

United States Court of Appeals  
for the Federal Circuit

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AR BUTUS BIOPHARMA CORPORATION, FKA  
PROTIVA BIOTHERAPEUTICS, INC.,  
*Appellant*

v.

MODERNATX, INC., FKA MODERNA  
THERAPEUTICS, INC.,  
*Appellee*

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2020-1183

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Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2018-00680.

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Decided: April 11, 2023

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DAVID I. BERL, Williams & Connolly LLP, Washington, DC, argued for appellant. Also represented by JESSICA PALMER RYEN; SONJA ROCHELLE GERRARD, MICHAEL T. ROSATO, Wilson Sonsini Goodrich & Rosati, Seattle, WA; LORA MARIE GREEN, Gemini Law LLP, Washington, DC.

AMY K. WIGMORE, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, argued for appellee. Also represented by NORA N. XU; MARK CHRISTOPHER FLEMING,

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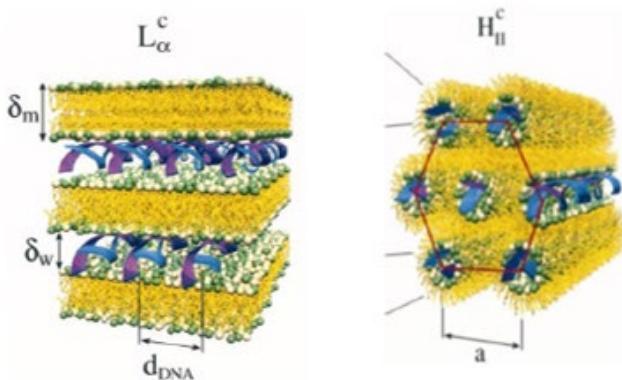
Before REYNA, SCHALL, and CHEN, *Circuit Judges*.

REYNA, *Circuit Judge*.

Appellant Arbutus Biopharma Corporation appeals a final written decision in an inter partes proceeding of the Patent Trial and Appeal Board that found claims 1–22 of U.S. Patent No. 9,404,127 invalid as anticipated. On appeal, Arbutus Biopharma Corporation challenges the Board’s anticipation finding. We affirm.

#### BACKGROUND

Protiva Biotherapeutics, once a wholly owned subsidiary of—and is now amalgamated into—Appellant Arbutus Biopharma Corporation (“Arbutus”), owned U.S. Patent No. 9,404,127 (the “127 patent”). *See Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, No. IPR2018-00680, 2019 WL 12447121, at \*1 & n.2. (P.T.A.B. Sept. 10, 2019) (“Decision”). The ’127 patent was filed on March 9, 2015 and claims priority to Application No. 61/360,480 that was filed on June 30, 2010. *Id.* at \*1. The ’127 patent issued on August 2, 2016, listing three co-inventors: Ed Yaworski, Lloyd B. Jeffs, and Lorne R. Palmer. *Id.* It is directed to an invention that provides stable nucleic acid-lipid particles (“SNALP”) that have a non-lamellar structure and “comprise a nucleic acid . . . methods of making the SNALP, and methods of delivering and/or administering the SNALP.” *Id.* at \*2 (quoting ’127 patent, Abstract). The three-dimensional structure of SNALP is a physical property that has one of two morphologies: lamellar or non-lamellar. Appellee’s Br. 6–8.



*Id.* A lamellar morphology is one in which sheets of lipid bilayers are arranged in layers (shown above in the picture on the left). Appellee's Br. 6. A non-lamellar form refers to a non-bilayer morphology of the particles, an example of which is an inverse hexagonal structure (shown above in the picture on the right). *Id.* at 7–8; *Decision* at \*2 n.5.

