

# THE PTAB REVIEW

This issue of *The PTAB Review* begins with a brief summary of the U.S. Supreme Court’s most recent pronouncement about America Invents Act (AIA) reviews. It then provides an update on the Patent Trial and Appeal Board’s (PTAB’s) institution rates in cases where the same patent also is involved in a parallel proceeding. Next, it explores a recent U.S. Court of Appeals for the Federal Circuit analysis of standing to appeal an AIA trial. It then examines admissibility pitfalls for unpublished documents and third-party declarations. Finally, it summarizes a recent Federal Circuit decision reversing a PTAB judgment of non-obviousness.

## Supreme Court Decides *Arthrex*

On June 21, 2021, in *United States v. Arthrex, Inc.*, the Supreme Court confirmed that administrative patent judges (APJs) at the PTAB were unconstitutionally appointed—because no senate-confirmed, executive branch officer could review their final decisions canceling patents. The remedy, the Court held, was to “sever” a portion of the PTAB’s authorizing statute (effectively amending it) to permit the Director of the U.S. Patent and Trademark Office to authorize rehearing of a PTAB decision by the



Director alone. The Court took the case because both parties and the intervenor sought review of the underlying Federal Circuit decision, which also held the appointments unconstitutional, but “severed” a different statute to make the APJs at-will employees. The Supreme Court held that the key problem was a lack of political accountability, so the proper remedy was to place the Director in the position of ultimate decision-maker. The Supreme Court’s holding does not necessarily mean the Director will review every decision as an aggrieved party will have to ask the Director for rehearing, and the Director would have discretion to say no. The USPTO already has begun to implement an interim procedure for making such requests.

The Court’s decision was remarkable for its divisions. The threshold unconstitutionality determination came from a 5-4 split. Chief Justice Roberts wrote the plurality decision, which was, joined by Justices Alito, Kavanaugh, and Barrett. Justice Gorsuch concurred that there was a Constitutional violation but agreed with Arthrex that no remedy was possible. The remedy determination came in a 7-2 split, based on a concurrence from Justice Breyer, joined by Justices Sotomayor and Kagan, who disagreed that the appointments were unconstitutional, but supported the plurality’s remedy. Justice Thomas dissented, noting the Court had held for the first time that inferior officers appointed by a Cabinet secretary (the Secretary of Commerce appoints

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APJs) are unconstitutional and that the plurality had provided a solution no one really sought. Justices Breyer, Sotomayor, and Kagan joined much of the dissent. Justice Thomas urged that the Court's Appointments clause jurisprudence has improperly started

to impinge on congressional power to set up agencies. The Court ordered the Federal Circuit to remand the case to the Director, but it left open how other cases that have been pending since the Federal Circuit's decision, including hundreds that have been stayed at the

PTAB, should be resolved.

For additional information on *Arthrex*, please see our recent [Client Alert](#).

## The Continuing Impact of *Fintiv*

It has been more than a year since the PTAB designated the *Fintiv*<sup>1</sup> decision precedential, requiring the PTAB to consider several factors to determine whether to institute trial when the same patent challenged in an AIA proceeding is also the subject of a parallel litigation. In the [April 2021 issue of \*The PTAB Review\*](#), we examined whether filing patent litigation in a so-called “rocket docket” ensured denial of institution under *Fintiv*. In this issue, we provide a brief evaluation of the PTAB's application of *Fintiv* absent the continuing oversight of the former Director.

To provide this comparison, we evaluated 158 decisions issued between January 1, 2021, and May 31, 2021. Although the administration transition occurred a few weeks into January, this time period provides a rough measure of decisions issued under (or arguably in anticipation of) the new presidential

