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Should the Federal Circuit Stand Down on Standing?

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NOTE

Should the Federal Circuit Stand Down on Standing?

ModernaTx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352 (Fed. Cir. 2021).

Avery J. Welker[*]

I. INTRODUCTION

On March 11, 2020, the World Health Organization officially declared COVID-19 a pandemic, just ninety days after patients in Wuhan, China, began experiencing an unknown pneumonia-like illness.[1] States rapidly responded, beginning shutdowns just a few days later.[2] Amidst the early shutdown chaos, Moderna began human trials on its new COVID-19 vaccine.[3] Moderna's road to vaccine development was not without bumps, however, as the company launched a patent validity attack on another company's technology it used while developing its vaccine. The dispute made its way to the Court of Appeals for the Federal Circuit, where the question focused on whether Moderna could even contest the results of an *Inter Partes* Review ("IPR"), which could have invalidated the patent and given Moderna license to use the technology, in the first place—i.e., did Moderna have standing?

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[1] *COVID-19 Timeline*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/museum/timeline/covid19.html [https://perma.cc/65XW-MDLG] (last visited Dec. 19, 2022).

[2] *Id.*

[3] *Id.*

The doctrine of standing is a fundamental building block of United States jurisprudence,[4] acting as a gatekeeper to federal court jurisdiction.[5] In *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, the Federal Circuit dismissed the appellant's appeal for lack of standing.[6] The Federal Circuit determined that the appellant failed to establish an injury-in-fact when it appealed merely the results of an IPR.[7] The IPR invalidated specific patent claims and validated the remaining ones.[8] The cross-appellant appealed the invalidated claims,[9] but the Federal Circuit held that the claims were invalid because another source had previously disclosed them before the patent was issued.[10] The decision followed previous Federal Circuit standing jurisprudence, showing the Federal Circuit's commitment to requiring a concrete injury-in-fact to present a case or controversy.[11]

This Note analyzes the Federal Circuit's approach to the doctrine of standing arising from appeals from the Patent Trial and Appeal Board ("PTAB") in the United States Patent and Trademark Office. Part II describes the facts and holding of *ModernaTX*. Part III details the doctrines of standing and patent nonobviousness and novelty requirements. In addition, Part III describes previous Federal Circuit jurisprudence on appealing PTAB decisions. Part IV explains the Federal Circuit's decision in *ModernaTX*. Lastly, Part V comments on how the Federal Circuit's decision, while in harmony with its precedent, is in tension with and diverges from the congressional intent of the America Invents Act.

II. FACTS AND HOLDING

Arbutus Biopharma Corporation is the owner of U.S. Patent No. 9,364,435 (the "'435 patent"), titled "Lipid Formulations for Nucleic Acid Delivery."[12] The '435 patent aims to address the process of RNA

[4] "[S]etting apart the "Cases" and "Controversies" that are of the justiciable sort referred to in Article III . . . is the doctrine of standing." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992).

[5] Standing is examined in Part III, Section A, *infra*.

[6] ModernaTx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352, 1355 (Fed. Cir. 2021).

[7] *Id.* at 1361. *Inter Partes* Reviews are described in Part III, Section B, *infra*.

[8] *ModernaTx*, 18 F.4th at 1357.

[9] *Id.*

[10] *Id.* at 1364.

[11] *See id.* at 1357–58.

[12] *Id.* at 1355; Lipid Formulations for Nucleic Acid Delivery, U.S. Patent No. 9,364,435 (filed Aug. 18, 2014) (issued June 14, 2016). Cross-Appellant Arbutus Biopharma Corporation was known as Protiva Biotherapeutics, Inc. at the time of filing this appeal. *ModernaTx*, 18 F.4th at 1355 n.1. While the Federal Circuit uses the two names of the cross-appellant depending on the "relevant context in th[e]

interference ("RNAi").[13] RNAi involves identifying double-stranded RNA and using small interfering RNA ("siRNA") to posttranscriptionally suppress gene expression.[14] The interfering RNA is single or double-stranded RNA that can silence a gene by inhibiting mRNA translation when that mRNA is "complementary to the interfering RNA sequence."[15] The siRNA "induces specific degradation of mRNA through complementary base pairing" to suppress gene expression.[16]

To be effective, interfering RNA must be successfully delivered to a therapeutic target.[17] The '435 patent is directed to facilitating the effective delivery of interfering RNA, which employs stable nucleic acid-lipid particles ("SNALP") containing "therapeutic agents" and the methods used to make and deliver the SNALP.[18] A SNALP is a lipid mixture made of: (1) cationic lipid(s), comprising about 50–85 mol % of the total lipid content; (2) non-cationic lipid(s), comprising about 13–49.5 mol % of the total lipid content; (3) a therapeutic agent, which may be a nucleic acid, such as the interfering RNA molecule (e.g., siRNA); and (4) conjugated lipid(s) "that inhibit aggregation of particles" and comprise about 0.5–2 mol % of the total lipid content.[19] The therapeutic agent is delivered to a cell by contacting the cell with the SNALP.[20]

The '435 patent claims the SNALP composition in its sole independent claim.[21] Over half of the dependent claims add limitations to

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appeal," this Note uses only Arbutus Biopharma Corporation for the sake of simplicity. *Id.* The cross-appellant, Arbutus Biopharma Corporation, is referred to as "Arbutus" throughout this note. A patent, as used here, refers to a utility patent, which protects inventions that are categorized as: (1) a process; (2) a machine; (3) a manufacture; or (4) a composition of matter, or an improvement to an invention in one of those categories. 35 U.S.C. § 101.

[13] Lipid Formulations for Nucleic Acid Delivery, U.S. Patent No. 9,364,435 at col. 1, ll. 39–42 (filed Aug. 18, 2014) (issued June 14, 2016). Though a newer technology, using RNAi to silence gene expression has many potential functions, such as treating liver diseases or atherosclerosis. *Id.* at col. 1, ll. 52–62.

