No. 21-746

In the Supreme Court of the United States

APPLE INC.,
Petitioner,
v.
QUALCOMM INCORPORATED,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF SENATOR PATRICK LEAHY AND CONGRESSMAN DARRELL ISSA AS *AMICI CURIAE* SUPPORTING CERTIORARI

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INTEREST OF AMICI CURIAE*

Senator Patrick Leahy is the senior United States Senator from Vermont, president *pro tempore* of the Senate, and Chair of the Committee on the Judiciary's Subcommittee on Intellectual Property. He was the lead sponsor in the Senate of the Leahy-Smith America Invents Act (AIA). In 2006, with Senator Orrin Hatch, Senator Leahy introduced the first Senate version of the bill that ultimately led to the AIA. Thereafter, Senator Leahy led the yearslong process through multiple Congresses of bringing the AIA from a series of bills to enacted law.

Congressman Darrell Issa is the Representative of California's 50th Congressional District in the United States House of Representatives. He is the Ranking Member of the Judiciary Subcommittee on Courts, Intellectual Property and the Internet, and the holder of 37 patents. With former Congressman Lamar Smith, Congressman Issa was one of the two original co-sponsors of the AIA in the House of Representatives.

Amici do not have a dog in the fight between Apple and Qualcomm. Amici express no view on the validity of Qualcomm's patents or the merits of the administrative decisions Apple has attempted to appeal. Amici's sole concern is for the continued availability of *inter partes* reviews as a meaningful tool to improve patent quality. No system of "post-issuance" review of

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* No counsel for any party authored this brief in whole or in part, and no person or entity other than *amici* or their counsel made any monetary contribution to the preparation or submission of this brief. Counsel of record for all parties received notice of *amici*'s intention to file this brief, at least ten days prior to the deadline. All parties have provided written consent to the filing of this brief.

patents (also called "post-grant review") can succeed if would-be petitioners are discouraged from using it. Amici, thus, are concerned that the Federal Circuit's approach to Article III standing goes beyond what this Court's precedents require, unnecessarily deters patent challengers from using *inter partes* review in the first place, and—thus—threatens to undermine one of the major achievements of the AIA.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The Leahy-Smith America Invents Act was the first comprehensive patent legislation in more than fifty years, since the Patent Act of 1952. One of the AIA's major components was the establishment of new procedures at the Patent Office to improve patent quality—both for the benefit of patent owners and for those seeking to avoid claims of infringement. The AIA's new procedures—*inter partes* reviews (IPRs) and two related procedures—were meant to improve patent quality by providing an efficient, effective way to test the validity of issued patents.

Post-issuance reviews are only effective if patent challengers actually use them. Earlier proceedings that allowed the public to challenge a patent's validity—*ex parte* and *inter partes* reexaminations—were largely ineffective at improving patent quality precisely because they were rarely used. Experience has shown that prompt availability of judicial review is an important feature for patent owners and potential challengers alike. Judicial review brings finality as well as confidence in the overall process. But when such review is disproportionately only available to one party (patent owners) and contingent or uncertain for

challengers, that discourages the use of IPRs. Simply put, fewer challenges will be filed in the first place.

That is the opposite of what the AIA contemplates. To ensure the broadest possible availability of IPRs, Sections 311 and 319 offer anyone other than the patent owner the right to file an *inter partes* review, and permit "dissatisfied" parties to appeal from the final written decision. *See also* 28 U.S.C. § 1295(a)(4)(A). In part because petitioners and owners alike can seek judicial review of adverse administrative decisions, sections 315(e) and 318(b) provide that the decisions have consequences. If a patent owner loses, the invalid claims are cancelled under § 318(b). If a petitioner loses, the confirmed claims are better insulated against further validity challenges under § 315(e)'s estoppel provisions.

