Fish & Richardson's

Post-Grant Report

2017

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2017 was the busiest year at the Patent Trial and Appeal Board (PTAB).

The PTAB remains the forum of choice for challenging the validity of patent claims, surpassing the Eastern District of Texas as the #1 venue for patent disputes. 2017 also marked the fifth anniversary of the America Invents Act (AIA) and the first anniversary of the PTAB Bar Association.

Fish's 2017 Post-Grant Report examines significant case law and decisions before the PTAB and Federal Circuit, as well as trends and statistics from the past year. The report also reviews appeals/due process concerns and estoppel, and takes a closer look at the biopharma industry and its use of *inter partes* review (IPR) in patent disputes.

As a Diamond Seed Funder of the PTAB Bar Association, Fish was proud to be involved in the association's inaugural conference in 2017. The sold-out event was well attended by practitioners, in-house counsel, and members of the bench. The association had an eventful year, offering educational and networking opportunities, providing frequent updates on case law to its members through PTAB Roundup emails, and writing its first amicus brief, relating to *Oil States Energy Services, LLC v. Greene's Energy Group, LLC.* The second Annual Conference is scheduled for March 22-23, 2018.

Fish & Richardson is the most active firm at the PTAB, and is the most active firm representing petitioners in patent validity challenges. We have pioneered case law, have among the highest institution rates, and host the most innovative educational platforms. For more information, visit **www.fishpostgrant.com.**

With over 770 matters, Fish & Richardson was recently named the most-active PTAB Law Firm in the United States, retaining our ranking from previous years.

Managing Intellectual Property Magazine, 2017

Patent Law Doubleheader at the Supreme Court

2017 turned out to be another big year for post-grant at the Supreme Court. Of the roughly 40 civil cases to be heard by the Court during the 2017-2018 term, two cases involved big questions about post-grant proceedings: *Oil States Energy Services, LLC v. Greene's Energy Group, LLC,* which challenged the constitutionality of IPR; and *SAS Institute Inc. v. Matal,* which challenged the PTAB's practice of partially instituting petitions for IPR. Both of these cases were argued on November 27, 2017, and decisions are expected sometime in the spring. Although making early predictions based on oral arguments is often like trying to read tea leaves, the tenor of the exchange in both cases seems to indicate that a majority of the Court will leave current post-grant practice unchanged.

Oil States

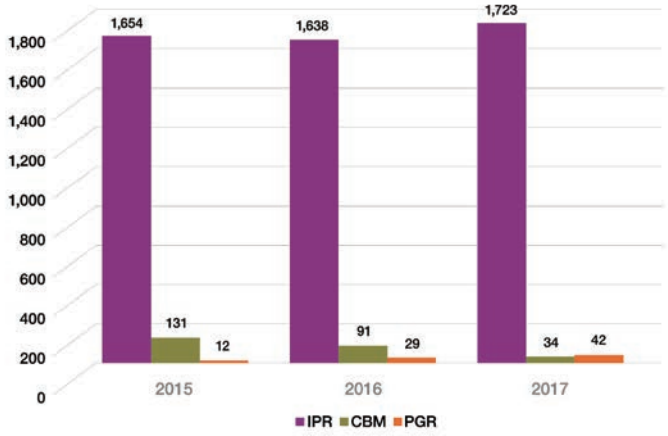
Oil States involved two separate constitutional challenges to IPR: (1) whether IPR violates Article III of the Constitution because it allows an administrative agency—not Article III courts—to extinguish a patentee's rights; and (2) whether IPR violates the Seventh Amendment because it allows administrative judges, rather than juries, to adjudicate validity. The Federal Circuit had already addressed these questions and had upheld the IPR regime against an identical challenge in *MCM Portfolio LLC v. Hewlett-Packard Co.,* 812 F.3d 1284 (Fed. Cir. 2015). In that case, the Federal Circuit held that because patent rights were "public rights," neither Article III nor the Seventh Amendment prohibited an administrative agency from making determinations about the validity of patents. Petitions for certiorari from *MCM* and other cases were denied, but Oil States' petition was granted shortly after Justice Gorsuch joined the Court (suggesting that Justice Gorsuch may have been the needed fourth vote to grant certiorari).