[14] *Id.* at col. 1, ll. 40–45.

[15] *Id.* at col. 6, ll. 49–57.

[16] *Id.* at col. 1, ll. 43–45.

[17] *Id.* at col. 1, ll. 63–64.

[18] *Id.* at Abstract.

[19] *Id.* at col. 3, ll. 22–40.

[20] *Id.* at col. 4, ll. 1–19. A mole is an SI unit expressing amount of substance, which could be atoms, molecules, or other particles. *Mole*, IUPAC GOLD BOOK, https://goldbook.iupac.org/terms/view/M03980 [https://perma.cc/JRT7-GFEQ] (last visited Jan. 5, 2023). A mole percent is the amount of molecules of a mixture's component divided by the total of the molecules in a mixture, expressed as a percentage. *Mole Fraction & Mole Percent*, LUMEN INTRODUCTION TO CHEMISTRY, https://courses.lumenlearning.com/introchem/chapter/mole-fraction-and-mole-percent/ [https://perma.cc/M32K-4XQ8] (last visited Jan. 5, 2023).

[21] ModernaTx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352, 1356 (Fed. Cir. 2021). Patent claims define the legally protected scope of an invention. Phillips v.

the SNALP composition in the independent claim.[22] The other dependent claims address the agent in the SNALP, the pharmaceutical composition of the SNALP, treatments employed using the SNALP, and delivery of the therapeutic agent.[23]

ModernaTx, Inc. ("Moderna") challenged all claims of the '435 patent in an *Inter Partes* Review proceeding.[24] Moderna asserted three grounds under 35 U.S.C. §§ 102 (anticipation) and 103 (obviousness), which purported to invalidate all independent and dependent claims of the '435 patent.[25] First, Moderna argued that the '435 patent's claims would be obvious over International Patent Publication WO 2005/007196 (the "'196 PCT") and U.S. Patent Publication 2006/0134189 (the "'189 publication").[26] Second, Moderna contended that the '435 patent's claims would be obvious over the combination of the '196 PCT, the '189 publication, and two articles, the Lin and Ahmad articles.[27] Finally, it argued that the claims in the '435 patent were anticipated by U.S. Patent Publication 2006/0240554 (the "'554 publication") or that the claims would be obvious under the '554 publication.[28]

In each of its various obviousness arguments, Moderna focused on the SNALP composition—claiming that some of the composition ranges claimed in the '435 patent overlapped with the ranges disclosed by the prior art.[29] In its anticipation claim, Moderna claimed that the "L054 formulation" found in the '554 publication contained all claimed components in its claimed ranges in the '435 patent.[30] The PTAB agreed with Moderna that claims 1–6, 9, 12, and 14–15 were previously disclosed and anticipated in the '554 publication.[31] However, the PTAB did not cancel the rest of the claims, noting that Moderna did not prove anticipation or obviousness on the remaining claims.[32]

Moderna appealed the PTAB's decision to not cancel some of the '435 patent claims, contending that the claims were either anticipated or

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AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

[22] *ModernaTx*, 18 F.4th at 1356.

[23] *Id.*

[24] *Id.* at 1356–57. ModernaTx, Inc. is referred to as Moderna throughout this Note. *Inter Partes* Reviews are discussed in Part III, Section B, *infra*.

[25] *ModernaTx*, 18 F.4th at 1357. Anticipation (35 U.S.C. § 102) and obviousness (35 U.S.C. § 103) in patent law are covered in Part III, Section D, *infra*.

[26] *ModernaTx*, 18 F.4th at 1357.

[27] *Id.* at 1357, n.2, n.3.

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.* at 1357.

[32] *Id.*

obvious.[33] Arbutus cross-appealed the PTAB's decision that the canceled claims were anticipated.[34] The Federal Circuit heard the case under the jurisdiction conveyed by 28 U.S.C. § 1295(a)(4).[35] However, as a threshold matter, Arbutus contended that Moderna lacked standing to challenge the patents.[36] Arbutus filed a motion to dismiss for lack of standing after Moderna filed its appeal in November 2019.[37] Arbutus argued that Moderna lacked standing because it suffered no injury in fact, as Arbutus never accused Moderna of infringing the '435 patent.[38] In Arbutus's view, the only way for Moderna to show standing would be to prove that Moderna was using or definitively planned to use the technology in the '435 patent, and, Arbutus claimed, Moderna did neither of these.[39]

To rebut the motion to dismiss, Moderna, relying on Federal Circuit precedent, argued that it had standing as a licensee of the '435 patent and that its "actual monetary obligations" change with the PTAB's IPR decision for the '435 patent.[40] Moderna's Senior Vice President and Deputy General Counsel, Shaun Ryan, declared that Arbutus licensed patents (including the '435 patent) to Acuitas Biotherapeutics ("Acuitas"), who then sublicensed the technology to Moderna for use with four viral targets, including Respiratory Syncytial Virus ("RSV").[41] During the RSV viral target development, Moderna made one milestone payment to Acuitas and could have more milestone payments and future royalty obligations.[42] Moderna claimed that these payment obligations from the '435 patent constituted its injury because the payments would increase financial burdens on Moderna's RSV program.[43] The Federal Circuit

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[33] *Id.*

[34] *Id.*

[35] *Id.*; 28 U.S.C. § 1295(a)(4) conveys the Federal Circuit exclusive jurisdiction over IPR decisions from the PTAB.

[36] ModernaTx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352, 1357 (Fed. Cir. 2021). Standing is a prerequisite in filing an appeal and is required for a court to hear a case under Article III. *See* Spokeo, Inc. v. Robins, 578 U.S. 330, 338 (2016) (citing Valley Forge Christian College v. Americans United for Separation of Church and State, Inc., 454 U.S. 464, 473 (1982); Warth v. Seldin, 422 U.S. 490, 498–99 (1975)).