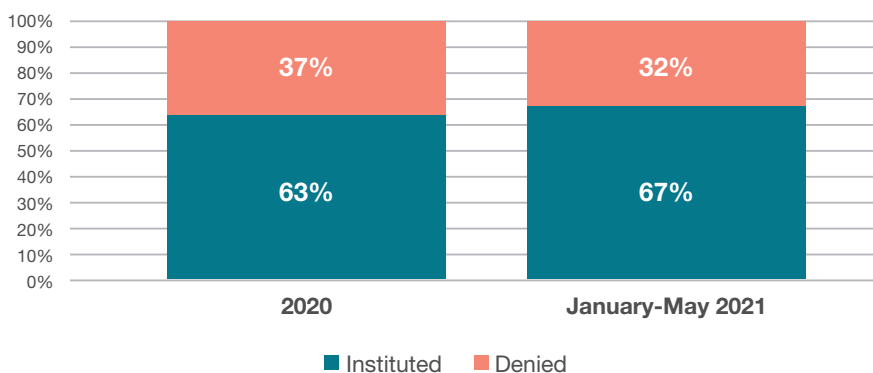
administration. In the 2021 institution decisions, the PTAB granted institution in 106 cases (67.1 percent) and denied institution in 51 cases (32.3 percent). In contrast, our analysis of *Fintiv* decisions in the last issue of *The PTAB Review* reported an overall institution rate of 63 percent. In other words, this preliminary data suggests that the board has become more likely to institute AIA trials despite the existence of parallel proceedings in 2021 than it was in 2020.

This does not necessarily mean that the increase in case institutions is a result of the change in administrations. One explanation for the increase in institution rates in 2021 could be greater predictability provided to litigants by the board's precedential decision regarding the use of stipulations to favor institution under *Fintiv*.<sup>2</sup> In *Sotero*, for example, the board held that a broad stipulation disclaiming in the parallel proceeding any ground that was raised

or reasonably could have been raised in the AIA trial “mitigates any concerns of duplicative efforts” and “potentially conflicting decisions,” thereby ameliorating concerns stemming from the overlap in the proceedings. In other words, even when a scheduled district court trial significantly precedes the AIA trial, institution still may be granted for an otherwise meritorious petition when a petitioner uses a stipulation to ensure the AIA trial will serve as a “true alternative” to the parallel proceeding.<sup>3</sup> Significantly, 93 out of the 158 decisions evaluated (59 percent) for this article involved a stipulation. The greater predictability *Sotera* provided in December 2020 thus appears at least as plausible an explanation for the increased institution rate in 2021 as any overall change in the governing administration.

The overall take home message for petitioners from the PTAB's application of *Fintiv* in 2021 remains the same as before: explore options for seeking an AIA trial as early as possible. Whenever the advanced stage of parallel litigation raises the specter of *Fintiv* denial, a petitioner may nonetheless improve its chances for institution by filing an appropriate stipulation. Patent owners should be aware that *Fintiv* does not necessarily divest defendants in district court from bringing the patent before the PTAB for an AIA trial, though *Fintiv* still remains a powerful tool to reduce duplicative and overlapping proceedings.

### Rate of Denial/Institution for *Fintiv* Cases



<sup>1</sup> *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (Mar. 20, 2020) (designated May 2020).

<sup>2</sup> *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, at 18-19 (Dec. 1, 2020) (designated Dec. 17, 2020).

<sup>3</sup> See, e.g., *Samsung Electronic Co., Ltd v. Nanoco Tech. LTD*, IPR2021-00184, Paper 17, at 14 (PTAB May 19, 2021).

## Standing to Appeal AIA Trials

In *Apple Inc. v. Qualcomm Inc.*,<sup>4</sup> a panel of the Federal Circuit was not convinced that tech titan Apple could continue with its appeals from losses in two IPRs it brought at the PTAB, having settled with its litigation nemesis Qualcomm and executed a license agreement that covered not only the two patents at issue but literally thousands of others, and that extended six years into the future. The district court litigation against Apple had been dismissed with prejudice; there was no evidence that Apple intended to market the allegedly infringing iPhones past the license expiration; and even if the contested claims of the two patents were found by the court to be unpatentable, there was no evidence the royalty Apple was committed to pay under the license would be reduced. Thus, the panel asked, how was Apple injured? Hearing nothing that sufficed to meet the constitutional requirement of a case or controversy under Article III of the Constitution needed to invoke the court's jurisdiction,<sup>5</sup> the court concluded that Apple lacked standing and dismissed the appeals.