The '127 patent states that its purpose is to allow for more efficient methods and compositions for introducing nucleic acids into cells and methods of downregulating gene expression. '127 patent, col. 2 ll. 54–61. The invention is, in part, the “surprising discovery” of the Morphology Limitation when one controls two factors: the lipid compositions of a SNALP formulation and formation process. '127 patent, col. 2 ll. 64–col. 3 l. 1. Thus, the physical property or morphology of the particles depends on two factors: (1) the lipids used for making the formulations and (2) the process used to form the particles. Appellant's Br. 5–6; Appellee's Br. 8–9. The '127 patent identifies five formulations of various compositions that can be prepared by either Stepwise Dilution Method (“SDM”) or Direct Dilution Method (“DDM”). *Decision* at \*2; '127 patent, Tables 1, 3; col. 104 ll. 44–60; col. 105 ll. 53–64. These formulations are 1:62, 1:57, 2:40, 2:30, and 10:15, with the first two being the most relevant to this case. *Decision* at \*2. The

numbers refer to molar percentages of the conjugated lipid and cationic lipid, respectively. *Decision* at \*2 n.6.

The '127 patent incorporates by reference U.S. Patent Publication No. 2007/0042031 (the "031 publication") to describe DDM and the apparatuses for carrying out DDM. '127 patent, col. 16 ll. 27–31, col. 93 ll. 14–18, col. 104 ll. 32–37. It also incorporates by reference Publication No. 2004/0142025 to describe SDM and the apparatuses for carrying out for carrying out SDM. '127 patent, col. 16 ll. 27–31, col. 93 ll. 47–50, col. 104 ll. 9–22. The disclosure for each incorporated patent or publication is "in its entirety for all purposes." '127 patent, col. 104 ll. 9–22, 32–37. Independent Claim 1 is representative:

1. A composition comprising:
  - a plurality of nucleic acid-lipid particles, wherein each particle in the plurality of particles comprises:
    - (a) a nucleic acid;
    - (b) a cationic lipid;
    - (c) a non-cationic lipid; and
    - (d) a conjugated lipid that inhibits aggregation of particles, wherein at least about 95% of the particles in the plurality of particles have a non-lamellar morphology. [Morphology Limitation]

'127 patent, col. 149 ll. 29–37.

#### PROCEDURAL HISTORY

Appellee Moderna Therapeutics ("Moderna") filed a petition for inter partes review ("IPR") challenging claims 1–22 of the '127 patent, and review was instituted on September 12, 2018. *Decision* at \*1. Moderna argued that U.S. Patent No. 8,058,069 (the "069 patent"), which was filed on April 15, 2009 and claims priority to Application No. 61/045,228 that was filed on April 15, 2008, anticipated every claim. *Id.* at \*7. The '069 patent lists five inventors,

three of which are listed on the '127 patent. *Id.* The '069 patent, its child patent (U.S. Patent No. 9,364,435 (the "435 patent")), and the '127 patent, are all commonly owned by Arbutus. *Id.* While the '127 patent was filed during the pendency of the '069 patent, it does not claim priority to it. *Id.* at \*7 n.16.

#### BOARD'S FINAL WRITTEN DECISION

The Patent Trial and Appeal Board ("Board") instituted the IPR and issued a final written decision ("FWD") finding all 22 claims anticipated by the '069 patent ("069 patent" or "prior art patent"). *Id.* at \*1. In doing so, it found the '069 patent to be prior art to the '127 patent.<sup>1</sup> *Id.* at \*9, 12. The Board then found several of the same components between the two patents. Both patents: are directed to the same purpose (providing SNALP, methods of making and delivering SNALP); disclose at least the 1:57 and 1:62 formulations; explain that SNALP can be formed by any method in the art including direct dilution, and direct the reader to rely on the '031 publication for details on using DDM. *Id.* at \*7–8; '069 patent, col. 57 ll. 50–55.

The Board's FWD also addressed several incorporated references. The '031 publication is incorporated by reference in both the '127 and '069 patents. *Decision* at \*2, 7–8. Several other references—including U.S. Patent Publication No. 2006/0083780 (the "780 publication"), U.S. Patent Publication No. 2004/0142025 (the "025 publication"), and U.S. Patent No. 5,885,613 (the "613 patent")—were incorporated by reference in the '069 patent, each "in its entirety for all purposes." '069 patent, col. 11 ll. 62–64, col. 51 ll. 58–61, col. 58 ll. 18–21, col. 47 ll. 59–64. The Board found that the disclosure of the '069 patent thus includes the