[37] *ModernaTx*, 18 F.4th at 1359.

[38] *Id.* An injury in fact is an "invasion of a legally protected interest," and is covered in greater detail in Part III, Section A, *infra*. *See* Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992).

[39] *ModernaTx*, 18 F.4th at 1359.

[40] *Id.* (quoting Responsive Brief for Petitioner at 3–4, 8–9, ModernaTx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352 (Fed. Cir. 2021)) (citing Samsung Elecs. Co. v. Infobridge Pte. Ltd., 929 F.3d 1363, 1368 (Fed. Cir. 2019).

[41] *ModernaTx*, 18 F.4th at 1359.

[42] *Id.* at 1359–60.

[43] *Id.* at 1360.

denied Arbutus's motion without prejudice to allow Arbutus to argue standing in its merits brief.[44]

Both sides filed their merits briefs and asserted the same arguments from the original motion to dismiss.[45] Arbutus added that licensing does not confer standing and Moderna's financial burdens from the '435 patent were too speculative.[46] Moderna filed a supplemental brief, adding more information from Ryan, which detailed that the RSV program and other programs covered under the Acuitas sublicenses, which were active during the start of the appeal, terminated—the exact termination date unknown—with no further plans to develop the viral targets.[47] Ryan added that Moderna was not abandoning the viral targets even though there were no plans to pursue further development.[48] Further, Ryan added that Moderna planned to develop a new COVID-19 vaccine and believed that Arbutus's insistence that Moderna needed to license the '435 patent for the COVID-19 vaccine, combined with Arbutus's refusal to agree to a covenant not to sue, brought a risk of Arbutus filing a patent infringement suit.[49]

Thus, there are two competing timeline views for Moderna's standing. In Moderna's view, standing existed at the beginning of the appeal from its active RSV development program and milestone payment and continued because of the potential milestone and royalty payments for future development.[50] Even though the RSV program stopped, Moderna argued that the COVID-19 vaccine development started and was commercialized.[51] In Arbutus's view, Moderna had no standing at the time of appeal because (1) the financial licensing obligations did not rise to the level of immediacy, and (2) Moderna did not sufficiently demonstrate *how* its financial obligations would change if the PTAB invalidated the '435 patent.[52] Additionally, Arbutus argued that Moderna left a potential gap in its standing timeline because there was insufficient evidence to prove Moderna stopped the RSV development and began COVID-19 vaccine development with no intervening gap.[53]

On Arbutus's cross-appeal, Arbutus argued that the claims of the '435 patent covered the finished product of lipid particles, while the referenced '554 publication disclosed an ingredient list for creating the

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[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Id.* at 1360–61.
[48] *Id.* at 1360.
[49] *Id.* at 1360–61.
[50] *Id.* at 1361.
[51] *Id.*
[52] *Id.*
[53] *Id.*

lipid particles.[54] Arbutus referenced expert testimony that claimed that the process employed in the '554 publication would result in a lipid particle with compositions outside the range claimed in the '435 patent.[55] The rest of Arbutus's evidence, Arbutus claimed, showed that a person of ordinary skill in the art would have recognized that the final lipid particle's composition would differ from the starting ingredients' composition.[56]

Moderna countered that the PTAB relied on substantial evidence in its conclusions regarding the '554 publication.[57] In addition, Moderna noted that the PTAB rejected Arbutus's argument that the '554 publication taught the final lipid particle's composition, and the PTAB concluded that it was standard practice to describe lipid particles by their initial ingredient list.[58]

The Federal Circuit ultimately dismissed Moderna's appeal and held that (1) Moderna did not show it was suffering a concrete injury and did not have standing when the appeal was filed,[59] and (2) even if it did have standing at the outset, it failed to prove its standing throughout the appeal.[60] Regarding Arbutus's cross-appeal, the Federal Circuit agreed with Moderna that substantial evidence supported the PTAB's decision.[61]

III. LEGAL BACKGROUND

The Constitution limits federal jurisdiction to "cases or controversies."[62] The standing doctrine grew from this constitutional requirement. Standing plays an important role in Federal Circuit patent law cases, especially in the context of *Inter Partes* Review proceedings. As such, the Federal Circuit's standing precedent has developed over the years concerning appeals from PTAB proceedings regarding issues of novelty and obviousness.

A. The Law of Standing and Mootness

The standing doctrine limits federal judicial authority to litigants "empowered to maintain a lawsuit in federal court to seek redress for a

[54] *Id.* at 1363.
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.* at 1361.
[60] *Id.* at 1362.
[61] *Id.* at 1363.
[62] U.S. CONST. art. III, § 2, cl. 1.

legal wrong."[63] To say a party has standing is to say that the party has a legally recognized case or controversy.[64]

The party seeking to invoke federal jurisdiction has the burden to prove standing.[65] To prove standing, the party must show that: (1) it suffered an injury-in-fact;[66] (2) there is a causal connection between the defendant's act and the injury suffered;[67] and (3) the court can redress the injury.[68]

An injury-in-fact is "an invasion of a legally protected interest which is (a) concrete and particularized and (b) 'actual or imminent, not "conjectural" or "hypothetical."'"[69] For an injury to be concrete, it must "actually exist."[70] In other words, the injury may not be "abstract," but it does not necessarily need to be tangible to be concrete.[71] A particularized injury "affect[s] the plaintiff in a personal and individual way."[72] The "actual or imminent" requirement of an injury-in-fact is fulfilled when a party shows that the challenged conduct has resulted in or is very likely to sustain an injury.[73] The threat of an injury must be real, immediate, and not the result of speculation.[74] A claim is moot when developments during litigation remove the present case or controversy.[75] Standing must

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[63] Spokeo, Inc. v. Robins, 578 U.S. 330, 338 (2016) (citing Valley Forge Christian College v. Americans United for Separation of Church and State, Inc., 454 U.S. 464, 473 (1982); Warth v. Seldin, 422 U.S. 490, 498–99 (1975)).