During argument, the justices focused on the Article III issue, particularly on whether patent rights were "public rights" or "private rights." Although most patent cases before the Supreme Court are nonpartisan, this case touches larger issues surrounding Article III and the administrative state that have previously divided the Court along traditional liberal/conservative lines. The justices here followed along this track, with liberal justices favoring upholding IPR and conservative justices favoring striking it down.

In particular, Justices Gorsuch and Roberts both seemed very skeptical of the constitutionality of IPR. Justice Gorsuch noted that 400 years of history suggested that patent rights were private rights and could not be adjudicated by an administrative agency. Justice Roberts grilled the government about the fairness of IPR procedures, particularly focusing on the PTAB's practice of "panel packing" to change the result in some cases, and pointed to cases from the public employment and welfare benefits context that hold that the government cannot deprive a person of a right without due process. Although Justice Thomas did not ask any questions during argument, he has previously opined that the United States Patent and Trademark Office (USPTO) cannot revoke trademark rights after they are issued, so he would presumably also find IPR unconstitutional.

Justices Ginsburg, Sotomayor, Kagan, and Breyer all seemed like strong votes for upholding the constitutionality of IPR. Justices Sotomayor and Kagan suggested that judicial review by the Federal Circuit may obviate any potential Article III problems. Justice Breyer noted that agencies routinely adjudicate all kinds of disputes, and Justice Ginsburg asked Oil States whether there was any way for the USPTO to correct mistakes after patent issuance.

AIA Petitions Filed: 2014-2016



Source: Lex Machina

Justices Kennedy and Alito appear to be the two swing votes who will decide the case. Both of them said relatively little, but the few comments they made seemed to suggest that Congress could condition the grant of a patent subject to the IPR. Justice Alito, for example, asked whether Congress was under a constitutional obligation to give patent rights at all, and, when Oil States said it was not, asked whether Congress could condition the grant of a patent on agreeing to IPR. Justice Kennedy asked Oil States whether Congress could change the patent term to 10 years, and when Oil States said it could, followed up by asking whether Congress could explicitly condition its grant of a patent on having the inventor agree that the patent would be subject to IPR procedure. Both justices also previously joined an opinion holding that PTO decisions regarding trademark validity should be given preclusive effect in an Article III court.

In short, the likely outcome here will be a split decision with Justices Alito and Kennedy joining the liberal justices and voting for affirmance, and Justices Roberts, Thomas, and Gorsuch dissenting.

Patent Law Doubleheader at the Supreme Court

Continued

SAS Institute

SAS involved a challenge to the PTO's practice of partially instituting petitions for IPR. According to petitioner SAS, 35 U.S.C. § 318(a), which states that the Board shall issue a final written decision "with respect to the patentability of any patent claim challenged by the petitioner," unambiguously requires the Board to issue a final written decision with respect to every claim addressed in a petition for IPR. In essence, SAS argued that the Board violated the statute by only addressing some claims from the petition in the final written decision and that the Board's choice at institution should be a binary yes/no decision as to whether to institute trial on the petition as a whole. The Federal Circuit held that the statute did not require the Board to issue a final written decision on all claims in a petition, in a series of decisions starting with *Synopsys, Inc. v. Mentor Graphics Corp.,* 814 F.3d 1309 (Fed. Cir. 2016), overruled on other grounds by *Aqua Products, Inc. v. Matal,* 872 F.3d 1290 (Fed. Cir. 2017). According to the Federal Circuit, Section 318(a) does not require a final written decision on all claims from the petition because (1) the provision-governing institution (which states that the Board may not institute unless it finds a likelihood of success "with respect to at least one of the claims *challenged in the petition"*) differed from the language of § 318(a), suggesting that § 318(a) was not meant to cover claims raised in the petition but only instituted claims; (2) the precatory phrase of § 318(a) ("If an *inter partes* review is instituted …") similarly suggested that § 318(a) only addresses instituted claims; and (3) institution is purely discretionary, the PTO can institute on less than the full petition, and it would make very little sense to require a final written decision on noninstituted claims based on an incomplete record.