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<sup>1</sup> Protiva did not dispute that the '069 patent was prior art under pre-AIA 35 U.S.C. § 102(e)(2). *Decision* at \*7 n.15.

disclosures of the '031 publication, the '613 patent, the '025 publication, and the '780 patent publication. *Decision* at \*8 (citing *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) and *Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011)). Together, the '069 patent and its incorporated references detail several of the same disclosures and experiments as the '127 patent. *Decision* at \*16, 21. The specificity of the disclosure in the prior art is the same as in the '127 patent. The '435 patent has the same disclosures and experiments as the prior art patent as well. *Id.*

The main issue before the Board was whether claim 1(d) of the '127 patent—wherein at least about 95% of the particles in the plurality of particles have a non-lamellar morphology (the “Morphology Limitation”—is inherently disclosed in the '069 patent. *Id.* at \*9. Moderna argued that the Morphology Limitation, while not expressly mentioned in the prior art, is an “inherent natural property” resulting from the lipid composition of the formulation and formation process. *Id.* at \*11. Arbutus disagreed, arguing that there was no presumption of inherency and that there was no evidence (such as testing or reasoning) showing that the '069 patent and its formulations would necessarily have the same morphology as disclosed by the '127 patent. *Id.* at \*12. Arbutus also submitted experimental evidence from its expert, who prepared two 2:30 lipid formulations from the '069 patent, to demonstrate that the Morphology Limitation was not met. *Id.* at \*17. After weighing the evidence, the Board found Arbutus’s arguments unavailing.

Arbutus argued that DDM is not a specific formulation process such that a person skilled in the art would understand that many parameters could be varied from classes of processes. *Decision* at \*16. The Board noted—and relied upon—Arbutus’s expert’s apparent concession that the '435 patent, a continuation of the prior art patent, would also disclose the Morphology Limitation. *Id.* at \*13–14. Thus,

the disclosure of the '069 patent and its incorporated references sufficiently demonstrate to a person skilled in the art how to make and use the claimed compositions, processed by DDM, that results in the Morphology Limitation. *Id.* at \*16. Accordingly, the Board found that all challenged claims were invalid as anticipated. The Board found independent claim 1, particularly, the Morphology Limitation, to be inherently anticipated by the '069 patent and its disclosures because the Morphology Limitation is an inherent property or natural result of the disclosures. *Id.* at \*21–22. It also found the remaining claims invalid as anticipated. Moderna appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

#### STANDARD OF REVIEW

We review the Board's legal conclusions de novo and its factual findings for substantial evidence. *ACCO Brands Corp. v. Fellowes, Inc.*, 813 F.3d 1361, 1365 (Fed. Cir. 2016). Substantial evidence “means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000) (citations omitted). Anticipation is a question of fact reviewed for substantial evidence. *In re Rambus Inc.*, 694 F.3d 42, 46 (Fed. Cir. 2012). Whether a claim limitation is inherent in a prior art reference is a question of fact that we review for substantial evidence. *Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336, 1342 (Fed. Cir. 2018) (quoting *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001)).

#### DISCUSSION

On appeal, Arbutus challenges the Board's finding of inherent anticipation of the Morphology Limitation, and both the inherent and express anticipation findings for dependent claims 3, 8–12 of the '127 patent.

A claim is anticipated if each and every element as set forth in the claim is found, either expressly or inherently,

in a single prior art reference. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). A finding of anticipation “does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure.” *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003).

A limitation is inherent if it is the “natural result flowing from” the prior art’s explicit disclosure. *Id.* at 1379. A patent “can be invalid based on inherency when the patent itself makes clear that a limitation is ‘not an additional requirement imposed by the claims . . . but rather a property necessarily present.’” *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1332 (Fed. Cir. 2020) (quoting *In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009)). Thus, inherent anticipation requires “merely that the disclosure of the prior art is sufficient to show that the natural result flowing from the operation as taught in the prior art would result in the claimed product.” *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343–44 (Fed. Cir. 2005) (internal quotation marks omitted) (modifications in the original). We have also explained that “[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.” *Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). “Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation.” *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1349 (Fed. Cir. 1999).