[64] *See* Whitmore v. Arkansas, 495 U.S. 149, 155 (1990) (overruled on other grounds).

[65] Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992).

[66] *Id.* at 560. The injury-in-fact requirement is at issue in *ModernaTx* and is analyzed in greater detail in Part III, Section B, *infra*.

[67] *Lujan*, 504 U.S. at 560. The causal connection must show that the injury is "'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'" *Id.* at 560 (quoting Simon v. Eastern Ky. Welfare Rights Organization, 426 U.S. 26, 41–42 (1976)).

[68] *Id.* at 561.

[69] *Id.* (citing numerous references therein) (internal citations omitted).

[70] Spokeo, Inc. v. Robins, 578 U.S. 330, 340 (2016).

[71] *Id.* Examples of intangible injuries include freedom of speech and freedom to exercise religion. *Id.*

[72] *Lujan*, 504 U.S. at 560 n.1. *See, e.g.*, *Spokeo*, 578 U.S. at 339.

[73] City of Los Angeles v. Lyons, 461 U.S. 95, 101–02 (1983).

[74] *Id.*

[75] Momenta Pharms., Inc. v. Bristol-Myers Squibb Co., 915 F.3d 764, 770 (Fed. Cir. 2019) (citing Canadian Lumber Trade Alliance v. United States, 517 F.3d 1319, 1338 (Fed. Cir. 2008)). There are some limited exceptions to mootness, including when an issue "avoids review and is likely to be repeated, [and] when the defendant voluntarily cease[s] the challenged activity and the plaintiff seeks to preserve its win." Momenta Pharms., Inc. v. Bristol-Myers Squibb Co., 915 F.3d 764, 770 (Fed. Cir. 2019) (citing Milwaukee Police Ass'n v. Bd. of Fire & Police Comm'rs of the City of Milwaukee, 708 F.3d 921, 929–30 (7th Cir. 2013)).

continue through the duration of the litigation.[76] If litigation developments "moot" a claim, federal courts lose jurisdiction.[77]

B. Inter Partes *Reviews: Overview and Standing*

Inter Partes Reviews are quasi-litigation proceedings conducted by the PTAB.[78] When a petitioner requests an IPR, the petitioner requests the PTAB to cancel one or more patent claims.[79] The petitioner in an IPR is a third party to the patent owner and, save for a few exceptions, generally includes *any* third party to the patent owner.[80] Once a party files an *Inter Partes* Review petition, the patent owner has the right to respond to the petition's allegations.[81] A petitioner may base its grounds for unpatentability only on anticipation or obviousness grounds, using only patents or printed publications—a reference shown to be sufficiently made available to the public that a person of ordinary skill in the art ("POSITA") could reasonably access the reference—to support their contentions.[82] If the PTAB decides to institute an IPR,[83] either party can request an oral argument.[84] After the PTAB has decided and adjudicated the merits of the unpatentability claims, the PTAB will issue a written final judgment.[85]

If a party is dissatisfied with the PTAB's decision, the party may seek relief from that decision. The party may request a rehearing from the PTAB; however, the party must identify all matters the PTAB potentially overlooked and where the parties previously addressed the information.[86]

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[76] *Id.* (citing *Milwaukee Police Ass'n*, 708 F.3d at 929).

[77] *Id.* (citing California v. San Pablo & Tulare R. Co., 149 U.S. 308, 313–14 (1893)). For example, if the parties settle a case, this moots the action. *See, e.g.*, Gould v. Control Laser Corp., 866 F.2d 1391, 1392–93 (Fed. Cir. 1989).

[78] 35 U.S.C. § 316(c) (governing conduct of IPRs); JANICE M. MUELLER, PATENT LAW, 699, 710 (6th ed. 2020). *See* 35 U.S.C. §§ 311–19 (United States Code chapter on *Inter Partes* Reviews).

[79] 35 U.S.C. § 311(b).

[80] *Id.* § 311(a) (noting who may petition for an IPR); 37 C.F.R. § 42.101 (2021) (describes when a third party is ineligible to petition for an IPR).

[81] 35 U.S.C. § 313.

[82] *Id.* § 311(b). A printed publication is a reference shown to be sufficiently made available to the public that a POSITA could reasonably access the reference. U.S. PATENT & TRADEMARK OFF., MPEP § 2128 "Printed Publications" as Prior Art (9th ed. Rev. Oct. 2019). *See also In re* Hall, 781 F.2d 897, 898–99 (Fed. Cir. 1986).

[83] 42 C.F.R. § 42.108 (2021). The PTAB may institute a review if there is a "reasonable likelihood that at least one of the claims challenged in the petition is unpatentable." *Id.* § 42.108(c).

[84] *Id.* § 42.120(a).

[85] 35 U.S.C. § 318(a).

[86] 37 C.F.R. § 42.71(d) (2021). A "party" is "at least the petitioner and the patent owner and, in a derivation proceeding, any applicant or assignee of the involved application." *Id.* § 42.2 (2023).

