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

Not every defense presents a triable issue. Defenses, like affirmative claims, can fail for a lack of evidence. Or they can fail because parties in patent cases only get to litigate an obviousness issue once, either in court or in IPR proceedings. But when a defendant offers admissible evidence, including an expert opinion, that creates a genuine issue of fact, then a jury must be the ultimate arbiter. In this case, Moderna[1] maintains several defenses against the patent infringement claims that Arbutus[2] asserts against it. Moderna already mounted many of its obviousness defenses in IPR proceedings, so it cannot do so again in this case. And it lacks evidence to support its derivation defense. However,

[1] "Moderna" means Defendants Moderna, Inc. and ModernaTX, Inc.
[2] "Arbutus" refers to Arbutus Biopharma Corp. and Genevant Sciences GmbH.

Moderna offers admissible expert opinions to support its enablement defense, and those opinions create disputed factual issues that require a jury trial.

I. BACKGROUND

A. Arbutus's Patents

There are four patents in dispute. Three, the "Molar Ratio Patents,"[3] are part of the same patent family and claim nucleic acid-lipid nanoparticles ("LNPs") that protect and deliver nucleic acid, such as the messenger RNA ("mRNA") in Moderna's COVID-19 vaccine, into the cells of the body. Without LNPs, the mRNA in Moderna's vaccine would rapidly degrade in the body before it could effectively fight the coronavirus. LNPs consist of three components: (1) a cationic lipid, which exhibits a positive charge under certain conditions; (2) one or two "non-cationic" lipids, such as a phospholipid or cholesterol; and (3) a conjugated lipid, such as a PEG-lipid that inhibits the aggregation of particles. The ratio of these lipids, which the Molar Ratio Patents claim as a mole percent ("mol %") of the total lipid in the particle, affects the properties of an LNP.

The fourth patent at issue, the '651 Patent,[4] claims a formulation of lipid vesicles with certain lipid components and high levels of fully encapsulated mRNA. The '651

[3] The Molar Ratio Patents are U.S. Patent Nos. 8,492,359 ("'359 Patent"); 9,364,435 (the "'435 Patent"); and 11,141,378 (the "'378 Patent"). At one point in this case, Arbutus also claimed that Moderna infringed two other patents in the same family: U.S. Patent Nos. 8,058,069 (the "'069 Patent") and 8,822,668. Arbutus dropped its infringement claims for these patents after Judge Goldberg ordered the Parties to narrow their asserted claims.
[4] U.S. Patent No. 9,504,651 (the "'651 Patent").

Patent's specification explains a method for manufacturing high levels of fully encapsulated mRNA. The high levels of fully encapsulated mRNA ensure that a large amount of mRNA is protected and thus delivered to the body's cells to fight off viruses.

B. Moderna's Use Of Patented Technology

In 2015, Moderna entered into the first of four sublicenses to use Arbutus's patents. The sublicenses were limited in scope to specific viruses, none of which included the coronavirus that causes COVID-19. In fact, Arbutus never entered a license agreement that covered the use of Arbutus's Patents in vaccines to fight the coronavirus that causes COVID-19.

Instead of entering a licensing agreement with Arbutus, Moderna sought to invalidate the '069 Patent and the '435 Patent by filing petitions for inter partes review with the Patent Trial And Appeal Board. The PTAB then issued "final written decision[s]" rejecting Moderna's challenges. *Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, IPR 2019-00554, 2020 WL 4237232, at *1 (PTAB July 23, 2020) ('069 Patent); *Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, 2019 Pat. App. LEXIS 13612, at *1 (Sept. 11, 2019) ('435 Patent). The Federal Circuit affirmed the PTAB's '069 Patent decision and dismissed for lack of standing Moderna's appeal of the PTAB's '435 Patent decision. *See ModernaTX, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364, 1372–77 (Fed. Cir. 2021) ('069 Patent); *ModernaTX, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1352, 1364 (Fed. Cir. 2021) ('435 Patent).

C. Procedural History

Arbutus filed this suit on February 28, 2022. Moderna answered on May 15, 2024, asserting counterclaims and several defenses. On August 1, 2025, Arbutus filed a motion for summary judgment as to three of Moderna's defenses: obviousness; enablement; and derivation. (D.I. 518.) At the same time, Arbutus filed a Motion To Exclude Expert Testimony from Dr. Daniel Anderson and Dr. Robert Prud'homme. (D.I. 518.) Moderna opposed both motions. The motions are now fully briefed and ready for disposition.

