United States Court of Appeals for the Federal Circuit

MODERNATX, INC., FKA MODERNA THERAPEUTICS, INC.,
Appellant

v.

ARBUTUS BIOPHARMA CORPORATION, FKA PROTIVA BIOTHERAPEUTICS, INC.,
Cross-Appellant

ANDREW HIRSHFELD, PERFORMING THE FUNCTIONS AND DUTIES OF THE UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2020-1184, 2020-1186

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2018-00739.

Decided: December 1, 2021

AMY K. WIGMORE, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, argued for appellant. Also

represented by MARK CHRISTOPHER FLEMING, EMILY R. WHELAN, Boston, MA.

DAVID I. BERL, Williams & Connolly LLP, Washington, DC, argued for cross-appellant. Also represented by THOMAS S. FLETCHER, JESSICA PALMER RYEN; SONJA ROCHELLE GERRARD, STEVEN WILLIAM PARMELEE, MICHAEL T. ROSATO, Wilson Sonsini Goodrich & Rosati, Seattle, WA; LORA MARIE GREEN, RICHARD TORCZON, Washington, DC.

ROBERT MCBRIDE, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for intervenor. Also represented by THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED.

Before LOURIE, O'MALLEY, and STOLL, *Circuit Judges*.

LOURIE, *Circuit Judge*.

ModernaTx, Inc. ("Moderna") appeals from the decision of the U.S. Patent and Trademark Office Patent Trial and Appeal Board ("Board") holding that claims 7–8, 10–11, 13, and 16–20 of U.S. Patent 9,364,435 are not unpatentable as obvious. *See Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, IPR2018-00739, 2019 Pat. App. LEXIS 13612 (Sept. 11, 2019) ("*Board Decision*"). Arbutus Biopharma Corporation ("Arbutus")[1] cross-appeals from the Board's decision holding that claims 1–6, 9, 12, and 14–15

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[1] At the time that this appeal was filed in November 2019, the cross-appellant was named Protiva Biotherapeutics, Inc. ("Protiva"). Subsequently, in June 2021, Protiva moved the court to revise the official caption to replace Protiva with Arbutus. In this opinion, unless otherwise indicated, we use "Protiva" and "Arbutus" interchangeably based on the relevant context to refer to the cross-appellant in this appeal.

are unpatentable as anticipated. *Id.* For the reasons provided below, we dismiss Moderna's appeal for lack of standing. Regarding Arbutus's cross appeal, we affirm.

BACKGROUND

I. The '435 Patent

Arbutus owns the '435 patent directed to "stable nucleic acid-lipid particles (SNALP) comprising a nucleic acid (such as one or more interfering RNA), methods of making the SNALP, and methods of delivering and/or administering the SNALP." '435 patent at Abstract. The patent, which issued on June 14, 2016, claims priority from a provisional application filed on April 15, 2008.

As described in the '435 patent, RNA interference ("RNAi") is a biological process in which recognition of double-stranded RNA "leads to posttranscriptional suppression of gene expression." *Id.* at col. 1 ll. 39–42. That biological process is mediated by small interfering RNA ("siRNA"), "which induces specific degradation of mRNA through complementary base pairing." *Id.* at col. 1 ll. 42–45. The '435 patent recognized that RNAi provided "a potential new approach to downregulate or silence the transcription and translation of a gene of interest." *Id.* at col. 1 ll. 52–54.

A "safe and effective nucleic acid delivery system is required for RNAi to be therapeutically useful." *Id.* at col. 1 ll. 63–64. The delivery system "should be small" and "should remain intact in the circulation for an extended period of time in order to achieve delivery to affected tissues." *Id.* at col. 2 ll. 38–42. This requires a "highly stable, serum-resistant nucleic acid-containing particle that does not interact with cells and other components of the vascular compartment." *Id.* at col. 2 ll. 42–45. The particle should also "readily interact with target cells at a disease site in order to facilitate intracellular delivery of a desired nucleic acid." *Id.* at col. 2 ll. 45–47. The '435 patent thus recognized that

there remained "a strong need in the art for novel and more efficient methods and compositions for introducing nucleic acids such as siRNA into cells." *Id.* at col. 2 l. 66–col. 3 l. 1.