The court's opinion dismissing Apple's appeal provides guidance to PTAB petitioners evaluating an unfavorable final written decision from the board for possible appeal to the Federal Circuit. It also is instructive for licensees in negotiating and drafting future patent license agreements, particularly when multiple patents and patent portfolios are involved.

As background, Qualcomm had sued Apple for infringement of five patents, including the two involved in the appeal. Apple countered by filing IPR petitions against the two patents at the board. Although the board instituted trial on both patents, in its Final Written Decisions the board ultimately

determined that Apple failed to prove the challenged claims of the patents were obvious and not patentable. Apple appealed the adverse decisions to the Federal Circuit. After the appeals were filed but before Apple filed its Opening Brief, Apple and Qualcomm settled the district court litigation as part of a global settlement, entering into a license agreement for "tens of thousands" of patents for six years, extendable for two additional years, and payment of royalties by Apple to Qualcomm. The district court dismissed the litigation between the parties for the two patents involved in the IPRs with prejudice.

### *Burden and Timing of Establishing Standing*

Appellants must remember that they have the burden to establish their standing. Evidence of standing must either be apparent from the record below (e.g., a pending litigation that is already of record at the PTAB), or it must be presented by the appellant "at the first appropriate time," whether in response to a motion to dismiss brought by the appellee or in the appellant's opening brief. If not made then, appellants risk having the argument forfeited and the appeal may be dismissed. Apple did not argue its standing until Qualcomm questioned it in its response brief, putting Apple on the defensive to prove its standing in its Reply brief. Although arguably Apple had forfeited the argument by not raising it in its opening brief, the court exercised its discretion to address the issue, although the belated briefing meant that it granted Qualcomm an unusual surreply to address arguments first raised in Apple's reply.

Appellants have always had the burden to prove standing if it is reasonably in question. In ordinary litigation (in an

Article III court), the issue normally will have been raised already in the district court, so the need to address it will have been apparent. Unless, that is, there has been a change in status, like the settlement here. Proceedings before the PTAB are different, however, because "standing" before the non-Article III PTAB is far more permissive. Essentially, anyone other than the patentee itself and the U.S. government can challenge a patent. Thus, a petitioner generally will not have needed to think about standing before filing an appeal. Frequently, the appellee will raise the issue in an early motion, permitting complete briefing of the issue before the close of briefing. Here, however, Qualcomm did not challenge standing, apparently lulling Apple into a false sense that it did not have to address the issue. Whether Qualcomm held its fire as a strategy or simply belatedly recognized the issue, Apple lucked out that the court did not hold the issue forfeit. An important take home lesson here is that both the appellant and the appellee should address standing at the earliest opportunity because deliberately waiting for the response brief might—or might not—work.

### *Concrete Evidence Needed to Support Standing*

Apple argued that it had standing based on its royalty payments to Qualcomm. This is usually a great argument for a licensee because it is injured (if the patent claims are unpatentable) by having to pay the license fee. Yet here Apple did not show that its ongoing royalty obligations would be reduced if the claims of two patents (out of thousands covered by the license) were unpatentable. No other contract terms were identified that might be affected by the patents' validity. Apple also argued

<sup>4</sup> 992 F.3d 1378 (Fed. Cir. 2021).

<sup>5</sup> Article III standing requires that an appellant must have 1) suffered an injury in fact, 2) that is fairly traceable to the challenged conduct of the [appellee], and 3) that is likely to be redressed by a favorable judicial decision. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992).

that Qualcomm might sue it for patent infringement after the license agreement expires. Yet Apple provided no evidence that it intended to engage in any activity that might give rise to an infringement suit under either patent after the license expires. An important lesson here is that whether or not Apple would in fact be injured, it failed to prove it in its reply brief. An important issue here is that reply briefs are short and have short briefing periods, making it difficult to address a new issue *with new evidence* in reply.

The court made the point that the declarations Apple provided as its evidence of standing were “the sparsest of declarations.” They did not mention any plans to engage in conduct after the license expires that might lead to an infringement suit. They did not even mention the patents at issue. Injury sufficient to support standing must be actual or imminent, not conjectural or hypothetical.<sup>6</sup> The court felt that it was left to speculate about Apple’s future activities, years removed, that might give rise to a charge of infringement after the license agreement expired. The judges declined to play the role of “fortune-tellers.”