Or a party may look *outside* of the PTAB for relief; specifically, a party may appeal a final IPR decision directly to the Federal Circuit.[87]

Standing plays a different role at each stage of an IPR. There is no requirement for standing for third-party IPR petitioners, and a challenging party may elect to remove itself from the proceeding because the Patent Office may decide to institute an IPR even though an adverse party may settle or elect to not further pursue an IPR.[88] After the final judgment, the parties can request a rehearing with the PTAB.[89] Finally, Congress granted a statutory right for those parties that wish to appeal to the Federal Circuit, which purports to grant dissatisfied parties the opportunity to file an appeal.[90]

C. Standing at the Federal Circuit: Appealing PTAB Decisions

The Federal Circuit does not require that an action fit within the "cases or controversies" limitation when it relates to actions before administrative agencies or boards.[91] As noted, Congress granted a statutory right to appeal final written decisions from the PTAB directly to the Federal Circuit.[92] Any party to the IPR may appeal the decision to the Federal Circuit,[93] but the Federal Circuit has remained steadfast that a statutory right to appeal cannot itself confer Article III standing where the plaintiff would not otherwise have standing.[94]

The Federal Circuit articulated its stance on statutory grants of procedural rights in *Consumer Watchdog v. Wisconsin Alumni Research Foundation*.[95] While a statutory grant of a procedural right can "relax" the requirements of immediacy and redressability, the grant cannot evade the requirement that a party has a "particularized, concrete stake in the

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[87] 35 U.S.C. § 141(c).

[88] Cuozzo Speed Techs., LLC v. Lee, 579 U.S. 261, 278–79 (2016). *See* 35 U.S.C. § 317(a).

[89] 37 C.F.R. § 42.71(d) (2021).

[90] 35 U.S.C. § 141(c). This provision provides:

> A party to an inter partes review or a post-grant review who is dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) or 328(a) (as the case may be) may appeal the Board's decision only to the United States Court of Appeals for the Federal Circuit.

Id.

[91] Momenta Pharms., Inc. v. Bristol-Myers Squibb Co., 915 F.3d 764, 768 (Fed. Cir. 2019).

[92] *See supra* note 88 and accompanying text.

[93] Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1372 (2018).

[94] Momenta Pharms., Inc. v. Bristol-Myers Squibb Co., 915 F.3d 764, 768 (Fed. Cir. 2019) (citing Consumer Watchdog v. Wisc. Alumni Rsch. Found., 753 F.3d 1258, 1262 (Fed. Cir. 2014)) (quoting Raines v. Byrd, 521 U.S. 811, 820 n.3 (1997)).

[95] 753 F.3d 1258 (Fed. Cir. 2014).

outcome of the reexamination."[96] In *Consumer Watchdog*, the court determined that an appellant had nothing more than a "general grievance" about the patent and, thus, no standing.[97] The appellant did not allege that (1) there were ongoing or planned activities that could form the basis of an infringement claim, (2) it was an actual or prospective licensee, or (3) it had any connection with the patent at issue other than its participation in the *Inter Partes* Reexamination.[98] Mere disagreement with the outcome of the *Inter Partes* Reexamination could not sufficiently confer standing to appeal the PTAB's decision.[99] Simply challenging a patent in an IPR does not mean the party could challenge that IPR in the Federal Circuit.[100]

A specific threat of infringement litigation is not a necessary element to show an injury-in-fact to appeal an IPR; rather, a party "must generally show a controversy 'of sufficient immediacy and reality' to warrant the requested judicial relief."[101] In *E.I. DuPont de Nemours & Company v. Synvina C.V.*, the Federal Circuit held that an appellant had standing to appeal an IPR where the appellant owned and operated facilities that *could* infringe the patent at issue.[102] In addition, the appellant presented sufficient evidence showing plans for activity that presented a strong risk of infringement or for the patent owner to claim infringement.[103]

Evidence of changing royalty obligations related to patent licensing tied to the outcome of an IPR may give rise to standing.[104] In *Samsung Elecs. Co., Ltd. v. Infobridge Pte. Ltd.*, the Federal Circuit held that the appellant had standing because the appellant sufficiently alleged that invalidating a patent in a "license pool" with an IPR would result in higher

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[96] Consumer Watchdog v. Wis. Alumni Rsch. Found., 753 F.3d 1258, 1262 (Fed. Cir. 2014). Note that the Federal Circuit decided this case after Congress adopted the America Invents Act. This affects this note only in that the procedure at issue involved an *Inter Partes* Reexamination rather than an *Inter Partes* Review, which superseded *Inter Partes* Reexaminations through the America Invents Act. Leahy-Smith America Invents Act, Pub. L. No. 112–29, 35 U.S.C. 1 note (to amend) (2011).

[97] *Consumer Watchdog*, 753 F.3d at 1262–63.

[98] *Id.* at 1261.

[99] *Id.*

[100] *Id.* at 1263.

[101] E.I. DuPont de Nemours & Co. v. Synvina C.V., 904 F.3d 996, 1004 (Fed. Cir. 2018) (quoting ABB Inc. v. Cooper Indus., LLC, 635 F.3d 1345, 1348 (Fed. Cir. 2011)).

[102] *E.I. DuPont de Nemours & Co.*, 904 F.3d at 1004.

[103] *Id.* at 1004–05. *See also* General Electric Co. v. Raytheon Techs. Corp., 983 F.3d 1334, 1341 (2020) (quoting JTEKT Corp. v. GKN Auto. LTD., 898 F.3d 1217, 1221 (Fed. Cir. 2018).

[104] *See* Apple Inc. v. Qualcomm Inc., 992 F.3d 1378, 1383–84 (Fed. Cir. 2021), *reh'g denied*, July 20, 2021, *petition for cert. filed*, Apple Inc. v. Qualcomm Inc., No. 21-746 (Nov. 19, 2021) (decided Apr. 7, 2021); Samsung Elecs. Co., Lte. v. Infobridge Pte. Ltd., 929 F.3d 1363, 1368 (Fed. Cir. 2019).

royalty payments to the appellant.[105] The patent at issue was part of a more extensive patent licensing pool, where each patent owner was paid a royalty share from licensees based on its proportion of patents in the pool.[106] Therefore, if the appellant had a larger proportion of patents, it would receive more royalties from licensees.[107] In *Apple v. Qualcomm, Inc.*, the Federal Circuit held that the appellant did not have standing because the appellant did not allege that ongoing royalty obligations would change with the validity of the patents at issue in the IPR on appeal.[108] Like *Samsung*, the patents at issue were in a larger pool.[109] However, because the appellant did not provide evidence that invalidating any of the patents at issue would change its ongoing royalty obligations nor that any contractual issue involving the royalty payments would be solved by examining the validity of the patents at issue, the Federal Circuit held that the appellant had no standing.[110]