The '435 patent describes the invention as "novel, serum-stable lipid particles comprising one or more active agents or therapeutic agents, methods of making the lipid particles, and methods of delivering and/or administering the lipid particles (e.g., for the treatment of a disease or disorder)." *Id.* at col. 3 ll. 9–13. The lipid particles are comprised of one or more cationic lipids, one or more non-cationic lipids, and one or more conjugated lipids. *See id.* at col. 3 ll. 22–31. As described in the patent, "[t]he present invention is based, in part, upon the surprising discovery that lipid particles comprising from about 50 mol % to about 85 mol % of a cationic lipid, from about 13 mol % to about 49.5 mol % of a non-cationic lipid, and from about 0.5 mol % to about 2 mol % of a lipid conjugate provide advantages when used for the in vitro or in vivo delivery of an active agent, such as a therapeutic nucleic acid (e.g., an interfering RNA)." *Id.* at col. 5 ll. 55–62. The '435 patent further states that the stable nucleic acid-lipid particles "advantageously impart increased activity of the encapsulated nucleic acid (e.g., an interfering RNA such as siRNA) and improved tolerability of the formulations in vivo, resulting in a significant increase in the therapeutic index" as compared to prior art nucleic acid-lipid particle compositions. *Id.* at col. 5 l. 62–col. 6 l. 2. And the particles are "stable in circulation, e.g., resistant to degradation by nucleases in serum, and are substantially non-toxic" to humans. *Id.* at col. 6 ll. 2–5

The '435 patent contains 20 claims. Claim 1, the only independent claim, recites:

> 1. A nucleic acid-lipid particle comprising:
>
> (a) a nucleic acid;

> (b) a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid present in the particle;
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> (c) a non-cationic lipid comprising from 13 mol % to 49.5 mol % of the total lipid present in the particle; and
>
> (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle.

Id. at col. 89 ll. 55–63. Many of the dependent claims contain additional limitations directed to one of the various components in the nucleic acid-lipid particle of claim 1. For example, claims 2 and 3 are directed to the nucleic acid component, claim 4 is directed to the cationic lipid component, claims 5–8 are directed to the non-cationic lipid component, and claims 9–12 are directed to the conjugated lipid component. *Id.* at col. 89 l. 64–col. 91 l. 21. The remaining dependent claims pertain to the encapsulation of the nucleic acid within the particle, *id.* at col. 91 ll. 22–24 (claim 13), pharmaceutical compositions comprising the particle, *id.* at col. 92 ll. 1–3 (claim 14), and methods for introducing a nucleic acid into a cell, in vivo delivery of a nucleic acid, and treatment using the particle, *id.* at col. 92 ll. 4–22 (claims 15–20).

II. *Inter Partes* Review of the '435 Patent

Moderna petitioned for *inter partes* review of the '435 patent. In its petition, Moderna asserted three grounds challenging all claims of the '435 patent. In the first ground, Moderna alleged that all claims of the '435 patent would have been obvious under 35 U.S.C. § 103 over a combination of International Pat. Publ. WO 2005/007196 ("the '196 PCT") and U.S. Pat. Publ. 2006/0134189 ("the '189 publication"). In the second ground, Moderna alleged that all claims of the '435 patent would have been obvious over

a combination of the '196 PCT, the '189 publication, Lin,[2] and Ahmad.[3] In the third ground, Moderna alleged that all claims of the '435 patent were anticipated by U.S. Pat. Publ. 2006/0240554 ("the '554 publication") under 35 U.S.C. § 102, and alternatively that the claims would have been obvious over the '554 publication.

Moderna's obviousness arguments with respect to all grounds centered on alleged overlapping ranges of components. For example, claim 1 of the '435 patent recites a composition range for the cationic lipid that is "from 50 mol % to 85 mol % of the total lipid present in the particle." *See* '435 patent at col. 89 ll. 57–58. In comparison, the '196 PCT and the '189 publication each disclose a range of between 2 mol % and 60 mol % for the cationic lipid. *See* '196 PCT ¶ 88; '189 publication ¶ 152. According to Moderna, the range for each lipid component in the claims—i.e., the cationic lipid, the non-cationic lipid, and the conjugated lipid—overlaps with the range for that lipid component taught by the prior art.