In general, the Court seemed skeptical of SAS's theory. Right out of the gate, Justice Sotomayor asked counsel for SAS whether its challenge was a backdoor way to get around *Cuozzo*'s prohibition on challenges to institution. Counsel for SAS countered by saying they're not asking the PTAB to institute on all claims, but merely to issue a final written decision with respect to all claims by, for example, including the explanation from the institution decision with respect to noninstituted claims in the final written decision. Several justices questioned this idea, asking why it would make sense to ask the Board to issue a final decision on an incomplete record.

Justices Ginsburg and Kagan were also active in questioning SAS, asking whether the Board ought to be required to issue a decision with respect to claims canceled during the pendency of IPR by the patent owner or claims that had been settled during IPR. When SAS said no, the justices asked why not if § 318(a) unambiguously required a decision with respect to every claim raised in the petition as SAS contended. And Justice Breyer, although he stated that he thought the language of the statute favored SAS, also thought the government's position was a more harmonious way of organizing IPR.

Some hope for SAS came from a few of the conservative justices. Justices Roberts, Alito and Gorsuch questioned the government about whether the statute was ambiguous and whether the government should be afforded deference in its interpretation. However, Justice Sotomayor raised the difference between the language of the institution provision and § 318(a), and the government quickly agreed that the difference in language was significant. Justice Kennedy seemed to be looking for a compromise position, asking SAS whether the Board could condition its institution on the petitioner accepting trial on less than all claims raised in the petition. SAS answered yes, and suggested that this might be a good solution, allowing the petitioner to decide whether to proceed at the PTO or raise challenges in a district court.

In all, affirmance seems likely, with a few of the conservative justices dissenting based on what they read as unambiguous language in § 318(a). However, it also seems clear that these justices would allow conditional institutions where the petitioner could choose whether to proceed on some claims.

Updates in Estoppel

In *Shaw Indus. Group, Inc. v. Automated Creel Sys., Inc.,* 817 F.3d 1293 (Fed. Cir. 2016), the Federal Circuit decided that estoppel arising from 35 U.S.C. § 315(e) does not apply to grounds denied institution that are presented in an otherwise instituted petition for IPR. *Shaw* left open how estoppel applies to grounds not advanced in an instituted petition, and district courts are split on how to apply *Shaw*'s reasoning to these grounds. Until the Federal Circuit addresses the split, parties seeking to use the USPTO's post-grant proceedings should weigh the possible outcomes in determining how to advance and defend against grounds of unpatentability before the PTAB.

Pursuant to Section 315(e), a petitioner (or its privy or real party-in-interest) is prevented from maintaining a challenge to any patent claim in civil litigation, ITC proceedings, or subsequent USPTO proceedings that is based "on any ground that the petitioner raised or reasonably could have raised during" an IPR in which a final written decision was issued on that claim. Interpreting this provision in *Shaw,* the Federal Circuit held that an "IPR does not begin until it is instituted," so grounds that are not raised—nor could reasonably be raised—in an instituted IPR are not subject to estoppel. See *Shaw,* 817 F.3d at 1300 (Fed. Cir. 2016). In *HP Inc. v. MPHJ Technology Investments, LLC*, the Federal Circuit reiterated that "noninstituted grounds do not become a part of the IPR," so "the noninstituted grounds were not raised and, as review was denied, could not be raised in the IPR." *HP Inc. v. MPHJ Technology Investments, LLC,* 817 F.3d 1339, 1347 (Fed. Cir. 2016). The Federal Circuit's reasoning in these cases, however, has left district courts divided regarding the scope of § 315(e).