Because the route of appeal for petitioners is statutory, the Federal Circuit has said that the requirements for proving immediacy and redressability of an injury-in-fact “may be relaxed” but they still require more than a generalized or abstract grievance.<sup>7</sup> Parties should also

keep in mind that timing is important: standing to appeal is distinct from mootness after the appeal has been filed. Had Apple settled after it appealed, the proper question would not have been standing but rather mootness, for which the burden is on the *appellee* and thus might have produced a different result, although self-inflicted mootness (like a settlement) is still likely to result in dismissal.<sup>8</sup> Moreover, parties should always bear in mind that self-inflicted mootness might also prevent vacatur of the underlying decision (no matter what the parties might have agreed in settling the appeal).<sup>9</sup>

#### *Estoppel Isn't Harm Enough*

Apple argued it would be harmed by the estoppel imposed under 35 U.S.C. §315(e) for a Final Written Decision of the Board that would prevent Apple from arguing in the future that the claims of the patents would have been unpatentable based on grounds Apple reasonably could have raised in the petitions. This harm, Apple argued, provided an independent basis for standing to appeal. The court rejected this argument, relying on its earlier decisions that also found estoppel an insufficient injury-in-fact.<sup>10</sup> The court found that Apple’s argument was weakened by its failure to show that it would be engaging in activities that could give rise to an infringement suit after the expiration of the license agreement. The Federal Circuit’s reaffirmance of its position on § 315(e) estoppel was not surprising, but there are

additional questions about this issue that the court should consider.

There may be good reason to think a petitioner is, in fact, worse off (harmed) by losing the ability to appeal an adverse PTAB decision. For example, unlike traditional estoppels—which are equitable so the subsequent court can consider whether the putatively-estopped issue has been fully litigated—§ 315(e) estoppel is statutory, seemingly leaving the subsequent court no discretion. In a concurring opinion to a leading standing case, Justice Thomas suggested that “the concrete-harm requirement does not apply as rigorously when a private plaintiff seeks to vindicate his own private rights.”<sup>11</sup> Hence, a statutory estoppel that affects the appellant’s present rights in its private capacity (as opposed to the “public” injury of an allegedly unpatentable patent) arguably could be sufficient for standing even if the appellant has no concrete plans to infringe. The Supreme Court already has recognized that potentially invalid patents impose burdens on competitors regardless of whether they are currently infringing.<sup>12</sup> Some petitioners previously have attempted to establish standing based on competitive harm but so far have been unsuccessful.<sup>13</sup> Nonetheless, future appellants relying on estoppel for standing may succeed by tying their potential injury to something beyond the immediate threat of infringement.

<sup>6</sup> *Lujan*, 504 U.S. at 560; *JTEKT Corp. v. GKN Auto. Ltd.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018).

<sup>7</sup> *Grit Energy Solutions v. Oren Technologies*, 957 F.3d 1309, 1319 (Fed. Cir. 2020).

<sup>8</sup> *ABS Global v. Cytonome/ST*, 984 F.3d 1017, 1019-20 (Fed. Cir. 2021) (appellee Cytonome/ST met *its* burden to show it would not end its voluntary cessation of patent enforcement against ABS).

<sup>9</sup> *US Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18, 25-26 (1994) (analogizing settlement to a lack of standing).

<sup>10</sup> *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357, 1362-63 (Fed. Cir. 2019); *Gen. Elec. Co. v. United Techs. Corp.*, 928 F.3d 1349, 1355 (Fed. Cir. 2019).

<sup>11</sup> *Spokeo*, 136 S. Ct. at 1552 (Thomas, J., concurring).

<sup>12</sup> *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 101 (1993) (“As this case demonstrates, the Federal Circuit’s practice of routinely vacating judgments of validity after finding noninfringement creates a similar potential for relitigation and imposes ongoing burdens on competitors who are convinced that a patent has been correctly found invalid.”).