Moderna's anticipation argument was based on one formulation—the "L054 formulation"—disclosed in the '554 publication. Moderna argued that the L054 formulation contained all of the claimed components in amounts within the claimed ranges of the '435 patent. Specifically, Moderna contended that the L054 formulation contained 50 mol % cationic lipid (which is within the 50–85 mol % range of claim 1), 48 mol % non-cationic lipid (which is

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[2] Alison J. Lin, et al., Three-Dimensional Imaging of Lipid Gene-Carriers: Membrane Charge Density Controls Universal Transfection Behavior in Lamellar Cationic Liposome-DNA Complexes, 84 Biophysical J. 3307–16 (2003).

[3] Ayesha Ahmad, et al., New Multivalent Cationic Lipids Reveal Bell Curve for Transfection Efficiency Versus Membrane Charge Density: Lipid-DNA Complexes for Gene Delivery, 7 J. Gene Med. 739–48 (2005).

within the 13–49.5 mol % range of claim 1), and 2 mol % conjugated lipid (which is within the 0.5–2 mol % range of claim 1).

The Board found that Moderna proved by a preponderance of the evidence that claims 1–6, 9, 12, and 14–15 were anticipated by the L054 formulation in the '554 publication. However, the Board found that Moderna failed to prove that the remaining claims were anticipated, or that those claims would have been obvious over the prior art.

Moderna appealed from the Board's decision that it had failed to show that claims 7–8, 10–11, 13, and 16–20 were not anticipated and/or would not have been obvious. Protiva cross-appealed from the Board's decision that claims 1–6, 9, 12, and 14–15 were anticipated. Subject to the parties' dispute about Moderna's standing to pursue its appeal, which we discuss further below, we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4).

DISCUSSION

I. Moderna's Appeal

Before we consider Moderna's arguments on the merits of the Board's decision upholding claims of the '435 patent, we must first determine whether Moderna has standing to pursue its appeal. After all, "no principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341–42 (2006) (quoting *Raines v. Byrd*, 521 U.S. 811, 818 (1997)).

Since the America Invents Act took effect nearly a decade ago, we have had a number of occasions to consider the question of standing in appeals from Board decisions in

IPR proceedings.[4] Our precedent generally makes clear that, as in all appeals before this court, an appellant seeking review of a Board decision in an IPR must have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the [appellee], (3) that is likely to be redressed by a favorable judicial decision." *Phigenix*, 845 F.3d at 1171–72 (Fed. Cir. 2017) (quoting *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540, 1547 (2016)).

Under the IPR statute, there is no standing requirement for petitioners to request institution of IPR by the Board. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2143–44 (2016) ("Parties that initiate [IPRs] need not have a concrete stake in the outcome; indeed, they may lack constitutional standing."). And we recognize that where a statute grants judicial review, as the IPR statute does, *see* 35 U.S.C. § 319, the criteria of immediacy and redressability may be "relaxed." *See Momenta*, 915 F.3d at 768. But we have always maintained that a party's participation in the underlying IPR before the Board is insufficient by itself to confer standing on that party to appeal the Board's decision to this Article III court. *See Phigenix*, 845 F.3d at 1175; *see also Momenta*, 915 F.3d at 768 ("Although the statutory grant of judicial review may 'relax' the Article III criteria, judicial review of agency action remains subject to the constitutional foundation of injury-in-fact, lest the court occupy only an advisory role."); *JTEKT*, 898 F.3d at 1219 ("[T]he statute cannot be read to dispense with the

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[4] *See, e.g.*, *Apple Inc. v. Qualcomm Inc.*, 992 F.3d 1378 (Fed. Cir. 2021); *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363 (Fed. Cir. 2019); *Momenta Pharms., Inc. v. Bristol-Myers Squibb Co.*, 915 F.3d 764 (Fed. Cir. 2019); *JTEKT Corp. v. GKN Auto. Ltd.*, 898 F.3d 1217 (Fed. Cir. 2018); *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168 (Fed. Cir. 2017); *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258 (Fed. Cir. 2014).

Article III injury-in-fact requirement for appeal to this court."). Accordingly, even when an appellant is "sharply opposed to the Board's decision and the existence of [a] patent, that is not enough to make th[e] dispute justiciable." *Consumer Watchdog*, 753 F.3d at 1263.

