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Pair of Federal Circuit Decisions Address Standing to Appeal Adverse IPR Decision

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In 2018 and 2019, ModernaTx, Inc. (Moderna) filed a pair of *inter partes* review petitions challenging the validity of two patents generally directed to RNA technology owned by Arbutus Biopharma Corp. (Arbutus). The Patent Trial and Appeal Board ("PTAB") held that certain challenged claims of each patent were not unpatentable. On Dec. 1, 2021, a Federal Circuit panel of Judges Lourie, O'Malley, and Stoll issued two opinions, each authored by Judge Lourie and captioned *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, Nos. 2020-1184, -1186 (Fed. Cir. Dec. 1, 2021) (*Moderna I*) and No. 2020-2329 (*Moderna II*), holding that Moderna had standing to appeal only one of the two adverse decisions by the PTAB and otherwise affirming the PTAB's findings on appeal and cross-appeal.

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Factual Background

The cases concern two related patents — U.S. Patent Nos. 8,058,069 (the '069 patent) and 9,364,435 (the '435 patent) — that are each entitled "lipid formulations for nucleic acid delivery" and are generally 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." '069 patent, Abstract.

Moderna, which is a licensee of both patents, filed *inter partes* review petitions challenging the validity of all claims of each patent. The PTAB rejected all of Moderna's challenges to the '069 patent. *See, Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, No. IPR2019-00554, 2020 WL 4237232 (PTAB July 23, 2020). As to the '435 patent, the PTAB held that claims 1-6, 9, 12, and 14-15 were obvious, but rejected Moderna's challenges to claims 7, 8, 10, 11, 13, and 16-20. Moderna appealed both decisions, and Arbutus's predecessor-in-interest cross-appealed as to the '435 patent.

Legal Standard for Standing to Appeal Adverse IPR Decision

Before turning to the merits of each appeal, the panel first addressed whether Moderna had standing to pursue an appeal of the PTAB's decisions. There is no standing requirement for a petitioner to request institution of an IPR. *Moderna I*, slip op. at 8. However, consistent with the Supreme Court's decision in *Spokeo*, in order for an IPR petitioner to have standing to appeal, it 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." *Id.* (alteration in original) (quoting *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540 (2016)).

Because the IPR statute "grants judicial review" of an adverse decision, the criteria of immediacy and redressability are somewhat "relaxed." *Id.* (quoting *Momenta Pharms., Inc. v. Bristol-Myers Squibb Co.*, 915 F.3d 764, 768 (Fed. Cir. 2019)). However, the statute "cannot be read to dispense with the Article III injury-in-fact requirement for appeal to this court," and Moderna bore the burden of establishing that it possesses the

requisite injury-in-fact. *Id.* at 8-9 (quoting *JTEKT Corp. v. GKN Auto. LTD.*, 898 F.3d 1217, 1219-20 (Fed. Cir. 2018)). The appellant must show that "standing existed at the time it filed its appeal and has continued to exist at all times throughout the appeal." *Id.* at 9 (citing *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974)).

Standing Analysis In *Moderna I*: No Standing To Appeal

Moderna conceded that, as a current licensee of the '435 patent for four viral targets, its Article III standing at the time the appeal was filed was not based on a threat of an impending infringement lawsuit. Instead, as a licensee, it had "actual monetary obligations" that are "impacted by the Board's validity determinations." *Id.* at 10. Moderna analogized its case to *Samsung Electronics Co. v. Infobridge Pte. Ltd*, 929 F.3d 1363 (Fed. Cir. 2019), in which Samsung was found to have had standing to appeal an adverse PTAB decision based on its contributions to a pool of standard-essential patents that divided the royalty to the owners of the patents based on the total number of patents in the pool. *Id.* at 1368. Because Samsung had a direct financial interest in the validity of the other patents in the pool, it had an injury-in-fact sufficient for standing. *Id.*

In response to a motion to dismiss the appeal, Moderna submitted a declaration explaining that it was a sublicensee of the '435 patent, that it had already made one milestone payment under that license, and that it could have future milestone payments or royalty obligations based on its development of viral targets for one particular virus, Respiratory Syncytial Virus (RSV). *Moderna I*, slip op. at 11. The motion was denied without prejudice. In the merits briefs, in response to the argument that Moderna's last milestone payment connected to RSV was in 2016, Moderna submitted a supplemental declaration explaining that, although the RSV development program had been active when the appeal was filed, it had since been terminated and that none of the four viral targets covered by the sublicense was in active development. *Id.* at 12. However, Moderna argued that its ongoing work in its COVID-19 vaccine program, along with a series of public statements by Arbutus regarding the scope of its patents and "aggressive public statements" by Arbutus created a significant risk of future litigation. *Id.* at 13.