Although Article III courts' jurisdiction is obviously limited to cases or controversies, the Federal Circuit's recent decisions have taken an unduly cramped view of its jurisdiction that is inconsistent with this Court's precedent. In so doing, the Federal Circuit's approach threatens to diminish the effectiveness of IPRs by chipping away at patent challengers' access to judicial review. The court has all but eliminated judicial review for organizations that petition for post-issuance review of patents, and has dismissed numerous appeals where a panel of the court was unconvinced that the appellant either had sufficiently concrete plans to engage in an activity that would risk infringement liability or had sufficient contractual rights at stake based on a determination of patent validity.

While those cases raise concerns, this one raises a red flag by requiring significantly more of IPR petitioners who face the prospect of a patent being asserted against them. In this case, the Federal Circuit commits the same mistakes this Court had to correct in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). Unfortunately, the Federal Circuit reads *MedImmune* as limited to licenses that either cover single patents or set itemized prices for each patent in a portfolio, Pet.App.6a-8a, and equates a "future" threat with a "speculative" threat. Pet.App.8a-11a.

According to the Federal Circuit's reasoning, Article III of the Constitution did not permit it to hear an appeal from a patent challenger who *has already been sued* on the challenged patents (for making and selling specific products), and who faces a concrete threat of being *sued again on the same patents* in the future. Why? Because the challenger has a *temporary* license to the patents in the interim. A concrete, discernible threat of future patent assertion is not speculative just because it is not imminent.

The Federal Circuit's recalcitrance on Article III—despite this Court's course corrections—is not limited to Apple and Qualcomm's dispute, nor to licensing practices in the electronics industry. The precedent has already spread to the life sciences field. Another decision cites the precedent of this case to dismiss a patent challenger's appeal in part because the challenger's license to the patent included unchallenged patents and did not set royalty prices on an individual patent-by-patent basis. *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, ___ F.4th ___, 2021 WL 5617751, at *5-6 (Fed. Cir. Dec. 1, 2021).

While Article III is an important check on the role of the judiciary, it does not support the path the Federal Circuit has taken. And the decision below clearly has consequences that reach far beyond Apple and Qualcomm's present dispute. In unnecessarily curtailing an IPR petitioner's appellate review rights in ways that the Constitution does not require, the Federal Circuit threatens to turn one of the Leahy-Smith America Invents Act's major achievements into an empty shell.

This Court should grant review.

ARGUMENT

I. A Major Achievement of the AIA Was to Create Effective, Efficient Post-Issuance Review Procedures That Could Meaningfully Test the Validity of Issued Patents.

In 2011, bipartisan supermajorities of both houses in the 112th Congress came together to enact the Leahy-Smith America Invents Act. The AIA was the first major patent legislation since 1952. One of the AIA's signature achievements was to establish new post-issuance review proceedings that interested parties could meaningfully use to test the validity of issued patents.

The point of any post-issuance review proceeding is to improve patent quality—for the benefit of patent owners and the public alike. The Patent Office receives hundreds of thousands of patent applications each year, has more than 8,000 examiners, and has a limited number of examiner hours to devote to each application. *See, e.g.*, Michael D. Frakes & Melissa Wasserman, *Is the Time Allocated to Review Patent*

Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data, 99 Rev. Econs. & Stats. 550, 552 (2017) ("[O]n average, a U.S. patent examiner spends only nineteen hours" on each patent application); *id.* at 550 n.2 (describing reports of examiners expressing the need for more time); *St. Regis Mohawk Tribe v. Mylan Pharms. Inc.*, 896 F.3d 1322, 1331 (Fed. Cir. 2018) (Dyk, J., concurring) ("Patent examiners receive roughly 22 hours to review each application, an amount of time that 70% of examiners report as insufficient." (citing Government Accountability Office report)). The Patent Office now issues more than 300,000 utility patents each year. Those patents vary widely in quality. Some cover diagnostic methods from Theranos that were already debunked before the patents issued, or a crustless peanut butter and jelly sandwich. Others cover groundbreaking and life changing new inventions.