D. 35 U.S.C. §§ 102–103: Patent Novelty and Obviousness

A patent is novel if each of its claims, defining a patent's exclusionary rights,[111] are not disclosed by the prior art (i.e., the claim is fully described elsewhere) before the effective filing date of a claimed invention.[112] If each of the claims are disclosed in a single reference, the patent is said to be anticipated by that reference.[113] The references that disclose the claims are termed "prior art."[114] Such reference demonstrates whether a "claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public" and whether a "claimed invention was described in a patent . . . or in an application for patent published or deemed published . . . in which the patent or application . . . names another inventor and was effectively filed before the effective filing date of the claimed invention."[115]

An invention is "obvious" if a POSITA, after considering prior art references and the invention as a whole, would find the invention to be

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[105] *Samsung Elecs. Co., Ltd.*, 929 F.3d at 1368.

[106] *Id.*

[107] *Id.*

[108] *Id.* at 1383–84.

[109] *Id.* at 1383.

[110] *Id.* at 1383–84.

[111] *See, e.g.*, Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citing numerous references).

[112] 35 U.S.C. 100(i) (defining effective filing date), 35 U.S.C. § 102(a) (defining the requirement of patent novelty).

[113] JANICE M. MUELLER, PATENT LAW 242 (6th ed. 2020). In other words, the disclosures cannot be combined to show anticipation.

[114] *See* 35 U.S.C. § 102(a).

[115] *Id.*

obvious before the claimed invention's effective filing date.[116] Congress codified the nonobviousness requirement in the Patent Act of 1952;[117] and the Supreme Court provided a four-factor test to determine if an invention is obvious in *Graham v. John Deere Co. of Kansas City*.[118] The inquiry involves examining: (1) "the scope and content of the prior art"; (2) "differences between the prior art and the claims at issue"; (3) "the level of ordinary skill in the pertinent art"; and (4) "secondary considerations [such] as commercial success, long-felt but unsolved needs, failure of others, etc. . . . to give light to the circumstances surrounding the origin of the subject matter sought to be patented."[119] In *ModernaTx*, the Federal Circuit considered whether Moderna had standing to challenge the PTAB decision that some of the claims in the '435 patent were not unpatentable for being obvious.[120]

IV. INSTANT DECISION

The Federal Circuit held that Moderna lacked standing at the time of appeal, or at least failed to maintain standing throughout the appeal, and affirmed the PTAB's decision to invalidate the '435 patent's claims 1–6, 9, 12, and 14–15.

A. Moderna's Standing at the Time of Appeal

The Federal Circuit began its standing analysis by noting that its precedent "generally makes clear" that appellants seeking review of an IPR must meet the standing requirement.[121] The court acknowledged that although 35 U.S.C. § 319 "relaxes" the immediacy and redressability requirements, a party's participation in an IPR does not automatically confer the right to appeal an unfavorable PTAB decision.[122] Rather, the court was required to consider whether Moderna had suffered an injury, which Moderna had the burden to prove.[123] The court drew from the evidence presented in the briefs, supplemental briefs, and oral argument

[116] *Id.* § 103. *See* Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 14–15 (1966).

[117] 35 U.S.C. § 103 (1952). Note that § 103 has undergone insubstantial amendments since its enactment.

[118] *Graham*, 383 U.S. at 17–18.

[119] *Id.*

[120] ModernaTx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352, 1358–63 (Fed. Cir. 2021).

[121] *Id*. at 1358.

[122] 35 U.S.C. § 319; *ModernaTx, Inc.*, 18 F.4th at 1358 (citing Momenta Pharm., Inc. v. Bristol-Myers Squibb Co., 915 F.3d 764, 768 (Fed. Cir. 2019)); Phigenix, Inc. v. Immunogen, Inc., 845 F.3d 1168, 1175 (Fed. Cir. 2017).

[123] *ModernaTx, Inc.*, 18 F.4th at 1358–59.

to make its decision.[124] First, the court noted that Moderna's alleged financial burdens from the Acuitas sublicenses were too speculative, even if Moderna licensed only the '435 patent.[125] The court noted that the last milestone payment Moderna made to Acuitas was five years before the appeal was filed and determined that Moderna would need to make another milestone payment only "if and when" the milestone would be reached.[126] The court determined that this evidence alone was insufficient to show that Moderna suffered or was suffering from a concrete injury.[127]

Next, the court analogized to *Apple* and *Samsung*.[128] Like Moderna, both cases involved multiple licensed patents.[129] Because Moderna presented insufficient evidence that invalidating the '435 patent would change its financial obligations, the court decided that *Apple* was the most analogous case.[130] In *Apple*, the appellant did not have standing because the appellant did not present sufficient evidence that the challenged patents would affect the appellant's contractual rights and royalty payments.[131] The court, finding that the facts mirrored *Apple*, held that Moderna lacked standing when the appeal was filed.[132]

B. Moderna's Standing Throughout the Appeals Process

The Federal Circuit also agreed that Moderna failed to continually have standing throughout the appeal.[133] Noting the corroborating Federal Circuit precedent, the court agreed with Arbutus's assessment that Moderna did not present enough evidence demonstrating the date Moderna terminated the RSV development program, resulting in a potential gap in Moderna's standing timeline between the RSV development and the COVID-19 vaccine development.[134] This was true *even if* Moderna initially had standing for appeal.[135] In addition, the court determined that because Moderna asserted that the basis for standing shifted, Moderna needed to prove the existence of continuing standing.[136]

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[124] *See id.* at 1360–61.

[125] *Id.* at 1361.