As the party seeking judicial review, Moderna "has the burden of establishing that it possesses the requisite injury." *See JTEKT*, 898 F.3d at 1220. Moreover, Moderna must show that standing existed at the time it filed its appeal and has continued to exist at all times throughout the appeal. *See Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974) ("[A]n actual controversy must be extant at all stages of review, not merely at the time the complaint is filed."); *Momenta*, 915 F.3d at 770 ("[I]t is established that jurisdiction must exist throughout the judicial review, and an intervening abandonment of the controversy produces loss of jurisdiction.").

Shortly after Moderna filed this appeal in November 2019, Protiva moved to dismiss for lack of standing. Protiva argued that Moderna had never established that it suffered an injury in fact. *See Protiva Opening Standing Br.*[5] at 1. Protiva emphasized that it had never initiated a patent infringement action or directly accused Moderna of infringing its patents, and thus Moderna could only show standing to appeal the Board's decision if it were "currently using claimed features" of the '435 patent "or nonspeculatively planning to do so." *Id.* at 4 (citing *Fischer & Paykel Healthcare Ltd. v. ResMed Ltd.*, No. 2018-2262 (Fed. Cir. Nov. 27, 2019) (Order, non-precedential)). Indeed, Protiva argued, Moderna had consistently taken the position that it was not using Protiva's patented technology and did not intend to do so. *Id.* at 5.

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[5] Dkt. 22.

In opposing Protiva's motion to dismiss, Moderna expressly stated in January 2020 that it did "not base its Article III standing on the threat of an impending infringement suit or Protiva's accusations of infringement." *Moderna Resp. Standing Br.*[6] at 3. Rather, Moderna argued, its standing was based on its status as a "current licensee to the '435 patent for four viral targets . . . with actual monetary obligations . . . that are impacted by the Board's validity determinations." *Id.* at 3–4. Moderna relied on our case law for the proposition that "[t]he risk of a future infringement suit is not the only way an IPR petitioner can show injury-in-fact." *Id.* at 4 (citing *Gen. Elec. Co. v. United Techs. Corp.*, 928 F.3d 1349, 1357 (Fed. Cir. 2019)). Moderna repeatedly cited our decision in *Samsung Electronics Co. v. Infobridge Pte. Ltd.*, to support its position that financial impacts to an appellant based on licensing obligations can be an independent means by which to establish an injury-in-fact supporting standing. *See Moderna Resp. Standing Br.* at 4, 8–9 (citing *Samsung*, 929 F.3d at 1368).

In support of its responsive brief in opposition to Protiva's motion to dismiss, Moderna submitted a declaration from Shaun Ryan, who was its Senior Vice President and Deputy General Counsel.[7] In his declaration, Mr. Ryan described information relating to Moderna's status as a

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[6] The non-confidential version of Moderna's responsive brief is Dkt. 28. Moderna filed the confidential version of its brief as Dkt. 30.

[7] For confidentiality purposes, Moderna filed Mr. Ryan's declaration under seal with the confidential version of its responsive brief in Dkt. 30. In this opinion, to the extent we reference information from that confidential declaration, we reference only material that Moderna has subsequently made public through its briefing and oral argument in this appeal.

sublicensee of the '435 patent. Specifically, Mr. Ryan attested that Protiva had licensed the '435 patent among other patents to a company called Acuitas Biotherapeutics ("Acuitas"), and that Acuitas had, in turn, granted a series of sublicenses to Moderna to practice the patented technology for four viral targets, one of which was Respiratory Syncytial Virus ("RSV"). Mr. Ryan further stated that, under its rights from the Acuitas sublicenses, Moderna was engaged in an active development program for the RSV viral target. According to Mr. Ryan, Moderna had already made one milestone payment to Acuitas, and potentially could have additional milestone and royalty obligations in the future. Thus, Moderna argued, the royalty and milestone obligations owed to Acuitas for the use of the '435 patent caused harm to Moderna by increasing the financial burdens on Moderna's RSV development program.