Improving patent quality is not a partisan issue. High-quality patents benefit everyone: they reward innovation, spur economic growth, and fulfill the Constitution's objective "[t]o promote the Progress of Science and the useful Arts." U.S. Const. art. I, §8. Low-quality patents harm everyone: they hinder innovation, enable nuisance suits, and unjustly diminish respect for all patents, including high-quality patents. *See* 157 Cong. Rec. 717-18 (2011). High-quality patents are worthy of respect, invalid patents should be cancelled, and interested parties should have an efficient way to know which is which. District court litigation is ill-suited to that purpose. It is expensive, time-consuming, and often arises late in a patent's term. Holders of questionable, untested patents can use the expense of district court litigation and threat

of market interruptions to gain undue leverage in negotiations. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 396-97 (2006) (Kennedy, J., concurring).

Post-issuance review proceedings improve patent quality by enlisting the assistance of interested parties in identifying which of the millions of patents in force at any given time warrant greater scrutiny, and in identifying relevant prior art. The public benefits both when the patent thicket is cleared of invalid patents, and when genuine innovation is recognized and rewarded. Patents that are tested and emerge from post-issuance review proceedings receive greater respect.

Congress created *ex parte* reexaminations in 1980 and *inter partes* reexaminations in 1999. H.R. Rep. No. 96-1307, pt. 1, at 3-4 (1980); H.R. Rep. No. 107-120, at 4 (2001). In both types of proceedings, third parties could challenge an issued patent by raising a substantial new question of patentability and requesting that the Patent Office reexamine the patent. Unfortunately, both were ineffective at improving patent quality *because their shortcomings led third parties rarely to use them*.

Ex parte reexaminations remain available and continue to be used to some extent. But the third-party requester has no involvement beyond the initial request to the Patent Office, and no right to appeal or to participate in a patent owner's appeal to the Federal Circuit. *See, e.g.*, 145 Cong. Rec. 29972 (1999). Those shortcomings led Congress to enact *inter partes* reexaminations in 1999.

Inter partes reexaminations are no longer available, and were underutilized during their time. In the first few years, almost no requests for *inter partes*

reexamination were filed. In 2000, 2001, and 2002, the Patent Office granted more than 500,000 patents, but received only *five* requests for *inter partes* reexamination. *See* U.S. Patent & Trademark Office, *U.S. Patent Statistics Chart* (updated May 2021) (patents granted), *available at* https://bit.ly/3sgPn0K; U.S. Patent & Trademark Office, *Report to Congress on Inter Partes Reexamination* 4-5 (2004) (requests).

More requests for *inter partes* reexaminations were filed after 2002, when Congress provided third-party requesters with appeal rights. Pub. L. No. 107-273, § 13106(a), 116 Stat. 1758, 1900-01 (2002). Even so, *inter partes* reexaminations remained underutilized. The Patent Office received only 48 total requests in 2003 and 2004—far short of the more than 1100 requests the Patent Office had projected. *Report to Congress on Inter Partes Reexamination* at 4-5.

Congress enacted the AIA in 2011 against the backdrop of decades of ineffective reexaminations, and amid renewed demands for a better system of post-issuance review to improve patent quality. *See* H.R. Rep. No. 112-98, at 45 (2011) (*ex parte* reexaminations were "a much less favored avenue to challenge questionable patents than litigation."); *see also id.* at 39, 48; S. Rep. No. 110-259, at 19 (2008) (both types of reexamination proved "troublesomely inefficient and ineffective as a truly viable alternative for resolving questions of patent validity.").

After bills were introduced in the House and Senate in 2005 and 2006, years of hearings, debate, and compromise ensued. Those efforts produced the AIA in 2011, with its revised set of proceedings that were designed to be fair to patent owners and at the same

time meaningful for would-be challengers. Those procedures were meant to succeed where reexaminations had failed by creating proceedings that interested parties would actually use to test the validity of issued patents—with the outcome, either way, benefiting the public.

IPRs were made broadly available. Any member of the public who might have information about the validity of a patent may file a petition. Section 311(a) permits any "*person* who is not the owner" of the patent to file. "Person" broadly includes "corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." *Return Mail, Inc. v. U.S. Postal Serv.*, 139 S.Ct. 1853, 1862 (2019) (quoting 1 U.S.C. § 1). In general, the only restrictions on access are imposed to prevent delay or to preclude repeated petitions by parties who have already challenged the same patent before. *See, e.g.*, 35 U.S.C. § 315(a)(1), (b), (d), (e).