This court has also discussed the effect of incorporated references. When a reference or material from various documents is incorporated, they are “effectively part of the host document as if [they] were explicitly contained therein.” *Advanced Display Sys., Inc.*, 212 F.3d at 1282. While looking at the reference as a whole, the court will “conclude whether or not that reference discloses all elements of the claimed invention arranged as in the claim.”

*Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 n.5 (Fed. Cir. 2008). While “[a]rtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art,” whether a reference anticipates is assessed from the perspective of one skilled in the art. *Atlas Powder*, 190 F.3d at 1347; *see also Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368–69 (Fed. Cir. 2003).

## I

With this backdrop in mind, we first address whether the Morphology Limitation of claim 1 of the ’127 patent is met, or inherently anticipated.

There is no dispute that the ’069 patent does not explicitly teach the Morphology Limitation. *Decision* at \*11; Appellee’s Br. 15; Appellant’s Br. 1. Moderna argues that the Morphology Limitation is inherently anticipated because it is a “natural result” and “inherent property” of the variables identified and claimed in the ’127 patent such that one skilled in the art would necessarily produce the limitation after controlling the two factors of the invention: the lipid composition of the SNALP formulation and using the formation process of DDM to prepare it. ’127 Patent, col. 2 l. 64–col. 3 l. 10; Appellee’s Br. 3, 15. Arbutus argues that, even if one skilled in the art *could* have met the Morphology Limitation, the legal test requires that the embodiment(s) must *necessarily* yield the limitation. Appellant’s Br. 2–3. Additionally, while Arbutus does not dispute that the references were properly incorporated, it takes issue with the Board’s understanding of DDM as a particular process as opposed to a “broad genus” or a “generic category” of formation methods. Appellant’s Br. 3, 11, 40. Arbutus has not shown that the Board erred in finding the Morphology Limitation inherently met by the disclosures.

First, we look at the disclosures of the formulations. As Moderna explains, the ’127 and ’069 patents disclose the same formulations with “almost identical wording.” Appellee’s Br. 28. Both patents disclose identical lipid

compositions for the 1:57 and 1:62 formulations. *Decision* at \*19–20. For the other formulations (2:30, 2:40, 10:15), Arbutus’s expert explained that the parameters such as encapsulation efficiency, particle size, and polydispersity, can be substituted without impacting the Morphology Limitation. Appellee’s Br. 31. The specificity of the disclosure in the ’069 patent is the same as in the ’127 patent. *See King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1276 (Fed. Cir. 2010). Thus, substantial evidence supports the Board’s finding that the formulations “are the same or essentially the same” across the patents.

Second, we look at the disclosures of the processes. The inquiry involves assessing how the ’127 and ’069 patents refer to the process parameter, DDM. Contrary to Arbutus’s argument, this does not involve a disclosure of an anticipating genus of a process. Appellee’s Br. 24; Oral Arg. at 17:30–18:52, 19:39–20:03, [https://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-1183\\_11042022.mp3](https://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-1183_11042022.mp3) (Moderna’s counsel explaining how the ’127 patent defines DDM); *contra* Appellant’s Br. 23 (arguing that DDM is a genus method). The ’069 patent states that “[the] processes and the apparatuses for carrying out these direct dilution processes are described in detail in [the ’031 publication].” ’069 patent, col. 59 ll. 11–16. The ’127 patent explains that the non-lamellar morphology can be “readily determined using techniques known to and used by those of skill in the art.” ’127 patent, col. 9 ll. 29–31. The ’127 patent—although it provides details that are not included in the ’069 patent—continually references “the Direct Dilution Method” and incorporates the ’031 publication to provide details for carrying out this process. ’127 patent, col. 104 ll. 33–37 (“The Direct Dilution Method (DDM), . . . as well as the apparatuses for carrying out the DDM are described in detail in [the ’031 publication], the disclosure of which is herein incorporated by reference in its entirety for all purposes.”). The Board’s finding that the references

disclose and describe DDM the same way is thus supported by substantial evidence.<sup>2</sup> *Decision* at \*21.