We denied Protiva's motion, but we specifically noted that our denial was without prejudice to allow Protiva to raise its standing argument in its merits brief. *See* Dkt. 35. Shortly thereafter, Moderna filed its opening brief on the merits, relying in its jurisdictional statement mainly on the same arguments and evidence it had presented in opposing Protiva's motion to dismiss. *Moderna Opening Br.* at 6–9. Protiva then filed its responsive brief, including its response to Moderna's assertions of standing. *Protiva Resp. Br.* at 5–9. Protiva argued that the mere existence of a license is not sufficient to support Article III standing, and that Moderna's alleged "obligations" were "nothing but rank speculation, which even Moderna characterizes as an if and when proposition." *Id.* at 5. Protiva noted that the last milestone payment Moderna had made to Acuitas was on or before February 2016, and emphasized that Moderna "fail[ed] to identify any recent milestone payment or any such payment reasonably forthcoming." *Id.* at 7.

In March 2021, approximately nine months after Moderna had filed its opening brief on the merits, Moderna filed a motion to supplement the record to provide

additional evidence of standing. In that motion, Moderna argued that "new facts supporting Moderna's ongoing standing to appeal have arisen, and the existing facts have continued to develop." *Moderna Mot. to Suppl.*[8] at 3.

The "existing facts" to which Moderna referred were those that Mr. Ryan had described in his original declaration more than a year earlier. With its motion to supplement, Moderna submitted a supplemental declaration from Mr. Ryan,[9] in which he stated that Moderna had, at some point during the previous year, terminated the RSV development program that had been active at the time that the appeal was filed. He also admitted that none of the four viral targets that were covered under the Acuitas sublicenses were being pursued to further phases, though he noted that they had not been fully abandoned. Importantly, Mr. Ryan did not provide an approximate date on which that RSV development program had been terminated, nor did he describe any concrete plans to further pursue development programs for any of the four viral targets.

The "new facts" to which Moderna referred related to Moderna's ongoing development of a vaccine for COVID-19. Mr. Ryan's supplemental declaration described Moderna's

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[8] The non-confidential version of Moderna's motion is Dkt. 111. Moderna filed the confidential version of its brief as Dkt. 112.

[9] Like his original declaration, Mr. Ryan's supplemental declaration also purports to contain confidential information. Again, we reference only material from the supplemental declaration that Moderna has made public. Moreover, attached to Mr. Ryan's supplemental declaration in this appeal was a supplemental declaration that he submitted on the same day in Appeal No. 20-2329. For purposes of this opinion, we treat these two supplemental declarations as one.

work that led to its concrete plans as of September 2020 to release a COVID-19 vaccine, its emergency use authorization as of December 2020, and its subsequent commercial shipments of the vaccine. Mr. Ryan also described a series of public statements made by Arbutus in 2017 regarding the alleged extensive scope of its patents. According to Mr. Ryan, those aggressive public statements by Arbutus, in combination with Arbutus's refusal to grant Moderna a covenant not to sue and Arbutus's consistent insistence that Moderna requires a license to Arbutus's patents, created a significant risk that Arbutus would sue for patent infringement.

During oral argument, counsel for Moderna explained its position that "Moderna had and continues to have standing to pursue this appeal." Oral Arg. at 1:32, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-1184_10072021.mp3. Moderna's counsel began by arguing that the basis for Moderna's standing "at the outset when this appeal was filed in November of 2019," *id.* at 1:38, was "contractual rights that are affected by a determination of patent validity," *id.* at 2:27. Counsel repeatedly emphasized the "active" status of Moderna's RSV development program at that time, which had resulted in one milestone payment and potentially could have resulted in future milestone and royalty obligations. But Moderna's counsel then argued that "the situation has evolved," *id.* at 6:53, and the "evolution keeps this controversy alive," *id.* at 8:24. Specifically, counsel conceded that "over time, . . . that particular RSV program was not pursued," *id.* at 8:36, but "at the same time, the COVID vaccine was developed and ultimately [] delivered to the market and commercialized," *id.* at 8:53.

Arbutus's counsel responded by challenging each aspect of Moderna's standing timeline, as well as the timeline as a whole. Counsel began by arguing, regarding Moderna's position on standing at the time the appeal was filed, that "any notion of immediacy is entirely absent"

from the evidence that Moderna presented on its "speculative" licensing obligations. *Id.* at 16:50. Arbutus's counsel also insisted that it was crucial that the '435 patent was only one of many patents licensed under the Acuitas sublicenses, and that Moderna had not shown how its payment obligations would change if the '435 patent were to be invalidated. Next, Arbutus's counsel turned to Moderna's concession that the RSV development program had at some point been abandoned, focusing on the lack of evidence regarding "when that happened versus when their COVID vaccine came into being and recreated" standing. *Id.* at 23:33.

