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Paper 22
Entered: May 15, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LIMITED,
Petitioner,

v.

GILEAD SCIENCES, INC.,
Patent Owner.

IPR2025-00033
Patent 11,744,802 B2

Before GRACE KARAFFA OBERMANN, SUSAN L. C. MITCHELL, and MICHAEL A. VALEK, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Cipla Limited ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–13 of U.S. Patent No. 11,744,802 B2 (Ex. 1001, "the '802 patent"). Paper 3 ("Pet."). Gilead Sciences, Inc. ("Patent Owner") filed a Preliminary Response requesting that we exercise discretion to deny the Petition under 35 U.S.C. § 314(a) in light of the advanced stage of the parallel district court proceeding with a trial date scheduled for October 6, 2025, the overlap of issues with that proceeding, Petitioner's delay in filing this Petition, and the alleged lack of compelling merits. Paper 14, 1–2, 10 ("Prelim. Resp.").

Petitioner filed an authorized Reply addressing whether discretionary denial is appropriate. Paper 19 ("Reply"). Patent Owner filed an authorized Sur-Reply in response. Paper 22 ("Sur-Reply").

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a).

For the reasons set forth below, we exercise discretion to deny the Petition under 35 U.S.C. § 314(a). Therefore, we decline to institute an *inter partes* review for claims 1–13 of the '802 patent.[1]

[1] Patent Owner also asserts that the Petition should be denied under 35 U.S.C. § 325(d), but we need not reach this issue because we are exercising discretion under Section 314(a) to deny the Petition. *See* Prelim. Resp. 2–3.

B. Related Proceedings

Petitioner states:

> Petitioner and Gilead are involved in an action that has been pending since May of 2022, brought by Gilead pursuant to the Hatch-Waxman Act in the District of Delaware. *Gilead Sciences, Inc. v. Lupin Ltd., Laurus Labs Ltd., and Cipla Limited*, C.A. No. 22-cf-00615 (MN) [the "district court litigation"]. The '802 Patent was first asserted against Cipla in that action on November 16, 2023.

No prior IPR petition for the '802 Patent has been filed. Pet. 3 (citing Ex. 1013); *see* Paper 5, 2. We note that the '802 patent did not issue until September 5, 2023, which was during the pendency of the district court litigation. *See* Ex. 1001, code (45).

C. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability.

Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1–13	103	WO '323,[3] WO '351[4]

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), included revisions to 35 U.S.C. §§ 102 and 103 that became effective on March 16, 2013, before the filing of the applications to which the '802 patent claims priority. Therefore, we apply the AIA version of Section 103.

[3] Jin et al., WO 2014/100323 A1, published June 26, 2014 (Ex. 1005, "WO '323").

[4] Juergen Renner, WO 2015/022351 A1, published Feb. 19, 2015 (Ex. 1006, "WO '351").

Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1–13	103	WO '323, WO '351, Bowker,[5] Paulekuhn[6]
1–13	103	WO '323, WO '351, US '079[7]

See Pet. 5. Petitioner relies on the Declarations of Prasanna Jagannathan, M.D. (Ex. 1003) and Jeffrey Winkler, Ph.D. (Ex. 1004) in support.

II. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(a)

Under 35 U.S.C. § 314(a), institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016); *see also* 35 U.S.C. § 314(a). In *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential), the Board set forth six non-exclusive factors for determining "whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding." *Id.* at 6. These factors are as follows:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;

[5] Michael J. Bowker, "A Procedure for Salt Selection and Optimization" in HANDBOOK OF PHARMACEUTICAL SALTS: PROPERTIES, SELECTION, AND USE 161–89 (P. Heinrich Stahl & Camille G. Wermuth eds., 2002) (Ex. 1008, "Bowker").
[6] Paulekuhn et al., "Trends in Active Pharmaceutical Ingredient Salt Selection Based on Analysis of the Orange Book Database," 50 J. MED. CHEM. 6665–72 (2007) (Ex. 1009, "Paulekuhn").
[7] Malhotra at al., US 2015/0231079 A1, published Aug. 20, 2015 (Ex. 1007, "'US '079").