Finally, the inherent anticipation analysis involves understanding whether, by making the formulations (1:57 or 1:62) by the DDM process, which are similarly disclosed in both the '127 and '069 patents with the disclosures of the incorporated references, would naturally result in a composition having the Morphology Limitation. The Board found that making the disclosed formulations according to the disclosed process would "naturally result in a composition having the claimed morphological property."<sup>3</sup> *Id.* at \*21.

We have explained that the "critical question" for inherent anticipation is "whether the [prior art] patent sufficiently describes and enables one or more embodiments—whatever the settings of their operational features—that necessarily include or result in the subject matter of [the] limitation. . . ." *See Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1321 (Fed. Cir. 2004). Here, because there is no error in the Board's determinations that the prior art teaches the

<sup>2</sup> Moderna argues that the prior art patent discloses the same SDM parameters as the '127 patent, which would also result in the Morphology Limitation. Appellee's Br. 12, 21, 51, 60 n.12. Because DDM used with at least two formulations renders the limitation inherent, we need not further address this method.

<sup>3</sup> The Board considered, but did not credit, the experimental evidence submitted by Arbutus because the Board found that the testing suffered from a myriad of problems that affected its reliability, including the involvement of Arbutus's counsel, the fact that the expert was an interested party, and the expert's apparent lack of experience in characterizing morphology. *Decision* at \*19. This was not error, because the Board's finding was supported by substantial evidence.

same formulations and the same DDM as the '127 patent, we see no error in the Board's conclusion that the '069 patent inherently anticipates the Morphology Limitation. To anticipate, the prior art need only meet the inherently disclosed limitation to the same extent as the patented invention. *King Pharms.*, 616 F.3d at 1276 (rejecting the argument that a prior art method did not "necessarily result" in a claimed limitation when the prior art described using the same method as the patent). The Board reasonably found that the '127 patent itself teaches making the formulations disclosed, such as the 1:62 formulation, with the DDM process described by the '031 publication, and would naturally result in a composition having the claimed morphological property. *Decision* at \*21 (citing '127 patent, col. 8 ll. 51–62, col. 104 ll. 32–37, col. 109 l. 11–col. 110 l. 21).

We are also not persuaded that this a case where there is only a probability that the Morphology Limitation would result from controlling several variations of formulations and processes. Appellant's Br. 24; *contra Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (citing *Hansgirg v. Kremmer*, 102 F.2d 212, 214 (C.C.P.A. 1939) ("The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.") (emphasis in original)). This is a case where there are a "limited number of tools"—five formulations and two processes—that a person skilled in the art would have to follow. *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1344 (Fed. Cir. 2016). The Board reasonably found that a person skilled in the art would follow these disclosures resulting in a composition with the inherent morphological property. The Board did not err in its determination that the Morphology Limitation of claim 1 is inherently anticipated by the '069 patent in that its determination is supported by substantial evidence. *Id.* at \*21–22.

## II

We next address whether dependent claims 3 and 8–12 of the '127 patent are anticipated. The Board found that Moderna demonstrated that each of the challenged dependent claims were anticipated by the '069 patent and its incorporated references.

Dependent claim 3 recites “[t]he composition of claim 1, wherein the nucleic acid is mRNA.” '127 patent, col. 149 ll. 40–41. The Board found that the '069 patent explicitly discloses that the nucleic acid can be mRNA. *See* '069 patent col. 10 ll. 16–26; *Decision* at \*22. Claim 8 recites “[t]he composition of claim 1, wherein the nucleic acid is fully encapsulated in the particles.” '127 patent, col. 149 ll. 60–61. The Board found that the prior art patent explicitly discloses that the nucleic acid may be fully encapsulated within the lipid portion of the particle. *Decision* at \*24 (citing '069 patent (claim 17)); *see also* '069 patent, col. 22 ll. 43–63. The Board’s finding of anticipation for dependent claims 3 and 8 is, therefore, supported by substantial evidence.