The proceedings themselves were designed to be more efficient and to produce higher-quality results than the predecessor reexaminations. Among other things, the AIA: **(1)** set time limits for the duration of IPRs, 35 U.S.C. §§ 314(b), 316(a)(11) (in contrast to reexaminations), **(2)** permitted limited discovery, *id.* § 316(a)(5) (in contrast to the absence of discovery in reexaminations and broad discovery in district court litigation), and **(3)** created the Patent Trial and Appeal Board, *id.* § 6, to conduct trial-like proceedings.

Because the proceedings are designed to distinguish effectively between valid and invalid patents, the resulting decisions bind the parties. If a patent owner loses, the invalid claims are cancelled under § 318(b). If a petitioner loses, the confirmed claims

are better insulated against further validity challenges under § 315(e)'s estoppel provisions. In other civil or administrative proceedings, the patent challenger—or its real party in interest or privy—may not challenge the patent claim again "on any ground that the petitioner raised or reasonably could have raised during that inter partes review." 35 U.S.C. § 315(e)(1), (2).

Both to provide a further check on the agency and to prevent the proceedings from falling into disuse, the AIA provides that all parties will have the same right to appellate review of final decisions that Congress added to *inter partes* reexaminations in 2002 to promote their use. Section 319 provides patent challengers and owners the same right to appeal, and the right to participate in each other's appeals: "[a] party dissatisfied with the final written decision" may appeal to the Federal Circuit, and "[a]ny party to the inter partes review shall have the right to be a party to the appeal." *See also* 28 U.S.C. § 1295(a)(4)(A) (providing jurisdiction over appeals from Patent Trial and Appeal Board decisions in *inter partes* reviews, "at the instance of a party who exercised that party's right to participate in the applicable proceeding before or appeal to the Board"). Congress' intent was that the Federal Circuit would exercise appellate jurisdiction to the fullest extent possible under Article III of the Constitution.

Early reports indicate that the AIA succeeded in creating a faster, cheaper, more accurate way to separate the wheat from the chaff in the patent system. More than a thousand petitions for *inter partes* review are filed each year. *See* U.S. Patent & Trademark Office, *PTAB Trial Statistics, FY21 End of Year Outcome*

Roundup 3, 5 (2021), *available at* https://bit.ly/3E4UqDx. A 2016 article co-authored by Federal Circuit Judge Evan Wallach commented that statistics "suggest[ed] that, more than thirty years after the creation of ex parte reexamination, the USPTO is finally empowered to administer a post-grant review proceeding that is efficient and effective enough for patent challengers to use in appreciable volume." Evan J. Wallach & Jonathan J. Darrow, *Federal Circuit Review of USPTO Inter Partes Review Decisions by the Numbers: How the AIA Has Impacted the Caseload of the Federal Circuit*, 98 J. Pat. & Trademark Off. Soc'y 105, 118 (2016).

In sum, Congress designed a system that works as intended: It provides a mechanism for interested parties to efficiently and effectively challenge dubious patents. It rewards patent owners whose patents are tested, by estopping challengers from bringing similar challenges in litigation. A decade later, however, artificial limitations on appellate review that are not compelled by the Constitution threaten to unravel this regime by discouraging interested parties from bringing such challenges in the first place. As explained below, Article III does not require these artificial restrictions, and as in *MedImmune*, this Court's intervention is once again required.

II. The Federal Circuit's Unnecessarily Restrictive Approach to Article III Standing Threatens the Viability of the AIA's Post-Issuance Review Procedures.