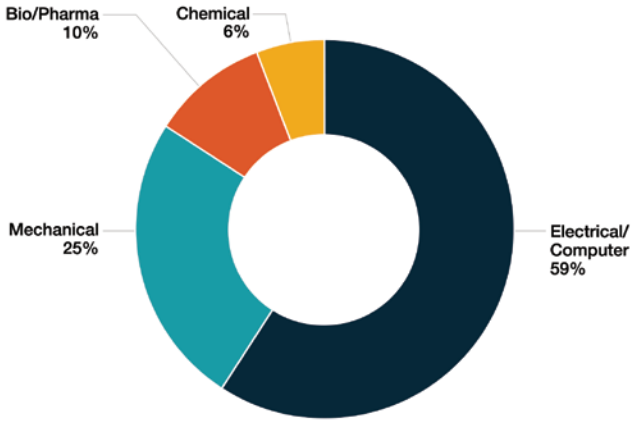
Judge Morgan summarized this split in a June 2017 order. See *Cobalt Boats, LLC v. Sea Ray Boats, Inc.,* No. 2:15cv21, 2017 WL 2605977, at *3 (E.D. Va. June 5, 2017).

*The split in district courts is whether the rationale in Shaw means that grounds not raised in the initial IPR petition are similarly exempt from estoppel. Shaw only addressed noninstituted grounds in the IPR petition, which leaves significant room for interpretation. Courts with a broad reading of Shaw follow its statutory analysis to find that estoppel only applies to grounds that are both in the petition and instituted, which would mean that grounds not raised in the petition at all are similarly exempt from estoppel. See, e.g., Verinata Health., Inc. v. Ariosa Diagnostics, Inc., No. 12cv5501, 2017 WL 235048, at *3 (N.D. Cal. Jan. 19, 2017). Courts with a narrow reading of Shaw have policy concerns that Defendants will preserve patent invalidity arguments from the IPR petition and get two chances to argue invalidity, completely eviscerating the advantages of staying litigation for an IPR petition. See, e.g., Douglas Dynamics, LLC v. Meyer Prod. LLC, No. 14cv886, 2017 WL 1382556, at *4 (W.D. Wis. Apr. 18, 2017), reconsideration granted in part. No. 14cv886, 2017 WL 2116714 (W.D. Wis. May 15, 2017) (not changing the analysis regarding scope of estoppel). Id.*

Judge Morgan went on to apply the "narrow" interpretation of *Shaw,* citing policy concerns regarding the implications of a defendant gaming the statute on a district court's stay of trial during IPR proceedings. *Id.* Yet Judge Morgan's approach is not universal.

While we await further word from the Federal Circuit on this split, parties that find themselves considering or forced into IPR must thoughtfully grapple with the current uncertainty. As petitioner, should all colorable grounds be asserted in your petition or should some be held back? What about "public use" prior art that is ineligible for IPR and can theoretically be reserved for a subsequent invalidity argument in district court? Do the eligible grounds you might raise in an IPR petition impact estoppel against this otherwise ineligible art? Compare *Clearlamp LLC v. LKQ Corp.*, No. 12C2533, 2016 WL 4734389 (N.D. Ill. March 18, 2016) (holding that estoppel does not extend to prior art that was not reasonably available during an IPR, even if redundant or cumulative of prior art used during the IPR) with Cobalt, 2017 WL 2605977, at *3 (E.D. Va. June 5, 2017) (describing a Report & Recommendation from the Eastern District of Texas that "recommends that prior art products are also estopped when they only support arguments that the petitioner could have raised in IPR through the underlying patents or printed publications"). As a patent owner, should you consider reserving strong arguments against a ground until the post-institution response in an attempt to ensure indisputable estoppel? Answers to these questions are likely to be fact-specific and are best approached with a thoughtful review of precedent and consideration of broader case strategies.

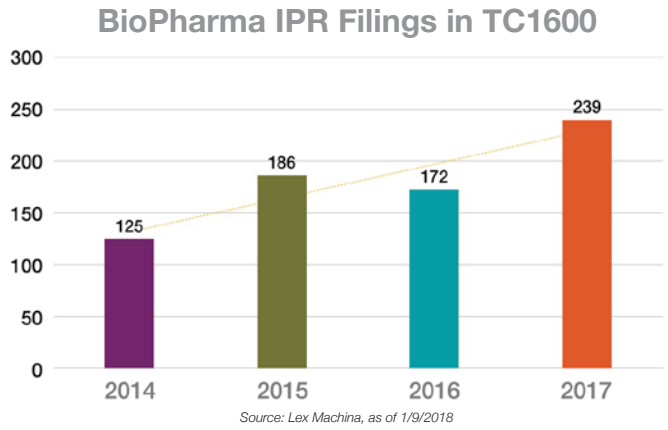
Technology Breakdown by USPTO Tech Center: 2012-2017