3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

Id. at 5–6.

In evaluating these factors, we take a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review. *Id.* at 6.

The Office recently issued Guidance on the USPTO's recission of previous guidance titled "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation." *See* Scott R. Boalick, *Guidance on USPTO's recission of "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* (March 24, 2025), *available at*: https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_recission_20250324.pdf. This guidance provides: (1) the Board will apply the *Fintiv* factors when there is a parallel proceeding at the International Trade Commission ("ITC"); (2) a timely-filed *Sotera*[8] stipulation is highly relevant, but not dispositive by itself; (3) the Board may consider any evidence that the parties make of record that bears on the proximity of the district court's trial date including median time-to-trial

[8] *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to § II.A.).

statistics for civil actions in the district court; and (4) compelling merits alone are not dispositive in making the *Fintiv* assessment for the application of discretionary denial. *Id*.[9]

A. Summary of Parties' Arguments

Patent Owner raises several arguments in favor of discretionary denial under 35 U.S.C. 314(a). *See* Prelim. Resp. 13–38. Namely, Patent Owner asserts:

> The district court case involving the '802 patent is well underway and scheduled for trial in early October 2025, more than six months before the statutory deadline for a final written decision. Cipla raises the same references to challenge the same claims in the district court, and two other defendants—who have not joined Cipla's Petition—sponsor the same challenges in the district court.

Prelim. Resp. 13.

Patent Owner also questions the merits of the Petition. Patent Owner states:

> Before the priority date of the '802 patent, Gilead selected a 75 mg dose of bictegravir for its Phase 2 clinical trials. *See* Petition at 17 (citing Ex. 1035). But the Petition's obviousness analysis under all three grounds effectively ignores that fact. Additionally, Gilead only moved away from the 75 mg dose

[9] This proceeding does not fall under the interim process for analysis of discretionary considerations. *See Interim Processes for PTAB Workload Management* (March 26, 2025), *available at*: https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf at 3 (stating "[t]he processes described herein will be implemented in IPR and PGR proceedings where the deadline for the patent owner to file a preliminary response has not yet passed").

> due to a problem that was not known as of the priority date.[10] Other facts and circumstances likewise weigh in favor of denial, including that the Petition is based on "the same or substantially the same prior art or arguments previously [that] were presented to the Office." 35 U.S.C. § 325(d).

Prelim. Resp. 14.

Petitioner responds that the district court litigation began more than a year before the filing of the application that led to the '802 patent. Reply 1. Therefore, Petitioner asserts:

> The parties' contentions, fact witnesses, depositions, document productions, claim construction proceedings, and expert discovery involve *substantial* efforts that have *nothing* to do with the '802 Patent. Indeed, ~500 pages of the final invalidity contentions are primarily directed to the patents not at issue in this proceeding. EX-1069. Moreover, the District[] Court's recent claim construction proceedings did not involve <u>any</u> claim terms of the '802 patent. EX-1065 at 5.

Id. at 1–2 (emphasis in original). Petitioner also points out that the parties together requested the October 6, 2025 trial date to accommodate adding the '802 patent that was listed in the Orange Book on October 4, 2023, which the district court granted. *Id*. at 2. The parties also noted in that request that the defendants could not market a generic product until after the December 19, 2033 expiration date for an unchallenged Orange Book patent. *Id*.

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[10] Patent Owner contends that it discovered that the 75 mg dose of bictegravir in its Phase 2 studies created a total exposure of bictegravir "that was approximately 30% higher when dosed in the bilayer tablet formulation F2, containing two additional therapeutic agents (TAF and FTC), compared to single agent tablet formulation F1, co-dosed with a fixed dose combination tablet containing TAF and FTC (F3)." Prelim. Resp. 33 (citing Ex. 1001, 61:24–42).

