

Standing requirements for appealing PTAB decisions: Recent developments

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When seeking to invoke federal jurisdiction, a party must meet the constitutional minimum for standing under Article III.

To establish standing, a party must show it has (1) suffered an injury in fact (2) that is fairly traceable to the opposing party's challenged action, and (3) a favorable judicial decision would likely redress that injury.¹

Although a party need not have Article III standing to appear before the Patent Trial and Appeal Board (PTAB), it must establish standing when appealing an unfavorable PTAB decision to the Federal Circuit.

If the appellant has been accused of infringing the challenged patent, it can show injury based on this potential infringement liability.

In May 2020, the Supreme Court denied another certiorari petition seeking review of the Federal Circuit's dismissal of a PTAB appeal based on lack of standing,² after denying two standing related certiorari petitions in 2019.³

The Federal Circuit's case law therefore remains controlling on standing. In a line of recent decisions following *AVX Corp. v. Presidio Components Inc.*, 923 F.3d 1357 (Fed. Cir. 2019), and *JTEKT Corp. v. GKN Auto. Ltd.*, 898 F.3d 1217 (Fed. Cir. 2018), the Court has further elaborated on the standing requirements an appellant must meet to appeal from the PTAB.

PROVING OR CHALLENGING INJURY IN FACT

The injury requirement remains the principal focal point of the standing analysis. To show an injury, an appellant must demonstrate "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical."⁴

The injury requirement, and standing in general, has primarily been a concern for patent challengers or PTAB petitioners.

Patent owners generally will have standing to appeal PTAB decisions that invalidate their patent claims. The injury to a patent

owner should be self evident given the potential loss of its patent rights.

Patent owners, however, should be mindful that they must also maintain standing throughout an appeal.

For example, transfer of patent rights, such as assignment to a third party, could moot any injury and thereby deprive the (now former) patent owner of standing.

A patent challenger seeking to appeal an unfavorable PTAB decision must submit sufficient evidence demonstrating injury to obtain review at the Federal Circuit.

If the appellant has been accused of infringing the challenged patent, it can show injury based on this potential infringement liability.

Absent existing infringement allegations, patent challenger appellants have sought to establish injury based on the risk of current or future infringement, economic harm, competitive or reputational injury, and the estoppel effect under 35 U.S.C.A. § 315.

However, of these various arguments, evidence of potential infringement liability has been most persuasive in establishing standing to appeal.

A. POTENTIAL INFRINGEMENT LIABILITY

1. Infringement risk must be personal to the appellant

Potential infringement liability has emerged as the single most important factor in the Federal Circuit's injury analysis.

To prove an injury through potential infringement liability, an appellant must show an infringement risk borne by and personal to the appellant itself.

That is, the appellant must be the entity that has or will perform the allegedly infringing activity and that would bear the potential liability for any infringement of the challenged patent.

For instance, in *Argentum Pharm. LLC v. Novartis Pharm. Corp.*, 956 F.3d 1374 (Fed. Cir. 2020), Argentum appealed a PTAB decision upholding the patentability of a Novartis patent related to Novartis' Gilenya drug.

Argentum argued that because it was pursuing a potentially infringing generic version of Gilenya, it faced an imminent litigation threat.

Argentum's CEO, however, testified that the Abbreviated New Drug Application (ANDA) for the generic drug would be filed by Argentum's partner KVK and, when that occurred, Novartis would sue KVK, not Argentum.

The Court therefore rejected Argentum's infringement-risk argument based on the lack of any evidence that Argentum itself bore any infringement liability or risk.

2. Details of infringing features must demonstrate risk

An appellant must sufficiently describe the potentially infringing product features or other activities to enable the Court to assess the alleged infringement risk.

In *Pfizer Inc. v. Chugai Pharm. Co.*, Nos. 2019-1513, 2019-1514, 2020 WL 1983197 (Fed. Cir. Apr. 27, 2020), for instance, Pfizer appealed the PTAB's decisions upholding the patentability of two Chugai patents.