II. LEGAL STANDARD

A. Summary Judgment

A court may 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. *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. *See Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1390–91 (Fed. Cir. 2003). 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, expert testimony is unnecessary. *See id.*

III. ANALYSIS

A. Obviousness

A court may invalidate a patent if it finds that "the differences between the claimed invention and ... prior art are such that the claimed invention as a whole would have been obvious." *See* 35 U.S.C. § 103. "Obviousness is based on underlying factual findings, including: (1) the level of ordinary skill in the art; (2) the scope and content of the prior art; (3) the differences between the claims and the prior art; and (4) secondary considerations of nonobviousness, such as commercial success, long-felt but unmet needs, failure of others, and unexpected results." *Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1097 (Fed. Cir. 2015). A defendant can challenge the validity of a patent by raising obviousness as a defense. *See, e.g.*, *id.* However, IPR estoppel and issue preclusion, both of which Arbutus invokes, can bar an obviousness defense.

1. IPR estoppel

Federal law prevents a defendant in a civil action from making obviousness arguments that the defendant made in an IPR proceeding. *See* 35 U.S.C. § 315(e)(2). IPR estoppel bars not only the arguments that a defendant made in the IPR but also arguments that it "reasonably could have raised." *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1297 (Fed. Cir. 2023).[5] A party reasonably could have raised an argument if "a skilled searcher conducting a diligent search reasonably could have been expected to discover" it. *Id.* at 1298.

IPR estoppel bars Moderna from asserting that the '435 Patent is obvious. Moderna already challenged several of the claims in the '435 Patent and lost. *See* 2019 Pat. App. LEXIS 13612. That challenge "result[ed] ... in a final written decision." 35 U.S.C. § 315(e)(2); *see also* 2019 Pat. App. LEXIS 13612. All of the obviousness challenges that Moderna raises in this case are ones that it raised or could have raised in the IPR, a fact that Moderna doesn't dispute. It therefore cannot assert those obviousness claims in this case.

Moderna argues that there was not a final written decision with respect to the '435 Patent IPR because the Federal Circuit dismissed Moderna's appeal for lack of standing rather than affirming the PTAB's decision. But the statutory text does not support Moderna's position. Section 315(e)(2) triggers statutory estoppel if a party asserting

[5] The interpretation of 35 U.S.C. § 315(e)(2) is an issue unique to patent law. *See Ironburg Inventions Ltd.*, 64 F.4th at 1296. Therefore, Federal Circuit law applies. *See id.*

obviousness was the petitioner in an IPR and that IPR "result[ed] in a final written decision under Section 318(a)." 35 U.S.C. § 315(e)(2). Section 318(a), in turn, explains that "[i]f an inter partes review is instituted and not dismissed under this chapter, the **Patent Trial and Appeal Board** shall issue a final written decision." 35 U.S.C. § 318(a) (emphasis added). Thus, pursuant to this statutory language, the PTAB issues final written decisions, not the Federal Circuit, and the PTAB's issuance of a final written decision triggers the statutory estoppel.

Moderna grounds its argument in cases that hold that issue preclusion does not apply unless a party has an opportunity to appeal. But IPR estoppel is not a common law doctrine; it is a Congressional creation. It deviates in several important respects from issue preclusion. For example, it does not require the actual litigation of an identical issue to apply. Moderna does not argue, nor could it, that Congress lacked the power to create a form of statutory estoppel that applies without need for an appeal. And that's what Congress did here. It created a statutory proceeding—an IPR—that does not require Article III standing, and it created a form of estoppel that applies when that statutory proceeding ends in a final written decision. It did not cabin estoppel only to those cases in which the petitioner also has Article III standing and can therefore appeal to the Federal Circuit. I therefore conclude that IPR estoppel applies whenever the PTAB issues a final written decision, even if a petitioner cannot appeal that decision. Thus, IPR estoppel bars Moderna's obviousness defense as to the '435 Patent.

2. Issue preclusion

Under the doctrine of issue preclusion (also known as collateral estoppel), there are no do-overs. *See B&B Hardware, Inc. v. Hargis Indus., Inc.*, 575 U.S. 138, 147 (2015). Under certain conditions, a tribunal's resolution of an issue can prevent the loser from later contesting that same issue in a different case. *See id.* at 148. Issue preclusion bars a party from raising an issue when (a) the same issue was previously adjudicated; (b) the issue was actually litigated; (c) the previous determination was necessary to the tribunal's decision; and (d) the party being precluded was fully represented in the prior action. *See Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006).[6]

Moderna is seeking to relitigate two issues that it litigated in the '069 Patent IPR: (a) whether it would have been routine for a person of ordinary skill in the art to optimize the lipid particle formulations in the prior art to match the claimed molar ratio ranges; and (b) whether prior art taught a phospholipid range that overlaps with the claimed ranges. Both the PTAB and Federal Circuit rejected these arguments in Moderna's obviousness challenge to the '069 Patent.