Source: Lex Machina

2017 Developments in the BioPharma Sector

The total number of post-grant petitions in the biopharma space, which we define as petitions involving Group 1600 patents, reached an all-time high in 2017, with 211 petitions filed. This compares to the 179 biopharma petitions filed in 2016 and the 188 petitions filed in 2015. In 2017, biopharma petitions accounted for 11 percent of all petitions filed. The vast majority of petitions were IPR petitions. Of the cases that reached an institution decision in the biopharma space, approximately 67 percent were instituted, which was slightly less than the average institution rate of 75 percent across all technology classes.[1]



Source: Lex Machina, as of 1/9/2018

In 2017, we saw a dramatic increase in the number of IPR petitions against patents covering biologic drugs. While fewer than 20 petitions challenging biologic patents were filed in 2015 and 2016, more than 70 petitions were filed against biologic patents in 2017. In some cases, the IPR process may form part of a "freedom to operate" strategy to clear out patents in the early stages of biosimilar development so that they do not become impediments when a biosimilar application is filed. It is worth noting that a handful of biologic drugs were the cause of the spike in activity in 2017. For example, 28 petitions were filed against HERCEPTIN® alone in 2017, as well as 13 for HUMIRA® and 15 for RITUXAN®. We also note there were many repeat players in terms of petitioners in this space. For HERCEPTIN®, there were only six different challengers, while HUMIRA® and RITUXAN® each had four different challengers.

The most active entities challenging biopharma patents in 2017 were generic manufacturers such as Mylan Pharmaceuticals, Apotex, and Lupin. The most active patent owners included Genentech, AstraZeneca, and Allergan. Despite being one of the most active petitioners in 2015, filing 34 petitions, hedge fund manager Kyle Bass did not challenge any biopharma patents in 2017.

The most commonly challenged types of patents in the biopharma space in 2017 remained method of treatment patents and formulation patents. Less frequently challenged were those patents covering composition of matter or methods of manufacture.

A notable development in 2017, the PTAB found unpatentable all claims of three AbbVie patents relating to treating rheumatoid arthritis with adalimumab (HUMIRA®).[2] These decisions represent the first successful IPR challenges to AbbVie's HUMIRA® portfolio.

In another development, the Saint Regis Mohawk Indian Tribe, to whom Allergan transferred patents covering Allergan's RESTASIS® dry eye drug, filed a motion to dismiss, on the basis of tribal sovereign immunity, IPR proceedings that Mylan had initiated against those patents.[3] The PTAB invited amicus briefing on the issue of tribal immunity. A decision on the motions to dismiss is expected in 2018.

In 2018, the biopharma industry obviously is awaiting the United States Supreme Court's decision in the *Oil States* case. Assuming that post-grant practice is not held unconstitutional, we expect further growth in this sector, including through the use of post-grant review filings.

[1] *Source: Lex Machina, 11/08/2017.*
[2] *See Final Written Decisions in IPR2016-00172, -00188, -00189, -00408, and -00409.*
[3] *Mylan v. Allergan and the Saint Regis Mohawk Indian Tribe, IPR2016-01127, -01128, -01129, -01130, -01131, and -01132.*

Due Process Issues at the Federal Circuit

The Federal Circuit focused on two types of procedural issues in IPR appeals in 2017: (1) allegations that a party was denied an ability to respond to a new issue raised relatively late in the proceeding, and (2) concerns that the Board did not adequately explain the reasoning for its decision.

With respect to the first issue, the Federal Circuit has continued to vacate PTAB decisions that rely on a new theory that appeared for the first time in reply or in the final written decision, where the opposing party had no chance to respond. The most recent example was *EmeraChem Holdings, Inc. v. Volkswagen Group of America, Inc.,* 859 F.3d 1341 (Fed. Cir. 2017), where the Board used a prior art reference to invalidate several dependent claims that neither the parties nor the institution decision had discussed in connection with those claims. It did not matter that the reference had been discussed extensively in connection with other claims, because that was "not in the same context" that the Board used to invalidate the dependent claims.

