "new and unexpected results" of the 1:57 SNALP (57 mol % cationic lipid) formulation and the advantages imparted by "increased" amounts of cationic lipid. (*E.g.*, D.I. 514-25 at 11.) The only anchor in the '069 Patent's prosecution history against which to judge an increase is MacLachlan, which discusses 40 mol % cationic lipid or less. From that, it's possible to conclude that Arbutus's arguments to the examiner foreclose any molar ratio below 40 mol %. Moderna's argument to extend the ratio to a 50 mol % relies on rhetorical points in IPR proceedings that do not support its proposed outcome.

Although this requirement "mandates clarity," it does not require "absolute precision." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014).

In the context of evaluating a claim that discloses a particular measurement, the Federal Circuit has said that a "claim is not indefinite if a person of skill in the art would know how to utilize a standard measurement method ... to make the necessary measurement." *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1376 (Fed. Cir. 2017). That is, "if a skilled person would choose an established method of measurement, that may be sufficient to defeat a claim of indefiniteness, even if that method is not set forth ... in the patent itself." *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 809 F.3d 1223, 1224 (Fed. Cir. 2015) (Prost, *C.J.*, Dyk & Wallach, *JJ.*, concurring).

The Parties dispute whether the asserted claims of the '651 Patent are indefinite. On the one hand, Moderna insists that the claims are indefinite as a matter of law. On the other hand, Arbutus argues that the claims are either definite as a matter of law or, at the very least, that there is a genuine dispute of material fact as to whether the claims provide a POSA with reasonable certainty about the scope of the invention. The Parties also argue over whether the claims in Arbutus's Molar Ratio Patents are definite as a matter of law.

1. Dr. Prud'homme's Indefiniteness Opinion

The law provides that claims are indefinite where the claims, when read in light of the specification and prosecution history, fail to inform a POSA as to the scope of the invention with reasonable certainty. *See Nautilius, Inc.*, 572 U.S. at 901. While a "potential

infringer" need not "be able to determine ex ante if a particular act infringes the claims," the patent must "apprise the public 'of what is still open to them[]'" such that "a person of ordinary skill in the art could determine whether or not an accused product or method infringes the claim." *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1346–47 (Fed. Cir. 2022). This is an inquiry about the scope of the patent; not one into whether a competitor can determine it infringed. *See id.*; *see also Nautilus, Inc.*, 572 U.S. at 901.

Dr. Prud'homme grounds his opinions in this law. He opines about the indefiniteness of both the '651 Patent and the Molar Ratio Patents. For both, he concludes that they are indefinite because (a) a POSA would not know what method to use to measure the claimed inventions and (b) the various methods of measurement available produce meaningfully different results. Thus, he says, a POSA could not determine the scope of the claim in order to determine infringement. Dr. Prud'homme might not be right, but it is a fair opinion, backed by a stated methodology, about the ability of a POSA to determine the metes and bounds of the asserted claims.

Arbutus's argument to the contrary conflates indefiniteness analysis with infringement analysis. Although the Federal Circuit has used the word "infringes," it has also made clear that the inquiry is one of scope, not infringement. *See Niazi Licensing*, 30 F.4h at 1346–47. While the ability to determine the scope of a patent can implicate a competitor's ability to determine if it has infringed, that does not mean an expert's opinion about a patent's scope is about a competitor's ability to determine infringement.

That is particularly true in a case like this, in which the patents define the inventions in numerical terms, which binds the measurement question inextricably to the scope of the claims. In short, Dr. Prud'homme's indefiniteness opinion was not based on an application of the incorrect legal standard. I will therefore deny Arbutus's motion to exclude his opinions, and I will consider them among the quantum of admissible evidence in resolving the Parties' competing summary judgment motions on indefiniteness.

2. The '651 Patent

Claim 1 of the '651 Patent recites, "A lipid vesicle formulation comprising: ... messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles."[10] (D.I. 512-4 at 30.) Judge Goldberg construed the phrase "fully encapsulated" to mean "fully, as distinct from partially" encapsulated. (D.I. 266 at 37.) Under this construction, to be fully encapsulated, the mRNA strand must be "fully contained inside the vesicle;" the claim does not cover strands that are "part-in-part-out" or not encapsulated at all. (D.I. 266 at 35–36.)

There are factual disputes about the definiteness of this claim that make summary judgment inappropriate. Each side has offered expert testimony about what a POSA would understand "fully encapsulated" to mean and what method of measurement that

[10] The other asserted claims of the '651 Patent are dependent on Claim 1. Claims 13 and 14 of the '651 Patent respectively require "at least 80%" and "about 90%" of the mRNA be "fully encapsulated." (D.I. 512-4 at 30.)

person would have understood the patent to require in order to measure encapsulation of mRNA. None of the Parties' arguments persuades me otherwise.

