

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

Case IPR2023-00565
U.S. Patent No. 10,076,269

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW

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I. INTRODUCTION

Patent Owner respectfully requests that the Director grant rehearing and reverse the Second Institution Decision (Paper 23) because the Board abused its discretion when accepting a case-narrowing stipulation that (1) admittedly exceeded the scope of the Director's Remand Order (Paper 15) and (2) violated the Director's precedential opinion in *NXP USA, Inc. v. Impinj, Inc.*, IPR2021-01556, Paper 13 (P.T.A.B. Sept. 7, 2022) (precedential). These actions also raise important questions of law and public policy, including whether agency employees may disobey orders emanating from the head of the agency.

After the Board initially denied institution pursuant to *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (Paper 13, the "Original Institution Decision"), Petitioner requested Director review to address statistics bearing on the district court judge's projected time-to-trial. See Paper 14 ("Rehearing Request"). Finding that Petitioner should have had the opportunity to address this evidence, the Director granted rehearing and remanded the case to the Board. Director's Remand Order at 5-6. The scope of the remand order from the Director was narrow: The Director granted Petitioner two pages to address arguments related to the judge's time-to-trial statistics and forbade the filing of new evidence. *Id.* Meanwhile, the Director instructed the Board to "issue a decision that reevaluates institution in light of all of the pre-institution papers" and the parties'

supplemental briefing. *Id.* Petitioner and the Board admittedly violated the Director's Order. Paper 20 at 2 (“[O]n its face Petitioner's supplemental brief exceeds the scope of the Director's order . . .”).

Instead of following the Director's Order, Petitioner's Supplemental Brief contained a purported *Sotera*-like stipulation. Paper 18. The Board then accepted the stipulation in clear violation of the Director's precedential opinion, which demands that petitioners file any case narrow stipulations prior to the institution decision and forbids “offer[ing] such a stipulation for the first time on rehearing.” *NXP*, Paper 13 at 4. The Board's finding that *NXP* is irrelevant because the initial institution decision was vacated cannot be reconciled with the Director's prohibition on filing stipulations “for the first time on rehearing.” *Id.* Petitioner had no shortage of opportunities to file a stipulation before the Board denied the Petition under *Fintiv* yet it made the deliberate choice to wait for rehearing. The Board's misapplication of *NXP*, therefore, also constitutes an abuse of discretion.

II. STATEMENT OF THE FACTS

ResMed Corp. (“Petitioner”) filed a Petition for *inter partes* review seeking to invalidate claims 1-20 of U.S. Patent No. 10,076,269 (the “’269 Patent”) on obviousness grounds. Paper 1. Petitioner disclosed as a “Related Matter” that the ’269 Patent was currently asserted in a lawsuit in the District of Delaware. *Id.* at 1. Despite the related patent litigation, the Petition contained no analysis relating to the

Fintiv factors. *Id.* at 5 (baldly stating “[t]he *Fintiv* factors weigh against discretionary denial” and reserving the right to provide additional briefing).

In its Preliminary Response (Paper 6, “POPR”), Patent Owner, Cleveland Medical Devices, Inc. (“PO”), provided a full analysis of each of the six *Fintiv* Factors. *Id.* at 9-20. PO asserted that *Fintiv* Factor 2 (proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision) weighed in favor of discretionary denial because the scheduled trial date (August 2024) was three months before the Final Written Decision was due in this case, and denying institution would avoid the duplication of efforts and “potentially conflicting outcomes.” *Id.* at 11-12.

After the Board granted its request to file a Preliminary Reply, Petitioner disputed PO’s analysis of Factor 2 (Paper 11 (“Reply”) at 4-8), relying on the Director’s *Fintiv* Memorandum,¹ which **allows** parties to “present evidence regarding the most recent statistics on median time-to-trial for civil actions in the district court in which the parallel litigation resides.” *Fintiv* Memorandum at 8-9. Citing publicly available statistics, Petitioner argued that the median time-to-trial in

¹ *Memorandum*, INTERIM PROCEDURE FOR DISCRETIONARY DENIALS IN AIA POST-GRANT PROCEEDINGS WITH PARALLEL DISTRICT COURT LITIGATION, June 21, 2022, available at https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621.pdf (“*Fintiv* Memorandum”).

the District of Delaware, was 33.7 months, resulting in a projected trial date of March 2025, six months after the projected FWD date. Reply at 5. Petitioner's Preliminary Reply was incomplete, however, because it did not include any "additional supporting factors such as the number of cases before the judge in the parallel litigation," which the Board **must** consider when "the parties rely on time-to-trial statistics." *Fintiv* Memorandum at 9; *In re Google LLC*, No. 2021-178, 2021 WL 5292267, at *3 (Fed. Cir. Nov. 15, 2021) (forbidding consideration of "time to trial statistics . . . unsupported by additional facts such as the number of cases per judge").