The panel found that Moderna "lacked standing at the time the appeal was filed." *Id.* Moderna's financial burden from the validity of the patent was "too speculative," particularly given that the last royalty payment was five years prior. *Id.* On these facts, Moderna failed to meet its burden of showing a "concrete" injury from the existence of the '435 patent.

Further complicating Moderna's standing was that the '435 patent is one of many patents sublicensed to Moderna under a single agreement. The panel distinguished these facts from *Samsung*, in which "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." *Id.* at 15 (citing *Samsung*, 929 F.3d at 1368). Instead, the instant facts more closely resembled *Apple Inc. v. Qualcomm Inc.*, 992 F.3d 1378 (Fed. Cir. 2021), in which Apple had entered into a global settlement with Qualcomm, and had presented no evidence that "invalidation of the particular patents it was challenging would affect its contractual rights by changing its royalty obligations." *Moderna I*, slip op. at 15 (citing *Apple*, 992 F.3d at 1383).

Finally, even if Moderna had standing at the time it filed the appeal, the panel agreed with Arbutus that Moderna's abandonment of its RSV program resulted in a "loss of jurisdiction." *Id.* (quoting *Momenta*, 915 F.3d at 770). Based on the record, "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.'" *Id.* (quoting *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1004-05 (Fed. Cir. 2018)). Since Moderna's theory of standing "shifted during the pendency of this appeal," it was Moderna's burden to prove the necessary "continuity of jurisdiction." *Id.* at 16. Because it failed to do so, Moderna's appeal was dismissed.

Standing Analysis In *Moderna II*: Standing To Appeal

Like in *Moderna I*, Moderna argued that its current status as a licensee of the '069 patent with monetary obligations gave rise to an injury affected by the validity of the patent. However, citing *Moderna I*, the panel rejected that argument in a footnote. *Moderna II*, slip op. at 10 n.4.

Instead, the panel found that Moderna had standing because there was a "substantial risk that Arbutus will assert the '069 patent in an infringement suit targeting Moderna's COVID-19 vaccine." *Id.* at 10. Importantly, while the notice of appeal in *Moderna I* was filed in late November 2019, the appeal in *Moderna II* was docketed in September 2020, during the COVID-19 pandemic. In a declaration, Moderna detailed 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." *Id.*

On these facts, Arbutus's public statements regarding the scope of its patent coverage and an attestation from Moderna that Arbutus has taken the position that Moderna requires a license to Arbutus's patents, including the '069 patent, was sufficient to confer an injury-in-fact. *Id.* at 10-11. The panel explained that an appellant need only show that "it has engaged in, is engaging in, or will likely engage in 'activity that would give ruse to a possible infringement suit.'" *Id.* at 11. The court therefore concluded that "Moderna has demonstrated enough of a risk that it will be faced with an infringement suit based on the combination of its own activities in developing the COVID-19 vaccine, Arbutus's broad public statements about its extensive patent coverage in this area, and Abutus's refusal to grant a covenant not to sue." *Id.*

Finally, the panel noted that "if we were to dismiss this appeal for lack of standing, Arbutus could sue Moderna for infringement immediately thereafter," and "Arbutus has done nothing to dispel" that possibility. *Id.* The panel sought to "avoid such a result," which would incentivize a patent owner to "remain silent regarding its intentions during the pendency of an appeal and wait to sue for infringement until after the appeal has been dismissed for lack of standing." *Id.* at 11-12. The panel did not attempt to reconcile this conviction with the result in *Moderna I*.

The Merits: PTAB Affirmed

In both *Moderna I* and *Moderna II*, the panel affirmed the PTAB's decision on the merits. In *Moderna I*, Arbutus cross-appealed the PTAB's finding that certain claims of the '435 patent were anticipated by published U.S. Patent Application No. 2006/0240554 (the '554 publication). The panel found that substantial evidence supported the PTAB's decision, including that the '554 publication discloses at least one composition that falls within the ranges recited by the '435 patent. *Moderna I*, slip op. at 16-19. The panel therefore affirmed the PTAB's final written decision finding certain of the challenged claims of the '435 patent unpatentable. *Id.*

Finally, in *Moderna II*, the panel rejected Moderna's arguments that the PTAB erred in finding the challenged claims of the '069 patent to be nonobvious. First, Moderna argued that the PTAB erred by failing to apply the presumption of obviousness based on overlapping ranges in the prior art. *Moderna II*, slip op. at 13. However, the court held that Moderna had failed to make a "threshold showing" that the two references "teach or suggest a range from the … component that overlaps with the claimed range." *Id.* at 14. The panel also found that substantial evidence supported the PTAB's rejection of Moderna's arguments concerning the "motivation to optimize result-effective variables in the prior art." *Id.* at 17-19. And, even if the recited ranges in the claim were result-effective variables, the panel found that Moderna had failed to make a showing that the claimed ranges were achievable through routine optimization. *Id.* at 18-19. Therefore, the court affirmed the PTAB's decision.

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