Before the PTAB and on appeal, Moderna argued that the claims of the '069 Patent would be obvious because a POSA would be able to use prior art references as a starting point before using routine optimization to reach the ranges claimed in the Molar Ratio

[6] Whether collateral estoppel applies is not unique to patent law, so Third Circuit law governs whether collateral estoppel applies. *See Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1314 (Fed. Cir. 2015).

Patents. The PTAB and Federal Circuit rejected this routine-optimization argument, concluding that it "failed to address the interdependence of the claimed lipid components" and their "unpredictable interactivity." *ModernaTX, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364, 1376–77 (Fed. Cir. 2021). Those decisions prevent Moderna from relitigating this issue before me.

Moderna cannot avoid this outcome based on citations by its expert, Dr. Anderson, of prior art different from the prior art referenced in the IPR. A defendant's attempt to "buttress [its] case through different evidence" does not necessarily create a new issue. *Dana v. E.S. Originals, Inc.*, 342 F.3d 1320, 1325 (Fed. Cir. 2003). In a similar vein, Judges Noreika and Andrews have rejected the notion that collateral estoppel cannot apply when a party asserts different prior art than what was presented in an earlier action. *See, e.g.*, *PureWick Corp. v. Sage Prods., LLC*, Case No. 22-102-MN, 2023 WL 2734779, at *5 (D. Del. Mar. 31, 2023); *Sprint Commc'ns. Co. v. Charter Commc'ns., Inc.*, Case No 17-1734-RGA, 2021 WL 982726, at *9 (D. Del. Mar. 16, 2021).[7]

[7] Even if I were to accept Moderna's argument that its reliance on different prior art prevents the application of collateral estoppel, Moderna's expert, Dr. Anderson, never disputed Arbutus's claim that the prior art "is substantially similar if not identical" to the prior art that Moderna presented before the PTAB and Federal Circuit. Therefore, Moderna's insistence that collateral estoppel cannot apply fails for the additional reason that the new references are "substantially identical teaching with respect to" the relevant issues. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 763 F. Supp. 2d 671, 679–80 (D. Del. 2010).

Moderna's attempt to distinguish the PTAB and Federal Circuit decisions on the basis that they concerned the '069 Patent is also unpersuasive. That is because the Molar Ratio Patents share the same specification as the '069 Patent, and Moderna has not provided any persuasive reason for why I should draw a distinction. I therefore hold that issue preclusion applies to Moderna's routine-optimization theory based on the rulings in the IPR.

The IPR Proceedings also resolved Moderna's argument related to the phospholipid range of the Molar Ratio Patents. The PTAB and Federal Circuit found that the prior art did not teach a phospholipid range and thus could not possibly teach an "overlapping range." *ModernaTX, Inc.*, 18 F.4th at 1373, 1375. Given this explicit holding, the only argument that Moderna can muster is that the phospholipid range of the Molar Ratio Patents would be obvious to a person of ordinary skill in the art given the prior art and "routine optimization of the lipid molar ratios." But because Moderna tied its phospholipid-range argument to its routine-optimization argument, the decision with respect to routine optimization also disposes of Moderna's phospholipid-range argument.

Moderna does not dispute the other issue preclusion elements, and for good reason. Moderna raised and litigated the issue of whether the Molar Ratio Patents were obvious in the IPR and the subsequent appeal. The decisions related to routine optimization and the lack of a phospholipid range in prior art were essential decisions to

the determination of nonobviousness. Sophisticated counsel represented Moderna in the IPR and before the Federal Circuit. Therefore, issue preclusion bars Moderna from relitigating the determinations that (1) "routine optimization" would not yield the claimed ranges due to the "unpredictable interactivity" of the four lipid components, and (2) the prior art does not disclose a phospholipid range.[8]

B. Enablement

To be valid, a patent "must enable a person of ordinary skill in the art to make and use the invention." *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013). "If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023). However a specification need not "describe with particularity how to make and use every single embodiment within a claimed class. For instance, it may suffice to give an example (or a few examples) if the specification also discloses some general quality running through the class that gives it a

[8] Arbutus notes that its arguments for the application of statutory estoppel and issue preclusion made in connection with its Motion To Exclude Dr. Anderson's obviousness opinions are "substantially identical to" those set forth in its Motion For Summary Judgment. Arbutus's Motion To Exclude Dr. Anderson's obviousness opinions thus rises and falls with its arguments for statutory estoppel and issue preclusion. *See Daubert*, 509 U.S. at 591. Therefore, I will grant Arbutus's Motion To Exclude Dr. Anderson's Obviousness Opinions. (D.I. 522.)

peculiar fitness for the particular purpose." *Id.* at 610–11 (cleaned up). Courts presume patents enabled, so a "challenger bears the burden, throughout the litigation, of proving lack of enablement by clear and convincing evidence." *Cephalon*, 808 F3d at 1337.