Section 319 of Title 35 provides patent owners and challengers alike with the same broad right to appeal from adverse final written decisions. Post-issuance reviews are more effective, and fairer to both parties,

if an adverse final decision is judicially reviewable. That ensures that the correct law was applied, that the agency's actions were not arbitrary, capricious, or an abuse of discretion, and that the agency's factual findings are supported by substantial evidence in the record. 5 U.S.C. § 706. As explained above, the appeal rights Congress provided in *inter partes* reviews under 35 U.S.C. § 319 mirror the provisions Congress added to reexaminations in 2002 to promote their use.

To be sure, Article III limits a litigant's ability to invoke the jurisdiction of the federal courts. But if appellate rights are wrongly rendered illusory, then fewer challenges will be filed in the first place. The AIA's estoppel provisions deter meritless challenges by providing that final agency decisions upholding patent claims have consequences: the petitioner (and privies or real parties in interest) cannot thereafter challenge the same claims "on any ground that the petitioner raised or reasonably could have raised during that inter partes review." 35 U.S.C. § 315(e)(1), (2). If judicial review is artificially restricted, and only asymmetrically available—*i.e.*, essentially guaranteed for patent owners but uncertain for patent challengers—that will unjustly deter meritorious challenges.

A. The Federal Circuit's Standing Decisions Have Eroded Interested Parties' Access to Judicial Review.

For approximately the past five years the Federal Circuit has invoked Article III of the Constitution to limit patent challengers' access to judicial review of adverse final written decisions in post-issuance review proceedings.

Consumer Watchdog v. Wisconsin Alumni Research Foundation, 753 F.3d 1258 (Fed. Cir. 2014) and *RPX Corp. v. ChanBond LLC*, 780 F.App'x 866 (Fed. Cir. 2018), *CVSG*, 139 S.Ct. 306, *cert. denied*, 139 S.Ct. 2713 (2019), largely eliminate judicial review for organizations that file for post-issuance review, and that are not prospective defendants in infringement suits. Those decisions dismiss appeals for lack of standing where the organizations could not demonstrate something in the nature of an economic or reputational injury from the continued existence of the challenged patents. The Federal Circuit has acknowledged that "Congress may create a statutory right or entitlement the alleged deprivation of which can confer standing to sue," *Warth v. Seldin*, 422 U.S. 490, 514 (1975), but has read the AIA as conferring only the right to file petitions and participate in the administrative proceedings. The Federal Circuit has reasoned that the AIA "did not guarantee a particular outcome favorable to the requestor," *Consumer Watchdog*, 753 F.3d at 1262; *RPX*, 780 F.App'x at 868. Once the agency has instituted adversarial proceedings and proceeded to a final decision, that reasoning is incomplete at best, as it ignores that the law guarantees decisions rendered under the correct law and in compliance with APA standards.

And for those who may be prospective defendants, numerous Federal Circuit decisions now hold that a patent challenger lacks standing to appeal if the panel is unconvinced that it either has sufficiently concrete plans to engage in potentially infringing activity or that its contractual rights would be affected by a determination of patent validity. *See, e.g.*, *Argentum Pharms., LLC v. Novartis Pharms. Corp.*, 956 F.3d 1374, 1375-78 (Fed. Cir. 2020), *cert. denied*, 141 S.Ct.

1685 (2021); *Momenta Pharms., Inc. v. Bristol-Myers Squibb Co.*, 915 F.3d 764, 769-70 (Fed. Cir. 2019); *Pfizer Inc. v. Chugai Pharm. Co.*, 812 F.App'x 979, 981 (Fed. Cir. 2020); *JTEKT Corp. v. GKN Auto., Ltd.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018), *cert. denied*, 139 S.Ct. 2713 (2019); *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1174-76 (Fed. Cir. 2017).

This Court explained in *MedImmune* that "[t]he rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business before seeking a declaration of its actively contested legal rights finds no support in Article III." 549 U.S. at 134. The Federal Circuit has acknowledged that "IPR petitioners need not concede infringement to establish standing to appeal," *JTEKT*, 898 F.3d at 1221, but the upshot of its decisions is that petitioners who do not concede infringement or have not been directly threatened with an infringement suit run a substantial risk of being denied access to judicial review. In those decisions, the Federal Circuit raised the bar—treating Article III as requiring *certainty* with respect to future conduct (a near impossibility) as opposed to merely requiring more than speculation about the future.