To show injury, Pfizer argued that Chugai might accuse Pfizer's rituximab biosimilar product of infringing those patents.

Pfizer submitted evidence that the FDA had approved its biosimilar and that it planned to sell the biosimilar in the United States. The Court held, however, that Pfizer failed to show any infringement risk because its evidence did not allow the Court to evaluate whether it practiced or intended to practice the patented methods in making the biosimilar product.

Fisher & Paykel Healthcare Ltd. v. ResMed Ltd., 789 F. App'x 877 (Fed. Cir. 2019), also illustrates the evidentiary requirements for demonstrating an alleged infringement risk.

There, Fisher appealed a PTAB decision upholding the patentability of a ResMed patent. After Fisher filed its notice of appeal, the parties settled a litigation involving the challenged patent.

To show standing, Fisher argued that it had an infringement risk because it "continue[d] to develop products that ResMed may at some future date allege infringe" the challenged patent.⁵

The Court concluded, however, that Fisher had failed to provide any "detail regarding features of its future products" to enable the Court to determine that its activities created a risk of future infringement.⁶

3. Past or discontinued activities may still create a sufficient controversy

In evaluating injury contentions based on infringement risk, the Court has also considered the parties' past conduct, such as previous activities and suits involving the challenged patent.

Past, potentially infringing activities, even if discontinued, may still create a controversy of "sufficient immediacy and reality" between the parties to confer standing.⁷

For example, in *Grit Energy Sols. LLC v. Oren Techs. LLC*, 957 F.3d 1309 (Fed. Cir. 2020), Grit Energy contended that it had standing to appeal a PTAB decision because Oren had previously sued it for infringing the patent involved in the PTAB proceeding, and Oren may reassert infringement.

The Court agreed, explaining that, because the previous suit was dismissed without prejudice and the statute of limitations had not run, Oren was free to reassert infringement.

The Court rejected Oren's position that only present and potential future activities can confer standing, holding that past activities can also create a controversy. "[T]he mere fact that [past] actions have not continued to the present does not necessarily dissipate a controversy over those actions."⁸

4. Patent owner's past allegations and refusal to grant covenants not to sue may prove risk is not 'conjectural'

A patent owner's infringement assertions or past dealings with an appellant may also establish the appellant's risk of infringement liability. For example, a patent owner's past infringement allegations against similar third party products and its refusal to grant a covenant not to sue can help prove that the appellant's infringement risk is not speculative or conjectural.

Appellants have so far had little success in relying on economic harm to establish standing to appeal to the Federal Circuit.

In *Choirock Contents Factory Co. v. Saucier*, 801 F. App'x 754 (Fed. Cir. 2020), for example, Choirock established an infringement risk based on (1) a 2015 letter from the patent owner to another entity alleging that a certain line of toy products in the United States would infringe its patents, including the challenged patent at issue, and (2) Choirock's plans to sell the same line of products in the United States.

The Court held that these facts demonstrated Choirock's risk of infringement liability, satisfying the injury requirement. The Court added that the patent owner's refusal to grant Choirock a covenant not to sue confirmed that Choirock's risk of liability was "not conjectural or hypothetical."⁹

Similarly, in *Adidas AG v. Nike Inc.*, Nos. 2019-1787, 2019-1788, 2020 WL 3455802 (Fed. Cir. June 25, 2020), the Court held that Adidas had standing to appeal the PTAB decisions upholding the patentability of two Nike patents, although Nike had not sued or threatened to sue Adidas for infringement of those patents.

The Court pointed out that in 2012, Nike had asserted that Adidas' Primeknit footwear infringed one of its German

patents, and that Nike had expressed its intent to “protect [its] rights globally in the future against further infringing acts” by Adidas.¹⁰

Nike had also asserted one of the challenged U.S. patents against a third party product similar to Adidas’ footwear. In addition, the Court stated that Nike had refused to grant Adidas a covenant not to sue, which confirmed that Adidas’ risk of infringement was “concrete and substantial.”¹¹

B. ECONOMIC HARM

Appellants have so far had little success in relying on economic harm to establish standing to appeal to the Federal Circuit.