Claim 9 recites “[t]he composition of claim 1, wherein the non-lamellar morphology of the particles comprises an inverse hexagonal (HII) or cubic phase structure.” '127 patent, col. 149 ll. 62–64. As compared to independent claim 1, the additional limitation for dependent claim 9 is the inverse hexagonal structure. *Decision* at \*24. The Board found that the structures recited in claim 9 were inherent properties of the non-lamellar Morphology Limitation that is, in turn, inherently anticipated in claim 1. *Id.* While Moderna identified various three-dimensional structures for nucleic acid-lipid particles that were well-known in the art, the Board stated that Arbutus only offered “one conclusory comment” that anticipation was not met. *Id.* (citing PO Resp. 40). Based on the “trial record as a whole,” the Board found this property to be disclosed by the prior art '069 patent through incorporation of another reference—

the '613 patent. *Id.* We agree that dependent claim 9 is inherently anticipated by the references.

Finally, claims 10 through 12 recite percentage ranges for a lipid component of claim 1. *Id.* at \*52; '127 patent, col. 149 l. 64–col. 150 l. 34. Claim 10 recites “[t]he composition of claim 1, wherein the cationic lipid comprises from about 10 mol % to about 50 mol % of the total lipid present in the particle.” '127 patent, col. 149 ll. 64–67. Claim 11 recites “[t]he composition of claim 1, wherein the cationic lipid comprises from about 20 mol % to about 50 mol % of the total lipid present in the particle.” '127 patent, col. 150 ll. 29–31. Claim 12 recites “[t]he composition of claim 1, wherein the cationic lipid comprises from about 20 mol % to about 40 mol % of the total lipid present in the particle.” '127 patent, col. 150 ll. 32–34. Arbutus argues that using different references to arrive at the limitations of the claimed ranges is error because the Board did not evaluate the claims as a whole. Appellant’s Br. 54–55. We disagree.

When a patent claims a chemical composition in terms of ranges and a single prior art reference discloses a composition that falls within each of the ranges, the range is anticipated. *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985). This court has found that where a prior art reference’s range “entirely encompasses, and does not significantly deviate from” the claimed ranges, the range is anticipated. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005).

The Board reviewed Moderna’s citations to several disclosures in the prior art patent, through incorporation by reference, to find the disclosure of cationic lipid amounts: 25% in the '025 publication; 30% in the '031 publication; and, in the '025 publication, about 10% to about 45%, from about 20% to about 40%, or about 30% of the total lipid present in the particle. *Decision* at \*25. The 2:40 formulation of the prior art patent includes a 36.4 mol % cationic lipid. *Id.* at \*26. The '780 publication, incorporated by reference

into the prior art patent, discloses the lipid amount “from about 2% to about 60%.” ’780 Pub. ¶ 51. The Board then found that the prior art patent and its incorporated references disclose each of the claimed ranges. *Decision* at \*25–26. More specifically, the Board found that Moderna had demonstrated, “by a preponderance of the evidence[,]” that the 25% and 30% disclosures fall within the ranges of and anticipate claims 10 and 11, while the disclosures of the ’069 patent with the incorporated disclosures anticipate claim 12. *Id.* The Board also found that the ranges are described with sufficient specificity such that a reasonable fact finder could conclude that there is no reasonable difference in how the invention operates over the ranges. *Id.* at \*25 (citing *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869 (Fed. Cir. 2015)).

Substantial evidence supports the Board’s finding that the ’069 patent and its incorporated references describe nucleic acid-lipid particles and disclose these amounts as an inherent property of the formulations. *Id.* at \*25–26. Accordingly, we agree that dependent claims 10–12 are anticipated. Because Arbutus chose to incorporate several references into both the prior art patent and ’127 patent, that material became incorporated into the host document. Those disclosures, when reviewed as a whole, sufficiently disclose and describe claims 10–12, rendering each anticipated.

#### CONCLUSION

We hold that the Board’s finding that independent claim 1 and its morphological property are inherently anticipated by the disclosures of the ’069 patent and its incorporated references is supported by substantial evidence, and that the Board properly found dependent claims 3 and 8–12 anticipated. Thus, we affirm the Board’s final written decision concluding that claims 1, 3, and 8–12 of the ’127 patent are invalid as anticipated.

#### AFFIRMED

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COSTS

No costs.