First, I disagree with Moderna that it offered unrebutted testimony about the meaning (or lack of meaning) of "fully encapsulated." (D.I. 508 at 30.) It offered Dr. Prud'homme's opinion, but Arbutus offered an opinion of Dr. Murthy, which uses the construction that Judge Goldberg applied, without confusion. (*See* D.I. 571-18 at 240–41.) That conflicting testimony precludes summary judgment, particularly in light of the high burden that Moderna has to demonstrate invalidity.

Second, there are factual disputes about what a POSA would have understood about how to measure encapsulation. Moderna offers evidence of at least one article that discloses seven different tests used to measure encapsulation efficiency and notes that the article reports different tests yield different results. (*See* D.I. 508 at 34.) However, the Parties offer conflicting testimony about what measurement method a POSA would have used. Dr. Prud'homme, for Moderna, suggests that a POSA wouldn't know which method to use. On the other hand, Dr. Murthy argues that a POSA would have known to use a dye-exclusion assay to measure full encapsulation within the context of the claimed invention. At this stage of the proceedings, both opinions are forms of admissible evidence, and I can't credit one over the other.

But even if I assumed that a POSA would use a dye-exclusion assay to measure full encapsulation, there would still be genuine issues of fact preventing the grant of summary

judgment. That is because, as Judge Goldberg noted, the technique known as, "fluorescent dyeing" "necessarily counts the inside section of part-in-part-out strands ... while containing no mechanism to identify which strands are part-in-part-out." (D.I. 266 at 36–37.) In other words, fluorescent dying cannot distinguish between partially encapsulated and fully encapsulated mRNA. Moderna argues that this means fluorescent dyeing cannot be a method of measurement that a POSA would have understood as a way of quantifying the "at least 70%," "at least 80%," and "about 90%" encapsulation of mRNA as required by the claims. However, Arbutus provides expert testimony that states partial encapsulation in lipid particles does not exist and, even if it could, there are techniques that can measure fully encapsulated mRNA and differentiate it from the hypothetical partially encapsulated mRNA. This amalgam of conflicting testimony makes summary judgment inappropriate.

3. The Molar Ratio Patents

The asserted claims in the Molar Ratio Patents recite three or four lipid-component ranges in "mol %" "of the total lipid present in the particle." However, nothing in the Molar Ratio Patents indicates how to determine the mol % of lipids in individual particles or the formulation. While there is no test to measure the "mol %" of the lipid components in an individual lipid particle directly, there are multiple tests to do so indirectly (*e.g.*, measuring

aggregates or fractionated samples of lipid compositions containing millions of lipid particles).[11]

There is conflicting evidence in the record as to whether the existing methods would give meaningfully different results. "[W]here different approaches to measurement are involved," "the patent and prosecution history must disclose a single known approach or establish that, where multiple known approaches exist, a person having ordinary skill in the art would know which approach to select." *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 803 F.3d 620, 630 (Fed. Cir. 2015). Moderna highlights that Arbutus's expert ran different tests, both fractionated and not, on the same batch of samples, and the tests resulted in some lipid amounts being inside the claimed molar ratio ranges while others were not. Arbutus claims this comparison is flawed because the non-fractionated testing method produces "one overall value," whereas the fractionated testing method "yields information about the underlying compositional distribution of particles within the sample." (D.I. 610 at 7–8.) According to Arbutus, even though the tests are different, they do not produce different results. But since the Parties present conflicting evidence over whether the test results are materially different and over which test a POSA would

[11] One technique, known as a fractionation technique, allows researchers to "fractionate" (*i.e.*, separate) the composition of lipid particles. (*See* D.I. 571-18 at 676.) Those fractions can then be analyzed for their lipid composition. (*See id.*) A different technique, referred to as an aggregation technique, involves researchers simply testing the composition without fractionating it. (*See id.* at 673, 677–78.)

understand to have produced the claimed mol % of the lipid components, summary judgment is inappropriate.

IV. CONCLUSION

Most of Moderna's vaccine doses were not for the Government, so Arbutus's claims about them belong here as Section 1498 does not apply to them. Moderna has proven that prosecution history estoppel bars Arbutus's doctrine-of-equivalents claims about the Molar Ratio Patents, so I will grant Moderna's Motion on that issue. A jury will have to resolve questions of invalidity. An appropriate Order follows.

BY THE COURT:

/s/ Joshua D. Wolson
JOSHUA D. WOLSON, J.

February 2, 2026