Indeed, the Federal Circuit's approach means that even when one party's patent meaningfully limits a competitor's design options (*i.e.*, to avoid infringement), the competitor cannot appeal an unsuccessful patent challenge unless its product is fully developed to the point of comparing it with specific patent claims. *JTEKT*, 898 F.3d at 1221. Article III is not so stingy. Patents can limit design and investment choices long before a fully-developed product exists. Post-issuance reviews enable innovators to challenge

questionable patents to clarify which are valid and must be licensed or designed around, and which are invalid.

And where the patent challenger has a developed product, but is forced to abandon further development due to failure while an appeal is pending, the Federal Circuit has held that the appeal must be dismissed if the challenger does not have immediate alternative plans that risk infringement liability. *Momenta*, 915 F.3d at 769-70 (patent challenger invested millions of dollars in a biologic product; appeal dismissed more than a year after oral argument). Again, the Constitution does not require the *certainty* of future use that the Federal Circuit has demanded.

B. This Case Further Erodes Access to Judicial Review in a Manner That Departs From This Court's Precedent.

This case sets a new high-water mark in denying judicial review, on reasoning that Article III cannot possibly require. The petitioner/appellant in this case *has been sued on the challenged patents for making and selling specific products*. It faces a concrete threat of being *sued again* on the same patents, asserted against the same or related products, when its temporary license expires. Under any reasonable application of this Court's standing precedents, Apple has Article III standing. The Federal Circuit's contrary ruling considers the temporary license in two ways that distort this Court's precedent.

First, citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992), the Federal Circuit holds that the duration of the temporary license makes Apple's risk of being sued "conjectural or hypothetical."

Pet.App.9a. But the Federal Circuit's sole basis for that conclusion was that Apple's risk is in the *future*. "Conjectural or hypothetical" is not the same thing as "in the future." Apple faces a concrete, obvious threat of infringement having been sued once on these very same patents. To be sure, *Lujan* cautions against finding standing based on a party's "'some day' intentions—without any description of concrete plans, or indeed even any specification of *when* the some day will be." 504 U.S. at 564. But here, there is no unspecified "some day." The threat of infringement will resume the day after the license expires—which will undisputedly be before the challenged patents expire.

Likewise, the Federal Circuit considers itself "left to speculate about what activity Apple may engage in after the expiration of the license agreement." Pet.App.9a. But that blinks reality. It is one thing to require a patent challenger to demonstrate its standing with detailed evidence of a product that may risk infringement liability. But that has already happened. Qualcomm *sued* Apple for making and selling specific products, and Apple has paid for a temporary license to secure its freedom to continue to do so. The threat of infringement liability is not "conjectural or hypothetical"; it is merely deferred.

The Federal Circuit reaches a contrary result by requiring a patent challenger who has *already been sued* for specific activity and paid for a license, to rebut an additional presumption that it will have abandoned that same activity when the license expires. That piled-on presumption is an unwarranted obstacle to judicial review with no basis in precedent.

Second, the Federal Circuit attempts to distinguish *MedImmune* by holding that the temporary license cannot support Apple's standing unless a ruling invalidating individual patents would reduce Apple's royalty payments. Pet.App.6a-7a. But as Apple's petition well explains, *MedImmune* is not limited to licenses with patent-by-patent itemized royalty rates. Pet. 14-24. *MedImmune* stated that it "probably makes no difference to the ultimate issue of subject-matter jurisdiction" whether the controversy was better framed as "a freestanding claim of patent invalidity" or a claim that "no royalties are owing under the license." 549 U.S. at 123. Either way, the "relevant coercion" was the potential infringement suit and remedies. *Id.* at 130 n.9, 132, 134. Multi-patent and entire-portfolio licenses like Apple's and Qualcomm's are increasingly common. *E.g.*, Marvin Blecker, Tom Sanchez, & Eric Stasik, *An Experience-Based Look at the Licensing Practices that Drive the Cellular Communications Industry: Whole Portfolio/Whole Device Licensing*, 51 Les Nouvelles 231, 235 (2016) ("this type of broad 'freedom of action' license to the patent holder's entire portfolio is desired by both parties and is the most efficient, and most common, result."). If *MedImmune* can be evaded with multi-patent licenses or in-bulk royalty terms, then patent owners will be encouraged to engineer licenses to avoid judicial review.