<sup>13</sup> See, e.g., *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1173-75 (Fed. Cir. 2017).

## Admissibility Pitfalls for Unpublished Documents and Third-Party Declarations

In *Wi-LAN Inc. v. Sharp Electronics Corp.*, the U.S. Court of Appeals for the Federal Circuit recently affirmed a district court ruling excluding certain declarations and unpublished documents as inadmissible hearsay and excluding the expert testimony that was based on them.<sup>14</sup> By regulation, the Federal Rules of Evidence apply in proceedings before the board.<sup>15</sup> *Wi-LAN* thus serves as a good reminder for those practicing before the board, where parties frequently proffer documents without sponsoring fact witnesses and submit testimony from experts relying on those documents. As shown in *Wi-LAN*, parties sometimes can undermine their opponent's case by excluding the underlying documents.

### *The Arguments Presented in Wi-LAN*

Wi-LAN owned a method patent whose purported infringement had to be shown by analysis of the accused device's source code to show that the code directed the accused device to practice the steps of the patented method. For complicated reasons related to the accused infringer's supply chain, this necessary showing posed a difficulty for Wi-LAN. To overcome this difficulty, Wi-LAN separately sued third-party suppliers of microchips for accused device. Once the suppliers provided Wi-LAN with a source-code printout and declarations that purportedly authenticated the source code, Wi-LAN dismissed these separate lawsuits. Despite this detour, Wi-LAN ultimately lost when the district court ruled that the source-code printout and the associated declarations were inadmissible hearsay. Without these documents as admissible evidence, the patent owner could not show infringement and, so, summary judgment was entered against it.



Wi-LAN appealed, asserting three reasons it believed that the trial court had abused its discretion in excluding the materials. First, it argued that the source-code printout and the declarations were admissible under Rule 803(6), the business-records exception to the hearsay rule. Second, it argued that the source-code printout was self-authenticating under Rule 901(b)(4) based on indicia of trustworthiness. Third, it argued under Rule 703 that expert testimony relying on and conveying the source-code printout and the declarations could be proffered. Furthermore, it argued that the underlying documents, even if hearsay, could be shown to the jury as a basis for the proffered expert testimony. The Federal Circuit disagreed with each argument.

### *Rule 803(6)*

Wi-LAN was unable to convince the Federal Circuit that the third-party source-code printout and declarations should have been admitted as business records. Regarding the declarations, the court first found the declarations inadmissible because the custodians who submitted them were unavailable to

appear at trial. Declaration testimony for summary judgment motions in district court is permitted only if the declarant is available to appear at trial.<sup>16</sup> Second, the court found that the declarations themselves were not admissible as business records because they were produced for litigation and not as a record of regularly conducted activity.

The Federal Circuit also affirmed the trial court's finding that Wi-LAN's opponents had shown sufficient indicia of untrustworthiness in the source-code printout. The court recounted indicia such as "inconsistent dates in the metadata, copyright, and revisions histories," "added commentary," and a lack of "change logs." Thus, by proving untrustworthiness, Wi-LAN's opponents rebutted the source-code printout's purported admissibility as a business record, even if the remaining requirements of the exception had been satisfied.

### *Rule 901(b)(4)*

The Federal Circuit also affirmed the trial court's determination that the same indicia of untrustworthiness that precluded admission as a business record also prevented admission as a self-authenticating document.

### *Rule 703*

Not only was Wi-LAN prevented from offering the source code printout and declaration into evidence for their own substantive value, but the Federal Circuit also affirmed the trial court's exclusion of the expert testimony relying on those documents. In theory, experts may rely on hearsay for their opinions and can even repeat the hearsay to a jury to disclose the basis of their opinions.

<sup>14</sup> 992 F.3d 1366 (Fed. Cir. 2021).

<sup>15</sup> See 37 C.F.R. §42.62(a).

<sup>16</sup> See F.R.C.P. 56(c)(2).