In summary, Petitioner asserts that we should not exercise discretion to deny the Petition because: (1) a stay may be granted; (2) "there is reason to believe the Court would be willing to again accommodate a later trial date;" (3) much of the time and resources invested by the district court involve other patents; (4) Petitioner's *Sotera* stipulation eliminates any overlap in issues with the district court; and (5) the Petition presents compelling merits. Reply 2–9.

Patent Owner responds that Petitioner's *Sotera* stipulation is "hollow" because the other two defendants in the district court litigation have not joined this petition and will continue to assert the same invalidity grounds at the district court. Sur-Reply 1. Patent Owner also asserts that "Cipla's obviousness arguments are fatally flawed, both because of what was known (75 mg dosage in Gilead's clinical trial) and what was unknown (the effect of combining three active ingredients into one tablet)." *Id.*; *see supra* n.10.

We evaluate each of the *Fintiv* factors in turn below to determine whether we should exercise discretion to deny the Petition.

B. Analysis

1. *Factor 1 – Stay*

Petitioner has not yet requested a stay ostensibly because the district court is not inclined to grant a stay absent an institution decision beginning an *inter partes* review. *See* Reply 2. Patent Owner responds that with two other defendants in the district court litigation that are not petitioners here and three other patents at issue in the district court litigation that are not at issue here, a stay is unlikely. Prelim. Resp. 15. Patent Owner points to two cases involving denials of stays for allegedly similar circumstances decided

by the judge in the district court case. *See id*. (citing *Ferring Pharms. Inc. v. Eugia Pharma Specialties Ltd*, 1:22-cv-0017-MN, D.I. 139 (D. Del. May 10, 2024); *PureWick Corp. v. Sage Prods., LLC*, 1:19-cv-1508-MN (D. Del. May 4, 2021)).

We determine that the absence of a request for a stay and consequently no stay in the district court litigation makes this factor neutral. Petitioner's argument that the district court would be inclined to enter a stay because it previously postponed the trial date to accommodate the addition of the '802 patent is too speculative to be given much weight in our analysis. Patent Owner's assertions about similar cases involving denial of a stay are more compelling, but absent an actual request and an actual denial of a stay in the district court litigation, Patent Owner's arguments also are too speculative.

Therefore, we find that this factor is neutral.

2. *Factor 2 – Trial Date*

We determine that this factor weighs heavily in favor of exercising discretion to deny the Petition. The trial date in the district court litigation is scheduled for October 6, 2025. *See* Prelim. Resp. 16 (citing Ex. 2010). This date is at least six months before our projected statutory deadline should we go forward in this case. Patent Owner points out that this trial date is nine months later than the median time to trial in the District of Delaware, and in Patent Owner's view, the parties are on track to satisfy the current schedule. *Id*. at 16–17 (citing Ex. 2011).

Petitioner points out that the district court has moved the trial date once before to accommodate adding the '802 patent and that there is no

special urgency because the defendants could not market a generic product until after the December 19, 2033 expiration date of an unchallenged Orange Book patent. Reply 2–3. Even so, Petitioner's assertion that "there is reason to believe the Court would be willing to again accommodate a later trial date" is merely speculative, and we decline to guess what the district court might do.

On the facts before us, the district court will complete trial well before our final written decision is due. Therefore, we determine that this factor weighs strongly in favor of exercising discretion to deny the Petition.

3. *Factor 3 – Investment in the District Court Proceeding*

We determine that this factor weighs in favor of exercising discretion to deny the Petition. Patent Owner provides support for its position that the district court litigation will be "close to trial-ready" when we issue our institution decision. *See* Prelim. Resp. 18–23. For instance, fact discovery has been completed, infringement and invalidity contentions have been served for the '802 patent, expert reports have been served, and expert discovery closes shortly after the statutory due date for our institution decision. *See id*. at 18–20.

Petitioner agrees that Patent Owner's assessment about the time and resources invested in the district court litigation is accurate, but asserts that most of that investment focuses on other patents than the '802 patent. Reply 3.

As Patent Owner points out, however, considerable work has been done on the '802 patent including fact and expert discovery constituting six

expert reports. Sur-Reply 4. Therefore, we determine that this factor weighs in favor of exercising discretion to deny the Petition.