A patent enables a POSA to practice it "when at the time of filing the application one skilled in the art, having read the specification, could practice the invention without 'undue experimentation.'" *Id.* at 1336. Whether the amount of experimentation required is undue is subject to a fact-intensive inquiry. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Courts consider eight factors, including: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* A "reasonable amount of routine experimentation" is not undue. *Cephalon*, 707 F.3d at 1336. Even an "extensive" amount of experimentation is not undue "where the experiments involve repetition of known or commonly used techniques." *Id.* at 1338. Experimentation is undue when a POSA must engage in "elaborate" or "painstaking experimentation" to practice a claim. *Amgen Inc.*, 598 U.S. at 610, 614.

Moderna challenges the enablement of each of the asserted claims in this case, and Arbutus contends that Moderna lacks evidence for any of those challenges. Much of the dispute turns on whether Dr. Prud'homme has offered admissible opinions about

enablement. I conclude that he has and that his opinions create disputed issues of fact on Moderna's enablement defenses.

For each of the asserted claims, Dr. Prud'homme analyzes the *Wands* factors and concludes that they require undue experimentation. His analysis of each factor, in turn, rests on specific, disclosed methodologies. He explains the breadth of combinations of compounds that the claims could cover. He reviews the state of prior art and the nature of the invention. He considers the predictability of the prior art, including Arbutus's own discussion of the state of the art during IPR proceedings. And, perhaps most importantly, he describes the amount of experimentation that a POSA would require. Specifically, he discusses the various methods by which one could measure the results of an experiment, explains the challenges of each, and highlights the ambiguity for a POSA to use any of them. His analysis satisfies Rule 702 and *Daubert* because it will "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. And with his analysis in the case, Moderna has admissible evidence to present to the jury to try to satisfy its burden. Whether Dr. Prud'homme's testimony will be enough, alone or with other evidence, to carry the heavy burden of clear and convincing evidence, is an issue for the jury.

Arbutus's various arguments challenging Dr. Prud'homme's testimony or asking me to ignore it do not convince me otherwise. First, Arbutus argues that Dr. Prud'homme imports unclaimed limitations such as stability, toxicity, potency, and tolerability into the

asserted claims of all the patents at issue. But Arbutus takes many of Dr. Prud'homme's opinions out of context. Dr. Prud'homme appears only to have made these unclaimed-features arguments in response to prior arguments that Arbutus made to distinguish the patents from prior art. In fact, Dr. Prud'homme limited his opinions "to the extent the claims are directed to particles with specific properties (e.g., stability)." (D.I. 526-7 at 126.) Moderna affirms that it "will not present any so-called 'unclaimed properties' if [Arbutus] stand[s] by [its] position that such properties are not required by the claims." (D.I. 557 at 17.) I will take Moderna at its word. At trial, Arbutus is free to renew its request to exclude Dr. Prud'homme's testimony in the event Moderna seeks to introduce it for purposes beyond what it has claimed.

Second, with respect to the '651 Patent, Arbutus argues that Dr. Prud'homme "improperly assume[d] that all modes of making the invention must be enabled." (D.I. 524 at 20.) That argument mischaracterizes Dr. Prud'homme's opinions, however. He opines that the '651 Patent does not provide **any** method – including the method listed in the specification – of making the invention. (*See* D.I. 566-3 at 71–74.) A jury might disagree with Dr. Prud'homme about that, but his opinion is relevant to the legal issue of whether a POSA could practice the claims without undue experimentation in view of the steps set forth in the specification. *See In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991).

Third, Arbutus contends that Dr. Prud'homme imports a measurement requirement into the various asserted claims. That's not how I read it, though. Dr. Prud'homme

discusses the challenges of measurement to illustrate how much experimentation a POSA would have to conduct to practice the claimed inventions. That is, Dr. Prud'homme highlights measurement problems to demonstrate how much work he thinks would be left for a POSA to try to practice the claimed inventions even after following the steps in the specification. Thus, Dr. Prud'homme is not importing a requirement into the patent claims, nor is he conflating infringement with enablement, as Arbutus suggests. Instead, his measurement opinions appropriately illustrate one of the *Wands* factors.