Because Petitioner presented an incomplete record to the Board, PO's Preliminary Sur-Reply provided the necessary information, arguing that the median time-to-trial in the district "does not, however, accurately reflect Judge Williams' median-time to trial." Paper 12 ("Sur-Reply") at 5-6. PO cited *Vector Flow, Inc. v. HID Global Corp.*, IPR2023-00353, Paper 8 (P.T.A.B. July 17, 2023), where the Board had already acknowledged Judge Williams' median time to trial was 25.6 months. *Id.* In response, Petitioner asked for additional briefing to address the *Vector Flow* decision and to respond to PO's argument relating to Judge Williams' time-to-trial statistics, but the Board denied this request. Ex. 3003. The Board then issued a Decision exercising its discretion to deny institution under the *Fintiv* Factors, including relying on *Vector Flow* for Factor 2. Paper 13.

Petitioner filed a request for rehearing by the Director, raising two issues: (1) whether the Board abused its discretion in denying Petitioner's request to address new arguments and evidence raised in PO's PR, and (2) an "important issue of policy" relating to Petitioner's differing claim constructions. Paper 14. The Director vacated the Original Institution Decision and remanded only as to issue (1) because Petitioner did not have a chance to address PO's time-to-trial arguments and because the predicate *Vector Flow* decision that the Board relied on had been vacated. Paper 15 at 5-6. The scope of the Director's remand was narrow and explicit:

I authorize Petitioner upon remand to file supplemental briefing addressing the vacated *Vector Flow* decision, **responding to Patent Owner's argument regarding Judge Williams' projected time-to-trial, and addressing any arguments based on case assignment.** See Ex. 3003; Paper 14, 6–10 The Board shall then issue a decision that reevaluates **institution in light of all of the pre-institution papers, including the supplemental briefings** from Petitioner and Patent Owner.

Paper 15 at 5-6 (emphasis added); Paper 16 (acknowledging the narrow scope of the remand and promising a decision on or before May 16, 2024).

By the time the Board issued its Order on the conduct of the remand, Judge Williams' time-to-trial statistics were moot. Even without adjusting for Judge Williams' comparative workload, the projected district court trial date based only on

the median time-to-trial was months earlier than the expected FWD date. Paper 21 at 4.

Consequently, Petitioner's Supplemental Brief did not address Judge Williams' time-to-trial statistics or any of the arguments PO raised in its Preliminary Sur-Reply. Paper 18. Instead, Petitioner filed a *Sotera*-like stipulation stating that "Petitioner no longer asserts in the district court invalidity of the '269 Patent based on the challenges in this IPR" because of court-imposed narrowing of its invalidity references.² Paper 18 at 1. PO asserted in its Response to Petitioner's Supplemental Brief that the *Sotera* stipulation impermissibly exceeded the scope of the remand order and violated the Director's precedential Order in *NXP*. Paper 21.

The Board then issued a Second Institution Decision, this time instituting *inter partes* review. Paper 23. In this Second Institution Decision, the Board accepted Petitioner's *Sotera* stipulation, did not address PO's arguments about Petitioner exceeding the scope of the remand, and did not explain how its decision to accept the stipulation was consistent with *NXP*'s prohibition on such stipulations for the first time on rehearing. Second Institution Decision at 10-12.

² This was a false statement. The paper in which Petitioner's RPI allegedly narrowed its invalidity grounds explicitly incorporated by reference the grounds raised in this IPR. Ex. 1024 at 4.

III. LEGAL STANDARD

Under the USPTO's interim procedures, Director review of a Board decision may be warranted to determine if it includes, among other things, (a) an abuse of discretion, or (b) important issues of law or policy. USPTO, Revised Interim Director Review Process at 2.B, Availability of Director Review: AIA Trial Proceedings (last modified July 24, 2023). "An abuse of discretion is found if the decision: (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on erroneous conclusions of law; (3) rests on clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (citation omitted).

IV. ARGUMENT

A. The Board's Abused its Discretion by Exceeding The Scope Of The Director's Remand Order

The Director should vacate the Board's Second Institution Decision because it exceeded the Director's narrow remand order and, therefore, constitutes abuse of discretion. Paper 21 at 6 (citing *Sullivan v. Hudson*, 490 U.S. 877, 886 (1989)) ("Deviation from the court's remand order in the subsequent administrative proceedings is itself legal error, subject to reversal on further judicial review."); see also *United States v. Campbell*, 168 F.3d 263, 265 (6th Cir. 1999) ("The basic tenet

of the mandate rule is that a district court is bound to the scope of the remand issued by the court of appeals.”).