[126] *Id.*

[127] *Id.* (citing Phigenix, Inc. v. Immunogen, Inc., 845 F.3d 1168, 1171 (Fed. Cir. 2017)).

[128] *Id.* at 1361–62.

[129] *Id.*

[130] *Id.* at 1362.

[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] *Id.*

The court concluded that Moderna provided insufficient evidence to meet its burden of proving continuous standing.[137]

V. COMMENT

The pieces of the standing puzzle were all in front of Moderna. Moderna was required to show that it suffered an injury-in-fact from the outset *and* that such an injury existed throughout the entirety of the appeal.[138] Each decision in the Federal Circuit's trail of precedent was a nail in Moderna's coffin. First, in no uncertain terms, the Federal Circuit proclaimed that procedural grants derived from statutory sources would not automatically grant a party a right to appeal.[139] Simply being a party to an IPR will not confer Article III standing.[140] When Moderna could not definitively "fill the gap" in its standing timeline,[141] Moderna became a party that was merely dissatisfied with the IPR, which is insufficient to confer standing.[142]

Next, Moderna's inability to show how its financial obligations would change if the Federal Circuit invalidated the '435 patent caused Moderna to fail another piece of the standing puzzle—requiring that a party show an immediate need for judicial relief.[143] In the Federal Circuit's view, because Moderna could not show how the financial obligations would change upon patent invalidation, Moderna could not show Article III standing.[144]

Finally, the Federal Circuit's *Apple* decision supports denying standing based on failure to show changing financial obligations.[145] Moderna did not prove any financial changes other than a "speculative

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[137] *Id.*

[138] *Momenta Pharms., Inc.*, 915 F.3d at 770 (citing *Milwaukee Police Ass'n*, 708 F.3d at 929; *San Pablo & Tulare R. Co.*, 149 U.S. at 313–14).

[139] *Momenta Pharms., Inc.*, 915 F.3d at 768 (Fed. Cir. 2019) (citing Consumer Watchdog v. Wisc. Alumni Rsch. Found., 753 F.3d 1258, 1262 (Fed. Cir. 2014)) (quoting Raines v. Byrd, 521 U.S. 811, 820 n.3 (1997)).

[139] *Momenta Pharms., Inc.*, 915 F.3d at 768 (citing *Consumer Watchdog*, 753 F.3d at 1262.

[140] *See Consumer Watchdog*, 753 F.3d at 1261.

[141] *See supra* notes 36–39 and accompanying text.

[142] *See Consumer Watchdog*, 753 F.3d at 1261.

[143] E.I. DuPont de Nemours & Co. v. Synvina C.V., 904 F.3d 996, 1004 (Fed. Cir. 2018) (citing ABB Inc. v. Cooper Indus., LLC, 635 F.3d 1345, 1348 (Fed. Cir. 2011).

[144] ModernaTx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352, 1362 (Fed. Cir. 2021).

[145] Apple Inc. v. Qualcomm Inc., 992 F.3d 1378, 1383–84 (Fed. Cir. 2021), *reh'g denied*, July 20, 2021, *petition for cert. filed*, Apple Inc. v. Qualcomm Inc., No. 21-746 (Nov. 19, 2021) (decided Apr. 7, 2021).

licensing obligation[]."[146] This contrasts the Federal Circuit's decision in *Samsung*, where the IPR petitioner affirmatively showed how royalty payments would change with patent invalidation.[147]

But even if the Federal Circuit's decision in *ModernaTX* is in harmony with its own precedent, is it in harmony with congressional intent? The Federal Circuit decided *Apple* in April 2021, just under eight months before *ModernaTX*.[148] After the Federal Circuit decided *Apple*, the losing party, Apple, Inc., petitioned the Supreme Court of the United States for review.[149] Senator Patrick Leahy, the former Chair of the Committee on the Judiciary's Subcommittee on Intellectual Property, and Congressman Darrell Issa, holder of thirty-seven patents and the current Chair and former Ranking Member of the Judiciary Subcommittee on Courts, Intellectual Property, and the Internet, filed an amicus brief supporting a grant of certiorari.[150] Though the brief was written in support of *Apple*, some of the arguments within reveal where the Federal Circuit may have strayed from congressional intent.

The Senator and Congressman argued that the Federal Circuit's handling of standing discourages potential IPR petitioners from using the IPR system because the Federal Circuit precedent "goes beyond" the Supreme Court's standing precedent.[151] They contended that the Federal

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[146] *ModernaTx, Inc*., 18 F.4th at 1361.

[147] Samsung Elecs. Co. v. Infobridge Pte. Ltd., 929 F.3d 1363, 1368 (Fed. Cir. 2019).

[148] *Compare* ModernaTx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352 (Fed. Cir. 2021) (decided Dec. 1, 2021), *with* Apple Inc. v. Qualcomm, Inc., 992 F.3d 1378 (Fed. Cir. 2021), *reh'g denied*, July 20, 2021, *petition for cert. filed*, Apple Inc. v. Qualcomm Inc., No. 21-746 (Nov. 19, 2021) (decided Apr. 7, 2021). *See supra* note 108 and accompanying text for a small description of *Apple*.

[149] Apple Inc. v. Qualcomm, Inc., 992 F.3d 1378 (Fed. Cir. 2021), *reh'g denied*, July 20, 2021, *petition for cert. filed*, Apple Inc. v. Qualcomm Inc., No. 21-746 (Nov. 19, 2021) (decided Apr. 7, 2021).

[150] Brief for Senator Patrick Leahy and Congressman Darrell Issa as Amici Curiae Supporting Certiorari at 1 *Apple Inc*., 992 F.3d 1378 (No. 21-746). [hereinafter Brief Supporting Apple Inc. Certiorari]. *The Subcommittee on Courts, Intellectual Property, and the Internet*, HOUSE OF REPRESENTATIVES JUDICIARY COMM., https://judiciary.house.gov/subcommittees/committee-judiciary/subcommittee-courts-intellectual-property-and-internet [https://perma.cc/PJN8-PMVK] (last visited Mar. 24, 2023).