That said, not all due process challenges are successful: *Novartis AG v. Torrent Pharms., Ltd.,* 853 F.3d 1316 (Fed. Cir. 2017), held that the Board was free to rely on a reference as evidence confirming what a skilled artisan would know, where it had been cited in the institution decision and discussed at length by the parties. The Board had used the reference slightly differently than the petition—i.e., as evidence of a skilled artisan's knowledge rather than a primary reference in the obviousness combination—but the patent owner had ample opportunity to address (and did address) the underlying substance of the reference through the proceeding.

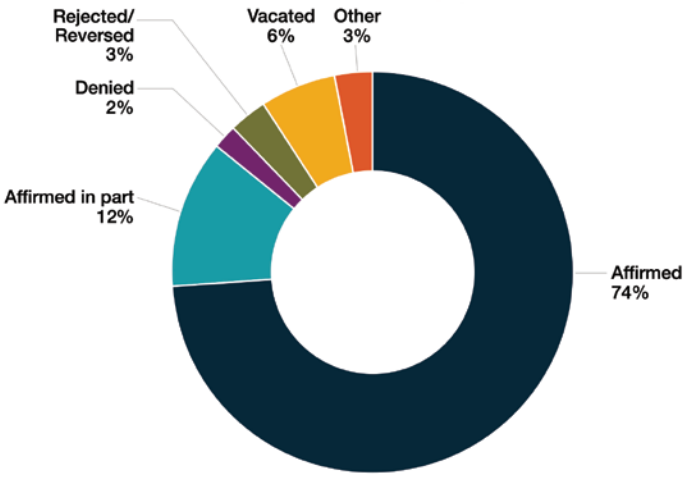
With respect to the second issue, the Federal Circuit has vacated several Patent Office decisions where the Board did not adequately explain its reasoning or did not fully address a party's arguments. Some cases, like *Personal Web Technologies, LLC v. Apple, Inc.,* 848 F.3d 987 (Fed. Cir. 2017), dealt with the Board's failure to explain its substantive rulings. There, the Board did not address one claim limitation at all, and for another, it relied solely on reference A even though the petitioner was relying solely on reference B for that limitation. The Board also failed to explain why a skilled artisan "would" have combined the reference, as opposed to just agreeing that she "could" have.

Other cases, like *Ultratec, Inc. v. CaptionCall, LLC,* 872 F.3d 1267 (Fed. Cir. 2017), dealt with the Board's failure to explain a procedural ruling. There, the court reversed the Board's refusal to admit an expert's testimony from a district court trial that contradicted his IPR testimony. It also criticized the Board for impeding its review by ruling on the issue during an untranscribed conference call, refusing to allow the proponent of the evidence to file a formal motion or make an offer of proof, and refusing even to allow the party to include in the record its email to the Board on the issue.

Procedural issues will continue to be a focus in 2018. Several Federal Circuit judges seem concerned about the limited opportunities for parties to submit evidence during IPR. Multiple Supreme Court justices asked "process"-related questions during the *Oil States* argument, suggesting that they may be amenable to hearing a case on these issues.

Given this interest, parties should ensure that they preserve all their procedural objections and make offers of proof where they are denied a chance to submit evidence. Parties will also want to think strategically about how to handle an adversary's request to submit further reply evidence. In some situations, the proper course may still be to seek to exclude the other side's evidence to ensure initial victory at the PTAB, while, in others, the wiser option may be to avoid any objection to the additional evidence, where such an objection would remove a potential appeal issue.

IPR Federal Circuit Decisions



Source: DocketNavigator

Thank you to this year's contributors to the Fish Post-Grant Report

Dorothy Whelan
Minneapolis, MN

Karl Renner
Washington, D.C.

Craig Countryman
San Diego, CA

Tasha Francis
Minneapolis, MN

David Holt
Washington, D.C.

Oliver Richards
San Diego, CA

Emma Brown
Washington, D.C.

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