Under Rule 703, the proponent of the expert testimony must establish that experts in the particular field would reasonably rely on the specific type of information in forming an opinion on the subject. The expert may disclose to the jury the basis for his opinion only if that disclosure's probative value in helping the jury evaluate the expert's opinion substantially outweighs the prejudicial effect of disclosing otherwise inadmissible material to the jury. The Federal Circuit agreed with the trial court in this case that the expert's testimony would serve only to improperly channel impermissible hearsay to the factfinder. As discussed above, the court found the source-code printouts were unauthenticated. *Wi-LAN's* expert failed to testify that unauthenticated source-code printouts were the sort of information reasonably relied upon in his field. Although the expert had stated that the declaration and the source-code printout were the type of information that an expert would reasonably rely on, the Federal Circuit discounted this statement as conclusory. The expert's statement did not address the issue as the Federal Circuit defined it: whether an expert would reasonably rely

on the declaration and the source-code printout despite the documents lacking authentication in the ways described above. As a result, the court affirmed the exclusion of the expert's testimony that the accused products were infringing and the resulting grant of summary judgment of non-infringement.

#### *Wi-LAN's Implications for Practice Before the PTAB*

*Wi-LAN* is a good reminder to pay careful attention to the requirements of the Federal Rules of Evidence. The same problems *Wi-LAN* encountered in district court easily could confront a party before the PTAB. Just as the Federal Rules of Civil Procedure require declarants relied upon at summary judgment in district court to be available for trial (where they would be subject to cross-examination), board rules similarly require declaration testimony to be subject to cross-examination at trial.<sup>17</sup> As illustrated in *Wi-LAN*, custodial testimony can be the weakest link for a party seeking to introduce a purported business record into evidence, especially when the custodian is a third party. Ideally, proponents would secure

contractual or other means to compel the custodial declarant to appear for a deposition well in advance. Otherwise, unavailability of the declarant for cross-examination at trial can result in the exclusion of the purported business record for lack of custodial foundation. If the proponent fails to secure the custodian's availability for cross-examination, that failure could result in the exclusion of the purported business records. As in *Wi-LAN*, such exclusion sometimes can sink a party's case.

Given the routine use of expert testimony in *inter partes* reviews, practitioners should scrutinize the exhibits and purported bases of the expert testimony for indicia of untrustworthiness. Typically, shaky or weak bases go to the weight or credibility of expert testimony, not its admissibility. But, under *Wi-Lan*, an opponent can also argue that the bases are so untrustworthy that an expert in the field would not reasonably rely on them. For exhibits potentially lacking a clear basis for admissibility on their own, practitioners should take care to ensure the expert lays the appropriate foundation for reliance on the exhibit under F.R.E. 703.

<sup>17</sup> 37 C.F.R. §§42.51(b)(1)(ii), 42.53.

## Be Careful What You Concede at Federal Circuit Arguments

In *Becton, Dickinson & Co. v. Baxter Corp. Englewood*,<sup>18</sup> the Federal Circuit reversed a PTAB decision upholding patent claims challenged in an *inter partes* review. The Federal Circuit held that substantial evidence did not support the PTAB's finding that the asserted reference failed to disclose the claim element of mandatory verification before proceeding between claim steps. The court also rejected the patent owner's

additional arguments in support of that fact-finding and therefore reversed the PTAB's conclusion of non-obviousness.

The challenged patent recites a system for preparing and managing patient-specific dose orders that have been entered into a system.<sup>19</sup> The system requires that "each of the steps must be verified as being properly completed before the operator can continue with

the other steps" of the process. The PTAB rejected the petitioner's contention that the prior art "Alexander" reference disclosed the claimed verification limitation. Alexander disclosed that a remote pharmacist "may" verify each step as it is performed and "may" provide an indication to the non-pharmacist that the step was performed correctly, called verification feedback.<sup>20</sup> The PTAB thus found that Alexander's disclosure

<sup>18</sup> 2020-1937 (Fed. Cir. May 28, 2021).

<sup>19</sup> Slip op. at 2-3.