To prove an injury through economic harm, an appellant must show investments or losses that directly implicate, or are caused by, the challenged patent.

Conclusory statements of economic harm will not pass muster under the Court’s scrutiny.

An appellant must detail any investments or losses that can be specifically tied to its development of potentially infringing products or design arounds, separate from costs attributed to unrelated products.

This evidence can include, for example, documentation of changes to product features, facilities, or activities to avoid the patent, business plans discussing such changes, and directly associated expenses.

On the other hand, an appellee, when seeking to refute an appellant’s economic injury arguments, should attack any general claims of economic harm as insufficiently tied to the challenged patent.

In *GE v. United Techs. Corp.*, 928 F.3d 1349 (Fed. Cir. 2019), for example, the Court rejected GE’s broad claim of economic loss as lacking support and thus insufficient to confer standing.

The Court found that GE had provided no “details” such as an “accounting for the additional research and development costs” caused by the challenged patent, or any evidence that it actually designed a product covered by the challenged patent.¹²

The Court reiterated the stringent evidentiary demands for economic injury in *Argentum*. There, *Argentum* asserted that it would incur significant economic losses given its investments in developing a generic drug and preparing an ANDA. To support its position, *Argentum* submitted declarations from its CEO and the CEO of KVK, *Argentum*’s manufacturing and marketing partner.

The Court found that evidence insufficient. Referring to admissions in the declarations, the Court pointed out that *Argentum*’s purported investments included KVK’s renovation of manufacturing facilities intended for other drugs, not only the generic drug at issue.

The Court found that *Argentum* had provided only “generalities” about its invested resources, costs, and joint development efforts with KVK, and that such general statements failed to show that *Argentum* had actually invested in the generic drug at issue.¹³

Citing its CEO’s testimony, *Argentum* also asserted that it would suffer lost profits of \$10-50 million per year once the FDA approved the ANDA.

The Court rejected that assertion, however, as “both conclusory and speculative.”¹⁴

C. POTENTIAL ESTOPPEL ALONE REMAINS INADEQUATE

Section 315 of the Patent Act limits the ability of a petitioner in a PTAB proceeding to subsequently assert any patentability challenges that the petitioner raised or could have raised in the proceeding.

Appellants have often raised this potential estoppel effect in their injury arguments.

The Federal Circuit, however, has consistently held that, if an appellant is not engaged in any activities that could give rise to infringement liability, the potential estoppel effect under Section 315 does not constitute an injury sufficient to support standing.

The Court has reiterated this principle in a number of cases. In *Pfizer*, for instance, *Pfizer* contended that the estoppel effect of Section 315 enhanced *Pfizer*’s stake in the outcome of the case and helped show injury.

The Court rejected that contention, holding that “the estoppel provision does not constitute an injury in fact” when there was “no evidence that [*Pfizer*] was or is engaged in any activity that would give rise to a possible infringement suit.”¹⁵

In *Google LLC v. Conversant Wireless Licensing S.A.R.L.*, 753 F. App’x 890 (Fed. Cir. 2018), estoppel injury was also alleged, and there the Court held that standing was established.

Importantly, however, the Court had already found that LGE and Google had engaged in potentially infringing activities such that their risk of infringement was concrete and substantial.

Accordingly, if the Court does not find other evidence sufficient to show injury, an appellant’s estoppel injury arguments most likely will not change that conclusion.

TIMING CONSIDERATIONS

To maintain an appeal, an appellant must show that standing exists at the outset of the appeal and at all later stages.

Cessation of potentially infringing activities during an appeal may moot the appellant’s injury and deprive it of standing to maintain the appeal.¹⁶

An appellant must also establish that standing existed when the appeal began, that is, when the notice of appeal was filed. Subsequent activities, even if concerning an injury, will likely not suffice absent proof of an injury at the outset of the appeal.