Remands may be limited or general. *Campbell*, 168 F.3d at 265 (“Limited remands explicitly outline the issues to be addressed by the district court and create a narrow framework within which the district court must operate General remands, in contrast, give district courts authority to address all matters as long as remaining consistent with the remand.”) (citations omitted). In this case, the Director’s Order set forth a limited remand, ordering Petitioner to address the limited issue of Judge Williams’ projected time to trial and ordering the panel to issue a new institution decision considering only the pre-institution record and the parties’ supplemental briefing. Paper 15 at 5-6. No new evidence was permitted. *Id.*

There is no question that Petitioner’s Supplemental Brief violated the Director’s Order and the Board’s initial Order following the remand. *See id.* (authorizing Petitioner to file a two-page supplemental brief addressing **only** the vacated *Vector Flow* decision and responding to PO’s argument relating to Judge Williams’ projected time-to-trial); *see also* Paper 16; Paper 20 at 2 (“[O]n its face Petitioner’s supplemental brief exceeds the scope of the Director’s order”). Nevertheless, Petitioner used its supplemental briefing to raise an entirely new argument (*i.e.*, that the Board need not consider the *Fintiv* factors based on its stipulation) based on new evidence (*i.e.*, its alleged case-narrowing actions before

the district court). Paper 18 at 1 (“Petitioner no longer asserts in the district court invalidity of the ’269 Patent based on the challenges in this IPR”). Petitioner made no effort to request a variance from the Director’s Order before violating it. 37 C.F.R. § 42.12(a)(1).

In the Second Institution Decision, the Board excused Petitioner’s violation without addressing PO’s argument that Petitioner’s Supplemental Brief should be disregarded because it “exceeds the scope of the Director’s limited remand.” Paper 21 at 6-7. This fact alone rises to the level of abuse of discretion because the Board may not reach a decision without considering the entirety of the record. *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1269, 1274 (Fed. Cir. 2017) (“Because the Board failed to consider material evidence and failed to explain its decisions to exclude the evidence, we vacate and remand.”).

The Board’s apparent view—that vacatur of the institution decision meant that it was “starting from scratch” (Ex. 1023 at 5:10-15)—ignores the Director’s Order and longstanding precedent that an agency abuses its discretion when it departs from the scope of the limited remand. *Sullivan*, 490 U.S. at 886 (citations omitted); see also *Campbell*, 168 F.3d at 265 (“The basic tenet of the mandate rule is that a district court is bound to the scope of the remand issued by the court of appeals.”). Although these decisions concern remands from an appellate court to a trial court or an appellate court to an administrative agency, the rule has just as much force for

remand from the head of an agency to an inferior officer. *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1982 (2021) (recognizing “the Appointments Clause as a ‘significant structural safeguard[]’ that ‘preserve[s] political accountability’ through direction and supervision of subordinates”) (citation omitted).

Although the Board did not address PO's argument on this issue, it cited—without comment—Petitioner's reliance on *Vector Flow, Inc. v. HID Global Corp.*, IPR2023-00353, Paper 15 at 8-9 (P.T.A.B. Oct. 17, 2023) for the proposition that providing a stipulation “on remand after vacatur of the previous institution decision is proper as found by the Board upon remand of the Vector Flow decision vacated by Director Vidal.” Paper 18 at 1-2. The scope of Director Vidal's remand in *Vector Flow*, encompassing all issues related to § 314(a), however, was far broader than her Order in this case. *See Vector Flow, Inc. v. HID Global Corp.*, IPR2023-00353, Paper 11 at 3 (P.T.A.B. Aug. 10, 2023) (“Accordingly, I vacate the Board's Decision, grant Petitioner's request for a reply solely to address § 314(a), and remand to the Board for additional proceedings consistent with this decision.”). The fact that the Board accepted a stipulation in *Vector Flow* following the broad remand order in that case has no bearing on whether the Board was entitled to exceed the scope of the Director's remand order here.

The Board's Second Institution Decision impermissibly considered arguments and evidence exceeding the scope of the Director's Order and should be

vacated. And because Petitioner's Supplemental Brief did not address the sole issue permitted on remand, the Director should simply reverse the Second Institution Decision because other than Judge Williams' projected time to trial, Petitioner has raised no other arguments concerning the propriety of the Board's original *Fintiv* analysis.

B. Petitioner's *Sotera* Stipulation Was Untimely and The Board Should Not Have Considered It

The Board erred in considering Petitioner's *Sotera* stipulation because it was untimely and directly violated the Director's remand order. *NXP*, Paper 13 at 3-4; *see also* Paper 21 at 3-6. Allowing Petitioner to file the stipulation instead of complying with the narrow remand order sanctioned Petitioner's gamesmanship in this case, the very gamesmanship that *NXP* warned of in its decision. The Board's failure to reject the stipulation constitutes abuse of discretion and the Second Institution Decision should be vacated.