Senator Leahy is the senior United States Senator from Vermont and Congressman Darrell Issa represents California's 50th Congressional District in the United States House of Representatives. *Id.* at 1. Senator Leahy was the lead sponsor of the America Invents Act in the Senate, and Congressman Issa was one of the original co-sponsors of the America Invents Act in the House of Representatives. *Id.* at 1. The America Invents Act represents a significant overhaul of patent law in the United States. Leahy-Smith America Invents Act, H.R. 1249, 112th Cong. (2011) (enacted).

[151] Brief Supporting Apple Inc. Certiorari, *supra* note 150, at 1–2.

Circuit essentially limits the road to filing an appeal in an Article III tribunal to patent owners and is "uncertain for challengers," which will lead to fewer IPRs.[152] In effect, the Federal Circuit's decision represents a step back—*Inter Partes* Reviews were designed to replace the severely underutilized *Inter Partes* Reexaminations, and inadvertently discouraging the filing of IPRs is "the opposite of what the AIA contemplates."[153]

Congress replaced *Inter Partes* Reexaminations with *Inter Partes* Reviews to improve patent quality.[154] Post-grant review processes outside district court litigation are generally quicker to resolve and help the public recognize high-quality inventions and improvements by removing low-quality patents from the "patent thicket."[155] Congress designed IPRs to be a system that practitioners would actually use to test patent validity.[156] Inefficiencies in the original *Inter Partes* Reexamination process drove practitioners away from the process, thus burdening the public by discouraging practitioners from challenging low-quality patents.[157] The Senator and Congressman argued that any discouragement to use the IPR system threatens to weaken this process.[158]

The amicus brief also helps outline estoppel issues in patent law cases.[159] IPRs are designed to be practical tools to solidify a patent's validity or invalidity.[160] If a petitioner loses an IPR, the claims that the PTAB certifies as valid are protected by estoppel.[161] The petitioner is not allowed to re-challenge that patent based on something the petitioner could have brought forth in the IPR.[162] If a dissatisfied party cannot meet the standing requirements outlined by the Federal Circuit, that party will be estopped from re-challenging the patent, a balance in favor of the patent owner who easily meets the Article III standing burden.[163]

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[152] *Id.* at 2–3.

[153] *Id.*

[154] *Id.* at 5–6.

[155] *Id.* at 6–7.

[156] *Id.* at 8–9.

[157] *Id.* at 8.

[158] *Id.* at 11.

[159] 35 U.S.C. § 315(e); Brief Supporting Apple Inc. Certiorari, *supra* note 150, at 9–10.

[160] 35 U.S.C. § 315(e); Brief Supporting Apple Inc. Certiorari, *supra* note 150, at 9.

[161] 35 U.S.C. § 315(e); Brief Supporting Apple Inc. Certiorari, *supra* note 150, at 9–10.

[162] 35 U.S.C. § 315(e); Brief Supporting Apple Inc. Certiorari, *supra* note 150, at 9–10.

[163] *See* ModernaTx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352, 1362 (Fed. Cir. 2021).

The Federal Circuit stood firm with its precedent in *ModernaTX*. However, the line of precedent strays away from congressional intent, as illuminated by the Senator and Congressman's amicus brief in *Apple*. With each decision in the trail, the standing bar became more challenging to overcome. The statute conferring the original procedural right to appeal is plain: "A party dissatisfied with the final written decision . . . may appeal the decision . . . . Any party to the inter partes review shall have the right to be a party to the appeal."[164] The Senator and Congressman noted that this is one crucial piece of the redesigned IPR process and that any "artificial" limitation to appealing "threaten[s] to unravel this regime by discouraging interested parties from bringing such challenges in the first place."[165]

Overall, Federal Circuit precedent and congressional intent are in tension. The *concrete* barriers the Federal Circuit has erected are more restrictive than those designed by Congress. On the other side, the Federal Circuit is interpreting Article III requirements and has decided that higher barriers are necessary to ensure that only justiciable cases reach federal courts.[166] The Federal Circuit's duty to protect jurisdiction to justiciable cases is a fundamental tenet of United States jurisprudence and must be protected.[167] However, in pursuit of this mission, the Federal Circuit has squeezed this requirement tightly. The IPR system works best as Congress intended—giving wide latitude for appeal (though not unlimited).[168] Preserving the existing IPR system will require careful balancing between protecting Article III jurisdiction and incentivizing the use of the IPR system.

VI. CONCLUSION

In *ModernaTX*, the Federal Circuit dug its heels in to reiterate its stance on standing. No appeals may be brought without a concrete injury-in-fact existing throughout the entirety of the appeal. *ModernaTX* represents the Federal Circuit's effort to protect Article III jurisdiction to actual cases and controversies. However, through its trail of precedent, the Federal Circuit diverged from congressional intent, inadvertently creating a disincentive to utilize the IPR system designed to remedy previous *Inter Partes* Reexamination usage issues. Both interests of Congress and the Federal Circuit can be balanced in future decisions to continue to encourage the use of the IPR system.

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[164] 35 U.S.C. § 319.

[165] 35 U.S.C. § 315(e); Brief Supporting Apple Inc. Certiorari, *supra* note 150, at 11.

[166] *See ModernaTx, Inc.*, 18 F.4th at 1358.

[167] *Id.* (citing DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 341–42 (2006)).

[168] *See* Brief Supporting Apple Inc. Certiorari, *supra* note 150, at 11.

In *ModernaTX*, Moderna failed to show standing by being too unclear about its financial obligations. One thing is clear: future litigants at the Federal Circuit incorporating *ModernaTX* in their arguments will vaccinate themselves against a motion to dismiss for lack of standing.