4. Factor 4 – Overlap in Issues

We determine that this factor weighs in favor of exercising discretion to deny the Petition. Patent Owner lays out how the same claims are challenged in each proceeding based on the same grounds and notes that Petitioner had not yet filed a *Sotera* stipulation at the time the Preliminary Response was filed. Prelim. Resp. 23–26.

Petitioner responds that it filed a *Sotera* stipulation in the district court litigation on March 27, 2025, stating that it would "not seek an adjudication of '802 Patent invalidity on any ground raised or that reasonably could have been raised in the Petition." Reply 4 (citing Ex. 1066). Petitioner also asserts that the District of Delaware will require all parties to narrow the number of claims to be adjudicated at trial, eliminating the complete overlap in claims at issue between the district court litigation and this proceeding. *Id*.

Patent Owner responds that Petitioner's *Sotera* stipulation is effectively meaningless because: (1) two other defendants with the same invalidity defenses in the district court litigation are not involved here and have not signed the *Sotera* stipulation, thus mandating that "the *same* claims, grounds, arguments, and evidence raised in the Petition will have to be adjudicated by the district court regardless of what happens before the Board," Sur-Reply 4; and (2) Petitioner has asserted obviousness-type double patenting in the district court litigation that Patent Owner asserts would not be precluded by the *Sotera* stipulation, *see id.* at 4–5.

We agree with Patent Owner that the two defendants in the district court litigation that have not joined this Petition or the *Sotera* stipulation are free to assert the overlapping invalidity defenses against all claims of the '802 patent, making the *Sotera* stipulation somewhat hollow. It is also speculative whether the number of claims of the '802 patent will be narrowed in the district court litigation. Currently, all claims at issue here appear to be at issue in the district court litigation as well. *See* Prelim. Resp. 25; Reply 4–5; Sur-Reply 4.

Therefore, we determine that this factor weighs in favor of exercising discretion to deny the Petition.

5. *Factor 5 – Same Parties*

It is undisputed that Petitioner here is a defendant in the district court litigation. Therefore, factor 5 weighs in favor of exercising discretion to deny the Petition.

6. *Factor 6 – Compelling Merits*

Petitioner asserts that the Petition presents compelling, meritorious challenges to claims 1–13 of the '802 patent. Pet. 70. Specifically, Petitioner states that at least as to the broadest claim, claim 1, "[t]he simple combination of three known antiretroviral drugs in a single tablet had been (repeatedly) accomplished by Gilead (and others) well before the Effective Date." *Id*.

Patent Owner counters that the selection of a 50 mg dose for bictegravir would not have been obvious. Prelim. Resp. 29. Patent Owner asserts that Petitioner's

> hindsight-driven obviousness theory for the 50 mg dose limitation depends on: (1) selecting compound 42 over others

> in WO '323, (2) identifying purported structural similarities between compound 42 and dolutegravir, (3) assuming that important structural differences between the compounds do not matter, and (4) dosing compound 42 at 50 mg like dolutegravir. To get there, a person of skill would have to cherry-pick compound 42 and dolutegravir's dose while blinding herself to all other compounds, dosing information of other integrase inhibitors, and WO '323's teachings.

Sur-Reply 6 (citing Pet. 47–56).

Based on this analysis, Patent Owner points out what appear to be deficiencies in Petitioner's obviousness case that would militate against a finding of compelling merits.

Based on the record before us, we do not find compelling merits here.

7. Conclusion

In weighing all of the factors set forth above, we determine that we should exercise discretion to deny the Petition under 35 U.S.C. § 314(a).

III. CONCLUSION

For the foregoing reasons, we exercise discretion under 35 U.S.C. § 314(a) to deny the Petition. Because we have made this determination, we need not reach whether we should discretionarily deny the Petition under 35 U.S.C. § 325(d).

IV. ORDER

For the foregoing reasons, it is:

ORDERED that the Petition is denied, and no *inter partes* review is instituted.

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