We agree with Arbutus that Moderna lacked standing at the time the appeal was filed. Even if the '435 patent was the only patent that Moderna had licensed under the Acuitas sublicenses, Moderna's evidence of financial burdens from the validity of that patent is too speculative. Notwithstanding Moderna's counsel's repeated characterization of the RSV development program as "active" at the time this appeal was filed, Moderna concedes that the last milestone payment it made under the Acuitas sublicenses was approximately five years earlier, and Mr. Ryan's declaration states only that Moderna would have to make an additional milestone payment "if and when" a future milestone is reached. On this evidence, Moderna falls short of its burden to demonstrate that at the time it filed this appeal, it had suffered or was suffering a "concrete" injury from the existence of the '435 patent. *See Phigenix*, 845 F.3d at 1171 ("To constitute a 'concrete' injury, the harm must 'actually exist' or appear 'imminent'—a 'conjectural or hypothetical' injury will not suffice." (internal citations omitted)).

Even more problematic for Moderna, the '435 patent is not the only patent licensed under the Acuitas sublicenses, but rather it is one of many licensed patents. On this point, the parties appear to agree that the two crucial cases are *Samsung* and *Apple*. In *Samsung*, we held that the

appellant had standing because, even though multiple patents were licensed, the appellant had provided evidence demonstrating that the express terms of the contract structured the patent pool in such a way that invalidation of the patent at issue in the underlying IPR would have changed the amount of royalties. *Samsung*, 929 F.3d at 1368. In contrast, in *Apple* we held that the appellant lacked standing because multiple patents had been licensed, and the appellant failed to present evidence that invalidation of the particular patents it was challenging would affect its contractual rights by changing its royalty obligations. *Apple*, 992 F.3d at 1383.

The facts here resemble those in *Apple*, not those in *Samsung*. Moderna has provided no evidence as to how, if at all, its obligations under the Acuitas sublicenses would change if it is successful in its attempts to have the '435 patent declared invalid while the remaining licensed patents continue to exist. Thus, Moderna has failed to meet its burden of demonstrating that it suffers an injury from the existence of the '435 patent, or that any such injury would be redressed by invalidation of that patent. *See id.* at 1383–84. Accordingly, we agree with Arbutus that Moderna lacked standing at the time this appeal was filed.

We also agree with Arbutus that, even if Moderna had standing at the time it filed this appeal, Moderna has failed to demonstrate that it continuously had standing throughout the pendency of the appeal. Under our precedent, an "intervening abandonment of the controversy produces loss of jurisdiction." *Momenta*, 915 F.3d at 770. Moderna's evidence fails to show an approximate date when the RSV development program was terminated. Thus, on the record before us, it is impossible to determine whether, by the time the RSV development program was terminated, Moderna was already sufficiently underway with its development of a COVID-19 vaccine to "create[] a substantial risk of future infringement or likely cause the patentee to assert a claim of infringement." *E.I. DuPont de Nemours*

& Co. v. Synvina C.V., 904 F.3d 996, 1004–05 (Fed. Cir. 2018).

As the appellant, Moderna bears the burden on the issue of standing, *JTEKT*, 898 F.3d at 1220, including the burden to demonstrate that there has been no gap in its standing while this appeal has been pending, *Momenta*, 915 F.3d at 770. In view of Moderna's concession that the basis for its standing shifted during the pendency of this appeal—*i.e.*, from the financial burdens of the Acuitas sublicenses to a potential infringement suit for the COVID-19 vaccine—Moderna had to come forth with evidence to demonstrate the necessary continuity of jurisdiction. Moderna failed to do so.

For the reasons explained above, we find that Moderna has failed to meet its burden on its standing to pursue this appeal. Therefore, Moderna's appeal must be dismissed.

II. Arbutus's Cross-Appeal

With respect to the cross appeal, there is no dispute that Arbutus, as the patent owner, has standing to appeal the Board's decision that claims 1–6, 9, 12, and 14–15 are unpatentable. Thus, we proceed to the merits.