In *NXP*, the petitioner requested rehearing of a decision denying *inter partes* review under *Fintiv*, wherein it "submitted a stipulation" agreeing to narrow its district court invalidity grounds "should trial be instituted." *NXP*, Paper 13 at 2-3. The Board rejected *NXP*'s gambit, finding that it "had not offered any explanation or justification as to why its stipulation is being offered so late in this proceeding." *Id.* at 3 (internal citations omitted). The Director then held that "the **only appropriate time** for a petitioner to offer a stipulation related to the *Fintiv* factor 4

analysis is prior to the Board's decision of whether to institute review.” *Id.* at 3-4 (emphasis added). In support of this holding, the Director found that “[p]ermitting a petitioner to wait and see if the Board denies institution under *Fintiv*, and then offer such a stipulation for the first time on rehearing, frustrates these goals [of mitigating potentially conflicting decisions and duplicated efforts] and would open the door to gamesmanship.” *Id.* at 4.

Nevertheless, the Board did not apply *NXP* because it determined that the Director's vacatur of the Original Institution Decision placed the parties in the pre-institution posture envisioned in *NXP*. Second Institution Decision at 12. The Board misreads *NXP*. Although the procedural posture of *NXP* was slightly different—*NXP* filed its stipulation in conjunction with its rehearing request—the holding of *NXP* still precludes the filing of a stipulation “for the first time on rehearing.” *NXP*, Paper 13 at 3-4. *NXP* sets an objective standard for determining whether a case-narrowing stipulation is timely—“prior to the Board's decision of whether to institute review”—and that timing was not met here. *Id.* Moreover, the Board entirely ignored all of PO's arguments as to why the mere specter of gamesmanship identified in *NXP* was inconsistent with allowing a Petitioner to file a stipulation “for the first time on rehearing.” *Id.* That was error. *Ultratec*, 872 F.3d at 1269, 1274 (“Because the Board failed to consider material evidence and failed to explain its decisions to exclude the evidence, we vacate and remand.”).

Petitioner's gamesmanship reinforces the applicability of *NXP* to this case. Prior to requesting rehearing of the Original Institution Decision, Petitioner had many opportunities to file a stipulation—in the Petition, in the Reply to the POPR, or in the period between PO's Sur-Reply and the Board's Original Institution Decision. Petitioner refused to do so. Paper 21 at 4. Instead, Petitioner chose to risk discretionary denial under *Fintiv* so it could maintain parallel invalidity challenges to the '269 Patent in two different forums. *Id.* at 6. Petitioner made the deliberate strategic decision not to file a stipulation in a timely fashion in order to keep its options open. Petitioner only sought to file a *Sotera* stipulation **after** the Board denied the Petition under *Fintiv*, **after** Petitioner lost its bid to assert over 30 references against the '269 Patent in the Related Matter, and **after** Judge Williams' projected time to trial became moot because the projected trial date of March 2025 estimated using the unadjusted median time-to-trial statistics (Paper 11 at 5) preceded the projected Final Written Decision date after remand. Paper 21 at 4. This type of gamesmanship is exactly what the Director sought to avoid when deciding *NXP* and should have led to the Board rejecting the stipulation as untimely.

Petitioner should not be rewarded for having violated the Director's Order once it realized the case could not be resolved in its favor. This is the exact gamesmanship that the Director was concerned about in *NXP*. It was, therefore, improper for the Board to accept Petitioner's untimely stipulation. The Board should

have exercised its discretion to deny institution under § 314(a) or at least considered the time-to-trial statistics of record, as required by the Director's Order.

The fact that the case is now on remand does not justify Petitioner's gamesmanship in this case; it reinforces it. Paper 21 at 5. The Petitioner's strategic decision to not file a stipulation until after an adverse decision in violation of a remand order should not have been accepted by the Board. This abuse of discretion mandates that the Second Decision be vacated.

V. CONCLUSION

PO respectfully requests that the Director grant its request for Director Review of the Institution Decision and either reverse or vacate the Board's decision.

Patent Owner's Request for Director Review
IPR2023-00565 (U.S. Patent No. 10,076,269)

Respectfully submitted,

Dated: May 20, 2024

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CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e), that
service was made on the Petitioner as detailed below.

<i>Date of service</i>	May 20, 2024
<i>Manner of service</i>	Electronic Mail (tiffany.miller@us.dlapiper.com; ed.sikorski@us.dlapiper.com; jim.heintz@us.dlapiper.com; DLA-ResMed-CleveMed-IPR@us.dlapiper.com)
<i>Documents served</i>	PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW
<i>Persons Served</i>	DLA Piper LLP (US) Tiffany C. Miller Edward H. Sikorski James M. Heintz

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