In Pfizer, for instance, the Court held that Pfizer failed to establish an injury at the beginning of the appeal.

Pfizer had filed its notice of appeal in January 2019. To show standing, Pfizer argued that the FDA had approved its potentially infringing rituximab biosimilar product in July 2019, and that it planned to sell the product in 2020.

However, because Pfizer did not establish its activities or plans before July 2019, it failed to show any injury when the appeal began in January 2019.

Pfizer contended at oral argument that it was “self evident to the parties” that there was “a product at issue” when the appeal began.¹⁷

The Court rejected that argument, holding that it was not self-evident “to the court” and that it was Pfizer’s responsibility to “submit evidence to make its standing evident” to the Court.¹⁸

Accordingly, to maintain an appeal, an appellant must present sufficient evidence, supplementing the PTAB record as necessary, to demonstrate standing at all stages of the appeal.

Where possible, an appellant should also consider strategically planning the timing for initiating PTAB proceedings and related commercial activities, such that in case of an unfavorable PTAB decision (typically about 18 months from the PTAB petition filing), sufficient evidence can be presented to show injury when the appeal begins.

An appellee, on the other hand, should investigate the appellant’s activities before and during the appeal to identify any potential deficiencies or gaps in demonstrating standing at all stages of the appeal.

CONCLUSION

The Board continues to be a popular forum for patent challenges, with its relatively fast pace, cost effectiveness, and technically and legally skilled administrative patent judges.

To appeal an unfavorable PTAB decision to the Federal Circuit, a party must establish the constitutional minimum of standing.

The Court has continued to elaborate on the standing requirements for PTAB appeals — and the injury requirement in particular.

When formulating PTAB and litigation strategies, parties should keep abreast of these evolving standing requirements.

By successfully establishing or refuting standing, a party can ensure that it has an opportunity to appeal an unfavorable PTAB decision or to secure a PTAB win by persuading the Court to dismiss an appeal.

Notes

¹ See, e.g., *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992).

² *GE v. Raytheon Techs. Corp.*, No. 19-1012, 2020 WL 2622041 (2020).

³ *JTEKT Corp. v. GKN Auto. Ltd.*, 139 S. Ct. 2713 (2019); *RPX Corp. v. ChanBond LLC*, 139 S. Ct. 2713 (2019).

⁴ *Lujan*, 504 U.S. at 560-61 (internal quotation marks omitted).

⁵ *Fisher & Paykel Healthcare Ltd. v. ResMed Ltd.*, 789 F. App’x 877, 878 (Fed. Cir. 2019).

⁶ *Id.*

⁷ *Grit Energy Sols. LLC v. Oren Techs. LLC*, 957 F.3d 1309, 1320 (Fed. Cir. 2020).

⁸ *Id.*

⁹ *Choirack Contents Factory Co. v. Saucier*, 801 F. App’x 754, 762 (Fed. Cir. 2020).

¹⁰ *Adidas AG v. Nike Inc.*, Nos. 2019-1787, 2019-1788, 2020 WL 3455802, at *1 (Fed. Cir. June 25, 2020).

¹¹ *Id.*

¹² *GE v. United Techs. Corp.*, 928 F.3d 1349, 1354 (Fed. Cir. 2019), cert. denied, 207 L.Ed.2d 152 (U.S. 2020).

¹³ *Argentum Pharm. LLC v. Novartis Pharm. Corp.*, 956 F.3d 1374, 1378 (Fed. Cir. 2020).

¹⁴ *Id.*

¹⁵ *Pfizer*, 2020 WL 1983197, at *3.

¹⁶ *Momenta Pharm. Inc. v. Bristol-Myers Squibb Co.*, 915 F.3d 764, 770 (Fed. Cir. 2019).

¹⁷ *Pfizer*, 2020 WL 1983197, at *3.

¹⁸ *Id.*

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