Arbutus argues that the Board erred by failing to recognize a critical distinction between starting ingredients versus a final product. Arbutus contends that the claims of the '435 patent are directed to completed lipid particles of defined composition. In contrast, Arbutus argues, the L054 formulation disclosed in the '554 publication is a lipid mixture of starting ingredients for making lipid particles, not a completed lipid particle itself. According to Arbutus, expert testimony and corroborating literature demonstrated that a person of ordinary skill in the art would have expected the composition of components in a final lipid particle to deviate from the composition of components in the mixture of starting ingredients. Arbutus further argues that its expert provided evidence that the '554 publication's

fabrication process would skew the L054 formulation's final lipid particle such that the final composition would fall outside the range of the '435 patent claims.

Moderna responds that substantial evidence supports the Board's factual findings regarding the disclosures of the '554 publication. Moderna notes that the Board specifically considered Arbutus's argument that the L054 formulation failed to teach the composition of the final lipid particle, but the Board rejected that argument. Moderna argues that after weighing the evidence, the Board found that it was standard practice in the field to describe lipid particles by the composition of components in the input formulation. The Board further relied on the disclosures of the prior art and the '435 patent itself, as well as the testimony of expert witnesses.

We review the Board's legal determinations de novo, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), but we review the Board's factual findings underlying those determinations for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

"Anticipation is a question of fact that we review for substantial evidence." *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016) (citing *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015)). A prior art reference anticipates a claim if it discloses "each and every element of the claimed invention . . . arranged or combined in the same way as in the claim." *Id.* (quoting *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009)).

We agree with Moderna that substantial evidence supports the Board's decision. Arbutus's arguments pertain to whether a person of ordinary skill in the art would have reasonably understood from the disclosure in a prior art

reference that every element of the claims is disclosed, which is the "dispositive question regarding anticipation." *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1055 (Fed. Cir. 2010). In evaluating that question, the Board first considered the substantial evidence that Moderna presented that a person of ordinary skill would understand that the mol % of each component in the L054 formulation would result in lipid particles within the claimed ranges of the '435 patent, which also describes lipid particles in terms of mol % of the formulation. *Board Decision*, 2019 Pat. App. LEXIS 13612, at *23. Thus, the Board turned to Arbutus's evidence and found that it, at best, suggested that there would be some variation in the final compositions of the lipid particles fabricated from the L054 formulation. *See id.* at *23–24. But the Board rejected as speculative Arbutus's expert's opinion that all of the particles formed from L054 formulation would fall outside the claimed ranges. *Id.* at *24–27. And the Board noted that anticipation "does not require that all of the formed particles from the L054 formulation . . . be within the claimed ranges . . . . Anticipation merely requires that a composition within the claimed ranges be disclosed." *Id.* at *28 (citing *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985)).

The Board's legal conclusions regarding the requirements of anticipation were correct. "When a patent claims a range, as in this case, that range is anticipated by a prior art reference if the reference discloses a point within the range." *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869 (Fed. Cir. 2015) (citing *Titanium Metals*, 778 F.2d at 782). Furthermore, an anticipating reference need not show that every disclosed compound anticipates; rather it is sufficient that it contains a disclosure of "at least one compound which anticipates." *See In re Sasse*, 629 F.2d 675, 682 (Fed. Cir. 1980). Thus, to anticipate the claims of the '435 patent, the question for the Board was whether the

'554 publication discloses at least one composition that falls within the claimed ranges.

The Board weighed the evidence and found, as a factual matter, that the '554 publication disclosed at least one composition that anticipates the claims. In challenging that factual determination in this appeal, Arbutus relies on the same evidence and argument that failed to convince the Board that the L054 formulation does not anticipate the completed lipid particles of the '435 patent claims. But Arbutus fails to persuade us that Moderna's evidence was insufficient to allow the Board to find that the L054 formulation does anticipate. Substantial evidence supports the Board's decision.

CONCLUSION

We have considered the parties' remaining arguments but we find them unpersuasive. Accordingly, we dismiss Moderna's appeal for lack of standing. We affirm the Board's final written decision that claims 1–6, 9, 12, and 14–15 are unpatentable as anticipated.

DISMISSED-IN-PART, AFFIRMED-IN-PART

COSTS

No costs.