Fourth, Arbutus argues that I should disregard Dr. Prud'homme's opinions because he does not describe what experimentation was necessary to make the claimed particles. Arbutus's argument goes too far, though. Dr. Prud'homme, admittedly, does not offer an opinion describing the specific experimental steps that he or some other POSA took to make a claimed particle. But he does identify, qualitatively, the host of roadblocks that a POSA would encounter in trying to make one of the claimed particles. Nothing in the caselaw prevents an expert from offering a qualitative opinion on this issue. Indeed, the need to move litigation forward and for parties to comply with operative scheduling orders would, at times, make it impossible (or cost-prohibitive) for an expert to conduct the experiments necessary when the expert opines that there are substantial challenges. Thus, while the kind of concrete, quantitative evidence that Arbutus seeks would certainly be helpful, it is not necessary to permit an expert to opine about experimentation, as long

as the expert describes in detail the necessary challenges in experimentation that a patent specification leaves for a POSA to sort through. Dr. Prud'homme does that.

Fifth, and finally, Arbutus argues that Moderna's experts "ignore or fail to rebut the overwhelming evidence demonstrating that numerous scientists … had no difficulty practicing the claimed invention based on the patent's guidance." (D.I. 519 at 29.) With this argument, Arbutus asks me to cross the line from gatekeeper to factfinder. It does not matter for either *Daubert* or summary judgment whether Arbutus can muster evidence that is at odds with Dr. Prud'homme's opinions. Trials are the time to assess competing evidence, not motions practice. Moderna has offered admissible evidence in the form of Dr. Prud'homme's opinions, and I will therefore permit a jury to resolve questions of enablement.

C. Derivation

A patent is invalid if the inventor did not invent the subject matter claimed in the patent. *See* 35 U.S.C. § 102(f). If an inventor derived an invention from another, then the patent is invalid. *See id.* To prove a lack of derivation, the party asserting invalidity must prove both (1) "prior conception of the invention by another" and (2) "communication of that conception to the patentee by clear and convincing evidence." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1344 (Fed. Cir. 2003) (quotation omitted).

Moderna failed to demonstrate that there was a prior conception of Arbutus's invention by another. Moderna's own expert, Dr. Prud'homme, conceded that an Arbutus

scientist, Stephen Reid, encapsulated mRNA in lipid-nanoparticles years before Moderna encapsulated mRNA. (*See* D.I. 526-9 at 45, 58.) In fact, Moderna does not dispute that Mr. Reid achieved 86–95 % encapsulation of mRNA using a lipid vesicle formulation, the '651 Patent's claimed invention embodies. It is thus impossible for Moderna's proposed prior conception (*i.e.*, the technology disclosed in its 2012 patent application) to have preceded a claim element that Arbutus practiced in 2009.

Moderna argues that because Mr. Reid is not a named inventor on any of Arbutus's patents, his own work demonstrates non-derivation. However, Mr. Reid was not working on his own. He was one of many scientists working for Ian MacLachlan, one of the named inventors on all of Arbutus's patents. (*See* D.I. 594-19.) "[E]xperiments conducted at the request of an inventory by another party may inure to the benefit of the inventor for purposes of establishing a reduction to practice." *Cooper v. Goldfarb*, 154 F.3d 1321, 1331 (Fed. Cir. 1998). Moderna does not have any evidence to dispute Mr. Reid's relationship with Mr. McLachlan. Therefore, there is not dispute that Mr. Reid's work inures to Dr. MacLachlan and does not undermine Arbutus's inventiveness claim.

Moderna also seeks to distinguish Mr. Reid's work by pointing to the fact that he used an EDTA buffer in his experiments. But, as Arbutus points out, the patent is not limited to a particular buffer. It's therefore not clear why the use of an EDTA buffer changes the analysis as to who the inventor is. Because it is Moderna's burden at trial to

show a lack of derivation, its lack of evidence on this issue is fatal to the claim. I will therefore grant summary judgment on Arbutus's claim of no derivation.

IV. CONCLUSION

IPR estoppel bars Moderna's obviousness defense as to the '435 Patent. Issue preclusion bars Moderna from relitigating issues from the IPR proceedings that "routine optimization" would not yield the claimed ranges due to the "unpredictable interactivity" of the four lipid components and that the prior art does not disclose a phospholipid range. And Moderna has no basis on which to challenge derivation. However, Dr. Prud'homme's opinions create a genuine factual dispute about enablement, and a jury will have to resolve that argument.

BY THE COURT:

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

February 17, 2026