<sup>20</sup> *Id.* at 6.

that verification feedback may be provided did not disclose that the remote pharmacist “must” verify each step before the operator can proceed.<sup>21</sup>

On appeal, the Federal Circuit held that substantial evidence did not support the PTAB’s finding.<sup>22</sup> The court applied the PTAB’s undisputed claim construction that the verification limitation requires that “the system will not allow the operator to proceed to the next step until the prior step has been verified.”<sup>23</sup> The court reasoned first that “‘may’ does not mean ‘occasionally,’ but rather that one ‘may’ choose to systematically check each step.”<sup>24</sup> The court also relied on the purpose of Alexander, which was to permit a remote pharmacist to supervise the non-pharmacist and “authorize” the work.<sup>25</sup> The court reasoned that Alexander provides an example where a pharmacist supervises, verifies, and subsequently authorizes the non-pharmacist to further process the work.<sup>26</sup> The court then concluded that “there is no significant difference” between Alexander’s teaching of a system in which a pharmacist supervises and authorizes a non-pharmacist’s work and the claimed system that “will not allow the operator to proceed to the next step until the prior step has been verified.”<sup>27</sup>

The court also considered and rejected two “grounds not adopted by the Board.”<sup>28</sup> Baxter first argued that Alexander does not disclose a system that would stop the operator from proceeding if a prior step was unverified. The court concluded that “[r]equiring authorization before proceeding necessarily stops the work if the authorization is not forthcoming.”



The court relied on a concession from Baxter’s counsel during oral argument that a non-pharmacist who proceeds without authorization likely would be disciplined. The court thus concluded that the “remote operator cannot further process the work without authorization.”

The court also rejected Baxter’s second argument that the claims require a “mechanical” prohibition on continuing work absent verification.<sup>29</sup> The court acknowledged that the patent teaches that dose order processing is prevented from continuing until the step is verified, but reasoned that nothing in the patent specification requires that the “stop” cannot be in the form of an instruction from a pharmacist not to proceed without verification.

*Becton* provides a relatively rare example of a Federal Circuit decision reversing a PTAB decision upholding patent claims challenged in an IPR. Although the PTAB often upholds challenged claims, the court infrequently reverses such decisions. The infrequency of such decisions is a direct result of the standard of review for PTAB factual

determinations, which requires affirmance if substantial evidence supports the determination.<sup>30</sup> Substantial evidence requires “more than a mere scintilla of evidence,” including consideration of contrary evidence, but does not require support by “the weight of the evidence.”<sup>31</sup> In other words, a decision reversing a PTAB factual finding has determined that the decision is not supported by “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.”<sup>32</sup> The court thus essentially concluded that no reasonable mind could accept that a system that permits a pharmacist to supervise and approve the actions of a non-pharmacist fails to provide a system that “will not allow the operator to proceed” absent verification.

Because Alexander did not specifically disclose mandatory authorization, the court deemed permissive verification to be essentially identical to mandatory authorization. In this case, the court created an equivalence between the claim element and the prior art disclosure using a limited concession made at oral argument about the real-

<sup>21</sup> *Id.* at 3-5.

<sup>22</sup> *Id.* at 5-9.

<sup>23</sup> *Id.* at 5.

<sup>24</sup> *Id.* at 6.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.* at 6-7.

<sup>27</sup> *Id.* at 7.

<sup>28</sup> *Id.* at 7.

<sup>29</sup> *Id.* at 7-8.

<sup>30</sup> *Id.* at 4.

<sup>31</sup> *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

<sup>32</sup> *In re Applied Materials, Inc.*, 692 F.3d 1289, 1294 (Fed. Cir. 2012).

world background involved in the practice of pharmacists. Patentees should account for the possibility that courts will, at times, rely on intuition about what is obvious even if the reference at issue does not strictly disclose it.

Another way to interpret the court's decision is that the verification step seemed to the court to be drafted so

broadly that it encompassed existing regulatory or employment practices (such as a pharmacist instructing assistants pursuant to local law not to fill prescriptions without authorization). In such cases, litigants might benefit from pointing out to the court how any technical features of the patent are different from a workplace in which individuals simply know what is expected

of them. Distinguishing existing business practices should be given careful consideration to address future patent eligibility problems as well as the type of obviousness concerns that were found here. Above all, any litigant defending patent claims at the Federal Circuit should not take for granted that a favorable decision below predicts success on appeal.

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