The Federal Circuit's errors in this case are not limited to Apple and Qualcomm or even the electronics industry. Within months, the Federal Circuit applied the precedent of this case to dismiss a patent challenger's appeal in the life sciences field—again reasoning that a multi-patent license eliminated the

patent challenger's standing to appeal. *ModernaTx*, ___ F.4th at ___, 2021 WL 5617751, at *5-6.

The Federal Circuit's approach is not compelled by the Constitution, nor consistent with this Court's precedents. But it threatens to undermine the statutory regime.

C. This Court's Review is Needed to Prevent the Federal Circuit From Undermining Post-Issuance Reviews.

There is evidence that the Federal Circuit's extra-constitutional approach to Article III standing is already discouraging *inter partes* review petitions and eroding the benefits to innovation that Congress worked for years to provide.

For example, a recent law review article advises that even patent challengers who risk damages and preclusion in real-world litigation cannot be assured that they will have standing to appeal from an adverse IPR decision, despite their putative interests in challenging a patent. Matthew J. Dowd & Jonathan Stroud, *Standing to Appeal at the Federal Circuit: Appellants, Appellees, and Intervenors*, 67 Cath. U. L. Rev. 661, 697 (2018) ("If a party may not have standing on appeal, and the loss of a case would lead to a damage claim or issue preclusion, formal or otherwise, that party should weigh the benefits of invoking the PTAB's jurisdiction, and the strength of its case, with the possibility of loss and adverse consequences.").

Similarly, a law firm warned automotive manufacturers that they now face "a difficult choice" and may need to plan their commercial activity around the Fed-

eral Circuit's increasing number of obstacles to judicial review. *See* Foley & Lardner LLP, *Inter Partes Review Appeals: The Federal Circuit's Standing Requirement* (Aug. 30, 2018), *available at* https://bit.ly/3dYqy1b. As the law firm put it, "[t]hey may either: (1) challenge a competitor patent early in the design process, risking estoppel and an adverse IPR decision that cannot be appealed for lack of standing; or (2) sink research and development dollars into designs that pose a higher infringement risk but create standing to appeal an adverse IPR decision." *Id.*

Another law firm's attorneys advise biosimilar manufacturers that they may face a "'win or go home' system" if they do not "save their patent challenges until a year and a half (the time for a final written decision) prior to submission of a marketing application so as to be able to rely on the filing of a regulatory application at the time of an appeal." Benjamin Jackson & Jordan Engelhardt, *Fed. Circ. Case May Change Biosimilar IPR Strategy*, Law360 (Apr. 12, 2018), *available at* https://bit.ly/3p35jBE.

Although some of these cautionary notes may overgeneralize, all are notably directed at companies making products, and all warn that filing a petition to clarify which options are open to them and which are covered by valid patents may come at an unacceptable cost. That strongly suggests that the Federal Circuit is over-reading Article III and undervaluing the concrete interests of parties in testing the validity of specific patents.

In any event, whatever might be said for the path the Federal Circuit has taken in other cases, *this case* is a step—indeed, a giant step—too far and illustrates why this Court's review is sorely needed. If a party

who has been sued on a particular patent, and faces future suit on the same patent, lacks standing to appeal an adverse IPR decision, then it is hard to see how anyone other than a party in ongoing active litigation would ever have standing. Article III does not impose such a steep requirement. If the Federal Circuit continues to pile obstacles in the path of judicial review, then *inter partes* reviews may fall into disuse in the manner of their reexamination predecessors, and the hard-fought legislative gains of the AIA will have been lost.

CONCLUSION

The petition should be granted.

December 20, 2021

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